

Results of the public consultation on the WHO draft guideline on use of non-sugar sweeteners

Comments were received from the following individuals and organizations

Government agencies

Agastya Bharadwaj	Australian Government Department of Health and Aged Care
Estella Hung	Office for Health Improvement and Disparities, UK
Omolara Okunlola	Standards Organization of Nigeria

Nongovernmental and consumer organizations and associations

Laís Amaral Mais	Brazilian Institute for Consumer Defense (IDEC)
Igor Castro	ABIR - Associação Brasileira das Indústrias de Refrigerantes e de Bebidas Não Alcoólicas, Brazil
Nancy Chapman	Oral Health Alliance, US
Alíz Erdélyi-Sipos	Hungarian Dietetic Association (HAD)
James Griffiths	Council for Responsible Nutrition (CRN), US
Bruna Hassan	ACT Promoção da Saúde, Brazil
Marisa Macari	El Poder del Consumidor, Mexico
Alexandre Novachi	Brazilian Food Trade Association (ABIA)
Elizabeth Orlan	Global Health Advocacy Incubator, US
Cherie Russell	Healthy Food Systems Australia
Andrea Schmidtke	Obesity Policy Coalition (OPC), Australia
Victoria Sibson	First Steps Nutrition Trust, UK

Private sector (including industry organizations and associations)

Carlos Antillon	Camara Costarricense de Industria Alimentaria, Costa Rica
Helen Benson/Nicholas Hodac	UNESDA Soft Drinks Europe, Belgium
Gislene Cardozo	Brazilian Association of the Food Industry for Special Purposes and Similars (ABIAD)
Christine Grit	Dutch Food, Drink and Groceries Association (FNLI), Netherlands
Karima Kendall	Calorie Control Council, US
Sara Lamonaca	FoodDrinkEurope, Belgium
Anthony R Leeds	Total Diet & Meal Replacements (TDMR) Europe, UK
Calisa Lim	Food Industry Asia, Singapore
Katherine Loatman	International Council of Beverages Associations (ICBA), US
Anne-Marie Mackintosh	Australian Food and Grocery Council (AFGC)
Richard F Mann	International Chewing Gum Association (ICGA), US
Petia Nenova	International Sweetener Association (ISA), Belgium
Guillermo Palacios García*	Asociación de la Industria de Bebidas y Refrescos sin Alcohol del Perú (ABRESA)
Alicia Páramo Ortega*	Asociación Nacional de Fabricantes de Chocolates, Dulces y Similares A.C, Mexico
Geoff Parker	Australian Beverages Council Limited
Rocco Renaldi	International Food & Beverage Alliance, Belgium
Ana Marcela Rodriguez	Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB), Costa Rica
Abhinav Singh	Federation of Indian Chambers of Commerce & Industry (FICCI), India

Leonel Tayés	Cámara Guatemalteca de Alimentos y Bebidas (CGAB), Guatemala
Jennifer Thompson	Australian Industry Group (Ai Group)
Karen Weikel	Bonumose, Inc., US
(Name not submitted)*	Cámara Argentina de la Industria de Bebidas sin Alcohol (CADIBSA)

Academic/research

Katherine Appleton	Bournemouth University, UK
Alan Barclay	(Self-employed), Australia
Clifton Carey	University of Colorado, School of Dental Medicine, US
Ana Clara Duran*	University of Campinas, Brazil
Kees de Graaf	Wageningen University and Research, Netherlands
Tauseef Khan	University of Toronto, Canada
Carlo La Vecchia	University of Milan I, Italy

* Comments submitted, but completed declaration of interest forms not received

UK, United Kingdom of Great Britain and Northern Ireland; US, United States of America

Summary comments and WHO responses

Comments were compiled and summarized (and/or paraphrased), and brief responses prepared. (Comments received without completed DOI forms were not included in this process).

Scope of the guideline

Summary comment	Response
It is noted several times in the guideline that because evidence was not reviewed for NSS effects on individuals with existing diabetes that the recommendation may not apply to those with diabetes. The recommendation to not use NSS has the potential to create confusion to people living with diabetes especially since many diabetes organizations such as the American Diabetes Association, Diabetes Canada and Diabetes UK, note that NSS have been shown to be safe and have concluded that the use of NSS has the potential to reduce overall calorie and carbohydrate intake when used as a sugars replacement and therefore can be used as part of a strategy for adults and children in the management of body weight and diabetes. Even though it is indicated in the guideline that the recommendations may not apply to those with diabetes, the “headline” is what will be looked at, not the details. The guideline should have included individuals with diabetes and pre-diabetes, as they represent more than 10% of the global population.	<p>The work of the NUGAG Subgroup on Diet and Health has consistently focused on prevention of unhealthy weight gain and noncommunicable diseases (NCDs), not treatment/management as this is in line with their task of updating the dietary goals for the prevention of NCDs established originally by the WHO Study Group in 1989 and updated by the 2002 Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases. Therefore those with existing diabetes were considered to be beyond the scope of the guideline. Accordingly, explicit declarations are made in the guideline indicating that because evidence was not reviewed for NSS effects on individuals with existing diabetes, the recommendation may not apply to those with diabetes.</p> <p>Regarding how the recommendation will be viewed or interpreted (e.g. risk of individuals only looking at the “headline”), policy-makers, programme managers, and others making public health decisions will need to review the guideline in its entirety and translate its recommendation and accompanying remarks into appropriate actions in their respective country contexts.</p>
That individuals with pre-existing diabetes were excluded from the systematic review is repeated several times in the guideline. This mention should only be included in the explanation of exclusion criteria, because if healthy people are at increased risk of NCDs and mortality with NSS use, people with diabetes may potentially have worse outcomes, so the recommendation should also include them.	As noted, because the intent of the guideline is for prevention on obesity and NCDs – and not to provide guidance on the use of NSS as a management tool for diabetes, studies assessing impact exclusively in individuals with diabetes were excluded from the systematic review, and this evidence was therefore not reviewed by the NUGAG Subgroup on Diet and Health.
The guideline indicates that sugar alcohols and low-calorie sugars are not considered NSS. The guideline and systematic review should have included sugar alcohols and low-calorie sugars	The focus of the guideline was on non-sugar sweeteners that do not provide calories. Because sugar alcohols and low-calorie sugars provide calories (and in the case of low-calories

such as allulose and tagatose. By excluding sugar alcohols and low-calorie sugars, the review failed to consider the evidence for the positive effect of these sweeteners on tooth mineralisation, and hence their role in reducing dental caries.	sugars, are free sugars) they were not included in the definition of NSS for the guideline. Consequently, the recommendation does not apply to these compounds. This has been clarified in the guideline.
The guideline does not consider the oral health benefits of NSS, including the beneficial effects of NSS on tooth mineralization and dental health.	<p>Evidence for effects of NSS on oral health was considered in the context of clinically-relevant outcomes (i.e. not markers or indicators of dental caries) from studies conducted in humans. While the evidence reviewed does suggest benefit of NSS in reducing risk of dental caries incidence, results were limited and inconsistent.</p> <p>In considering the balance of desirable and undesirable effects, the limited evidence for beneficial effects of NSS on dental caries observed in studies of children was noted. However, this was generally only observed in studies where NSS were compared with free sugars, suggesting NSS does not have any inherent properties that impact risk of dental caries, rather the effect is a result of displacing free sugars. Because the evidence for dental caries was limited, and a reduction in free sugars intake can be achieved and corresponding desirable health benefits realized without the use of NSS, the NUGAG Subgroup on Diet and Health concluded that the potential undesirable effects outweighed the potential desirable indirect effects of NSS on dental caries. This has been clarified in the <i>Balance of desirable and undesirable effects</i> subsection of the <i>Evidence to recommendations</i> section.</p>
The guideline should consider the economics of caries treatment.	The economic burden of caries treatment along with the economic burden of treating the NCDs possibly relevant to NSS use, was noted as being significant and well-appreciated by the members of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health in their deliberations during the guideline development process.
The review failed to include literature on post-prandial blood glucose levels. The guideline should consider and mention the beneficial effects of NSS on post-prandial blood glucose levels.	The guideline acknowledges in the <i>Background</i> section “results of randomized controlled trials have generally suggested NSS may have limited impact on glucose metabolism and result in lower body weight (when coupled with energy restriction) in the short-term”. It is further

	<p>noted that the systematic review found that there was little to no impact on fasting glucose or other measures of glycaemic control measured on the order of days or weeks. Because sustained or longer-term blood glucose control is more clinically relevant than effects on post-prandial blood glucose, and the results from literature on post-prandial effects are consistent with what has been observed in control of blood glucose in the systematic review, it was considered unnecessary to review the literature on post-prandial effects of NSS use.</p>
The guideline should clearly indicate how to prevent industry influence in policy-making.	WHO considers management of conflict of interest a critical component of the policy-making process. However, discussion of this topic is beyond the scope of the guideline on the use of NSS.
The guideline should also consider the effects of NSS on taste preferences, if sufficient data are available. [Studies were suggested].	The impact of NSS on sweet taste preference was assessed in the systematic review, but results were mixed and therefore conclusions could not be drawn. Assessing the impact on taste preferences beyond sweet taste was not identified as a priority by the NUGAG Subgroup on Diet and Health, and is therefore beyond the scope of the guideline.
Noting that NSS consumption amongst pregnant women is discussed in the guideline, the document would benefit from some discussion on the consumption of NSS amongst lactating women and any associated impacts on their babies.	Very little evidence for possible effects/associations of NSS specifically during lactation in women themselves or their babies was identified in the systematic review. Because the guideline applies to all children and adults, the remarks have been clarified to include lactating women (in addition to pregnant women).
The guideline states that “However, NSS-free versions of these items, when readily obtainable, can be considered.” Non-food sources of NSS, such as cosmetics, toothpaste, mouthwash, pharmaceuticals, were not considered in the review and should therefore be removed from the guideline.	While the systematic review was not designed to exclude exposures of NSS from products such as cosmetics, toothpaste, mouthwash, pharmaceuticals, no studies evaluating associations between these sources of NSS and outcomes of interest were identified. As noted in the guideline, the underlying mechanisms of potentially increased risk of NCDs and mortality with NSS use are unknown, though if the amount of NSS consumed is a contributing factor, intake of NSS through cosmetics, toothpaste, mouthwash and pharmaceuticals could add to the total exposure to NSS. Nevertheless, because evidence with respect to these products is lacking, the text has been

	modified to state further that the recommendation does not apply to these products, without any qualifications.
It should be noted that there are currently no public health or dietary recommendations which make explicit mention of the level of processing of foods. There is a need for WHO to provide further guidance on how to regulate ultra-processed products in particular to reduce their consumption and encourage consumption of foods without free sugars or NSS.	Making recommendations on the level of processing in foods and beverages is beyond the scope of the guideline. As noted elsewhere in this document, WHO guidance on level of processing in foods and beverages is planned.

WHO guideline development process

Summary comment	Response
Recommendations should only be made on strong, high quality evidence and shouldn't be based on low quality evidence. The evidence supporting this recommendation is of low to very low quality from observational studies.	<p>WHO develops recommendations and guidance on matters of public health importance even when the certainty of evidence is <i>low</i> or <i>very low</i>.</p> <p>The certainty in (i.e. quality of) the evidence as assessed by GRADE is relative to the high certainty benchmark of well-conducted, double-blind, randomized controlled trials. Because disease incidence and mortality are key patient-relevant outcomes and generally the most relevant for decision-making, and such outcomes are generally only feasibly addressed in long-term prospective cohort studies (for various reasons including rising costs and logistical challenges, very few randomized controlled trials are conducted in which follow-up extends long enough to capture a sufficient number of events for disease and mortality outcomes), evidence from well-conducted prospective cohort studies is an invaluable resource for assessing potential impact of interventions and development of guidance. It is therefore unrealistic to consider only evidence of high or even moderate to high quality when developing guidance as the majority of relevant studies would then need to be excluded. Relative to prospective cohort studies generally, most of those included in the NSS review were very well-done, were at low risk for bias, displayed limited heterogeneity, adjusted extensively for multiple confounders, included attempts to address reverse causality, and many included robust, validated dietary assessment</p>

	<p>tools. These were considered <i>low</i> only because they couldn't be upgraded to <i>moderate</i> with confidence.</p> <p>In addition, the certainty in the evidence is only one factor considered when formulating recommendations; other factors include: desirable and undesirable effects of the intervention; priority of the problem that the recommendation addresses; values and preferences related to the recommendation in different settings; the cost of the options available to public health officials and programme managers in different settings; feasibility and acceptability of implementing the recommendation in different settings; and the potential impact on equity and human rights.</p>
Policy decisions shouldn't be made on conditional/weak recommendations – strong recommendations are necessary. Therefore WHO should not issues conditional recommendations.	<p>Within the GRADE framework as utilized by the WHO and many other organizations, there are options for making recommendations that take into consideration the certainty in the evidence as well as a number of additional factors which allow for recommendations to be made when there is less confidence in the evidence and/or that the other factors considered strongly support a recommendation. Such conditional (or weak) recommendations acknowledge the possibility that all may not benefit from a recommended intervention regardless of any particular circumstance, and provide end users with more flexibility in translating the recommendations given their particular situations or country contexts. Policy decisions can therefore be made on conditional recommendations, but may require substantial debate and involvement of various stakeholders.</p>
Further clarity on how a conditional recommendation should be interpreted and implemented is needed. The WHO “conditional recommendations” establishment is a relevant statement that implies “further debate and involvement of various stakeholders” on policy making and, therefore, should be highlighted and explained more explicitly in the final guideline version.	<p>A text box has been added to the guideline providing explanation as to what is meant by a conditional or strong recommendation. The text is as follows:</p> <p>WHO recommendations can either be strong or conditional, based on a number of factors including overall certainty in the supporting scientific evidence, balance of desirable and undesirable consequences, and others as described in the <i>Evidence to recommendations</i> section of the guideline.</p>

	<p><i>Strong</i> recommendations are those recommendations for which the WHO guideline development group is confident that the desirable consequences of implementing the recommendation outweigh the undesirable consequences. <i>Strong</i> recommendations can be adopted as policy in most situations.</p> <p><i>Conditional</i> recommendations are those recommendations for which the WHO guideline development group is less certain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences or when the anticipated net benefits are very small. Therefore, substantive discussion amongst policy-makers may be required before a <i>conditional</i> recommendation can be adopted as policy.</p> <p>The reasoning behind the strength of the recommendation in this guideline is provided in the rationale for the recommendation</p> <p>Additional information on the assessment of the strength of WHO recommendations can be found in the <i>WHO handbook for guideline development (37)</i>.</p>
It may be more suitable that this document be published as a research summary and additional dietary guidance attached to the WHO sugars guideline. This could reference the systematic literature review, with recommendations for where further research could be undertaken, rather than publishing this as a formal guideline, given the potential for it to impact trust and credibility of the broader suite of WHO Guidelines.	This guideline was developed according to the principles of the WHO guideline development process, just as all other WHO guidelines on healthy diets. The evidence base and all other supporting information support a standalone guideline. There is no expectation that publishing the guideline will impact credibility of other guidelines.
The NUGAG subgroup failed to include experts in dentistry or pharmacy.	While the NUGAG Subgroup on Diet and Health did not include experts whose primary area of expertise is dentistry or pharmacy, the group contains experts with broad nutrition experience and understanding of current areas of discussion regarding NSS; including the role of NSS in oral health. In addition, an expert in oral health who has contributed to evidence gathering for other guidelines, did participate in discussions of the evidence for NSS in the context of oral health.
The use of the GRADE tool in this document and others should be revisited, as it understates the	The debate surrounding the appropriateness of using GRADE to assess the certainty in public

findings of research and may conflict with following the precautionary principle for public health, which should be followed when possible.	health evidence is acknowledged. Nevertheless, GRADE provides a robust and transparent framework for assessing elements of studies that are relevant for determining certainty in the evidence regardless of study type. Because of this, WHO has adopted the use of GRADE as part of its guideline development process.
---	--

Guidance in the context of safety assessments

Summary comment	Response
NSS have been determined to be safe by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and other authoritative bodies when consumed within the ADI (acceptable daily intake). The guideline and recommendation therein are therefore likely to raise questions, confusion, and potential concerns about the safety assessments conducted. The guideline should be in alignment with the guidelines from all WHO bodies. The guideline states that “there is no clear consensus on whether NSS are effective for long-term weight loss or if they are linked to other long-term health effects at habitual intakes within the ADI”. With this statement the draft WHO guideline raises doubts about the safety of NSS as noted above, but is also outside of the scope of the WHO NUGAG Subgroup on Diet and Health and of this draft guideline.	The questions asked by safety assessments and the guideline are different, and therefore the evidence base on which each is based is largely different. As noted in several places within the guideline the guideline is not a safety assessment and does not supersede conclusions and decisions made by JECFA and other authoritative bodies, which are largely based on toxicological evidence. Such evidence generally comes from studies assessing a wide range of NSS doses in animal and in vitro models, and often does not include long-term epidemiological evidence in humans; this may often be out of necessity, given that long term epidemiological evidence for individual sweeteners may not be available at the time a sweetener is being assessed for safety. This is particularly true when assessing whether NSS is effective for managing body weight or otherwise impacts body weight, which is generally out of scope for safety assessments of NSS. Therefore, while there may some overlap in the evidence base used in safety assessments and the evidence base used in the development of the guideline, they are generally distinct and in the case of the guideline more up to date given that safety assessments of most NSS are at least several years old. Consequently, the specific statement highlighted in the comment (and found in the <i>Background</i> section of the guideline) does not question the safety assessments performed by JECFA and authoritative bodies, but alludes to the different questions being asked and different bases of evidence as described above.
The recommendations in the guideline may cause alarm for consumers. Careful messaging of the recommendation and underlying	Noted. WHO will work closely with its communications experts and partners to develop messaging that distinguishes the

evidence base is required, to maintain the trust and credibility of the WHO.	guideline from safety assessments by JECFA and other authoritative bodies and facilitates broad understanding of what the guideline and recommendation means practically.
As JECFA is established as a joint FAO/WHO committee, ideally, those sweeteners for which health concerns have been raised by new studies should be prioritised for an updated assessment by JECFA.	Noted. As noted in the guideline, in 2021, JECFA was requested to re-evaluate the safety of aspartame. In 2019, an international Advisory Group identified the evaluation of aspartame as a high priority for the International Agency for Research on Cancer (IARC) Monographs programme during 2020–24. These two evaluations will be complementary: IARC will assess the potential carcinogenic effect of aspartame (hazard identification), while JECFA will update its risk assessment exercise, including the reviewing of the ADI and aspartame diet exposure assessment. IARC's hazard identification is planned for 6-13 June 2023, and JECFA's risk assessment for 27 June-6 July 2023.

Evidence

Summary comment	Response
Evidence: interpretation and use of evidence	
In formulating the recommendation, RCT evidence of weight loss was dismissed in favour of evidence based on observational studies. The draft WHO guideline places disproportionately more weight on very low to low quality data from observational studies, without giving sufficient weight to higher quality evidence from RCTs supporting benefits of NSS use, without evidence of harm.	The totality of the evidence compiled via the systematic review was considered when formulating recommendations, and how the evidence was reviewed and interpreted is described in detail in the guideline. As indicated in the guideline, the results from observational studies were not considered in favour of the randomized controlled trials, nor were the results from the randomized controlled trials dismissed. Rather, after reviewing the evidence, the NUGAG Subgroup on Diet and Health concluded that the evidence from randomized controlled trials and observational studies were essentially answering different questions in terms of short-term effects and long-term effects. The NUGAG Subgroup on Diet and Health acknowledged that there was a small effect on some measure of body fatness in short term randomized trials (though as indicated below and in the guideline, there were concerns about how well the trials overall answered the specific question about replacing free sugars with NSS, as well as the relevance of the results from experimental settings of NSS use to likely

	<p>complex ways of NSS in the real-world) but that evidence for long-term weight loss or management was lacking in trials, and prospective cohort studies in fact suggested increased risk of weight gain. As further indicated in the guideline, the NUGAG Subgroup on Diet and Health concluded that short-term weight loss/weight maintenance without evidence of sustaining the effect long-term was not considered a long-term health benefit. Similar conclusions were drawn for NCDs: while randomized controlled trials generally suggested no effect on biomarkers for NCDs (which are generally short-term indirect indicators of future disease), observational studies suggested increased incidence of disease and mortality.</p> <p>The certainty in the evidence between randomized controlled trials and observational studies was generally similar. As noted in the guideline therefore, “the NUGAG Subgroup on Diet and Health concluded that the lack of evidence to suggest that NSS use is beneficial for body weight or other measures of body fatness over the long term together with possible long-term undesirable effects in the form of increased risk of NCDs and mortality, outweighed any potential short-term health effects resulting from the relatively small reductions in body weight and BMI observed in randomized controlled trials.”</p>
<p>The WHO draft recommendation ignored the hierarchy of evidence as followed by GRADE by disregarding evidence from RCTs and basing their recommendations solely/predominantly on the observational cohort studies from which causality cannot be inferred. In the GRADE approach, evidence from RCTs start at high certainty due to the greatest protection against bias and cohort studies, with their lesser protection from bias and inability to estimate a causal relationship, start at low certainty of evidence. When evidence comes both from RCTs and cohort studies, and results are divergent, then RCTs are given precedence. The hierarchy of study design in which RCTs are the most robust and reliable should be adhered to and therefore the effects observed in RCTs should be given more weight.</p>	<p>The hierarchy of epidemiological study design is well-noted. Randomized controlled trials are in general higher quality than prospective cohort studies. However, poorly conducted randomized controlled trials may provide lower quality results than well-conducted prospective cohort studies. The GRADE framework allows one to formally assess the certainty in (i.e. quality of) study results independent of the hierarchy (noting however that observational studies are inherently more prone to bias and are therefore started at <i>low</i> certainty of evidence, rather than <i>high</i> as randomized controlled trials are).</p> <p>In the case of the NSS systematic review, several outcomes evaluated in randomized controlled trials were assessed as <i>low</i> (including body weight and BMI), generally because of risk of</p>

	<p>bias (including that randomization processes and allocation concealment was unclear) and inconsistency (i.e. high heterogeneity of effect sizes across studies; $I^2 > 50\%$). This level of certainty was similar to that of many of the outcomes in prospective cohort studies, though a small number of outcomes for which no effect was observed in randomized controlled trials were assessed as <i>moderate</i> and one as <i>high</i>. Overall, in the case of the evidence for NSS, the certainty in the evidence for key outcomes was the same or similar across randomized controlled trials and prospective cohort studies.</p> <p>Also, the NUGAG Subgroup on Diet and Health concluded that the randomized controlled trials and prospective cohort studies were answering different questions in terms of short-term effects and long-term effects.</p>
<p>The draft WHO guideline interpreted as a limitation what the scientific community widely recognises as a strength of randomised controlled trial design, i.e. that they are carefully planned and controlled in order to allow cause-effect relationships to be investigated and established with confidence.</p>	<p>That the randomized controlled trials were carefully planned and controlled was not interpreted as a limitation per se by the NUGAG Subgroup on Diet and Health. Rather, it was importantly noted that the interventions in the trials (i.e. explicit consumption of NSS in place of free sugars) may not be how NSS are consumed in free-living populations and therefore the results of the randomized controlled trials may possibly be less relevant to “real world” settings. From the guideline: “The manner in which individuals consume NSS in the “real world” likely differs significantly from how they were consumed in the trials and is more accurately reflected in the prospective cohort studies. In free-living populations, NSS are likely consumed in complex ways, often not as a conscious replacement for free sugars, but alongside free sugars and carbohydrates, in a compensatory manner in which a food or beverage containing NSS is consumed so that another, often energy dense food can be consumed, or with a general belief that NSS containing foods are simply “healthier”. Rather than consuming fewer calories as observed in many of the randomized controlled trials included in the systematic review, some evidence suggests that those using NSS in free-living populations may consume more calories than those who don't use NSS. There is also limited evidence to suggest that health effects may differ when certain NNS are consumed</p>

	<p>together with sugars compared to when they are consumed alone, though more research is needed to understand if this is broadly applicable and what the implications may be.</p> <p>In addition, as noted in the guideline): “the design of the intervention in randomized controlled trials included in the systematic review varied considerably, which decreased confidence that the overall results observed were highly relevant for the primary, intended purpose of NSS, which is to replace free sugars in the diet, particularly in the diet of individuals habituated to high levels of sweetness. Most trials provided NSS or free sugars (in beverage form) as an addition to the regular diet, often in order to assess whether individuals compensated energy intake when provided with additional free sugars, with NSS serving as a control. While such studies can assess whether when added to the diet, NSS impact energy intake or other relevant outcomes compared to added free sugars, they do not assess the behavioural component of switching from free sugars to NSS, and thus are an indirect measure of the effects of replacing free sugars with NSS. Only four trials specifically assessed the effects on habitual users of sugar-sweetened beverages of replacing these beverages with NSS-sweetened alternatives, and while effects on body weight remained, an effect on BMI was no longer observed. In the three studies that also assessed water as a replacement in a separate arm, water was found to be as effective or more effective than NSS sweetened beverages with respect to lowering body weight. In addition to these trials, a small number of trials provided NSS with water or nothing (placebo) as the comparator (with or without accompanying instructions to restrict energy intake), provided NSS in capsule form, or assessed the effects of asking habitual users of NSS-sweetened beverages to switch to water. Therefore, although it was possible to compare how individuals responded to NSS compared to free sugars across a fairly large number of trials, the evidence for effects of specifically replacing free sugars with NSS is somewhat limited.”</p>
The guideline states that “because weight loss or the maintenance of a healthy weight must be sustained over the long-term in order to realize	The evidence for long-term weight control as assessed in randomized controlled trials is limited and not conclusive: only six of the trials

<p>associated health benefits, there must be evidence for sustained weight loss or maintenance for any intervention being investigated for effects on body weight". Contrary to the conclusion in the guideline that there is little to evidence for long-term weight loss and/or maintenance with NSS use, the systematic review includes evidence from randomized controlled trials of up to two years (one trial of two years duration, two RCTs of one year duration, and three trials of six months duration) which show benefit of NSS with respect to weight control and no evidence of effect-modification by study duration.</p>	<p>lasted six months or longer and collectively showed no effect on body weight in subgroup analysis by study duration. Three of the trials lasting from six months to one year showed no effect on body weight. Two other trials lasting up to 18 months assessed the effects of asking habitual NSS users to stop using NSS – and were therefore not a highly relevant study design for assessing the effects of replacing free sugars with NSS in those habituated to free sugars intake – but nevertheless showed strongly opposite effects on body weight. The third trial, lasting two years, was also effectively an assessment of what happens when habitual users of NSS are asked to stop using NSS and thus not a direct assessment of the effects of replacing free sugars with NSS. In addition, both those that were instructed to continue using NSS and those that were instructed not to use NSS, lost an equivalent amount of weight during the active weight loss phase of the trial (first 16 weeks). It was only during the subsequent weight maintenance and follow-up phases that those not using NSS regained more weight, although at one year post weight-loss energy intakes were equivalent between the two groups, and at three years post-weight-loss phase (though less than 50% of the original participants provided data), the difference in aspartame intakes between the two groups narrowed considerably.</p> <p>Because results from the longer term trials were inconsistent and difficult to interpret, and evidence from long-term observational studies suggested increased BMI and risk of obesity with NSS use, the NUGAG Subgroup on Diet and Health did not consider the observed weight loss in randomized controlled trials – driven primarily by those lasting three months or less – to be indicative of health benefit.</p>
<p>The guideline relies on evidence from observational studies that are prone to bias and at high risk of residual confounding and reverse causation, and are therefore unreliable in assessing causal relationships.</p>	<p>Bias inherent to observational studies is addressed via GRADE by starting observational studies at <i>low</i> risk of certainty. While it is acknowledged in the systematic review and guideline that all prospective cohort studies are risk of residual confounding and that the results for NSS in particular are at risk of reverse causation, it is also noted that the authors of the individual cohort studies recognized the risk for reverse causation and most made great</p>

	<p>efforts to address it. From the systematic review: “They undertook extensive adjustments for potential confounders and robust sensitivity analyses to test the impact of removing data that might contribute to reverse causation – for example, excluding data from the first several years after baseline assessment, or from participants with identified risk factors for disease, or who had experienced unplanned weight change prior to baseline assessment. In the case of type 2 diabetes and stroke, the positive association remained in the majority of studies that performed such analyses, and in some cases strengthened. In addition, more than half the cohort studies assessing the effects of NSS on incident type 2 diabetes that reported a P_{trend} value reported a statistically significant P_{trend}, suggesting the possibility of a dose–response relationship. The results of these additional analyses are difficult to reconcile with reverse causation being the sole cause of the positive association between NSS use and type 2 diabetes as it would suggest a long latency period before manifestation of disease, and that those at increasingly greater risk of disease at baseline would have consumed proportionately more NSS, which is possible but not necessarily self-evident or logically explained.”</p>
<p>NSS use did not impact risk factors for NCDs as observed in RCTs (e.g. no significant impact on glucose or insulin levels, blood lipids, blood pressure). Thus, there is no mechanistic evidence to support possible long-term adverse effects in the form of increased risk of NCDs.</p>	<p>Several possible mechanisms for the observed associations between NSS use and risk of NCDs are presented in the systematic review and guideline and in summary include effects on: feeding behaviour (i.e. how NSS are used, which evidence suggests may often not be as a replacement for free sugars), taste perception (e.g. sweet taste preference, thresholds of sweet-taste sensitivity), eating behaviour (e.g. hunger, appetite) and other neural responses (e.g. hedonic response to sweet-taste, memory and reward pathways in the brain); pathways that link the sensing of sweet-taste in the oral cavity with the expectation of subsequent energy delivery to the digestive tract; release of metabolic hormones and other biological molecules; and alterations to the bacteria colonising the small and large intestine (i.e. gut microbiota). This is suggestive of a possibly complex aetiology that might not be adequately reflected in short term effects on biomarkers of disease.</p>

Evidence: consistency of systematic review supporting the guideline with other reviews	
<p>A recent systematic review and network analysis of trials (McGlynn et al. 2022), which applied substitution analyses, reported that the substitution of beverages containing non- sugar sweeteners or water for sugar-sweetened beverages resulted in reductions in body weight and improvements in cardiometabolic risk factors.</p>	<p>McGlynn 2022 was published after the systematic review supporting the guideline was published. Results of this review (as with other recent reviews) were similar to those reported in the review supporting the guideline, despite limiting analyses only to NSS exchanged for sugars: small decrease in body weight and BMI, but no significant impact on cardiometabolic risk factors (although the comment suggests that improvements in cardiometabolic risk factors were observed when NSS were exchanged for sugars in the McGlynn 2022 review, there were no statistically significant effects reported for any common risk factor). This is not surprising given that generally the same studies are available to reviewers and any differences in results are therefore largely a result of which studies were included. This in turn is dependent on inclusion and exclusion criteria which can vary from review to review.</p>
<p>A recent systematic review and meta-analysis of prospective cohort studies (Lee et al. 2022) which sought to minimise the effects of reverse causality and residual confounding, reported that NSS did not show any cardiometabolic harm, similarly to the results of the RCTs in the WHO review, but contrary to the findings of the meta-analyses of prospective cohort studies in the WHO review.</p>	<p>This review conducted two analyses, both of which were limited to studies with beverage exposures that adjusted for adiposity at the beginning of the study (i.e. at baseline) and:</p> <ul style="list-style-type: none"> • one in which they also limit the inclusion of studies to those that made multiple exposure assessments and thus are able to assess associations with health outcomes in the context of changes in NSS intake over time (i.e. change analysis); and • one in which they also limit studies to those that modelled the effects of substituting NSS for sugars. <p>All the studies included in this review assessed NSS exposure in beverage form; i.e. NSS intake was via NSS-containing beverages, and was compared to consumption of sugar sweetened beverages (SSBs). Adjusting for baseline adiposity helps to address any imbalance in measure of adiposity that may be present in groups who are classified based on the level of NSS intake (i.e. to help address the case where those reporting the highest levels of NSS intake are also slightly heavier on average than groups reporting lower or no NSS intake, or vice-versa).</p>

	<p>Regarding the first analysis, while repeated assessments of exposure generally provide a more reliable picture of exposures in prospective cohort studies than a single measurement at baseline, in this case of NSS it greatly limited the number of studies the authors were able to include in the analyses and consequently the number of outcomes that could be assessed: five studies for body weight, one for waist circumference, and three for type 2 diabetes. For an increase of one serving of beverages sweetened with NSS, an estimated 8 gram reduction (or difference) in body weight and a 1.15 cm reduction (or difference) in waist circumference per year was observed. For type 2 diabetes there was no association observed (i.e. there was neither increased or decreased risk of type 2 diabetes with each serving of NSS-sweetened beverage). While the results are suggestive of no harm with respect to body weight or type 2 diabetes, they also don't suggest benefit, as though a difference was observed in body weight, an 8 gram difference is almost negligible, even on a yearly basis. Regardless, definitive conclusions can't be reached from the very limited data.</p> <p>The substitution analysis is intended to try and address the health effects specifically associated with replacing SSBs with NSS-containing beverages. Given the nature of prospective cohort studies, this is modelled data and does not actually assess the effects of individuals actively replacing SSBs with NSS-containing beverages as one might observed in a randomized controlled trial. As with the change analysis, for some outcomes the number of studies included are very limited; in fact, results from a single cohort study provide data for more than half the outcomes reported. Results shows a small reduction in body weight of 120 grams per year, as well as a 12% decrease in risk of obesity and 11% decrease in coronary heart disease incidence. Very small reductions in risk of 4-5% were observed for death from cardiovascular diseases or non-specific cause (i.e. all-cause mortality). No associations were observed for type 2 diabetes, stroke or coronary heart disease mortality. In simple terms, and keeping in mind that more than half the results are based on single studies, what these results</p>
--	--

	<p>would suggest is that while consuming NSS-containing beverages instead of consuming SSBs may reduce risk of adiposity and coronary heart disease, consuming NSS-containing beverages carry about the same risk for type 2 diabetes, stroke and dying from coronary heart disease as consuming SSBs, and only slightly less risk of dying from cardiovascular diseases or a non-specific cause.</p> <p>In addition to the mixed results and limited number of studies informing the substitution analyses, it must be reiterated that the intent of this analysis was to assess specifically the health effects of the “intended use” of NSS, i.e. replacing free sugars. It does not therefore take into consideration the likelihood that many who use NSS do so in a manner that is not strictly according to their intended use as noted elsewhere in this document and in the guideline. It also by design can't provide information on any potentially inherent effects of NSS as they are only assessed in this analysis in relation to consumption of SSBs. (The change analysis can assess inherent properties and different patterns of NSS intake, but as noted is extremely limited in the number of studies and outcomes included).</p> <p>The results of this review are therefore not entirely inconsistent with the results observed for the systematic review supporting the guideline, and do not provide sufficiently compelling evidence to conclude that are NSS are risk free and provide benefit even when users consciously replace free sugars-containing food and beverages with NSS-containing alternatives. What they do suggest is the need for further research into the long-term effects of NSS using repeated exposure assessments as well as other more robust dietary assessment tools (which may need to be developed). Further research into the possible mechanisms of “real world use” are also needed to address whether any observed health effects, if real, manifest only in the context of free sugars intake, or do NSS have inherent effects via mechanisms described elsewhere in this document.</p>
Prospective cohort evidence that explicitly modelled caloric substitution with NSS (such as	Keller et al. 2020 was included in the systematic review supporting the guideline, but was not

<p>Keller et al 2020) were not included in the systematic review supporting the guideline. This approach contrasts with WHO's approach on interpreting evidence from the systematic review on saturated fatty acids and <i>trans</i>-fatty acids, in which it was noted that when assessing evidence for these nutrients it is critically important that the effect of different replacement nutrients be carefully considered.</p>	<p>included in meta-analyses as analyses restricted to modelled substitution were not conducted. Data for associations between higher compared to lower intake of NSS and relevant outcomes for the individual cohorts included in Keller et al. 2020 were included in meta-analyses in the systematic review supporting the guideline. The same is true for other studies that performed substitution modelling as they generally also presented results for unmodelled, higher compared to lower intakes in the same publication.</p> <p>With respect to assessing replacement nutrients, replacing free sugars with NSS is not analogous to replacing a nutrient with caloric value with another nutrient with caloric value (e.g. replacing saturated fat with other nutrients as suggested in the comment). With respect to saturated fatty acids and <i>trans</i>-fatty acids (and other nutrients with caloric value), unless an individual is energy imbalance, reducing the intake of saturated fatty acids for example requires the consumption of another nutrient to replace the caloric deficit and maintain energy balance. Because nutrients can have different impacts on health, the nature of the replacement nutrient must be known, as it is possible that the replacement nutrient is associated with "worse" health outcomes than the nutrient being replaced. Because NSS are chemicals without caloric value, they can be – and likely are – consumed without the need to replace any nutrients (i.e. free sugars). They can therefore be assessed for effects/associations based on level of intake, independently of any nutrient they might replace.</p>
<p>The guideline should be based on the totality of evidence, but it ignores results of other systematic reviews showing benefits of NSS in terms of body weight and biomarkers for NCDs.</p>	<p>The results of the systematic review supporting the guideline are very much consistent with previous reviews of NSS in that small short-term differences in body weight and little to no effect on biomarkers for NCDs have been observed in randomized controlled trials, and increased risk for certain NCDs in observational studies. That the results of reviews conducted at similar times report similar results is not surprising given that generally the same studies are available to reviewers and any differences in results are therefore generally as result in which studies were included which in turn is dependent on inclusion and exclusion criteria which can vary</p>

	<p>from review to review. The only difference between results of reviews appears to be between the review supporting the guideline (and previous ones) and a recent review mentioned earlier in this document (McGlynn et al. 2022) which shows largely null or slightly protective associations between NSS, body weight and NCD risk. For reasons described earlier in this document however, despite a different approach to meta-analysing the data, the results of McGlynn et al. 2022 are not entirely inconsistent with the results of the systematic review supporting the guideline.</p>
<p>Evidence: Methodological considerations</p>	
<p>When assessing association for dietary exposures against the Bradford Hill criteria for assessing causation, it is generally recommended that summary relative risks be ≤ 0.83 or ≥ 1.20.</p>	<p>Noted. In practice, different thresholds of changes in risk and other criteria are used in deciding whether an effect or an association is in fact present and whether it is clinically relevant.</p>
<p>The sub-section 'NCDs and mortality' in the <i>Summary of Evidence</i> section could benefit from comparisons between NSS and equivalent amounts of sugar if available. Simply stating higher intakes of NSS result in higher risk of type 2 diabetes, cardiovascular disease and all-cause mortality neglects the fact that most individuals/countries introduce NSS as a substitute to sugar, which has significant impacts on risk factors for type 2 diabetes, cardiovascular disease and all-cause mortality.</p>	<p>Assessing comparison of NSS and free sugars was not possible for many of the prospective cohort studies included in the systematic review. A recent review has modelled the replacement of sugar-sweetened beverages with NSS-containing beverages in a smaller number of cohort studies (McGlynn et al. 2022) and results suggest that in terms of NCDs and mortality, with the exception of coronary heart disease (for which a significant reduction in risk was observed when NSS replaced sugars) there was little difference between beverages containing free sugars or NSS. This means that according to this analysis, consuming NSS-containing beverages instead of consuming SSBs may reduce risk of coronary heart disease, consuming NSS-containing beverages carry about the same risk for type 2 diabetes, stroke and dying from coronary heart disease as consuming SSBs, and only slightly less risk of dying from cardiovascular diseases or a non-specific cause.</p> <p>However, as noted in the guideline, considering the evidence only in the context of how NSS are intended to be used ignores both potential inherent effects of NSS (e.g. on gut microbiota) and the likelihood that significant portions of the population that consume NSS do not explicitly use them as replacements for free sugars.</p>

<p>In the short term, the reported weight loss and reduced BMI in the RCTs did not take attribution for individuals undergoing weight reduction programmes into account. It is critical to confirm if the analysis considered the issue of attribution.</p>	<p>Subgroup analyses by whether or not the study was a weight loss study were conducted for body weight and BMI and results for the former were reported in the guideline. Only four of the randomized controlled trials were active weight loss trials and did not show an effect on BMI relative to non-weight loss trials. There was a larger effect observed for body weight in weight loss trials, but there was high heterogeneity, and the effect was not statistically significant.</p>
<p>The guideline should note that it is difficult to look specifically at the effects of sweeteners alone as the results may be influenced by a number of factors (e.g. the diet of people consuming sweetened products may contain more processed, higher fat and therefore higher energy products).</p>	<p>Potential confounding factors such as overall diet are discussed at length in the guideline in the <i>Interpreting the evidence</i> section. Overall diet is specifically noted in the guideline as follows: “Overall dietary quality has also been cited as a potential confounder, however, there was no consistent difference between levels of NSS use and diet quality at baseline in the studies included in the systematic review (i.e. diet quality was not consistently lower, higher or equivalent in those using more NSS compared to those using less), and many studies controlled for dietary quality without a significant impact on the observations associations.”</p>
<p>Many outcomes had high heterogeneity in meta-analyses (where the I^2 is greater than 50%), rendering the results as unreliable from a statistical standpoint.</p>	<p>The GRADE framework provides a way of addressing outcomes with high heterogeneity, in that the certainty in the evidence for the outcome can be downgraded (e.g. from high to moderate, moderate to low, etc.). In the NSS systematic review, the certainty in the evidence for outcomes with moderate to high heterogeneity (I^2 greater than 50%) were downgraded once. While there is less confidence in the results for outcomes with high heterogeneity (i.e. they are less “reliable”) they are not unreliable in the sense that they can still represent a real effect or association.</p>
<p>The weighting of the individual studies included in the meta-analyses are suspect and not related to sample size. No reason is given for the weighting. The weighting of the various studies can introduce huge bias in the interpretation of the comparisons.</p>	<p>Random effects meta-analyses were conducted using the DerSimonian–Laird (inverse-variance) method. This approach weights studies based on the inverse variance of the effect-size estimate for each study (which is often, but not always, correlated with study size) and is a well-accepted method of meta-analysis. Sensitivity analyses in which the pooled effect for body weight was calculated with fixed effects meta-analysis (which weights based on study sample size), yielded results that were similar to those from the DerSimonian–Laird method.</p>

Most of the observational studies adjusted from BMI but not body weight. Human fluid requirements are directly related to body weight (35-45mL per kg body weight), not BMI. All but two of the included observational studies were confounded by this factor.	It is not clear how fluid requirements would be relevant in the context of considering different levels of NSS intake. Most of the prospective cohort studies assessed intake of NSS-containing beverages and quantified the number of servings of NSS. When assessing the effects on body fatness and disease outcomes of higher compared to lower (or no) NSS, why someone consumed more or less is irrelevant; what is important is the level of intake.
Evidence: GRADE assessments and certainty in the evidence	
Based on results from randomised, controlled trials in children, the certainty in the evidence for a beneficial effect on body weight, waist circumference, and body fat mass was considered to be moderate. The overall certainty in the available evidence for outcomes in children was considered to be very low. It is suggested that there is some discussion of how this very low overall certainty was derived.	Because there was limited evidence in children and the results observed in adults were considered relevant to children, including increased risk of NCDs, the certainty in the evidence for children was assessed both from the evidence directly obtained from studies conducted in children and the evidence from studies conducted in adults. Therefore, the overall certainty for children was assessed as being the same for adults. The text in the <i>Summary of evidence</i> section has been modified to better clarify this, as follows: "The certainty in the available evidence for an effect of NSS intake on outcomes assessed directly in children was assessed as <i>moderate</i> overall. GRADE assessments for each outcome can be found in Annex 6; GRADE evidence profile 3. In formulating the recommendations, because both adult data and child data were considered for children, the certainty in the available evidence across all population groups was assessed as <i>low</i> ."
The authors have not downgraded evidence based on number of studies and notably most of the results that are considered of 'moderate certainty' are based on very few studies and very few participants. There is clear potential for bias when limited studies are considered.	Under the GRADE framework, outcomes are not downgraded based on number of studies, but can be downgraded based on the total number of individuals across all studies; i.e. an outcome can be downgraded if the total number of individuals from all studies is small. Therefore, the systematic review authors did not downgrade outcomes simply because there were very few studies, but did downgrade studies where the total number of individuals was considered small enough to possibly impact the ability to detect a difference. In assessing the evidence however, the NUGAG Subgroup on Diet and Health did acknowledge potential shortcomings in cases where there was only a single study providing evidence for an outcome (e.g. only a single study population, etc.).

<p>The combination of very low and low-quality studies with higher quality studies as equally valid runs the risk of introducing significant bias in the meta-analyses. There was no effort presented where the meta-analyses calculations were performed with high quality studies (excluding the very low and low quality studies) to evaluate the impact of study quality on the conclusions reached.</p>	<p>The certainty of evidence (i.e. quality of evidence) is assessed at the outcome level, not at the study level. Therefore, assessing higher “quality” studies separately from lower quality studies is generally not done. Sometimes subgroup and/or sensitivity analyses are done based on risk of bias of individual studies, but in the case of the NSS systematic review, most randomized controlled trials were considered to have serious risk of bias (primarily because randomization processes and allocation concealment was unclear) and prospective cohort studies to have low risk of bias (beyond that inherent to observational studies and resulting in a starting certainty of <i>low</i> within the GRADE framework), and therefore such analyses were not considered informative.</p>
<p>Evidence: oral health</p>	
<p>The review only included six studies on oral health and did not include any study on sugar-free chewing gums. The review also failed to include literature on tooth mineralization, particularly in the context of sugar-free chewing gums, for which EFSA has concluded that sugar-free chewing gum helps to maintain tooth mineralization as part of 2009 and 2011 scientific opinions on substantiation of health claims regarding chewing gum.</p>	<p>The literature was searched for studies assessing oral health, but many studies were excluded as they did not meet the inclusion criteria; many were excluded because they assessed the effects of sugar alcohols or low calorie sugars, did not report an outcome of interest (i.e. dental caries), or used animal or in vitro models. Studies on chewing gum also weren’t explicitly excluded from the systematic review. However, such studies were ultimately excluded because they didn’t meet inclusion criteria; mostly because they assessed sugar alcohols and/or they assessed an outcome other than dental caries. Regarding outcomes, although several studies reported on markers of dental caries (e.g. plaque pH, plaque amount, etc.), these were not considered critical outcomes in the context of dental caries incidence. Similarly, it is noted that tooth mineralization also can’t readily be measured directly in humans. In addition, when assessing the effect of sugar-free chewing gums on indicators of tooth mineralization, a significant portion of the observed activity is attributed to saliva stimulation resulting from the action of chewing, and not on actions of NSS per se.</p>
<p>We are concerned that the oral health literature included in the WHO systematic meta-analysis, i.e. the study by Marshall et al 2003, is limited and may not fully represent the conclusions of the authors. The Marshall et al 2003 study</p>	<p>The results for Marshall et al 2003 are explicitly stated in the systematic review as follows: “A prospective cohort study found that low intakes of NSS-sweetened beverages were associated</p>

found children consuming sugar-free beverages and sugar-free powder at 5 years had a decreased risk of caries experience. This data supports the hypothesis that beverages that contain sucrose could be more detrimental to oral health than beverages that are sweetened with other sugars.	with fewer teeth surfaces having caries compared with no intake ($P < 0.025$). However, the association with high intakes of NSS-sweetened beverages was not reported.” This result, along with other data for oral health in children and adults was considered by the NUGAG Subgroup on Diet and Health.
Evidence: general	
In the systematic review, the authors discuss some possible scenarios where the consumption of NSS may not result in reduced body weight in the real world, but they fail to discuss the comparable situation where NSS can aid body weight reductions, e.g. when NSS replace sugar, despite the evidence of a benefit in their review.	The inclusion of this information was to provide a possible explanation for the discordant results between the randomized controlled trials and prospective cohort studies and to acknowledge that NSS use in the real world is complex, and that not everyone uses NSS as a deliberate replacement for free sugars. All observed effects and associations between NSS use and health outcomes in randomized controlled trials and observational studies whether they favoured NSS or not using NSS are presented. A long term effect on body weight (i.e. as used in the real world) was not observed in prospective cohort studies.
There is limited interpretation of evidence on the possible adverse effects from non-use of NSS, which may exacerbate weight gain and associated ill-health.	The effects on body weight and other measure of body fatness, and risk of NCDs were discussed in detail in the context of higher vs lower intake of NSS. Therefore any adverse effects of non-use (i.e. lower NSS use) would have been captured in the systematic review.
A large part of the literature included in the systematic review was funded or affiliated with the food industry. As there is a clear conflict of interest in this literature, we caution its inclusion in WHO’s decision making process.	Using GRADE as a tool for assessing certainty in the evidence allows one to focus on elements of studies which could be problematic irrespective of funding source. The GRADE assessments did identify issues with respect to risk of bias in the randomized controlled trials which ultimately led to body weight, BMI and other outcomes being assessed as <i>low</i> certainty. It should also be noted that while sensitivity analyses of body weight and BMI in which randomized controlled trials funded or supported by industry were removed resulted in attenuation of the effects observed for these outcomes, the effect on body weight was still present.
No evidence is provided in the systematic review or guideline to suggest that small reductions in energy intake over time may not be beneficial, or would be disadvantageous, to warrant a recommendation that NNS not be used	It is acknowledged that the nature of long-term weight loss and maintenance generally occurs gradually, over time. Therefore small, but sustained reductions in energy intake over time can be beneficial. In the context of the evidence reviewed for the guideline, as noted in the guideline, the reduction in energy intake

	observed in the randomized controlled trials does not appear to be sustained over the long-term based on the evidence reviewed, as evidence for long-term benefit on body weight was lacking. This topic was therefore not discussed in the guideline or systematic review.
The guideline does not discuss evidence on the effects of discontinuing NSS use in habitual users of NSS.	The systematic review identified a small number of randomized controlled trials in which habitual users of NSS were asked to stop using NSS but were results were inconsistent and therefore no conclusions could be drawn.
The guideline indicates that 283 unique studies were identified in the systematic review, and lists the number of randomized controlled trials, prospective cohort studies, and case-control studies, which do not add up to 283 (the nature of 89 studies is not clear).	The 89 unmentioned studies were non-randomized intervention studies, cross-sectional studies, and ongoing or registered randomized controlled trials. A footnote was added to the guideline that relevant publications with these study designs were also identified and noted in the systematic review.
It is stated that some studies could not be meta-analysed. It is suggested that the reason(s) for this are described in the guideline.	The reasons for this are common methodological challenges encountered in many systematic reviews (e.g. units reported differently, etc.) and vary for different outcomes, which is explained in the systematic review. This level of detail regarding methodology of the systematic review is not appropriate for a guideline, but can be found in the systematic review.

Rationale for the recommendation

Summary comment	Response
<p>In the context of the short duration (several months or less) of most randomised, controlled trials on non-sugar sweeteners, it is stated in the <i>Rationale</i> section that “...weight loss and maintenance of a healthy weight must be sustained over the long-term to have a meaningful impact on health...”. It is suggested that some discussion or definition of “long-term” is included (noting that maintenance of a healthy weight over a lifetime is clearly the most desirable scenario and reducing sugars intake over the long-term through use of non-sugar sweeteners may aid the achievement of this goal).</p> <p>The term “meaningful impact”, which is used in the <i>Rationale</i> section in the context of the text</p>	<p>Noted that “maintenance of a healthy weight over a lifetime is clearly the most desirable scenario” in terms of weight loss and maintenance. However, providing an explicit cut-off for what constitutes long-term weight loss or maintenance as assessed in the evidence by the NUGAG Subgroup on Diet and Health is not directly relevant or necessarily helpful to end-users in terms of considering and implementing the recommendation. What is important is that the majority of trials were very short (lasting three months or less) and are not informative when assessing long-term benefit, which is clearly noted in the guideline. For reference, when considering the evidence for the WHO guideline on total fat intake, the NUGAG Subgroup on Diet and Health only</p>

<p>“weight loss and maintenance of a healthy weight must be sustained over the long-term”, is subjective and may have a different definition depending on the situation or specific individual. Meaningful impact with regard to the use of non-sugar sweeteners could also relate to weight management as opposed to only weight reduction.</p>	<p>considered studies reporting body fatness outcomes that lasted a minimum of six months. In the case of NSS, only six of the trials lasted six months or longer and collectively showed no effect on body weight in subgroup analysis by study duration. We have added some additional text in the form of footnotes in several places within the guideline to clarify the concept of long-term maintenance of healthy weight. The text is as follows: “Ideally, healthy body weight is maintained throughout the life course.”</p> <p>Regarding the comment on the use of the term “meaningful impact”, the NUGAG Subgroup on Diet and Health, as noted in the phrase “weight loss and maintenance of a healthy weight must be sustained over the long-term”, acknowledged that meaningful impact could relate to weight management or weight reduction.</p>
<p>In the <i>Rationale</i> section it states the NUGAG Subgroup on Diet and Health noted that ‘there were no identified undesirable effects or other mitigating factors that would argue against not using NSS’. This statement is very confusing as there are many double negatives in this sentence which makes it difficult to understand.</p>	<p>Because the recommendation is on not using NSS and the evidence to recommendations process assessed this “action” specifically, changing it to avoid double negatives would change the nature of the statements in the rationale.</p>
<p>The position in the text of the quality of the evidence, e.g. “(very low to low certainty evidence)”, can be confusing. For example, in the <i>Rationale</i> section it states that “In prospective observational studies with up to 10 years of follow-up, higher intakes of NSS were associated with higher BMI and increased risk of incident obesity, but not other measures of body fatness, (very low to low certainty evidence)”.</p>	<p>These are summaries of the evidence designed to give a very brief overview in the context of formulating the recommendations. In order to provide sufficient detail but maintain readability, the text is constructed in this way. The certainty in the evidence for each outcome can be found in the tables in the <i>Summary of evidence</i> section as well as the GRADE evidence profiles in Annex 6.</p>
<p>Because for example the totality of evidence for effects of NSS on oral health was not considered when developing the recommendation, the wording of the recommendation itself should focus on the specific findings of the systematic review (i.e. list the outcomes for which associations were observed) and not generalise the findings to all NCDs.</p>	<p>Studies conducted in humans that assessed clinically relevant outcomes related to oral health were included in the systematic review and considered by the NUGAG Subgroup on Diet and Health. Also noted is that while the evidence reviewed does suggest benefit of NSS in reducing risk of dental caries incidence, results were limited and inconsistent.</p> <p>Additionally, citing specific outcomes in recommendations is not recommended by GRADE methodologists, except possibly in rare instances where only a single outcome has been</p>

	<p>assessed, in which case the title might be qualified to include the outcome in order to convey that only a single outcome was considered. Otherwise, general practice is not to include specific outcomes in the title as generally a range of outcomes are considered and guidance to do something or not do something is based on the overall impact on health and should therefore not need qualification. In the case of NSS, the additional, qualifying text "...as a means of achieving weight control or reducing risk of noncommunicable diseases" was included to acknowledge that NSS is already widespread and that for individuals using it for weight control or reducing risk of NCDs may not be receiving that benefit.</p>
--	---

Evidence to recommendations

Summary comment	Response
The <i>Evidence to recommendations</i> section notes the recommendation/intervention is a 'dietary goal' and a suggestion to exclude NSS in the diet. The recommendation is focused on not using NSS as a means of weight loss. This section discusses health benefits, this link could be made clearer.	The conditional recommendation to not use NSS is considered a dietary goal along with other WHO guidance on healthy diets. The <i>Evidence to recommendations</i> section discusses many different facets of NSS use/not using NSS related to different health outcomes.
In the <i>Evidence to recommendations</i> section it indicates that individual level acceptability of the recommendation "may be low." We do not believe that this recommendation would be particularly impactful on an individual level, nor should it be. In public health, creating mandatory policies provides a population level impact and ultimately increases public acceptability of these measures. This justifies the need for stronger policies at the national level that encourage reduction of NSS as well as sugar, and ultimately create a food supply that will not depend on NSS. The onus should not be put on the consumer to make decisions about whether they are choosing products with NSS or not, particularly without interventions to communicate potential harms of NSS and consumption of ultra-processed products.	The guideline is targeted to policy-makers, programme managers and others involved in addressing public health issues. The translation of the recommendation into action requires the consideration of various elements including particular situations or country contexts. Therefore, the recommendation provided in the guideline does not put the onus on consumers but does require their input, along with the participation and cooperation of many stakeholders. The guideline indicates that many ways of implementing the recommendation can be considered including education programmes and other interventions targeting behaviour change.
It is noted that "There were no identified undesirable effects or other mitigating factors that would argue against not using NSS". If	The statement that there were no <u>identified</u> undesirable effects, together with other text describing the results of the systematic review,

evidence is lacking, it cannot be stated there are no undesirable effects, only that they were not observed in studies.	indicates that no undesirable effects were observed in the studies assessed, not that there are no undesirable effects in absolute terms.
An undesirable effect of the recommendation is that people could revert from using NSS to using sugar.	The possibility that the recommendation could lead individuals to revert or otherwise switch from using NSS to free sugars is noted. The <i>Evidence to recommendations</i> section has been updated to reflect this with the following text: “The recommendation to not use NSS could result in potential undesirable effects, not inherent to NSS, if some individuals currently using NSS discontinue use and increase free sugars intake in order to maintain the level of sweetness in their diet. However, the undesirable effects of free sugars intake are well documented, and awareness of these effects among the general public is fairly high. Together with the fact that the recommendation in this guideline should be considered in the context of the WHO recommendations to reduce free sugars intake (14), this suggests that individuals switching from NSS to free sugars would not be a widespread occurrence.”
In the <i>Evidence to recommendations</i> section it is stated that “The overall certainty in the evidence was considered low and is based on undesirable effects of non-sugar sweetener use on prioritised health outcomes observed in prospective cohort studies which were individually considered to be very low to low.” This statement could cause confusion. Whether the observed effects are undesirable or not is irrelevant to the assessment of certainty in the evidence. Moreover, this statement should also include the certainty in the evidence from RCTs.	The overall certainty in the evidence reported is that for the evidence on which the recommendation is based. Because the recommendation is primarily based on evidence from prospective cohort studies, the overall certainty is <i>low</i> as indicated.

The recommendation in the context of diet quality

Summary comment	Response
The guideline reaches beyond the matter of the safety and recommended intake of NSS by making assumptions on their ultimate role in the diet. This overreach of the guideline’s scope is in conflict with actions taken worldwide by public health authorities and private sector organisations to reduce sugar intake. The overall draft recommendation is based, among other things, on the suggestion that NSS could –	Regarding these observations, the guideline states the following, and includes references to scientific studies as noted: “In free-living populations, NSS are likely consumed in complex ways (<i>four references provided</i>), often not as a conscious replacement for free sugars, but alongside free sugars and carbohydrates, in a compensatory manner in which a food or beverage containing NSS is consumed so that

<p>in addition to being a safe, sugar free alternative to high-caloric sugar – ultimately shape the overall diet of consumers: “Because free sugars are often found in highly processed foods and beverages with undesirable nutritional profiles, simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected.” This statement is unsubstantiated, not supported by science, and discounts the many nutritious and affordable products that positively contribute to overall diet quality by delivering under-consumed food groups like whole grain, dairy and fruits, as well as important nutrients like fiber, protein, and vitamins/minerals.</p> <p>The guideline acknowledges a perception that NSS- and sugars-sweetened beverages tend to be consumed alongside other ‘unhealthy’ foods and appears to assume that removal of the beverage would remove the consumption of the associated foods. Yet, no evidence has been presented to support this perspective.</p>	<p>another, often energy dense food can be consumed, or with a general belief that NSS containing foods are simply “healthier” (<i>one reference provided</i>). Rather than consuming fewer calories as observed in many of the randomized controlled trials included in the systematic review, some evidence suggests that those using NSS in free-living populations may consume more calories than those who don't use NSS (<i>one reference provided</i>).</p> <p>In addition, the systematic review notes also with references: “... real-world consumption of NSS as assessed in cohort studies is more complex and could follow a variety of patterns including as a conscious, specific replacement of sugars, but also as a general part of the diet without concern for whether or not they are replacing sugars, or have low or no calories. NSS could also be used as a justification for consuming other sugary or unhealthy foods – that is, people who have consumed a food or beverage with NSS might feel that it is acceptable to then consume sugar-containing (or otherwise unhealthy) foods or drinks (<i>one reference provided</i>). Evidence does suggest that many people consume products with NSS not in replacement of, but in addition to, foods containing sugars, as well as other unhealthy foods (<i>four references provided</i>), and results of a cross-sectional study of children completing the NHANES survey in the United States suggest that consuming both NSS and sugars is associated with greater total energy intake than consuming either alone (<i>one reference provided</i>).</p> <p>The guideline doesn't suggest directly that stopping the consumption of NSS-containing foods and beverages will impact other food choices, or necessarily shape the overall diet, but it does suggest that because NSS are often included in foods and beverages as a replacement for free sugars (i.e. sugars that have been added, not naturally-occurring sugars) which are often highly processed and may contain little nutritional value, reducing the consumption of such foods and beverages may improve the overall quality of the diet. The guideline doesn't suggest that all foods containing NSS are of low nutritional value.</p>
---	---

	<p>Therefore, while the concept illustrated by the statement “Because free sugars are often found in highly processed foods and beverages with undesirable nutritional profiles, simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected” was considered when assessing the evidence and other relevant factors described in the <i>Evidence to recommendations</i> section, the recommendation does not heavily rely on this concept; rather it is one of many possible undesirable effects considered.</p>
<p>Processed foods are discussed in the guideline in a negative manner. Processed foods help to ensure food safety, increase palatability, provide stability in transportation, and facilitate the production of convenient and affordable foods. As such, processed foods are integral in diets across many cultures, and make up vital parts of the global food supply. The guideline should therefore not be focused on the condemnation of processed foods, but it should rather encourage raising the nutrition quality of packaged food products through robust reformulation programmes, while making it accessible and affordable for all.</p>	<p>The guideline is not on processed foods and does not condemn process foods. Noting that there is a wide spectrum of how foods may be processed, which can impact nutrition quality in vastly different ways, the guideline in fact does not mention “processed foods” but does refer to “minimally processed foods” and “highly processed foods” in the context of how NSS may impact the diet and dietary quality. Improving the nutrition quality of packaged foods is supported.</p>
<p>The guideline should include evidence on how NSS could help improve diet quality.</p>	<p>Evidence on this was not collected or reviewed. Other than replacing free sugars, it is not clear how NSS would improve diet quality.</p>
<p>The guideline should give stronger prominence on the need to promote minimally processed, nutritious, whole foods in the draft guideline.</p>	<p>This is the goal of all of the healthy diet guidelines collectively. WHO guidance on level of processing in foods and beverages is planned.</p>
<p>When discussing diet quality and level of food processing the NOVA classification scheme can help to identify and categorize healthy and unhealthy foods. NOVA and the health harms related to consumption of “ultra-processed products” should be highlighted more explicitly in the guideline so that users understand that products reformulated with NSS likely remain ultra-processed products.</p>	<p>Noting that there is a wide spectrum of how foods may be processed, which can impact nutrition quality in vastly different ways, the guideline refers to “highly processed foods”. However, it is beyond the scope of the guideline to adopt and/or promote a particular scheme for classifying the level of processing in foods and beverages.</p>

Implementation of the recommendation

Summary comment	Response
<p>The guideline should not include specific policy suggestions (e.g. marketing regulation, fiscal policies, and nutrition labelling), which have not been supported by impact assessments or other evidence.</p>	<p>The guideline is not recommending or suggesting that specific policy actions be implemented in the context of the NSS recommendation. In the <i>Translation and Implementation</i> section of the guideline, possible options are listed in a conceptual sense. This section of text has been reorganized and revised in several places to try to clarify this further.</p>
<p>The guideline should include guidance on how the proposed audience of policy makers, health professionals, scientists, industry, educators etc, should utilise the guidance (dietary goal). If not, there is a risk that this guidance will result in messaging to consumers which will create confusion and fear. The section "<i>Monitoring and evaluation</i>" should include suggested ways to implement the recommendation to support broad adoption of the guideline across all countries and reduce confusion among member states.</p>	<p>The section on <i>Translation and Implementation</i> in the guideline describes some of the possible policy actions which can be implemented to translate the recommendation as part of promoting healthy diets in the general population. Possible ways to facilitate understanding and uptake of the recommendation is explored and possible development of policy actions and implementation tools covering the recommendation on the use of NSS as well as other healthy diet guidance is also stated. It should be noted that WHO guidance on policy actions covering some ways that the recommendation could be implemented is currently being developed (e.g. fiscal policies, policies to restrict marketing, nutrition labelling policies, school food and nutrition policies).</p>
<p>Although the WHO NSS draft guideline recommends fiscal policies and nutrition labelling (including front-of-pack (FOP) labelling systems) as strategies to reduce or prevent the use of NSS in the Evidence to recommendations section, the generalist approach of these recommendations may impair the achievement of the desirable results. In the case of labelling, NSS declaration on foods and beverages can sometimes create confusion among consumers related to what they actually contain, especially when only listed on the list of ingredients. We suggest that WHO emphasizes clear recommendations on these policies, including the necessity of clearer description of the presence of NSS on product labels, and providing more specific labelling recommendations, including FOP. Additionally, the impacts of both voluntary and mandatory policies on reformulation, and subsequently, increased consumption of NSS should be considered.</p>	<p>Recommending or suggesting specific policy actions to implement the recommendation – including particular labelling schemes – is beyond the scope of the guideline. The development of nutrition labelling policies including front-of-pack labelling, is often not a one-size-fits-all endeavour and requires consideration of many context-specific factors.</p>

<p>The recommendation on nutrition labelling is too general and may impair the achievement of the desirable results. NSS declaration on foods and beverages can sometimes create confusion among consumers related to what they actually contain, especially when only listed on the list of ingredients. We suggest that WHO emphasises the necessity of clearer description of the presence of NSS on product labels, providing more specific labelling recommendations. We suggest the inclusion of a combined labelling strategy (warning label or informative declaration to indicate the presence of NSS plus NSS clear description) in the WHO document.</p>	
<p>The literature which indicates that NSS are being consumed more in geographies with policies restricting sugar should be reviewed. Case studies from Mexico and Chile, which have in place mandatory healthy food policies like front of package warnings, have shown cases of NSS being used as substitutes for sugar. These real-world cases should be investigated and included as strong justification for incorporating all NSS in nutrient profile models and subsequent guidelines and regulations.</p>	<p>The text in the <i>Feasibility</i> section has been revised to reflect the evidence that NSS use has increased in settings where policies targeting free sugars reduction have been implemented, as follows: “However, existing efforts to reduce free sugars intake also have the potential to make implementing the NSS recommendation more challenging, as recent evidence suggests that in regions which have implemented multiple policy actions targeting free sugars intake are experiencing a greater increase in sales of NSS-containing beverages (but not in NSS-containing foods) relative to those that have implemented fewer or none (23).</p> <p>The section on <i>Translation and Implementation</i> in the guideline describes some of the possible policy actions which can be implemented to translate the recommendation as part of promoting healthy diets in the general population. Possible ways to facilitate understanding and uptake of the recommendation is explored and possible development of policy actions and implementation tools covering the recommendation on the use of NSS as well as other healthy diet guidance is also stated. It should be noted that WHO guidance on policy actions covering some ways that the recommendation could be implemented is currently being developed (e.g. fiscal policies, policies to restrict marketing, nutrition labelling policies, school food and nutrition policies).</p>
<p>The guideline should explicitly mention that: 1) governments should consider discouraging the</p>	<p>Government implementing monitoring intake of NSS and its use in food and beverage production</p>

addition of NNS as a part of product reformulation; 2) governments should consider monitoring and reporting of NNS use in food production; 3) governments should collect data on NNS consumption (intakes and dietary sources beyond NNS soft drinks) among infants, young children, pregnant and breastfeeding women through national dietary surveys.	would be very helpful in order to assess consumption patterns. The following text is now included in the bulleted list in the <i>Translation and implementation</i> section: “monitoring of NSS intake and its use in food and beverage production”.
The guideline states that “messaging about potable water as a preferred replacement for sugar-sweetened beverages and as a mode of hydration generally can be incorporated into public health communications and food-based dietary guidelines”. This could potentially give way to unintended public health consequences (i.e., no change or increased consumption of food and beverages containing added sugar).	This statement is designed to inform guideline users that potable water is an alternative to both sugar-sweetened beverages and beverages sweetened with NSS, thus reducing free sugars intake without the need for NSS.
The guideline should include some guidance on how feasible it is for the various stakeholders to utilise this recommendation and link to existing interventions around sugar.	As noted in the guideline, because of the several ways the recommendation can be implemented, a full discussion on implementation, particularly in the context of actions and interventions to reduce free sugars intake, is beyond the scope of the guideline. WHO guidance on policy actions to improve food environment is currently being developed (e.g. fiscal policies, policies to restrict marketing, nutrition labelling policies, school food and nutrition policies).

Implications of the recommendation

Summary comment	Response
NSS are crucial to ensure a low enough energy content and palatability in formula foods for total diet replacements and meal replacements, which are an effective and safe way of helping people with overweight and obesity to lose weight. We ask the WHO to recognise that the use of sweeteners remains essential in such products for weight control.	The NUGAG Subgroup on Diet and Health noted that NSS use may result in improvement in some measures of body fatness in the short term, though evidence for specific replacement of sugars was less robust. Because the recommendation is conditional, short-term use of NSS is something that relevant stakeholders would need to discuss. The option of decreasing free sugars intake without the use of NSS in the short term is possible.
In 2018, the Political Declaration of the UN High-Level Meeting on NCDs called on the private sector to “strengthen its commitment” to further efforts to reformulate foods and beverages to reduce the excessive use of salts, sugars and fats. The NSS guideline could have a	The guideline does not make any recommendations on reformulation. Free sugars in foods and beverages can be reduced without the use of NSS. Collectively, WHO guidelines on healthy diets aim to support efforts to reduce risk of NCDs and obesity,

very significant impact on the ability to reduce sugars levels in food and drink products via product reformulation, and therefore discourage efforts to reformulate sugar-containing products. As a consequence sugars levels in foods and drinks may continue to increase, thus hindering global efforts to reduce intake of free sugars and more generally NCDs, including obesity.	including the reduction of free sugars intake, without the use of NSS.
The guideline could risk undercutting key WHO priorities by Member States related to diabetes and dental health.	This guideline should not impact priorities by Member States related to diabetes and dental health, though it has the potential to stimulate discussion and/or change how the priorities are met. The guideline is developed as part of WHO's efforts to provide evidence-informed guidance and recommendations to promote healthy diets and prevent obesity and diet-related NCDs in order to achieve the global nutrition and NCD targets which were adopted by Member States at the World Health Assembly as well as the health and nutrition related SDGs endorsed by the UN General Assembly.

Research gaps and future initiatives

Summary comment	Response
This section should include studies on impacts of medium- and long-term cumulative ingestion of one or more NSS ("cocktail effect"), especially when combined with other compounds, and in the context of increasing NSS consumption worldwide and the formation of new food additive clusters. It should also include research on the impact of NSS and other food additives in children, who are more susceptible to their potential toxic effects due to their smaller body weight in comparison to adults. These remarks in the WHO guideline should encourage further research in this field, resulting in the revision of ADIs, so that they more accurately reflect safe consumption amounts of NSS, considering the current diet profile of the population.	<p>Noted. It is suggested that combinations of different NSS be assessed where possible as this is often how NSS are used in foods and beverages. Prospective cohort studies already largely address combinations of NSS, however the precise identities of the NSS are mostly unknown. The relevant bullet point in the list in the <i>Research gaps and future initiatives</i> section has been modified as follows: "health effects of consuming mixtures of NSS, and NSS concurrently with other nutrients and components of foods, including sugars and other carbohydrates compared to NSS alone, and whether this contributes to observed differences in health effects across studies".</p> <p>Food additives are beyond the scope of this guideline and are addressed by JECFA and other authoritative bodies. The need for more research in children is already suggested. Regarding the revision of ADIs, this is beyond</p>

	the scope of the guideline and is addressed by JECFA and other authoritative bodies.
This section should include research in Sub-Saharan Africa, particularly Nigeria, and investigate the effects of NSS in regions where stunted growth and underweight is widespread and where NSS beverages are consumed for hydration due to high temperatures.	Noted. It is already suggested that further research is needed in LMICs.
This section should include the impact of NSS beverages on the oral health of infants and young children, and the impact of NSS consumption in infancy and early childhood on the child's palate and sweet preference in later life.	This is already listed.
This section states "more robust exposure assessments". This should be more explicitly described as to what data or evidence should be collected or generated.	This refers to more precise evaluations of NNS intake, including consistent use of multiple exposure assessments as well as the development of more robust dietary assessment tools such as robust biomarkers of NSS intake. A bullet point has been added to the list in the <i>Research gaps and future initiatives</i> section: "more precise evaluations of NNS intake (e.g. different sources of NSS exposure, types of NNS consumed, exposure of NNS in mg/d), including the development of objective biomarkers of NSS intake to allow for more accurate exposure assessments". It is beyond the scope of the guideline to develop and/or propose new dietary assessment tools.
This section should include research on the increase in consumption of ultra-processed products and foods containing still undisclosed amounts of sweeteners.	Providing suggestions for future research on highly processed foods and beverages is beyond the scope of the guideline. WHO guidance on level of processing in foods and beverages is planned. This would be an appropriate document in which to provide suggestions on future research of highly processed foods and beverages.
There may be benefit for further guidance (possibly at a later date) around individual NSS if some provide greater benefits/risks than others. This would help member states/food companies make more specific recommendations and reformulation decisions going forward.	The need for research into effects of individual NSS is noted. Also noted in the guideline, the evidence is being monitored regularly and should newly identified evidence suggest that the guideline needs to be updated, WHO will consider doing so through the WHO guideline development process.

Other sections of the guideline

Summary comment	Response
The <i>Translation and implementation</i> section "Translation and implementation" would benefit from comparison with the "WHO Guideline: sugars intake for adults and children". For example, consideration of the evidence and the strength of the evidence on NSS vs sugar, where should Member States focus their efforts to improve health outcomes.	WHO recommendations on the use of NSS and free sugars intake are complementary.
The guideline does not mention the 2018 Political Declaration of the UN High-Level Meeting on NCDs in the <i>Objective</i> section.	Noted. The first bullet point in the <i>Objective</i> section has been modified as follows: "the implementation of the Political Declarations of the UN High-level Meetings on the prevention and control of NCDs held in New York in 2011 and 2018, and the outcome document of the high-level meeting of the UN General Assembly on NCDs (A/RES/68/300) held in New York in July 2014"
In the <i>Background</i> section of the guideline, it states "Global trends on NSS use are unclear as NSS have yet to appreciably enter some markets and robust longitudinal intake data is not readily available for most countries outside North America, Europe and Australasia". However, since this draft was released, a study has been published (Russell et al. 2022) that assessed the global, regional, and country income category trends in added sugar and non-sugar sweetener sales globally. This study found that the sale of non- sugar sweeteners (and by proxy consumption) in both food and beverages is increasing globally and in most regions and country income categories. Of particular concern, the study found that the sweetness of the packaged food supply increased over time. Additionally, regions with more sugar- related policy actions had a significant increase in the volume of non-sugar sweetener from beverage sales.	This reference has been added and the Background text modified as follows: "Global trends on NSS use are unclear as NSS have yet to appreciably enter some markets and robust longitudinal intake data is not readily available for many low-and middle-income countries". The last sentence in this paragraph was also modified to: "Evidence suggests that the shift from free sugars to NSS occurring in the United States and elsewhere may also be occurring in other countries as global efforts to reduce the intake of free sugars intensify, particularly in settings that are implementing multiple policy actions targeting free sugars intake". The information within Russell et al. 2022 was also used to modify the <i>Feasibility</i> subsection of the <i>Evidence to recommendations</i> section, by the inclusion of the following text: "However, existing efforts to reduce free sugars intake also have the potential to make implementation of the NSS recommendation more challenging: recent evidence suggests that sales of NSS-containing beverages (but not NSS-containing foods) are increasing in regions that have implemented multiple policy actions targeting free sugars intake, relative to regions that have implemented fewer or no actions".
In the <i>Objective</i> section it states that the recommendation and other elements of the guideline will hopefully support the 2030 Agenda on Sustainable Development and	Target 2.2 of SDG 2, Zero Hunger, states: <i>By 2030, end all forms of malnutrition, including achieving, by 2025, the internationally agreed targets on stunting and wasting in children</i>

achieving the Sustainable Development Goals (SDGs), including Goal 2 of Zero Hunger. However, there is no discussion of how the guideline could potentially support this goal.	<i>under 5 years of age, and address the nutritional needs of adolescent girls, pregnant and lactating women and older persons.</i> Overweight and obesity are forms of malnutrition and therefore the recommendation in the guideline is relevant for Goal2 (and Goal 3) of the SDGs. Providing a rationale for <i>why</i> in the guideline is beyond the scope of the guideline.
In the section on how the guideline was developed it is noted that there is a “rapidly evolving evidence base” with respect to NSS which raises the question of the anticipated timeframe for a future update of the guideline. It is noted that this issue is discussed under the <i>Updating the guideline</i> section. It is suggested that a cross-reference to this information is added to this section.	Noted. The text in the <i>Updating the guideline</i> section has been modified to include the following text: “Because the evidence base for NSS is rapidly evolving, the literature will be monitored on a regular basis. It is planned that the recommendation in this guideline will be reviewed when new data and information becomes available that might alter the overall body of evidence such that it would need to re-evaluated.”
In the <i>Interpreting the evidence</i> section, it is stated that “...it can be difficult for some [individuals] to switch from free sugars to NSS”. It is suggested that additional information is provided on this point, particularly evidence indicating the prevalence of this difficulty.	The passage on post-ingestive sensing of sugars in rodent models (which includes the quoted statement) has been removed from the guideline, as evidence from rodent models is not discussed elsewhere in the guideline.

General comments

Summary comment	Response
NSS should not have been grouped together, as they differ in the chemical structure, and how they are digested, absorbed, metabolised and excreted.	That NSS are different entities is acknowledged in the guideline as well as that the evidence is currently insufficient to adequately assess relevant health effects of individual NSS: “The recommendation in the guideline was made based on evidence which suggests that there are health effects associated with NSS use irrespective of which NSS is being used; i.e. NSS as a class of compounds, despite individual NSS having different chemical structures, have an impact on health. It is recognized that NSS are not a homogenous class of compounds: each has a unique chemical structure and as a result, individual NSS have different sweetness intensities and organoleptic properties, and are processed differently by the body. Limited evidence suggests that individual NSS may also differ in their physiological effects in humans, however, evidence is currently insufficient to make recommendations for individual NSS.”

The guideline is confusing and contradictory to previous guidelines recommending the reduction of free sugars.	The recommendations on NSS and free sugars intake are complementary. Collectively the recommendations should be interpreted as trying to minimize intake of free sugars without using NSS.
While the draft guidelines noted that minimally processed, unsweetened foods and beverages should be the preferred choice among consumers, it would not be realistic for consumers to eliminate sweetness from their diet. The liking for sweetness is both innate and universal and sweetness increases the palatability of foods and beverages. When used to replace sugar in food and beverages, NSS can therefore help satisfy the innate desire and preference for sweetness. In the absence of NSS, consumers could revert back to full-sugar options.	<p>The level of preferred sweetness in foods and beverages varies greatly from individual to individual. As with many dietary behaviours and preferences, sweet preference may be shaped by intensity and/or frequency of exposure throughout the lifecourse.</p> <p>It is feasible to achieve the recommendations of WHO sugars' guideline without using NSS because a wide variety of whole and fresh foods can provide sweet taste, but are naturally low in sugars. It may therefore require time to achieve the transition of reducing the preference of the overall sweetness of the diet.</p>
The guideline should acknowledge that NSS can be a useful dietary tool in providing wider options for sweet-tasting foods and beverages with fewer calories and sugars and help people living with obesity to adhere to an overall higher quality diet while trying to manage their body weight. Weight control and especially long-term weight loss maintenance has been proven to be very challenging to individuals living with overweight and obesity.	It is acknowledged that long-term weight control particularly maintaining weight loss can be very challenging to individuals living with overweight and obesity. However, the results of the systematic review indicate that NSS may not help in this endeavour and may increase risk of NCDs.
The title use of non-sugar sweeteners should be clarified to align with the scope of the evidence assessment and recommendation, i.e. specifically include the outcomes assessed as being impacted by NSS in the systematic review, and not generalize to all NCDs (i.e. WHO guideline: use of non-sugar sweeteners for outcomes X, Y, Z). This would acknowledge that the totality of the evidence base for oral health was not considered, and provide additional clarity that the guidance is not intended to provide alternative safety guidance to assessments undertaken by JECFA.	It is noted in several places within the guideline that the guideline is not intended to provide alternative safety guidance to assessments undertaken by JECFA. As with citing specific outcomes in recommendations, general practice is not to include specific outcomes in the title as generally a range of outcomes are considered and guidance to do something or not do something is based on the overall impact on health and should therefore not need qualification. Possible exceptions are rare instances where only a single outcome has been assessed, in which case the title might be qualified to include the outcome in order to convey that only a single outcome was considered.
The guideline should mention that NSS are consumed by humans in very small amounts and that in most foods and beverages, NSS are diluted with either water, dietary fibres, polyols	Noted. The following text has been added to the <i>Background</i> section: "NSS include a wide variety of synthetically derived chemicals and natural extracts that may or may not be chemically

or maltodextrins, with the exact bulking agent varying significantly between different foods and beverages.	modified and are generally many times sweeter than sugars, which allows them to be added to foods and beverages in very small quantities.”
Other (national) authoritative bodies tasked with providing dietary guidance to their citizens have indicated that NSS may be useful in weight control and efforts to reduce sugars intake.	WHO performs its own independent assessment of the evidence as well as review of contextual factors, and develops guidelines based on the WHO guideline development process. While some national bodies have indicated NSS may be useful for weight control, others have issued guidance that is largely in line with the draft guidance from WHO.
Consider abiding by the precautionary principle, when finalizing the guideline, i.e. safety is primary and when there are suspected harms, scientific uncertainty must be resolved in favour of prevention. If there are unintended consequences of sweetener use, the WHO should recommend that their use be restricted to protect public health from uncertain consequences.	As noted in the guideline, under the <i>Rationale</i> for the recommendation: “Based on the evidence and other considerations as noted above, the NUGAG Subgroup on Diet and Health concluded that the lack of evidence to suggest that NSS use is beneficial for body weight or other measures of body fatness over the long term together with possible long-term undesirable effects in the form of increased risk of death and disease, outweighed any potential short-term health effects resulting from the relatively small reductions in body weight and BMI observed in randomized controlled trials.” Therefore largely, but not exclusively, because of the potential for increased risk of NCDs and mortality, the NUGAG Subgroup on Diet and Health, issued the conditional recommendation.
We agree with the point made about public misperceptions on NSS based on “artificial” or “natural” language used in marketing, and therefore, the guideline should outright recommend that these claims should be banned to thwart these misperceptions.	Making recommendations on labelling requirements – including nutrition and health claims – is beyond the scope of the guideline.
The definition of non-sugar sweeteners (NSS) could be confusing, as different jurisdictions and regulatory agencies include and exclude certain compounds which are broadly non-sugar sweeteners, but may also be termed “low-calorie sweeteners” and/or “non-nutritive sweeteners” (NNS). NSS is overly all-encompassing, as it would capture all future sweetening agents that simply do not include sugar, but may in and of themselves be perfectly appropriate.	<p>As noted in the guideline: “For the purposes of this guideline NSS are defined as all synthetic and naturally occurring or modified non-nutritive sweeteners that are not classified as sugars. Because low-calorie sugars and sugar alcohols (polyols) are sugars or sugar derivatives containing calories, they are not considered to be non-sugar sweeteners”</p> <p>Also as noted in the guideline, every effort was made to compile evidence for individual NSS without ignoring the large body of evidence assessing unspecified sweeteners (e.g. NSS-sweetened beverage consumption assessed in</p>

	prospective cohort studies). Because the evidence for increased risk of NCDs and mortality comes from prospective cohort studies in which the nature of NSS is largely unknown with certainty, as are the underlying mechanisms, which may in part occur through behavioural modification, the recommendation was formulated to cover all NSS as defined by the guideline.
The guideline should clarify whether where external sweeteners are used, sugar is preferred over NSS (or otherwise).	As indicated in the guideline, this recommendation must be considered in the context of other WHO recommendations on healthy diets, particularly recommendations on free sugars intake. When taken together, the recommendations for NSS and free sugars indicate no preference for NSS over free sugars or vice-versa. Rather, collectively the recommendations should be interpreted as trying to minimize intake of free sugars without using NSS.
The guideline states that "evidence suggests that some consumers may not be aware that many of the food and beverages they are purchasing contain NSS". However, on a global level the Codex General Standard for the Labelling of Pre-packaged Foods ensures that consumers are sufficiently informed about the presence of NSS in foods and beverages.	This is noted, however the presence of a nutrient declaration label or other labelling does not mean that consumers can find it or understand what the information contained within means. Part of this may relate to not everyone being familiar with the names of individual sweeteners.
The guideline should also mention the following additional potential harms of NSS: 1) habitual non-sugar sweetener consumption may contribute to shifting population taste preferences towards sweeter palates; 2) non-sugar sweeteners are used exclusively in ultra-processed foods which are markers of poor diets and have known adverse health and environmental impacts. UPFs which contain non-sugar sweeteners often carry health claims which could potentially displace nutritious whole foods from the diet. 3) Certain NSS are considered environmental contaminants because they are not effectively removed from wastewater.	<p>The guideline touches on the topics in items 1 and 2, noting that NSS are not only found in highly processed foods, but can also be added by consumers to foods and beverages to (coffee and tea for example, which are not considered highly processed foods) Detailed discussions of these topics is beyond the scope of the guideline, however.</p> <p>Similarly, although it is acknowledged that there is a substantial body of literature documenting the presence of NSS in wastewater, the resulting environmental and/or health effects of this are not yet known. Therefore, the role of NSS as a potential environmental contaminant is not discussed in the guideline.</p>
[A number of references to additional studies covering various topics were suggested to be included].	Most studies that were suggested for addition to the guideline were either beyond the scope of the systematic review, were excluded for other reasons (e.g. did not meet inclusion/exclusion criteria), or were published

	after the systematic review was published. Adding individual studies without formally updating the systematic review is not possible.
--	--

Annex. Original comments as received during the call for comments

Comments are listed in the order in which they were received.

Annex. Original comments as received during the call for comments

Comments are listed in the order in which they were received.

Call for comment: draft WHO guideline on use of non-sugar sweeteners

Survey response 1

General information

Family/last name
Nenova
Given/first name
Petia
Organization/affiliation
International Sweetener Association (ISA)
Sector
Private sector
Sector [Other]
Country
Belgium

Comments on the draft guideline

Summary of evidence

2. Comments on the section: "Summary of evidence"

The draft WHO guideline on use of NSS was based exclusively on a systematic review of medium- to long-term randomised controlled trials (RCTs) and observational studies that assessed the health effects of NSS use in adults, children, and pregnant women (Rios-Leyvraz and Montez, 2022). The beneficial role of NSS use in reducing total energy intake and assisting with weight loss, without evidence of harm, is confirmed by the results of RCTs reviewed in Rios-Leyvraz and Montez, while observational studies report conflicting outcomes.

Meta-analyses of RCTs in this study showed that NSS use in any manner resulted in reduced energy intake (by approx. 130 calories), modest but robust short-term weight loss, and lower BMI, and did not significantly affect intermediate markers of cardiometabolic health, including blood glucose and insulin levels, blood pressure or blood lipids (Rios-Leyvraz and Montez, 2022).

Results from numerous systematic reviews and meta-analyses of RCTs also support that NSS can help people reduce overall calorie intake and thus be a useful tool in weight management, when used in place of sugar and as part of a calorie-controlled diet and a healthy lifestyle, without evidence of harm (Miller and Perez, 2014; Rogers et al, 2016; Nichol et al, 2018; DGAC, 2020; Greyling et al, 2020; Laviada-Molina et al, 2020; Lee et al, 2021; Movahedian et al, 2021; Rogers and Appleton, 2021; McGlynn et al, 2022).

In interpreting the evidence from the systematic review by Rios-Leyvraz and Montez (2022), the draft WHO guideline places disproportionately more weight on very low to low quality data from observational research at high risk of reverse causality, without giving sufficient weight to higher quality evidence from RCTs supporting benefits of NSS use, without evidence of harm. The draft WHO guideline interpreted as a limitation what the scientific community widely recognises as a strength of randomised controlled design, i.e. that they are carefully planned and controlled in order to allow cause-effect relationships to be investigated and established with confidence (Richardson et al, 2017; Serra-Majem et al, 2018; Ashwell et al, 2020; Mela et al, 2020). In contrast, observational research in this field is exposed to major sources of bias, as also acknowledged by the NUGAG Subgroup on Diet and Health. By design, observational studies cannot establish a cause-and-effect relationship and provide low certainty evidence due to their observational nature and the inability to exclude both unmeasured and measured residual confounding, make any causal relationships, or, importantly, attenuate the effects of reverse causality (Lee et al, 2022).

A systematic review and meta-analysis of observational studies including change and substitutions analyses that mitigate the influence of reverse causality providing more consistent and robust associations found that NSS beverages are associated with lower risk of obesity, coronary heart disease, and cardiovascular disease (CVD) and total mortality in the intended substitution for sugar-sweetened beverages, with no adverse associations across other outcomes (Lee et al, 2022). These findings are in line with evidence from RCTs of intermediate cardiometabolic risk factors (McGlynn et al, 2022) and in contrast to the results of meta-analyses of observational studies as assessed in the WHO review (Rios-Leyvraz and Montez, 2022). Importantly, there is no mechanistic evidence to support "possible long-term adverse effects" in the form of increased risk of NCDs. This is confirmed by food safety bodies worldwide including the Joint Expert Committee on Food Additives of the United Nations Food and Agriculture Organization (FAO) and of the World Health Organization (WHO), the European Food Safety Authority (EFSA), and the US Food and Drug Administration (FDA), who consistently support that all approved NSS are safe.

Finally, the draft WHO guideline on use of NSS did not consider the totality of available scientific data assessing the health benefits of NSS, including on dental health (tooth mineralisation) and post-prandial blood glucose levels when NSS are consumed instead of sugars (EFSA, 2011a).

Comments on the interpretation of the evidence

The NUGAG Subgroup on Diet and Health made several observations "in interpreting the results of the systematic review, some based directly on data from the review and others supported by background questions and information that helps to establish the context for the recommendation." The ISA would point to several considerations regarding the interpretation of the evidence in the draft WHO guideline:

- Evidence from a wealth of "varied interventions in randomized controlled trials" consistently supports the data that NSS use can help reduce total energy intake and assist with weight loss, when NSS are used to replace free sugars in the diet (i.e., the "intended purpose of NSS"). This is supported by the results of the WHO systematic review itself (Rios-Leyvraz and Montez, 2022).
- Non sugar sweeteners are food additives that are used in foods and beverages as well as in table-top sweeteners in place of sugar to provide the desired sweetness with fewer or zero calories and should not be expected to have "inherent pharmacological properties". Indeed, NSS benefits in weight control are evident when used to replace sugars and calories in the diet (Ashwell et al, 2020). This is clearly supported by data reviewed in the WHO study (Rios-Leyvraz and Montez, 2022) and by previously published systematic reviews (Lee et al, 2021; Rogers and Appleton, 2021).
- The NUGAG Subgroup on Diet and Health notes that, "Because weight loss or the maintenance of a healthy weight must be sustained over the long-term in order to realize associated health benefits, there must be evidence for sustained weight loss or

maintenance for any intervention being investigated for effects on body weight". Evidence reviewed by WHO includes also data from longer-term RCTs studying the impact of NSS on weight control for a duration up to 2 years. These large, long-term trials are supportive of NSS useful role in long-term weight loss and maintenance for both adults and children (Blackburn et al, 1997; de Ruyter et al, 2012; Peters et al, 2016).

- The draft guideline considers as a limitation what is a recognised strength of well-designed RCTs (Serra-Majem et al, 2018; Ashwell et al, 2020; Mela et al, 2020). The randomised controlled design is the most reliable study design for drawing causal inferences, and therefore regarded as the gold standard in the hierarchy of research designs (Richardson et al, 2017), especially because RCTs are "carefully planned and controlled" (including randomisation) to eliminate bias affecting observational research (mainly residual confounding and reverse causality). According to the GRADE approach, used by organisations in the guideline development process, including by the WHO (2014) and the United States Department of Agriculture (USDA) in developing the Dietary Guidelines for Americans (Spill et al, 2022), the best estimates of the effects of an intervention come from systematic reviews of RCTs in which the intervention is tested against alternative management approaches (Balshem et al, 2011).

- "The potential role of reverse causation in the results from the prospective cohort studies" is poorly addressed in the draft WHO guideline despite the fact that observational research on the field of NSS is at particularly high risk of reverse causality, as widely recognised by the scientific community (Lohner et al, 2017; Serra-Majem et al, 2018; Toews et al, 2019; Ashwell et al, 2020; DGAC, 2020; Mela et al, 2020; Normand et al, 2021; Lee et al, 2022). In contrast, a systematic review and meta-analysis of observational studies including change and substitutions analyses that mitigate the influence of reverse causality providing more robust and reliable associations found that NSS are associated with a lower, rather than higher, risk in incident obesity and important cardiometabolic outcomes in the intended substitution for SSBs (Lee et al, 2022); this finding is in line with the evidence from systematic reviews and meta-analyses of RCTs of intermediate cardiometabolic risk factors (McGlynn et al, 2022; Rios-Leyvraz and Montez, 2022).

- Neither the draft WHO guideline, or the systematic review by Rios-Leyvraz and Montez, examined data regarding the "Potential mechanisms for negative associations with cardiometabolic health in prospective cohort studies". No mechanistic evidence or results from RCTs support any of the proposed mechanisms, including: effects on taste perception (Appleton et al, 2018; Rogers, 2018); eating behaviour (Bellisle, 2015; Lee et al, 2021), neural responses (Yeung et al, 2020); alterations to gut microbiota (Lobach et al, 2019).

In addition to these comments on "Summary of evidence", we would also like to bring to your attention a more detailed scientific analysis of the published evidence regarding the use of non-sugar sweeteners, which you may find in the Appendix in the enclosed PDF document.

A full list of references is also provided on page 26 in the enclosed PDF document

Evidence to recommendations

3. Comments on the section: "Evidence to recommendations"

In going from evidence to recommendation, the NUGAG Subgroup on Diet and Health has assessed the evidence in view of the certainty in the evidence and has considered several other aspects, including desirable and undesirable effects of the intervention, priority of the problem that the intervention would address, values and preferences related to the effects of the intervention in different settings, the cost of the policy options in different settings, feasibility and acceptability of implementing the intervention in different setting. While the certainty of the evidence pertains directly to the recommendation itself, the rest of the aspects considered relate to the implementation of specific policy interventions which have been suggested to public health policy-makers. Therefore we would like to bring to your attention the following comments on the certainty of the evidence and the potential impact of implementing the dietary recommendation based on such certainty in the evidence via public health and nutrition policies.

3A. Overall certainty in the evidence

The draft WHO guideline states that: "The overall certainty in the evidence was considered low and is based on undesirable effects of NSS use on prioritized health outcomes observed in prospective cohort studies which were individually considered to be very low to low."

It is unscientific and against the best interests of public health to base dietary recommendations - in this case, to remove helpful dietary options using NSS - on such poor-quality evidence (Alexander et al, 2016), and at the same time disregard higher quality research from RCTs consistently supporting beneficial effects of NSS use on reduced energy intake, weight and glucose control and dental health, without evidence of harm (EFSA, 2011a; Rios-Leyvraz et al, 2022).

Furthermore, it is aimed with the guideline to provide a "recommendation [to] be used by policymakers and programme managers to address NSS use in their populations through a range of policy actions and public health interventions". Public policies should be developed on the basis of the highest quality, objective and comprehensive evidence which is available. In line with this fundamental principle, ISA would question the rationale for a WHO recommendation and its implementation via policy actions, that is based on overall low certainty in the evidence.

3B. Balance of desirable and undesirable effects

In assessing the balance of desirable and undesirable effects of the draft WHO recommendation, the NUGAG Subgroup on Diet and Health base their conclusion about "undesirable anticipated effects" on the groundless assumption that "the associations observed in prospective cohort studies are valid" (Annex 7, pp78 in the draft WHO guideline). Observational data of poor quality and at high risk of reverse causation should not have been considered as, basically, the primary evidence in formulating a recommendation about NSS use unless the issues of reverse causality and residual confounding have been comprehensively addressed, especially when evidence from RCTs is available and supports opposing (beneficial) effects. Experts raise concerns about the weight that should be placed on observational data when data from controlled clinical studies are available (Mela et al, 2020); a body of evidence based on RCTs is rated as being of high quality at the outset and, thus RCTs are the preferred source of evidence for measuring the effects of interventions (WHO, 2014). According to the GRADE framework, the best estimates of the effects of an intervention come from systematic reviews of randomized controlled trials (RCTs) (Balslem et al, 2011), which are positioned at the highest level in the hierarchy of clinical evidence and should be considered as a primary source of information in science-based public health decisions and policies (Richardson et al, 2017). On this basis, ISA would call on the WHO to revisit this assumption.

Furthermore, it is stated that because NSS are frequently a component of 'highly processed foods and beverages [...] one of the implicit, possible undesirable effects of NSS use in the context of reducing free sugars intake is the inclusion of a greater number of highly processed foods and beverages in the diet than would be included if free sugars were reduced without NSS use'. The proposed alternative to NSS, as mentioned in a different part of the document, is "replacing free sugars in the diet with sources of naturally occurring sweetness, such as fruits, as well as minimally processed unsweetened foods and beverages". Importantly, no evidence has been provided in the draft guideline exploring the potential effect of use of NSS on diet quality. In fact, research supports the assertion that NSS can help people follow an overall healthy diet, when used in place of sugars, which is their intended purpose of use. A positive association between NSS intake and improved diet quality has been reported in several studies in different populations globally (Drewnowski and Rehm, 2014; Gibson et al, 2016; Leahy et al, 2017; Patel et al, 2018; Silva-Monteiro et al, 2018; Barraj et al, 2019). For example, a study analysing data from the United Kingdom's National Diet and Nutrition Survey (NDNS), found that consumers of NSS sweetened beverages had a better diet quality, lower free sugars' consumption and higher chances of meeting the UK recommendation for free sugars' intake, compared to consumers of sugar-sweetened beverages (Patel et al, 2018). It is essential that any potential impact of implementing the draft WHO recommendation is assessed on the basis of robust evidence and in line with key principles of developing responsible public policy.

NSS are used in very small amounts in foods, drinks and tabletop sweeteners to provide sweet taste with fewer or virtually no calories. As regulated ingredients, the amount of NSS used in such food and drink products is determined by their acceptable daily intake (ADI), so as to ensure we cannot overconsume them.

The safety of approved NSS has been repeatedly confirmed by food safety bodies around the world, including the joint

WHO/FAO's own expert food additives committee JECFA (Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives). They are amongst the most thoroughly researched ingredients and global research has shown that our intake of them is well below the ADI level set by the authorities. (Martyn et al, 2018; Tennant, 2019; Tennant and Vlachou, 2019; Martínez et al, 2020; ACHIPIA, 2021; Barraj et al, 2021a; Barraj et al, 2021b; Martyn et al, 2022) The ADI is a measure of the amount – of NSS in this case – which we can consume on a daily basis, over a lifetime, without an appreciable health risk. It is based on the maximum amount that test animals can be given throughout their life without any noticeable harmful effects, divided by a safety factor of 100. The 100-fold safety factor takes into account potential differences between animals and humans, as well as among different population groups ensuring the safety of the most vulnerable including children and pregnant women.

The draft guideline acknowledges that the safety of NSS is evaluated by food safety agencies, including JECFA at global level and states that it is not intended to provide updated or alternative guidance on safe or maximal levels of intake. Nonetheless, it is also stated that “there is no clear consensus on whether NSS are effective for long-term weight loss or if they are linked to other long-term health effects at habitual intakes within the ADI”. With this statement the draft guideline raises doubts about the safety of NSS. We would highlight that this is inconsistent with the safety evaluation of all approved NSS by the responsible regulatory bodies at global and national level. Furthermore, assessing the safety of NSS is neither in the scope of the work of the WHO NUGAG Subgroup on Diet and Health and of this draft guideline, nor has the relevant toxicological evidence formed part of the review conducted by Rios-Leyvraz and Montez (2022). It is therefore fundamental that this lack of alignment between different WHO bodies and their respective responsibilities, is addressed. Such inconsistency has the potential to lead to considerable confusion among public health professionals, policy-makers and the general public.

From a public health policy perspective, a key undesirable effect of the WHO recommendation would be the potential discouragement of the industry's sugar reduction effort and its contribution to Member States efforts to deliver on their commitment to stem the rise of obesity (1, 2) and NCDs. This in turn could have a negative impact on the availability of lower sugar and no sugar food and drink options on the market, limiting consumer choice and potentially hindering individuals' efforts to reduce their free sugars intake.

In particular, a disproportionate effect may be seen in people living with diabetes for whom NSS are an important dietary tool. While it is pointed out that the recommendation may not be relevant to people with diabetes, a potential negative effect of the recommendation on this population group must be considered. Maintaining the confidence in NSS as a safe and helpful alternative to sugar is critical for people living with diabetes. The WHO recommendation on use of NSS is part of the global effort to tackle NCDs and their diet-related risk factors and must be aligned with this broad global agenda, including the recent WHO recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, which was adopted at the World Health Assembly in May 2022 (3).

The absence in the draft guideline of the benefits of NSS for oral health is a missed opportunity and a disalignment with the global NCD agenda. WHO has recommended reducing the intake of free sugars to below 5% of total energy in order to have benefit for oral health. The recent WHO Global strategy on oral health (4), adopted at the WHA in May 2022, further points to the importance of addressing oral health. It is therefore essential to consider the potential undesirable effect of not including oral health in the draft guideline on the global effort to address NCDs.

Overall, since reviewing the evidence base to inform policy interventions is beyond the scope of the draft guideline on use of NSS, an impact assessment on the implementation of the recommendation via specific policy actions is not provided. The potential undesirable effect of implementing the recommendation must be considered, including in particular the above-mentioned potential impact on sugar reduction reformulation, availability of food and drink choices for people living with diabetes, effect of NSS use on diet quality and impact on oral health. Lastly, the recommendation and its suggested implementation should be aligned with the overarching global NCD agenda to which all Member States have committed.

3C. Priority of the problem and values and preferences

Escalating rates of obesity and NCDs continue to be an unabating health challenge globally, impacting the lives of millions of people. Importantly, beyond impact on health and quality of life, NCDs are the leading cause of death globally. The COVID-19 pandemic has aggravated the problem, showing that chronic health conditions, such as obesity and diabetes, are associated with increased risk and severity of COVID-19 outcomes (ECDC, 2020). Furthermore, the COVID-19 pandemic has impacted access to dental preventative care and treatments and widened the inequality seen with access to oral care specifically in children, older populations, and those with disabilities (Mac Giolla Phadraig et al, 2021; Stennett and Tsakos, 2022). Worryingly, COVID-19 also reduced adherence to health diets (González-Monroy et al, 2021). It is therefore all the more urgent to tackle NCDs, including their diet-related risk factors. In the pandemic context which global public health groups must continue to navigate, making conflicting scientific recommendations is not beneficial to the publics' trust in scientific processes and institutions.

Member States have acknowledged this shared challenge and have committed to addressing it within the broader framework of the Sustainable Development Goals (SDGs) with a political declaration (5) which recognised that effective NCDs prevention and control requires a 'whole-of-society effort' through an integrated multi-sectoral approach including the engagement of the food and beverage industry. Member States called upon the private sector to contribute to reducing NCDs risk factors and creating health-promoting environments by “reformulating products to provide healthier options that are affordable and accessible and that follow

relevant nutrition facts and labelling standards". The draft WHO guideline is inconsistent with this stated objective, as NSS are a critical tool for manufacturers to help achieve products with less sugar and fewer calories, while continuing to meet consumer demand for sweet taste.

Removing significant amounts of sugars from a food or drink has a noticeable impact on the sensory profile of the product, which can impact on overall consumer liking for the product. NSS are important ingredients for manufacturers as they are the only means of giving foods and beverages a sweet taste without all the calories of sugar.

Manufacturers have responded to the call to contribute to food and drink reformulation, with innovation and product development and have brought to the market less energy dense foods and drinks. To sustain and scale up these efforts, industry relies on consumer confidence in NSS as approved food ingredients which provide the consumer with choice.

The draft guideline recommendation suggesting NSS not be used as a means to achieve weight control or reducing risk of NCDs may undermine consumer confidence in these ingredients as a safe and valuable alternative to sugar and may consequently discourage reformulation for sugar reduction, hindering a valuable contribution to the global objective to stem the rise of NCDs.

From a broader policy perspective, following the third UN High-level Meeting on NCDs on 27th September 2018 (6) when stakeholders took stock of the progress made and re-confirmed their commitment, as well as the UN Food Systems Summit in September 2021 (7) which launched ambitious new actions towards progress on the SDGs, it is important to reinforce an inclusive and aligned public policy on prevention and control of NCDs within the agreed global multi-stakeholder process. Food and drink reformulation has been an integral part of the global effort to address NCDs. Maintaining confidence in NSS as a safe and helpful alternative to sugar which enables reformulation for sugar reduction, would indeed be in line with the comprehensive and integrated global approach to tackling NCDs.

On an individual level, the draft WHO recommendation suggesting NSS not be used as a means to achieve weight control may hinder efforts by people living with obesity to manage their calorie and sugars intake, and in turn their body weight. This is particularly concerning at a time when overweight and obesity affect nearly 40% of the global adult population, as well as millions of children, and in light of the link between the excess consumption of free sugars to overweight and obesity, described by WHO as justifying a sugars guideline based on strong evidence (WHO, 2015). In fact, the draft guideline could confuse consumers, who are less familiar with the strength of the evidence that WHO has relied on, to revert back to full sugar alternatives.

Globally, 537 million, approximately 1 in 10 adults, are living with diabetes (IDF, 2021). NSS are a useful dietary tool for people living with diabetes which helps support efforts to reduce the intake of sugars. The availability of the approved NSS has made possible a wider range of lower sugar products that can provide a greater choice for people with diabetes. By potentially discouraging reformulation, the draft WHO recommendation may negatively impact the availability of food and drink choices that can be safely used by people living with diabetes, inadvertently hindering individual efforts to limit the intake of sugars, negatively impacting quality of life and jeopardising the proven public health outcomes that could be achieved through effective reformulation. Furthermore, the draft guideline may also cause those living with diabetes to erroneously believe that using NSS in place of sugar cannot cause a lower rise in blood glucose levels, thereby disregarding the advice of relevant authorities, such as the American Diabetes Association (Evert et al, 2019) and Diabetes UK (2018).

Furthermore, there are 3.5 billion cases of dental caries, resulting in periodontal (gum) disease and eventual tooth loss globally. The prevalence rates over the past three decades have remained unchanged at 45%, making oral diseases the most prevalent NCD globally (Bernabe et al, 2020). Yet, these oral conditions are almost entirely preventable, in part by reduction in free sugars (FDI, 2015; WHO, 2015). In order to reduce the intake of free sugars for health benefits, as recommended by WHO, NSS are utilised in product reformulations. NSS are critical ingredients in sugar-free chewing gum, hygiene, and personal care oral products, providing benefits for oral health. It should be more strongly highlighted in the final WHO guideline that there were some publications highlighting the oral health benefits of NSS, and that more research in this area is needed for a robust meta-analysis to be performed in the future.

The importance of addressing oral health as part of the global commitment to the prevention and control of NCDs, within the broader framework of the Sustainable Development Goals (SDGs), has been consistently acknowledged, including with the recent Global Strategy on Oral Health (4), adopted at the World Health Assembly in May 2022. Failing to address the role of NSS in supporting the prevention and control of the most prevalent NCDs globally - oral diseases - is inconsistent with the objectives of the global NCDs agenda, disaligned with the comprehensive integrated approach to tackling NCDs to which Member States have committed, and has the potential to hinder efforts to address oral diseases and to stem the rise of NCDs globally.

3D. Feasibility and acceptability

The draft guideline looks at the feasibility of implementing the recommendation on use of NSS via specific suggested policy interventions, namely regulation of marketing food and non-alcoholic beverages; restricting the sales and promotion of food and beverages containing NSS in schools; fiscal policies targeting foods and beverages that contain NSS; nutrition labelling; consumer education. It is pointed out that while feasibility may vary depending on specific approaches, the recommendation can be incorporated into existing health and nutrition policy activities and 'would naturally complement existing efforts to reduce free sugars'. The draft guideline suggests an approach for efficient, i.e. feasible, implementation.

The implementation of any policy intervention, including its feasibility and acceptability, should be considered on the basis of a review of strong evidence, specific to the policy intervention, including a comprehensive impact assessment. Such evidence base is not presented and is beyond the scope of the draft guideline on use of NSS. On this basis, ISA would question the basis for including guidance on the implementation of the above-mentioned policies.

In addition, a specific example states that 'appropriate messaging on NSS can readily be added to existing food-based dietary guidelines and the increasing number of actions being taken to address free sugars intake, such as behaviour change and education campaigns, fiscal policies, marketing and labelling policies, and reformulation'. This suggestion to approach together free sugars and NSS may potentially have the effect of further confusing health-related stakeholders and consumers, in addition to the diabetes patient community, by addressing sugar and NSS intake within the same policy actions and tools while simultaneously removing a critical tool for the reduction of sugar in the food supply.

A point is made that the successful implementation of the recommendation to reduce the use of NSS would also depend on 'the extent to which consumers are aware of the NSS content in products they purchase: evidence suggests that some consumers may not be aware that many of the food and beverages they are purchasing contain NSS'.

NSS must be indicated in the list of ingredients on the packaging of food and beverage products that contain them by their specific name or number and the functional class 'sweetener'. Indeed, the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) (8) requires in section 4.2: List of ingredients, sub-section 4.2.3.3 that for labelling of food additives, including sweeteners, 'functional classes shall be used together with the specific name or recognized numerical identification'. Among the functional classes the class of 'sweeteners' is listed. Therefore on a global level the Codex General Standard for the Labelling of Pre-packaged Foods ensures that consumers are sufficiently informed about the presence of NSS in foods and beverages.

Furthermore, in Europe in accordance with EU labelling regulation Regulation (EU) No 1169/2011 (9), in addition to the labelling in the ingredients list, the term 'with sweetener(s)' must be stated on the label together with the name of the food or beverage product.

It is acknowledged that acceptability of the draft guideline to policy-makers and at consumer level may vary across different countries and cultural contexts depending on several factors, including the accustomed sweetness level in the diet and the specific policy interventions. It is therefore essential that robust evidence on the feasibility and acceptability of a policy intervention in a specific cultural/national context underpins any implementation.

The feasibility and acceptability of the recommendation at an individual level have, similarly, never been examined and may be particularly low because the draft guideline ignores evidence from a wealth of studies conducted over several decades which show that humans' liking of sweet taste is innate and universal (Public Health England, 2015). NSS have the unique property of being food ingredients with sweet taste and no, or virtually no, calories that are used in foods and beverages as well as in table-top sweeteners in place of sugar to provide the desired sweetness with fewer or zero calories (Gibson et al, 2014). While NSS might not be the only way to achieve a reduction in free sugars, as stated in the draft guideline, NSS represent a helpful dietary tool to enjoy sweet taste with fewer calories and low or no sugar.

Humans are born with a natural preference for sweetness, which decreases from childhood to adolescence and into adulthood (Bellisle, 2015; Mennella and Bobowski, 2015; Rogers, 2018; Wittenkind et al, 2018). In fact, in many studies, the use of NSS is associated with a lower intake of sweet tasting substances (de Ruyter et al, 2013; Piernas et al, 2013; Maloney et al, 2019; Rogers et al, 2020; Appleton et al, 2021; Appleton, 2021). This suggests that NSS may help to satisfy a desire for sweetness (Bellisle 2015; Rogers 2018; Appleton et al, 2018). Eroding consumer confidence in NSS as a safe and valuable alternative to sugar and discouraging reformulation may cause consumers to revert back to full-sugar options.

3E. Resource implications

While it is acknowledged that impact assessment or assessment of the evidence base for the implementation of the suggested policy actions is beyond the scope of the draft guideline on use of NSS, references to the potential impact of implementing the draft guideline from a resource perspective, are in fact included. Importantly, such impact assessment should be robust, comprehensive and specific to the suggested policy intervention and the national/cultural context. Including suggestions or guidance about resource implications without such comprehensive impact assessment may be damaging to the effect of any policy intervention and may cause confusion among health professionals and policy-makers.

For example, it is stated that 'Generally speaking, not using NSS would imply that both the purchase of NSS themselves (for use by the consumer) and the purchase of foods and beverages containing them would decrease. In the case of NSS and certain foods and beverages with no caloric value, further adjustments to the diet would not be needed and money could be saved by simply not purchasing them.' No impact assessment data is provided to substantiate this assumption. Importantly, consumer data suggests that some consumers would move away from foods and beverages with NSS towards sugar-containing counterparts. ISA would propose that this statement be reconsidered on the grounds that an evidence base has not been provided and is beyond the scope of the draft guideline.

Footnotes:

1. WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf
2. Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf
3. Political declaration of the third high-level meeting of the General Assembly on the prevention and control of noncommunicable diseases. Report by the Director-General, EB150/7, WHA75, Annex II. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf
4. Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of NCDs, A75/10 Add.1 Annex 3 - Draft global strategy on oral health https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add1-en.pdf
5. UN High-level Meeting on NCDs, September 2011. <https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>
6. UN High-level Meeting on NCDs, September 2018 http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2
7. UN Food Systems Summit, Sep 2021. <https://www.un.org/en/food-systems-summit/about>
8. Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf
9. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:en:PDF>

A full list of references is provided on page 26 in the enclosed PDF document.

Recommendations and supporting information

4. Comments on the section: "Recommendation and supporting information"

The conditional WHO recommendation that "NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases" is inconsistent with the global integrated approach to addressing NCDs to which Member States have committed, and of which sugar reduction reformulation is an integral part. Such disalignment may be detrimental to global efforts to address the complex challenge of NCDs.

The draft WHO guideline aims to contribute to the global NCD agenda to which Member States have consistently committed. At the UN General Assembly meeting in September 2011 (1) global leaders committed to responding to the challenge of non-communicable diseases. with a political declaration which recognised that effective NCDs prevention and control requires a 'whole-of-society effort' through an integrated multi-sectoral approach including the engagement of industry. At subsequent UN High-level Meetings on NCDs in 2014 (2) and 2018 (3) governments took stock of the progress made and re-confirmed their commitment to a coherent, inclusive, multi-stakeholder effort to stem the rise of NCDs.

Industry was called upon to contribute to reducing NCDs risk factors and creating health-promoting environments by "reformulating products to provide healthier options". In seeking to support this global public health objective through product reformulation, NSS are an important option for manufacturers to help achieve products with less sugar and fewer calories, while still being palatable to consumers. This has allowed manufacturers to respond with innovation and product development and to bring to the market less energy-dense foods and drinks. To sustain and scale up these efforts, industry relies on consumer confidence in NSS as approved food ingredients which provide the consumer with wider choice. To advance the efforts to tackle the complex challenge of NCDs, the recognition of NSS as a safe and useful alternative to sugar is essential.

The conditional WHO recommendation suggesting that "NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases" risks hindering sugar and calorie reduction efforts and, hence, actions to align with current public health recommendations to reduce free sugars and address the epidemic of obesity (4, 5), and associated noncommunicable diseases (NCDs) including type 2 diabetes and cardiovascular diseases. Similarly, with dental caries being amongst the most widespread NCDs in the world, preventing efforts to reduce free sugars intake by recommending against NSS use puts at risk global efforts to improve oral and dental health.

Importantly, the conditional WHO recommendation lacks scientific rigour. It is largely and disproportionately based on very low to low certainty evidence from observational studies, which are at high risk of reverse causality, while higher-quality research of randomised controlled design confirming benefits of NSS use and no evidence of harm is overlooked. In the interest of public health, it is imperative that any recommendation regarding NSS use be based on the totality of the science and interpreted considering the hierarchy and weight of the scientific evidence. A conditional recommendation on NSS use for which "the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences" risks hindering public health efforts to reduce excess free sugars intake and tackle the obesity epidemic. ISA would further question the rationale for making policy recommendations on this basis.

The draft WHO recommendation suggesting NSS not be used as a means to achieve weight control may hinder efforts by people living with obesity to manage their calorie and sugars intake, and in turn their body weight. This is particularly concerning at a time that overweight/obesity affects nearly 40% of the global adult population as well as millions of children, and in light of the link between the excess consumption of free sugars to overweight and obesity, described by WHO as justifying a sugars guideline based on strong evidence (WHO, 2015). It is therefore essential that people living with obesity are responsibly informed in the final WHO guideline that, while NSS might not be the solution to the obesity epidemic, current evidence reviewed by WHO does indeed support short-term benefits of NSS use in sugar and energy intakes reduction and, in turn, in assisting with short-term weight loss (Rios-Leyvraz and Montez, 2022).

Supporting information in the draft guideline stating that "evidence of minor weight loss or reduced BMI over several months or less as observed in the randomized controlled trials without additional evidence of long-term impact, does not represent a health benefit" is not supported by scientific evidence. Indeed, evidence supports that a 5–10% weight loss is sufficient to obtain substantial health benefits from reduced obesity-related comorbidities in adults (WHO European Regional Obesity Report 2022). NSS use in place of caloric sweeteners and as part of a behavioural weight control programme is one amongst a pool of different dietary strategies that can help reduce total energy intake and, hence, assist with weight loss. In addition, by providing sweet taste with fewer or no calories, products sweetened with NSS can help improve adherence to a calorie-reduced healthy diet and lifestyle (Catenacci et al, 2014; Miller and Perez, 2014). Available long-term RCTs are also supportive of NSS useful role in weight loss and weight loss maintenance (Blackburn et al, 1997; Peters et al, 2016). For example, in a 1-year RCTs in 303 adult participants living with overweight or obesity, Peters and colleagues found greater maintenance of weight loss with NSS use compared with control: 44,2% of subjects in the NSS group lost at least 5% of their body weight from baseline to year one compared with 25,5% in the water group (Peters et al, 2016).

In addition, neither the draft WHO guideline, nor the systematic review by Rios-Leyvraz and Montez, examined data regarding NSS use in medications, personal care and hygiene products. Therefore, there is no scientific support for the remark on page 11 of the draft that "NSS-free versions of these items, when readily obtainable, can be considered." In fact, as the WHO draft guideline points out these hygiene products, along with sugar-free chewing gum, contain NSS in small amounts to make them

more palatable which encourages their use for oral health benefits. A remark should not be made without scientific evidence to support it nor without considering the public health impacts such a recommendation would have on compliance and adherence to well established routines such as utilizing fluoridated toothpastes. On this basis, the remark should be removed from the final draft.

Finally, the potential adverse implications for public health have not been considered in the draft WHO guideline and do not support the statement: “there were no identified undesirable effects or other mitigating factors that would argue against not using NSS”. We call the WHO to consider the serious implications that such a recommendation, based on poor science, would have on public health.

Footnotes

1. UN High-level Meeting on NCDs, September 2011.

<https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>

2. UN High-level Meeting on the comprehensive review and assessment of the progress achieved in the prevention and control of NCDs, July 2014

<https://digitallibrary.un.org/record/774662>

3. UN High-level Meeting on NCDs, September 2018

http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

4. WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

5. Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12.

https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf

A full list of references is provided on page 26 in the enclosed PDF document.

Other comments

Summary

There is an important disalignment between the draft WHO guideline and the objectives and approach of the global NCDs agenda to which all Member States have committed and which includes reformulation as an integral part. The ISA would call on the WHO to consider the serious implications that such a conditional recommendation, based on science lacking in rigour and overall low certainty in the evidence, would have on public health. In particular we would highlight the following:

- Member States committed to responding to the challenge of non-communicable diseases (NCDs) at the UN General Assembly meeting in September 2011 (1) with a political declaration which recognised that effective NCDs prevention and control requires a “whole-of-society effort” through an integrated multi-sectoral approach including the engagement of industry. At subsequent UN High-level Meetings on NCDs in 2014 (2) and 2018 (3) governments took stock of the progress made and re-confirmed their commitment to a coherent, inclusive, multi-stakeholder effort to stem the rise of NCDs.

Industry was called upon to contribute to reducing NCDs risk factors and creating health-promoting environments by “reformulating products to provide healthier options”. In seeking to support this global public health objective through product reformulation, non-sugar sweeteners (NSS) are a useful option for manufacturers to help achieve products with less sugar and fewer calories, while still being palatable to consumers. This has allowed manufacturers to respond with innovation and product development and to bring to the market less energy-dense foods and drinks.

To sustain and scale up these efforts, industry relies on consumer confidence in NSS as approved food ingredients which provide the consumer with wider choice. To advance the efforts to tackle the complex challenge of NCDs, the recognition of NSS as a safe and useful alternative to sugar is paramount.

The WHO recommendation that “NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases” is inconsistent with the global integrated approach to addressing NCDs to which Member States have committed, of which sugar reduction reformulation of foods and drinks is an integral part. Global efforts to address the complex challenges of NCDs reduction requires joined-up policies based on rigorous scientific and policy evaluations.

- The draft WHO guideline on the use of NSS includes specific suggestions to policy-makers for the implementation of the recommendation, aiming to reduce or prevent the use of NSS, including marketing regulation, fiscal policies, and nutrition labelling. Assessing the impact of the suggested policy interventions, including the possibility of consumers moving away from foods and beverages with NSS towards sugar-containing counterparts, is beyond the scope of the draft guideline and the work of the NUGAG Subgroup on Diet and Health. Nonetheless, some aspects related to implementation, such as desirable and undesirable impact of the policies, feasibility, acceptability and resource implications, have been raised. It is vital that any suggestions for policy recommendations are substantiated by a robust evidence base, including a full impact assessment. Such evidence base is not included in the draft guideline.

- The conditional WHO recommendation suggesting that “NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases” is not scientifically rigorous since it is not based on a robust evidence base or supported by the evidence presented in the WHO systematic review itself (4). It is largely and disproportionately based on very low to low certainty evidence from observational studies, which are at high risk of reverse causality (5), while higher-quality research of randomised controlled design that concludes there are benefits of NSS use and that there is no evidence of harm, is not given due priority (6). In the interest of public health, it is imperative that any recommendation regarding NSS use be based on the totality of the science and interpreted considering the hierarchy and weight of the scientific evidence.

- A conditional recommendation on NSS use for which “the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences” risks hindering public health efforts to reduce excess free sugars intake, a strong recommendation by WHO (7), and ultimately to provide one approach to tackling the obesity epidemic (8, 9), improving oral and dental health (10) and making a valuable contribution to global efforts to address NCDs. ISA would question the rationale for a WHO recommendation, and its implementation via policy actions, that is based on overall low certainty in the evidence.

- In particular, a disproportionate effect may be seen in people living with diabetes for whom NSS are an important dietary tool. While it is stated that the conditional recommendation may not be relevant to people with diabetes, a potential negative impact on this population group must be considered. The availability of the approved NSS has made possible a wider range of lower sugar products that can provide a greater choice for people with diabetes. By potentially discouraging reformulation and suggesting to policy-makers to implement policies to reduce or prevent the use of NSS (e.g., marketing regulation, fiscal policies, labelling), the draft WHO recommendation may negatively impact the availability of food and drink choices that can be safely used by people living with diabetes, inadvertently hindering individual efforts to limit the intake of sugars and negatively impacting quality of life. The draft WHO recommendation on the use of NSS is part of the global effort to address the prevention and control of NCDs (1,2,3), including the recent WHO recommendations to strengthen diabetes responses within national NCDs programmes. Therefore it is essential that the draft WHO recommendation, including any impact on the diabetes community, be aligned with the global integrated approach to NCDs to which Member States have consistently committed.

- Importantly, there is no mechanistic evidence to support “possible long-term adverse effects” in the form of increased risk of NCDs. This is confirmed by food safety bodies worldwide including the Joint Expert Committee on Food Additives (JECFA) of the United Nations Food and Agriculture Organization (FAO) and of the World Health Organization (WHO), the European Food Safety Authority (EFSA), and the US Food and Drug Administration (FDA), who consistently support that all approved NSS are safe.

While it is acknowledged that the safety of NSS is evaluated by food safety agencies, including JECFA, it is also stated that “there is no clear consensus on whether NSS are effective for long-term weight loss or if they are linked to other long-term health effects at habitual intakes within the ADI”. With this statement the draft WHO guideline raises doubts about the safety of NSS. This is not only inconsistent with the safety assessment of all approved NSS by the responsible regulatory bodies at global and national level, but also outside of the scope of the WHO NUGAG Subgroup on Diet and Health and of this draft guideline. It is therefore fundamental that this lack of alignment between different WHO bodies and their respective responsibilities, is addressed. Such inconsistency has the potential to lead to considerable confusion among public health professionals and policy-makers, and serious concerns among the users of NSS.

Footnotes:

1. UN High-level Meeting on NCDs, September 2011. <https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>
2. UN High-level Meeting on the comprehensive review and assessment of the progress achieved in the prevention and control of NCDs, July 2014. <https://digitallibrary.un.org/record/774662>
3. UN High-level Meeting on NCDs, September 2018. http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2
4. Rios-Leyvraz M and Montez J (World Health Organization). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization (WHO) 2022. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO
5. Lee JJ, Khan TA, McGlynn N, Malik VS, Hill JO, Leiter LA, Jeppesen PB, Rahelić D, Kahleová H, Salas-Salvadó J, Kendall CWC, Sievenpiper JL. Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages With Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies. *Diabetes Care*. 2022 Aug 1;45(8):1917-1930
6. Numerous systematic reviews and meta-analyses of RCTs support that NSS can help people reduce overall calorie intake and thus be a useful tool in weight management, when used in place of sugar, without evidence of harm (Miller and Perez, 2014; Rogers et al, 2016; Nichol et al, 2018; DGAC, 2020; Greyling et al, 2020; Laviada-Molina et al, 2020; Lee et al, 2021; Movahedian et al, 2021; Rogers and Appleton, 2021; McGlynn et al, 2022).
7. WHO Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015
8. WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf
9. Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf
10. Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of NCDs, A75/10 Add.1 Annex 3 - Draft global strategy on oral health https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add1-en.pdf
11. Political declaration of the third high-level meeting of the General Assembly on the prevention and control of noncommunicable diseases. Report by the Director-General, EB150/7, WHA75, Annex 2. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

A full list of references is provided on page 26 in the enclosed PDF document.

Upload comments

```
[{"title":"Comments from the International Sweeteners Association (ISA)","comment":"","size":"495.9287109375","name":"ISA%20response%20to%20consultation_Draft%20WHO%20guideline%20on%20NSS%20use_12Aug2022.pdf","filename":"fu_f97eebekfjya9hm","ext":"pdf" }]
```

Brussels, 12th August 2022

World Health Organization Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health: Draft guideline on use of non- sugar sweeteners

ISA comments for submission via online consultation procedure

The [International Sweeteners Association \(ISA\)](#) is an association with scientific aims representing producers and users of low/no-calorie sweeteners, also called non-sugar sweeteners (NSS). ISA welcomes the opportunity to contribute to the public consultation on the Draft WHO guideline on use of non-sugar sweeteners and to provide comments in particular on the summary of evidence, evidence to recommendations, and recommendation on the use of non-sugar sweeteners.

Summary

There is an important disalignment between the draft WHO guideline and the objectives and approach of the global NCDs agenda to which all Member States have committed and which includes reformulation as an integral part. The ISA would call on the WHO to consider the serious implications that such a conditional recommendation, based on science lacking in rigour and overall low certainty in the evidence, would have on public health. In particular we would highlight the following:

- Member States committed to responding to the challenge of non-communicable diseases (NCDs) at the UN General Assembly meeting in September 2011¹ with a political declaration which recognised that effective NCDs prevention and control requires a “*whole-of-society effort*” through an integrated multi-sectoral approach including the engagement of industry. At subsequent UN High-level Meetings on NCDs in 2014² and 2018³ governments took stock of the progress made and re-confirmed their commitment to a coherent, inclusive, multi-stakeholder effort to stem the rise of NCDs.

Industry was called upon to contribute to reducing NCDs risk factors and creating health-promoting environments by “*reformulating products to provide healthier options*”. In seeking to support this global public health objective through product reformulation, non-sugar sweeteners (NSS) are a useful option for manufacturers to help achieve products with less sugar and fewer calories, while still being palatable to consumers. This has allowed manufacturers to respond with innovation and product development and to bring to the market less energy-dense foods and drinks.

To sustain and scale up these efforts, industry relies on consumer confidence in NSS as approved food ingredients which provide the consumer with wider choice. To advance the efforts to tackle the complex challenge of NCDs, the recognition of NSS as a safe and useful alternative to sugar is paramount.

The WHO recommendation that “*NSS not be used as a means of achieving weight*

¹ UN High-level Meeting on NCDs, September 2011.

<https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>

² UN High-level Meeting on the comprehensive review and assessment of the progress achieved in the prevention and control of NCDs, July 2014

<https://digitallibrary.un.org/record/774662>

³ UN High-level Meeting on NCDs, September 2018

http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

control or reducing risk of noncommunicable diseases” is **inconsistent with the global integrated approach to addressing NCDs to which Member States have committed, of which sugar reduction reformulation of foods and drinks is an integral part.** Global efforts to address the complex challenges of NCDs reduction requires joined-up policies based on rigorous scientific and policy evaluations.

- The draft WHO guideline on the use of NSS includes specific suggestions to policy-makers for the implementation of the recommendation, aiming to reduce or prevent the use of NSS, including marketing regulation, fiscal policies, and nutrition labelling. Assessing the impact of the suggested policy interventions, including the possibility of consumers moving away from foods and beverages with NSS towards sugar-containing counterparts, is beyond the scope of the draft guideline and the work of the NUGAG Subgroup on Diet and Health. Nonetheless, some aspects related to implementation, such as desirable and undesirable impact of the policies, feasibility, acceptability and resource implications, have been raised. **It is vital that any suggestions for policy recommendations are substantiated by a robust evidence base, including a full impact assessment. Such evidence base is not included in the draft guideline.**
- The *conditional* WHO recommendation suggesting that “*NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases*” is not scientifically rigorous since **it is not based on a robust evidence base or supported by the evidence presented in the WHO systematic review itself.**⁴ It is largely and disproportionally based on very low to low certainty evidence from observational studies, which are at high risk of reverse causality⁵, while higher-quality research of randomised controlled design that concludes there are benefits of NSS use and that there is no evidence of harm, is not given due priority⁶. **In the interest of public health, it is imperative that any recommendation regarding NSS use be based on the totality of the science and interpreted considering the hierarchy and weight of the scientific evidence.**
- A *conditional* recommendation on NSS use for which “*the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences*” **risks hindering public health efforts to reduce excess free sugars intake, a strong recommendation by WHO⁷, and ultimately to provide one approach to tackling the obesity epidemic^{8,9}, improving**

⁴ Rios-Leyvraz M and Montez J (World Health Organization). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization (WHO). <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO

⁵ Lee JJ, Khan TA, McGlynn N, Malik VS, Hill JO, Leiter LA, Jeppesen PB, Rahelić D, Kahleová H, Salas-Salvadó J, Kendall CWC, Sievenpiper JL. Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages With Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies. *Diabetes Care*. 2022 Aug 1;45(8):1917-1930

⁶ Numerous systematic reviews and meta-analyses of RCTs support that NSS can help people reduce overall calorie intake and thus be a useful tool in weight management, when used in place of sugar, without evidence of harm (Miller and Perez, 2014; Rogers et al, 2016; Nichol et al, 2018; DGAC, 2020; Greyling et al, 2020; Laviada-Molina et al, 2020; Lee et al, 2021; Movahedian et al, 2021; Rogers and Appleton, 2021; McGlynn et al, 2022).

⁷ WHO Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015

⁸ WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

⁹ Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf

oral and dental health¹⁰ and making a valuable contribution to global efforts to address NCDs. ISA would question the rationale for a WHO recommendation, and its implementation via policy actions, that is based on overall low certainty in the evidence.

- In particular, a disproportionate effect may be seen in people living with diabetes for whom NSS are an important dietary tool. While it is stated that the conditional recommendation may not be relevant to people with diabetes, a potential negative impact on this population group must be considered. The availability of the approved NSS has made possible a wider range of lower sugar products that can provide a greater choice for people with diabetes. By potentially discouraging reformulation and suggesting to policy-makers to implement policies to reduce or prevent the use of NSS (e.g., marketing regulation, fiscal policies, labelling), the draft WHO recommendation may negatively impact the availability of food and drink choices that can be safely used by people living with diabetes, inadvertently hindering individual efforts to limit the intake of sugars and negatively impacting quality of life. The draft WHO recommendation on the use of NSS is part of the global effort to address the prevention and control of NCDs^{11,12,13}, including the recent WHO recommendations¹⁴ to strengthen diabetes responses within national NCDs programmes. Therefore **it is essential that the draft WHO recommendation, including any impact on the diabetes community, be aligned with the global integrated approach to NCDs to which Member States have consistently committed.**
- Importantly, **there is no mechanistic evidence to support “possible long-term adverse effects” in the form of increased risk of NCDs.** This is confirmed by food safety bodies worldwide including the Joint Expert Committee on Food Additives (JECFA) of the United Nations Food and Agriculture Organization (FAO) and of the World Health Organization (WHO), the European Food Safety Authority (EFSA), and the US Food and Drug Administration (FDA), who consistently support that **all approved NSS are safe.**

While it is acknowledged that the safety of NSS is evaluated by food safety agencies, including JECFA, it is also stated that *“there is no clear consensus on whether NSS are effective for long-term weight loss or if they are linked to other long-term health effects at habitual intakes within the ADI”*. With this statement the draft WHO guideline raises doubts about the safety of NSS. This is not only inconsistent with the safety assessment of all approved NSS by the responsible regulatory bodies at global and national level, but also outside of the scope of the WHO NUGAG Subgroup on Diet and Health and of this draft guideline. **It is therefore fundamental that this lack of alignment between different WHO bodies and their respective responsibilities, is addressed. Such inconsistency has the potential to lead to considerable confusion among public**

¹⁰ Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of NCDs, A75/10 Add.1 Annex 3 - Draft global strategy on oral health
https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add1-en.pdf

¹¹ UN High-level Meeting on NCDs, September 2011.

<https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>

¹² UN High-level Meeting on the comprehensive review and assessment of the progress achieved in the prevention and control of NCDs, July 2014

<https://digitallibrary.un.org/record/774662>

¹³ UN High-level Meeting on NCDs, September 2018

http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

¹⁴ Political declaration of the third high-level meeting of the General Assembly on the prevention and control of noncommunicable diseases. Report by the Director-General, EB150/7, WHA75, Annex 2.

https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

health professionals and policy-makers, and serious concerns among the users of NSS.

1. Introduction

Rising rates of non-communicable diseases (NCDs) is a shared global challenge, affecting lives and economies worldwide. Heads of State and Government committed to responding to this challenge at the UN General Assembly meeting in September 2011¹⁵ with a political declaration which recognised that effective NCDs prevention and control requires a “*whole-of-society effort*” and Member States leadership.

As a global authority in public health, committed to addressing the challenge of NCDs, the WHO strives to support its Member States by providing evidence-informed guidance. The WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health has developed a draft guideline on use of non-sugar sweeteners (NSS) with the objective “*to provide evidence-informed guidance on the use of NSS by consumers*”. It is further stated that “*The recommendation in this guideline can be used by policymakers and programme managers to address NSS use in their populations through a range of policy actions and public health interventions*”.

Following WHO’s recommendations to limit free sugars intake, various actions are being taken to reduce consumption of free sugars as part of global efforts to address the epidemic of obesity^{16, 17} and associated diseases. The use of NSS in foods and drinks has enabled manufacturers to develop foods and drinks with less sugar and less calories, while responding to consumer taste preferences. Reformulation for sugar reduction has helped support Member States efforts to deliver on their commitment to address NCDs.

WHO has invited Member States and all relevant stakeholders to comment on the draft guideline on use of NSS via an online public consultation. The objective of the current document is therefore to provide scientific and policy comments on the draft WHO guideline on the use of NSS, including feedback on overall clarity, missing scientific data, considerations and implications for adaptation and implementation of the draft guideline.

2. Comments on the section: “Summary of evidence”

The draft WHO guideline on use of NSS was based exclusively on a systematic review of medium- to long-term randomised controlled trials (RCTs) and observational studies that assessed the health effects of NSS use in adults, children, and pregnant women (Rios-Leyvraz and Montez, 2022). The beneficial role of NSS use in reducing total energy intake and assisting with weight loss, without evidence of harm, is confirmed by the results of RCTs reviewed in Rios-Leyvraz and Montez, while observational studies report conflicting outcomes.

Meta-analyses of RCTs in this study showed that **NSS use in any manner resulted in reduced energy intake (by approx. 130 calories), modest but robust short-term weight loss, and**

¹⁵ UN High-level Meeting on NCDs, September 2011.

<https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>

¹⁶ WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

¹⁷ Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf

lower BMI, and did not significantly affect intermediate markers of cardiometabolic health, including blood glucose and insulin levels, blood pressure or blood lipids (Rios-Leyvraz and Montez, 2022).

Results from numerous systematic reviews and meta-analyses of RCTs also support that NSS can help people reduce overall calorie intake and thus be a useful tool in weight management, when used in place of sugar and as part of a calorie-controlled diet and a healthy lifestyle, without evidence of harm (Miller and Perez, 2014; Rogers et al, 2016; Nichol et al, 2018; DGAC, 2020; Greyling et al, 2020; Laviada-Molina et al, 2020; Lee et al, 2021; Movahedian et al, 2021; Rogers and Appleton, 2021; McGlynn et al, 2022).

In interpreting the evidence from the systematic review by Rios-Leyvraz and Montez (2022), **the draft WHO guideline places disproportionately more weight on very low to low quality data from observational research at high risk of reverse causality, without giving sufficient weight to higher quality evidence from RCTs supporting benefits of NSS use, without evidence of harm.** The draft WHO guideline interpreted as a limitation what the scientific community widely recognises as a strength of randomised controlled design, i.e. that they are carefully planned and controlled in order to allow cause-effect relationships to be investigated and established with confidence (Richardson et al, 2017; Serra-Majem et al, 2018; Ashwell et al, 2020; Mela et al, 2020). In contrast, observational research in this field is exposed to major sources of bias, as also acknowledged by the NUGAG Subgroup on Diet and Health. By design, observational studies cannot establish a cause-and-effect relationship and provide low certainty evidence due to their observational nature and the inability to exclude both unmeasured and measured residual confounding, make any causal relationships, or, importantly, attenuate the effects of reverse causality (Lee et al, 2022).

A systematic review and meta-analysis of observational studies including change and substitutions analyses that mitigate the influence of reverse causality providing more consistent and robust associations found that **NSS beverages are associated with lower risk of obesity, coronary heart disease, and cardiovascular disease (CVD) and total mortality in the intended substitution for sugar-sweetened beverages, with no adverse associations across other outcomes** (Lee et al, 2022). These findings are in line with evidence from RCTs of intermediate cardiometabolic risk factors (McGlynn et al, 2022) and in contrast to the results of meta-analyses of observational studies as assessed in the WHO review (Rios-Leyvraz and Montez, 2022). Importantly, **there is no mechanistic evidence to support “possible long-term adverse effects” in the form of increased risk of NCDs.** This is confirmed by food safety bodies worldwide including the Joint Expert Committee on Food Additives of the United Nations Food and Agriculture Organization (FAO) and of the World Health Organization (WHO), the European Food Safety Authority (EFSA), and the US Food and Drug Administration (FDA), who consistently support that **all approved NSS are safe.**

Finally, the draft WHO guideline on use of NSS **did not consider the totality of available scientific data assessing the health benefits of NSS**, including on dental health (tooth mineralisation) and post-prandial blood glucose levels when NSS are consumed instead of sugars (EFSA, 2011a).

Comments on the interpretation of the evidence

The NUGAG Subgroup on Diet and Health made several observations “*in interpreting the results of the systematic review, some based directly on data from the review and others supported by background questions and information that helps to establish the context for the*

recommendation.” The ISA would point to several considerations regarding the interpretation of the evidence in the draft WHO guideline:

- Evidence from a wealth of “*varied interventions in randomized controlled trials*” consistently supports the data that NSS use can help reduce total energy intake and assist with weight loss, when NSS are used to replace free sugars in the diet (i.e., the “*intended purpose of NSS*”). This is supported by the results of the WHO systematic review itself (Rios-Leyvraz and Montez, 2022).
- Non sugar sweeteners are food additives that are used in foods and beverages as well as in table-top sweeteners in place of sugar to provide the desired sweetness with fewer or zero calories and should not be expected to have “*inherent pharmacological properties*”. Indeed, **NSS benefits in weight control are evident when used to replace sugars and calories in the diet** (Ashwell et al, 2020). This is clearly supported by data reviewed in the WHO study (Rios-Leyvraz and Montez, 2022) and by previously published systematic reviews (Lee et al, 2021; Rogers and Appleton, 2021).
- The NUGAG Subgroup on Diet and Health notes that, “*Because weight loss or the maintenance of a healthy weight must be sustained over the long-term in order to realize associated health benefits, there must be evidence for sustained weight loss or maintenance for any intervention being investigated for effects on body weight*”. Evidence reviewed by WHO includes also data from longer-term RCTs studying the impact of NSS on weight control for a duration up to 2 years. These large, long-term trials are supportive of NSS useful role in long-term weight loss and maintenance for both adults and children (Blackburn et al, 1997; de Ruyter et al, 2012; Peters et al, 2016).
- The draft guideline considers as a limitation what is a recognised strength of well-designed RCTs (Serra-Majem et al, 2018; Ashwell et al, 2020; Mela et al, 2020). **The randomised controlled design is the most reliable study design for drawing causal inferences**, and therefore regarded as the gold standard in the hierarchy of research designs (Richardson et al, 2017), especially because RCTs are “*carefully planned and controlled*” (including randomisation) to eliminate bias affecting observational research (mainly residual confounding and reverse causality). According to the GRADE approach, used by organisations in the guideline development process, including by the WHO (2014) and the United States Department of Agriculture (USDA) in developing the Dietary Guidelines for Americans (Spill et al, 2022), the best estimates of the effects of an intervention come from systematic reviews of RCTs in which the intervention is tested against alternative management approaches (Balshem et al, 2011).
- “***The potential role of reverse causation in the results from the prospective cohort studies***” is poorly addressed in the draft WHO guideline despite the fact that **observational research on the field of NSS is at particularly high risk of reverse causality, as widely recognised by the scientific community** (Lohner et al, 2017; Serra-Majem et al, 2018; Toews et al, 2019; Ashwell et al, 2020; DGAC, 2020; Mela et al, 2020; Normand et al, 2021; Lee et al, 2022). In contrast, a systematic review and meta-analysis of observational studies including change and substitutions analyses that mitigate the influence of reverse causality providing more robust and reliable associations found that NSS are associated with a lower, rather than higher, risk in incident obesity and important cardiometabolic outcomes in the intended substitution for SSBs (Lee et al, 2022); this finding is in line with the evidence from systematic reviews and meta-analyses

of RCTs of intermediate cardiometabolic risk factors (McGlynn et al, 2022; Rios-Leyvraz and Montez, 2022).

- Neither the draft WHO guideline, or the systematic review by Rios-Leyvraz and Montez, examined data regarding the *“Potential mechanisms for negative associations with cardiometabolic health in prospective cohort studies”*. **No mechanistic evidence or results from RCTs support any of the proposed mechanisms**, including: effects on taste perception (Appleton et al, 2018; Rogers, 2018); eating behaviour (Bellisle, 2015; Lee et al, 2021), neural responses (Yeung et al, 2020); alterations to gut microbiota (Lobach et al, 2019).

In addition to these comments on “Summary of evidence”, we would also like to bring to your attention a more detailed scientific analysis of the published evidence regarding the use of non-sugar sweeteners. Please find it enclosed in an Appendix to this paper.

3. Comments on the section: “Evidence to recommendations”

In going from evidence to recommendation, the NUGAG Subgroup on Diet and Health has assessed the evidence in view of the certainty in the evidence and has considered several other aspects, including desirable and undesirable effects of the intervention, priority of the problem that the intervention would address, values and preferences related to the effects of the intervention in different settings, the cost of the policy options in different settings, feasibility and acceptability of implementing the intervention in different setting. While the certainty of the evidence pertains directly to the recommendation itself, the rest of the aspects considered relate to the implementation of specific policy interventions which have been suggested to public health policy-makers. Therefore we would like to bring to your attention the following comments on the certainty of the evidence and the potential impact of implementing the dietary recommendation based on such certainty in the evidence via public health and nutrition policies.

3A. Overall certainty in the evidence

The draft WHO guideline states that: *“The overall certainty in the evidence was considered low and is based on undesirable effects of NSS use on prioritized health outcomes observed in prospective cohort studies which were individually considered to be very low to low.”*

It is unscientific and against the best interests of public health to base dietary recommendations - in this case, to remove helpful dietary options using NSS - on such poor-quality evidence (Alexander et al, 2016), and at the same time disregard higher quality research from RCTs consistently supporting beneficial effects of NSS use on reduced energy intake, weight and glucose control and dental health, without evidence of harm (EFSA, 2011a; Rios-Leyvraz et al, 2022).

Furthermore, it is aimed with the guideline to provide a *“recommendation [to] be used by policymakers and programme managers to address NSS use in their populations through a range of policy actions and public health interventions”*. **Public policies should be developed on the basis of the highest quality, objective and comprehensive evidence which is available. In line with this fundamental principle, ISA would question the rationale for a WHO recommendation and its implementation via policy actions, that is based on overall low certainty in the evidence.**

3B. Balance of desirable and undesirable effects

In assessing the balance of desirable and undesirable effects of the draft WHO recommendation, the NUGAG Subgroup on Diet and Health base their conclusion about “*undesirable anticipated effects*” on the **groundless assumption that “the associations observed in prospective cohort studies are valid”** (Annex 7, pp78 in the draft WHO guideline). **Observational data of poor quality and at high risk of reverse causation should not have been considered as, basically, the primary evidence in formulating a recommendation about NSS use unless the issues of reverse causality and residual confounding have been comprehensively addressed, especially when evidence from RCTs is available and supports opposing (beneficial) effects.** Experts raise concerns about the weight that should be placed on observational data when data from controlled clinical studies are available (Mela et al, 2020); a body of evidence based on RCTs is rated as being of high quality at the outset and, thus RCTs are the preferred source of evidence for measuring the effects of interventions (WHO, 2014). According to the GRADE framework, the best estimates of the effects of an intervention come from systematic reviews of randomized controlled trials (RCTs) (Balslem et al, 2011), which are positioned at the highest level in the hierarchy of clinical evidence and **should be considered as a primary source of information in science-based public health decisions and policies** (Richardson et al, 2017). **On this basis, ISA would call on the WHO to revisit this assumption.**

Furthermore, it is stated that because NSS are frequently a component of ‘*highly processed foods and beverages [...] one of the implicit, possible undesirable effects of NSS use in the context of reducing free sugars intake is the inclusion of a greater number of highly processed foods and beverages in the diet than would be included if free sugars were reduced without NSS use*’. The proposed alternative to NSS, as mentioned in a different part of the document, is “*replacing free sugars in the diet with sources of naturally occurring sweetness, such as fruits, as well as minimally processed unsweetened foods and beverages*”. Importantly, no evidence has been provided in the draft guideline exploring the potential effect of use of NSS on diet quality. In fact, **research supports the assertion that NSS can help people follow an overall healthy diet, when used in place of sugars, which is their intended purpose of use.** A positive association between NSS intake and improved diet quality has been reported in several studies in different populations globally (Drewnowski and Rehm, 2014; Gibson et al, 2016; Leahy et al, 2017; Patel et al, 2018; Silva-Monteiro et al, 2018; Barraj et al, 2019). For example, a study analysing data from the United Kingdom’s National Diet and Nutrition Survey (NDNS), found that consumers of NSS sweetened beverages had a better diet quality, lower free sugars’ consumption and higher chances of meeting the UK recommendation for free sugars’ intake, compared to consumers of sugar-sweetened beverages (Patel et al, 2018). It is essential that any potential impact of implementing the draft WHO recommendation is assessed on the basis of robust evidence and in line with key principles of developing responsible public policy.

NSS are used in very small amounts in foods, drinks and tabletop sweeteners to provide sweet taste with fewer or virtually no calories. As regulated ingredients, the amount of NSS used in such food and drink products is determined by their acceptable daily intake (ADI), so as to ensure we cannot overconsume them.

The safety of approved NSS has been repeatedly confirmed by food safety bodies around the world, including the joint WHO/FAO’s own expert food additives committee JECFA (Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives). They are amongst the most thoroughly researched ingredients and global research has shown

that our intake of them is well below the ADI level set by the authorities. (Martyn et al, 2018; Tennant, 2019; Tennant and Vlachou, 2019; Martínez et al, 2020; ACHIPIA, 2021; Barraj et al, 2021a; Barraj et al, 2021b; Martyn et al, 2022) The ADI is a measure of the amount – of NSS in this case – which we can consume **on a daily basis, over a lifetime**, without an appreciable health risk. It is based on the maximum amount that test animals can be given throughout their life without any noticeable harmful effects, divided by a safety factor of 100. The 100-fold safety factor takes into account potential differences between animals and humans, as well as among different population groups ensuring the safety of the most vulnerable including children and pregnant women.

The draft guideline acknowledges that the safety of NSS is evaluated by food safety agencies, including JECFA at global level and states that it is not intended to provide updated or alternative guidance on safe or maximal levels of intake. Nonetheless, it is also stated that *“there is no clear consensus on whether NSS are effective for long-term weight loss or if they are linked to other long-term health effects at habitual intakes within the ADI”*. With this statement the draft guideline raises doubts about the safety of NSS. **We would highlight that this is inconsistent with the safety evaluation of all approved NSS by the responsible regulatory bodies at global and national level. Furthermore, assessing the safety of NSS is neither in the scope of the work of the WHO NUGAG Subgroup on Diet and Health and of this draft guideline, nor has the relevant toxicological evidence formed part of the review conducted by Rios-Leyvraz and Montez (2022). It is therefore fundamental that this lack of alignment between different WHO bodies and their respective responsibilities, is addressed. Such inconsistency has the potential to lead to considerable confusion among public health professionals, policy-makers and the general public.**

From a public health policy perspective, a key undesirable effect of the WHO recommendation would be the potential discouragement of the industry’s sugar reduction effort and its contribution to Member States efforts to deliver on their commitment to stem the rise of obesity^{18,19} and NCDs. This in turn could have a negative impact on the availability of lower sugar and no sugar food and drink options on the market, limiting consumer choice and potentially hindering individuals’ efforts to reduce their free sugars intake.

In particular, a disproportionate effect may be seen in people living with diabetes for whom NSS are an important dietary tool. While it is pointed out that the recommendation may not be relevant to people with diabetes, a potential negative effect of the recommendation on this population group must be considered. Maintaining the confidence in NSS as a safe and helpful alternative to sugar is critical for people living with diabetes. The WHO recommendation on use of NSS is part of the global effort to tackle NCDs and their diet-related risk factors and must be aligned with this broad global agenda, including the recent WHO recommendations²⁰ to strengthen and monitor diabetes responses within national noncommunicable disease programmes, which was adopted at the World Health Assembly in May 2022.

¹⁸ WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

¹⁹ Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf

²⁰ Political declaration of the third high-level meeting of the General Assembly on the prevention and control of noncommunicable diseases. Report by the Director-General, EB150/7, WHA75, Annex II. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

The absence in the draft guideline of the benefits of NSS for oral health is a missed opportunity and a disalignment with the global NCD agenda. WHO has recommended reducing the intake of free sugars to below 5% of total energy in order to have benefit for oral health. The recent WHO Global strategy on oral health²¹, adopted at the WHA in May 2022, further points to the importance of addressing oral health. It is therefore essential to consider the potential undesirable effect of not including oral health in the draft guideline on the global effort to address NCDs.

Overall, since reviewing the evidence base to inform policy interventions is beyond the scope of the draft guideline on use of NSS, an impact assessment on the implementation of the recommendation via specific policy actions is not provided. The potential undesirable effect of implementing the recommendation must be considered, including in particular the above-mentioned potential impact on sugar reduction reformulation, availability of food and drink choices for people living with diabetes, effect of NSS use on diet quality and impact on oral health. Lastly, the recommendation and its suggested implementation should be aligned with the overarching global NCD agenda to which all Member States have committed.

3C. Priority of the problem and values and preferences

Escalating rates of obesity and NCDs continue to be an unabating health challenge globally, impacting the lives of millions of people. Importantly, beyond impact on health and quality of life, NCDs are the leading cause of death globally. The COVID-19 pandemic has aggravated the problem, showing that chronic health conditions, such as obesity and diabetes, are associated with increased risk and severity of COVID-19 outcomes (ECDC, 2020). Furthermore, the COVID-19 pandemic has impacted access to dental preventative care and treatments and widened the inequality seen with access to oral care specifically in children, older populations, and those with disabilities (Mac Giolla Phadraig et al, 2021; Stennett and Tsakos, 2022). Worryingly, COVID-19 also reduced adherence to health diets (González-Monroy et al, 2021). It is therefore all the more urgent to tackle NCDs, including their diet-related risk factors. In the pandemic context which global public health groups must continue to navigate, making conflicting scientific recommendations is not beneficial to the publics' trust in scientific processes and institutions.

Member States have acknowledged this shared challenge and have committed to addressing it within the broader framework of the Sustainable Development Goals (SDGs) with a political declaration²² which recognised that effective NCDs prevention and control requires a 'whole-of-society effort' through an integrated multi-sectoral approach including the engagement of the food and beverage industry. Member States called upon the private sector to contribute to reducing NCDs risk factors and creating health-promoting environments by *"reformulating products to provide healthier options that are affordable and accessible and that follow relevant nutrition facts and labelling standards"*. The draft WHO guideline is inconsistent with this stated objective, as NSS are a critical tool for manufacturers to help achieve products with less sugar and fewer calories, while continuing to meet consumer demand for sweet taste.

Removing significant amounts of sugars from a food or drink has a noticeable impact on the sensory profile of the product, which can impact on overall consumer liking for the product. NSS

²¹ Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of NCDs, A75/10 Add.1 Annex 3 - Draft global strategy on oral health
https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add1-en.pdf

²² UN High-level Meeting on NCDs, September 2011.
<https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>

are important ingredients for manufacturers as they are the only means of giving foods and beverages a sweet taste without all the calories of sugar.

Manufacturers have responded to the call to contribute to food and drink reformulation, with innovation and product development and have brought to the market less energy dense foods and drinks. To sustain and scale up these efforts, industry relies on consumer confidence in NSS as approved food ingredients which provide the consumer with choice.

The draft guideline recommendation suggesting NSS not be used as a means to achieve weight control or reducing risk of NCDs may undermine consumer confidence in these ingredients as a safe and valuable alternative to sugar and may consequently discourage reformulation for sugar reduction, hindering a valuable contribution to the global objective to stem the rise of NCDs.

From a broader policy perspective, following the third UN High-level Meeting on NCDs on 27th September 2018²³ when stakeholders took stock of the progress made and re-confirmed their commitment, as well as the UN Food Systems Summit in September 2021²⁴ which launched ambitious new actions towards progress on the SDGs, it is important to reinforce an inclusive and aligned public policy on prevention and control of NCDs within the agreed global multi-stakeholder process. Food and drink reformulation has been an integral part of the global effort to address NCDs. Maintaining confidence in NSS as a safe and helpful alternative to sugar which enables reformulation for sugar reduction, would indeed be in line with the comprehensive and integrated global approach to tackling NCDs.

On an individual level, the draft WHO recommendation suggesting NSS not be used as a means to achieve weight control **may hinder efforts by people living with obesity to manage their calorie and sugars intake, and in turn their body weight.** This is particularly concerning at a time when overweight and obesity affect nearly 40% of the global adult population, as well as millions of children, and in light of the link between the excess consumption of free sugars to overweight and obesity, described by WHO as justifying a sugars guideline based on strong evidence (WHO, 2015). In fact, the draft guideline could confuse consumers, who are less familiar with the strength of the evidence that WHO has relied on, to revert back to full sugar alternatives.

Globally, 537 million, approximately 1 in 10 adults, are living with diabetes (IDF, 2021). NSS are a useful dietary tool for people living with diabetes which helps support efforts to reduce the intake of sugars. The availability of the approved NSS has made possible a wider range of lower sugar products that can provide a greater choice for people with diabetes. By potentially discouraging reformulation, the draft WHO recommendation may negatively impact the availability of food and drink choices that can be safely used by people living with diabetes, inadvertently hindering individual efforts to limit the intake of sugars, negatively impacting quality of life and jeopardising the proven public health outcomes that could be achieved through effective reformulation. Furthermore, the draft guideline may also cause those living with diabetes to erroneously believe that using NSS in place of sugar cannot cause a lower rise in blood glucose levels, thereby disregarding the advice of relevant authorities, such as the American Diabetes Association (Evert et al, 2019) and Diabetes UK (2018).

²³ UN High-level Meeting on NCDs, September 2018
http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

²⁴ UN Food Systems Summit, Sep 2021. <https://www.un.org/en/food-systems-summit/about>

Furthermore, there are 3.5 billion cases of dental caries, resulting in periodontal (gum) disease and eventual tooth loss globally. The prevalence rates over the past three decades have remained unchanged at 45%, **making oral diseases the most prevalent NCD globally** (Bernabe et al, 2020). Yet, these oral conditions are almost entirely preventable, in part by reduction in free sugars (FDI, 2015; WHO, 2015). In order to reduce the intake of free sugars for health benefits, as recommended by WHO, NSS are utilised in product reformulations. NSS are critical ingredients in sugar-free chewing gum, hygiene, and personal care oral products, providing benefits for oral health. **It should be more strongly highlighted in the final WHO guideline that there were some publications highlighting the oral health benefits of NSS, and that more research in this area is needed for a robust meta-analysis to be performed in the future.**

The importance of addressing oral health as part of the global commitment to the prevention and control of NCDs, within the broader framework of the Sustainable Development Goals (SDGs), has been consistently acknowledged, including with the recent Global Strategy on Oral Health²⁵, adopted at the World Health Assembly in May 2022. **Failing to address the role of NSS in supporting the prevention and control of the most prevalent NCDs globally - oral diseases – is inconsistent with the objectives of the global NCDs agenda, disaligned with the comprehensive integrated approach to tackling NCDs to which Member States have committed, and has the potential to hinder efforts to address oral diseases and to stem the rise of NCDs globally.**

3D. Feasibility and acceptability

The draft guideline looks at the feasibility of implementing the recommendation on use of NSS via specific suggested policy interventions, namely regulation of marketing food and non-alcoholic beverages; restricting the sales and promotion of food and beverages containing NSS in schools; fiscal policies targeting foods and beverages that contain NSS; nutrition labelling; consumer education. It is pointed out that while feasibility may vary depending on specific approaches, the recommendation can be incorporated into existing health and nutrition policy activities and *‘would naturally complement existing efforts to reduce free sugars’*. The draft guideline suggests an approach for efficient, i.e. feasible, implementation.

The implementation of any policy intervention, including its feasibility and acceptability, should be considered on the basis of a review of strong evidence, specific to the policy intervention, including a comprehensive impact assessment. Such evidence base is not presented and is beyond the scope of the draft guideline on use of NSS. **On this basis, ISA would question the basis for including guidance on the implementation of the above-mentioned policies.**

In addition, a specific example states that *‘appropriate messaging on NSS can readily be added to existing food-based dietary guidelines and the increasing number of actions being taken to address free sugars intake, such as behaviour change and education campaigns, fiscal policies, marketing and labelling policies, and reformulation’*. This suggestion to approach together free sugars and NSS may potentially have the effect of further confusing health-related stakeholders and consumers, in addition to the diabetes patient community, by addressing sugar and NSS intake within the same policy actions and tools while simultaneously removing a critical tool for the reduction of sugar in the food supply.

²⁵ Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of NCDs, A75/10 Add.1Annex 3 - Draft global strategy on oral health
https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add1-en.pdf

A point is made that the successful implementation of the recommendation to reduce the use of NSS would also depend on *‘the extent to which consumers are aware of the NSS content in products they purchase: evidence suggests that some consumers may not be aware that many of the food and beverages they are purchasing contain NSS’*.

NSS must be indicated in the list of ingredients on the packaging of food and beverage products that contain them by their specific name or number and the functional class ‘sweetener’. Indeed, the Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985²⁶) requires in section 4.2: List of ingredients, sub-section 4.2.3.3 that for labelling of food additives, including sweeteners, *‘functional classes shall be used together with the specific name or recognized numerical identification’*. Among the functional classes the class of ‘sweeteners’ is listed. **Therefore on a global level the Codex General Standard for the Labelling of Pre-packaged Foods ensures that consumers are sufficiently informed about the presence of NSS in foods and beverages.**

Furthermore, in Europe in accordance with EU labelling regulation Regulation (EU) No 1169/2011²⁷, in addition to the labelling in the ingredients list, the term ‘with sweetener(s)’ must be stated on the label together with the name of the food or beverage product.

It is acknowledged that acceptability of the draft guideline to policy-makers and at consumer level may vary across different countries and cultural contexts depending on several factors, including the accustomed sweetness level in the diet and the specific policy interventions. It is therefore essential that robust evidence on the feasibility and acceptability of a policy intervention in a specific cultural/national context underpins any implementation.

The feasibility and acceptability of the recommendation at an individual level have, similarly, never been examined and may be particularly low because **the draft guideline ignores evidence from a wealth of studies conducted over several decades which show that humans’ liking of sweet taste is innate and universal** (Public Health England, 2015). NSS have the unique property of being food ingredients with sweet taste and no, or virtually no, calories that are used in foods and beverages as well as in table-top sweeteners in place of sugar to provide the desired sweetness with fewer or zero calories (Gibson et al, 2014). While NSS might not be the only way to achieve a reduction in free sugars, as stated in the draft guideline, NSS represent a helpful dietary tool to enjoy sweet taste with fewer calories and low or no sugar.

Humans are born with a natural preference for sweetness, which decreases from childhood to adolescence and into adulthood (Bellisle, 2015; Mennella and Bobowski, 2015; Rogers, 2018; Wittenkind et al, 2018). In fact, in many studies, the use of NSS is associated with a lower intake of sweet tasting substances (de Ruyter et al, 2013; Piernas et al, 2013; Maloney et al, 2019; Rogers et al, 2020; Appleton et al, 2021; Appleton, 2021). This suggests that NSS may help to satisfy a desire for sweetness (Bellisle 2015; Rogers 2018; Appleton et al, 2018). Eroding consumer confidence in NSS as a safe and valuable alternative to sugar and discouraging reformulation may cause consumers to revert back to full-sugar options.

3E. Resource implications

²⁶ Codex General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%252B1-1985%252FCXS_001e.pdf

²⁷ REGULATION (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:en:PDF>

While it is acknowledged that impact assessment or assessment of the evidence base for the implementation of the suggested policy actions is beyond the scope of the draft guideline on use of NSS, references to the potential impact of implementing the draft guideline from a resource perspective, are in fact included. Importantly, such impact assessment should be robust, comprehensive and specific to the suggested policy intervention and the national/cultural context. **Including suggestions or guidance about resource implications without such comprehensive impact assessment may be damaging to the effect of any policy intervention and may cause confusion among health professionals and policy-makers.**

For example, it is stated that *‘Generally speaking, not using NSS would imply that both the purchase of NSS themselves (for use by the consumer) and the purchase of foods and beverages containing them would decrease. In the case of NSS and certain foods and beverages with no caloric value, further adjustments to the diet would not be needed and money could be saved by simply not purchasing them.’* No impact assessment data is provided to substantiate this assumption. Importantly, consumer data suggests that some consumers would move away from foods and beverages with NSS towards sugar-containing counterparts. ISA would propose that this statement be reconsidered on the grounds that an evidence base has not been provided and is beyond the scope of the draft guideline.

4. Comments on the section: “Recommendation and supporting information”

The *conditional* WHO recommendation that “NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases” is **inconsistent with the global integrated approach to addressing NCDs to which Member States have committed, and of which sugar reduction reformulation is an integral part. Such disalignment may be detrimental to global efforts to address the complex challenge of NCDs.**

The draft WHO guideline aims to contribute to the global NCD agenda to which Member States have consistently committed. At the UN General Assembly meeting in September 2011²⁸ global leaders committed to responding to the challenge of non-communicable diseases. with a political declaration which recognised that effective NCDs prevention and control requires a ‘whole-of-society effort’ through an integrated multi-sectoral approach including the engagement of industry. At subsequent UN High-level Meetings on NCDs in 2014²⁹ and 2018³⁰ governments took stock of the progress made and re-confirmed their commitment to a coherent, inclusive, multi-stakeholder effort to stem the rise of NCDs.

Industry was called upon to contribute to reducing NCDs risk factors and creating health-promoting environments by “reformulating products to provide healthier options”. In seeking to support this global public health objective through product reformulation, NSS are an important option for manufacturers to help achieve products with less sugar and fewer calories, while still being palatable to consumers. This has allowed manufacturers to respond with innovation and product development and to bring to the market less energy-dense foods and drinks. To sustain

²⁸ UN High-level Meeting on NCDs, September 2011.

<https://documents-dds-ny.un.org/doc/UNDOC/LTD/N11/497/77/PDF/N1149777.pdf?OpenElement>

²⁹ UN High-level Meeting on the comprehensive review and assessment of the progress achieved in the prevention and control of NCDs, July 2014

<https://digitallibrary.un.org/record/774662>

³⁰ UN High-level Meeting on NCDs, September 2018

http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

and scale up these efforts, industry relies on consumer confidence in NSS as approved food ingredients which provide the consumer with wider choice. To advance the efforts to tackle the complex challenge of NCDs, the recognition of NSS as a safe and useful alternative to sugar is essential.

The *conditional* WHO recommendation suggesting that “*NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases*” **risks hindering sugar and calorie reduction efforts and, hence, actions to align with current public health recommendations to reduce free sugars and address the epidemic of obesity^{31,32} and associated noncommunicable diseases (NCDs) including type 2 diabetes and cardiovascular diseases.** Similarly, with dental caries being amongst the most widespread NCDs in the world, **preventing efforts to reduce free sugars intake by recommending against NSS use puts at risk global efforts to improve oral and dental health.**

Importantly, the *conditional* WHO recommendation lacks scientific rigour. It is largely and disproportionally based on very low to low certainty evidence from observational studies, which are at high risk of reverse causality, while higher-quality research of randomised controlled design confirming benefits of NSS use and no evidence of harm is overlooked. **In the interest of public health, it is imperative that any recommendation regarding NSS use be based on the totality of the science and interpreted considering the hierarchy and weight of the scientific evidence.** A *conditional* recommendation on NSS use for which “*the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences*” **risks hindering public health efforts to reduce excess free sugars intake and tackle the obesity epidemic. ISA would further question the rationale for making policy recommendations on this basis.**

The draft WHO recommendation suggesting NSS not be used as a means to achieve weight control **may hinder efforts by people living with obesity to manage their calorie and sugars intake, and in turn their body weight.** This is particularly concerning at a time that overweight/obesity affects nearly 40% of the global adult population as well as millions of children, and in light of the link between the excess consumption of free sugars to overweight and obesity, described by WHO as justifying a sugars guideline based on strong evidence (WHO, 2015). It is therefore essential that people living with obesity are responsibly informed in the final WHO guideline that, while NSS might not be the solution to the obesity epidemic, current evidence reviewed by WHO does indeed support short-term benefits of NSS use in sugar and energy intakes reduction and, in turn, in assisting with short-term weight loss (Rios-Leyvraz and Montez, 2022).

Supporting information in the draft guideline stating that “*evidence of minor weight loss or reduced BMI over several months or less as observed in the randomized controlled trials without additional evidence of long-term impact, does not represent a health benefit*” **is not supported by scientific evidence.** Indeed, evidence supports that a 5–10% weight loss is sufficient to obtain substantial health benefits from reduced obesity-related comorbidities in adults (WHO European Regional Obesity Report 2022). NSS use in place of caloric sweeteners and as part of a behavioural weight control programme is one amongst a pool of different dietary strategies that can help reduce total

³¹ WHO Draft recommendations for the prevention and management of obesity over the life course, including potential targets. EB150/7, Annex 9. https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf

³² Follow-up to the political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable disease. Acceleration plan to support Member States in implementing the recommendations for the prevention and management of obesity over the life course. A75/10 Add.6, Annex 12. https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_10Add6-en.pdf

energy intake and, hence, assist with weight loss. In addition, by providing sweet taste with fewer or no calories, products sweetened with NSS can help improve adherence to a calorie-reduced healthy diet and lifestyle (Catenacci et al, 2014; Miller and Perez, 2014). Available long-term RCTs are also supportive of NSS useful role in weight loss and weight loss maintenance (Blackburn et al, 1997; Peters et al, 2016). For example, in a 1-year RCTs in 303 adult participants living with overweight or obesity, Peters and colleagues found greater maintenance of weight loss with NSS use compared with control: 44,2% of subjects in the NSS group lost at least 5% of their body weight from baseline to year one compared with 25,5% in the water group (Peters et al, 2016).

In addition, neither the draft WHO guideline, nor the systematic review by Rios-Leyvraz and Montez, examined data regarding NSS use in medications, personal care and hygiene products. Therefore, there is **no scientific support for the remark on page 11 of the draft that “NSS-free versions of these items, when readily obtainable, can be considered.”** In fact, as the WHO draft guideline points out these hygiene products, along with sugar-free chewing gum, contain NSS in small amounts to make them more palatable which encourages their use for oral health benefits. A remark should not be made without scientific evidence to support it nor without considering the public health impacts such a recommendation would have on compliance and adherence to well established routines such as utilizing fluoridated toothpastes. **On this basis, the remark should be removed from the final draft.**

Finally, the potential adverse implications for public health have not been considered in the draft WHO guideline and do not support the statement: *“there were no identified undesirable effects or other mitigating factors that would argue against not using NSS”*. **We call the WHO to consider the serious implications that such a recommendation, based on poor science, would have on public health.**

5. Conclusions

The draft WHO recommendation is not scientifically rigorous, since it is not based on a robust evidence base. It risks hindering public health efforts to reduce excess free sugars intake, to tackle the obesity epidemic and to improve oral and dental health. Policy recommendations are proposed without a comprehensive impact assessment and without taking into account the safety and benefits to health of NSS as acknowledged by international regulatory authorities. There is an important disalignment between the draft WHO recommendation and the objectives and approach of the global NCD agenda to which all Member States have committed and which includes reformulation as an integral part.

References:

A full list of references is provided on page 26.

Appendix – Scientific comments regarding the section “Summary of evidence”

A. Review of evidence on the effect of non-sugar sweeteners on body weight

Non-sugar sweeteners can be a useful dietary tool for weight control

Non-sugar sweeteners (NSS) can help individuals reduce overall energy (calorie) intake and thus be a useful tool in weight control, when used in place of sugar and as part of a calorie-controlled diet and a healthy lifestyle. Contrary to evidence from RCTs supporting their helpful role in reducing total energy intake and body weight, **there is no causal evidence to support the notion that NSS, or products containing them, can lead to weight gain.** The association between NSS use and increased obesity incidence reported in observational studies is at high risk of reverse causality. These assertions are confirmed by the results of the WHO-supported study itself (Rios-Leyvraz and Montez, 2022), as well as by previously published comprehensive systematic reviews (Miller and Perez, 2014; Rogers et al, 2016; DGAC, 2020; Laviada-Molina et al, 2020; Rogers and Appleton, 2021; McGlynn et al, 2022; Lee et al, 2022).

Randomized controlled trials (RCTs)

The beneficial role of NSS use in assisting with weight loss is confirmed by the results of the WHO systematic review that informed the draft WHO guideline (Rios-Leyvraz and Montez, 2022). Meta-analyses of RCTs in this WHO-supported study showed that **NSS use in any manner resulted in reduced energy intake (by approx. 130 calories), modest weight loss, and lower BMI, and did not significantly affect other measures of body fatness or intermediate markers of cardiometabolic health, including blood glucose and insulin levels or blood lipids** (Rios-Leyvraz and Montez, 2022). Results from numerous systematic reviews and meta-analyses of RCTs also support that NSS can help people reduce overall calorie intake (Lee et al, 2021; Rogers and Appleton, 2021) and thus be a useful tool in weight management, when used in place of sugar and as part of a calorie-controlled diet and a healthy lifestyle (Miller and Perez, 2014; Rogers et al, 2016; DGAC, 2020; Laviada-Molina et al, 2020; Rogers and Appleton, 2021; McGlynn et al, 2022).

A systematic review and meta-analysis of 20 RCTs concluded that the use of NSS results in clinically appreciable lower body weight/ body mass index (BMI), especially in the adult population, in people with overweight or obesity, and in those who follow an unrestricted diet (Laviada-Molina et al, 2020). Another systematic review and meta-analysis, which represents the largest work to date including meta-analyses of 60 articles that report 88 RCTs, concluded that the evidence from human intervention studies supports the use of NSS in weight management, when they are used to replace sugars in the diet (Rogers and Appleton, 2021). The study found that the more sugar is removed from the diet, the greater the impact is: for every 1 MJ (approx. 240 kcal) of energy replaced by NSS, body weight decreases by ~1.06 kg in adults. More recently, a network meta-analysis of 17 RCTs examining the cardiometabolic effects of drinks sweetened with NSS, involving 1733 adult participants with overweight or obesity who were at risk for or had diabetes, found that substituting sugar-sweetened beverages with NSS beverages is associated with reductions in adiposity and cardiometabolic risk factors, with no evidence of harm (McGlynn et al, 2022). The benefit of replacing added sugars with NSS in reducing calorie intake in the short-term and aiding in weight management is also supported by a systematic review by the US

Dietary Guideline Advisory Committee of the Dietary Guidelines for Americans, 2020-2025 (DGAC, 2020).

Importantly, **longer-term RCTs with a duration up to 2 years studying the impact of NSS on weight control are also supportive of their useful role in long-term weight management for both adults and children** (Blackburn et al, 1997; de Ruyter et al, 2012; Peters et al, 2016). An RCT in 163 adult participants investigating whether the addition of the NSS aspartame to a multidisciplinary weight-control program would improve weight loss and long-term control of body weight found that the use of foods and beverages with NSS helped individuals with obesity lose more weight and maintain it more effectively for a 2-year period compared to non-users (Blackburn et al, 1997). Similarly, a large RCT in 303 adults with overweight or obesity that evaluated the effects of water versus NSS beverages on body weight over one year found that the group that included NSS in their diet had greater maintenance of weight loss, higher reduction in waist circumference, and less hunger during the year-long weight loss and maintenance programme (Peters et al, 2016). In children, a well-conducted 18-month RCT involving 641 children found that the replacement of sugar-containing beverages with noncaloric beverages significantly reduced weight gain and fat accumulation in normal-weight children (de Ruyter et al, 2012). In secondary analysis, this beneficial effect was found to be greater in children with higher BMI: body weight gain was reduced by 0.62 kg in the lower BMI group and by 1.53 kg in the higher BMI group (Katan et al, 2016).

Evidence supports that the **beneficial role of NSS in weight control is greater for people living with overweight or obesity**, who need to manage their body weight (Toews et al, 2019; Laviada-Molina et al, 2020). Research suggests that substituting sugar-sweetened foods and beverages with their NSS sweetened alternatives may be a useful dietary tool to improve compliance with weight loss or weight maintenance plans (Miller and Perez, 2014). People from the US National Weight Control Registry who have successfully lost and maintained the reduced weight stated that NSS helped them manage their energy intake by using them in place of products with caloric sweeteners (Catenacci et al, 2014).

Therefore, **by suggesting that NSS not be used as a means for weight control, the draft WHO guideline is particularly unhelpful to people living with overweight or obesity**. It is important that people with obesity are responsibly informed that, while NSS might not be the solution to the obesity epidemic, current evidence reviewed by WHO does indeed support short-term benefits of NSS use in energy intake reduction and weight loss, without evidence of harm. Consumers and healthcare professionals have few tools to help in the fight against obesity, and a recommendation not to use NSS for weight control can limit choice and undermine the efforts of people living with obesity in managing their body weight.

Observational studies

Contrary to results from RCTs which consistently show a modest but significant weight reduction with NSS use instead of sugar, prospective observational studies that report a positive association between NSS use and increased body weight or risk of incident obesity provide inconsistent and unreliable evidence about the association between NSS and body weight, as **observational research in this field is prone to reverse causality**. This is also recognised in the draft WHO guideline, stating that “*in the case of NSS, reverse causation would suggest that those already at elevated risk of disease initiated or increased use of NSS because of their risk status, rather than NSS leading to increased risk in otherwise healthy or low-risk individuals*”. The previously published WHO-supported scoping and systematic reviews made similar points: for example, the WHO-supported scoping review by Lohner et al. recognized that: “*a positive association between*

NNS [non-nutritive sweeteners] consumption and weight gain in observational studies may be the consequence of and not the reason for overweight and obesity.” (Lohner et al, 2017; Towes et al, 2019; Rios-Leyvraz & Montez, 2022). This is also confirmed by data from the US National Health and Nutrition Examination Survey (NHANES) reporting that NSS use is associated with the prior intent to lose weight (Drewnowski and Rehm, 2016).

With the aim to address the issue of reverse causality in observational research of NSS, a recently published meta-analysis of 14 prospective cohort studies that used change analyses of repeated measures of intake and substitution analyses **led to different results: increased intake of NSS beverages was associated with lower body weight and the substitution of sugar-sweetened beverages (SSBs) with NSS beverages was associated with reduced adiposity and lower incidence of obesity** (Lee et al, 2022). This is in contrast to the evidence of “possible long-term adverse effects” in the form of increased risk of disease and to the rationale of the draft guideline suggesting against NSS use for weight control and prevention of NCDs (type 2 diabetes, cardiovascular disease).

By design, observational studies cannot establish a cause-and-effect relationship and provide low certainty evidence due to their observational nature and the inability to exclude both unmeasured and measured residual confounding, make any causal relationships, or attenuate the effects of reverse causality. As expected, this is also reflected in individual reviews of observational studies, which often report a positive association between NSS and obesity (Normand et al, 2021). In contrast, reviews that conclude to a beneficial effect/ association of NSS with body weight cite mainly randomised controlled trials (RCTs) (Normand et al, 2021), which, by their design, provide higher quality evidence than human observational studies. Indeed, **a body of evidence based on RCTs is rated as being of high quality at the outset and, thus RCTs are the preferred source of evidence for measuring the effects of interventions** (WHO, 2014). Systematic reviews with meta-analysis of RCTs are positioned at the highest level in the hierarchy of clinical evidence (Burns et al, 2011). According to the GRADE framework, the best estimates of the effects of an intervention come from systematic reviews of randomized controlled trials (RCTs) (Balshem et al, 2011), which should be considered as a primary source of information in science-based public health decisions and policies (Richardson et al, 2017). Indeed, experts raise concerns about the weight that should be placed on observational data when data from controlled clinical studies are available (Mela et al, 2020).

Finally, NSS impart either no or virtually no calories, so they cannot be a cause of body weight gain by virtue of their (lack of) energy content. Also, important to consider is the lack of evidence for a likely mechanism for a NSS to cause body weight gain and none of the suggested mechanisms examined in animal studies has ever been confirmed in human studies (Rogers, 2018).

It is therefore **surprising why the draft WHO guideline is essentially based on poor-quality data from observational research** (Alexander et al, 2016), while evidence from RCTs supporting the benefit of using NSS as a way to reduce excess sugar and calorie intake, and in turn, to assist in weight control, is not acknowledged in the draft guideline, nor reflected in the recommendation, which only suggests against using NSS for weight control.

B. Review of evidence on the association between the use of non-sugar sweeteners and risk of non-communicable diseases

Evidence does not support a causal link between non-sugar sweeteners and non-communicable diseases (type 2 diabetes, cardiovascular diseases, cancer)

There is no causal evidence that NSS could affect cardiometabolic health or increase the risk of NCDs including type 2 diabetes, cardiovascular diseases (CVDs) and cancer (Rios-Leyvraz and Montez, 2022; Lee et al, 2022). Food safety authorities globally such as the Joint Food and Agriculture Organisation (FAO)/ World Health Organization (WHO) Expert Committee on Food Additives (JECFA), the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA) have extensively evaluated all kinds of studies examining potential side effects and, on a basis of a wealth of data, have consistently confirmed that **all approved NSS are safe** (Serra-Majem et al, 2018; Ashwell et al, 2020). Importantly, there is no evidence of a plausible mechanism to support potential effects of NSS use on NCDs (Pyrogianni and La Vecchia, 2019). Such notions come from observational studies that, by nature, cannot prove causation.

Randomized controlled trials (RCTs)

The WHO systematic review and meta-analyses of RCTs found no significant effect of NSS on biomarkers used in the assessment and diagnosis of diabetes and insulin resistance, including fasting glucose, fasting insulin, or haemoglobin A1c (HbA1c), or on biomarkers used in the assessment and diagnosis of cardiovascular diseases (CVDs), including blood pressure, LDL cholesterol and other blood lipids (Rios-Leyvraz and Montez, 2022). This evidence is consistent with previously published systematic reviews of RCTs indicating a lack of plausible mechanism of how NSS could increase the risk of obesity, diabetes and CVDs in humans, since they do not negatively affect risk factors linked to these diseases, including blood pressure, blood lipids, glycemia, or body weight (Pham et al, 2019; Toews et al, 2019; Greyling et al, 2020; Movahedian et al, 2021; McGlynn et al, 2022).

Pham and colleagues concluded that NSS have demonstrated minimal or no effect on postprandial blood pressure (Pham et al, 2019), while Toews and colleagues reported that data from three RCTs showed that systolic and diastolic blood pressure were lower in people receiving NSS than in those receiving sugar or placebo, and two other RCTs reported a neutral effect (Toews et al, 2019). In their systematic review and meta-analysis of 26 papers (including 34 trials examining NSS effects on post-prandial glucose and 29 trials on post-prandial insulin levels), Greyling and colleagues concluded that the ingestion of NSS, administered alone or in combination with a nutrient-containing preload, has no acute effects on the mean change in postprandial glycemic or insulinemic responses compared with a control intervention (Greyling et al, 2020). Movahedian and colleagues systematically reviewed and meta-analysed data from 14 RCTs, involving 1407 participants, that examined the impact of NSS on blood triglyceride levels, total cholesterol, LDL- and HDL cholesterol. The results failed to demonstrate any statistically significant effect of NSS on lipid profile (serum levels of triglycerides, total-, LDL-, and HDL-cholesterol), with moderate certainty of evidence (Movahedian et al, 2021).

A network meta-analysis of 17 RCTs with 24 comparisons, involving 1733 adult participants with overweight or obesity who were at risk for or had diabetes, found that **the intended substitution of SSBs with NSS beverages was associated with modest but significant reductions in body weight, BMI, percentage of body fat, and intrahepatocellular lipid**, with moderate certainty of evidence (McGlynn et al, 2022). Also, there was no evidence of cardiometabolic harm or adverse events associated with this substitution. A small reduction in body weight and a greater decrease in systolic blood pressure was also associated with NSS compared with water, while water was associated with lower level of glycosylated haemoglobin. The findings of this study

support the assertion that **substituting SSBs with NSS beverages is associated with reductions in body weight and cardiometabolic risk factors, with no evidence of harm.**

Observational studies

Despite a lack of effect of NSS on risk markers of NCDs, the WHO meta-analyses of prospective observational studies reported that higher intakes of NSS were associated with increased risk of type 2 diabetes, CVDs incidence and mortality, and all-cause mortality, but were not associated with overall cancer incidence or mortality (Rios-Leyvraz and Montez, 2022). However, **adverse associations of NSS with cardiometabolic outcomes in observational studies may be explained by reverse causality and residual confounding**, as confirmed by a recent systematic review and meta-analysis of 14 prospective cohort studies that used change analyses of repeated measures of intake and substitution analyses to mitigate the influence of reverse causality (Lee et al, 2022).

Similar to issues affecting observational research studying the association between NSS and obesity risk, prospective cohort studies investigating associations of NSS with other health outcomes are also at high risk of reverse causality. Individuals who are at high risk for diabetes or CVDs may increase NSS intake as a risk reduction strategy, as opposed to the other way around (Sievenpiper et al, 2017; Lee et al, 2022). In addition, residual confounding from an incomplete adjustment of confounders and behaviour clustering is another major limitation of observational studies (Lee et al, 2022). Previously published WHO-supported reviews recognised that results of observational studies on the health effects of NSS should be interpreted with caution, and attention should focus on plausible residual confounding as well as reverse causality (Toews et al, 2019).

Prospective observational studies that have used substitution analyses that model the intended replacement strategy for NSS sweetened beverages (i.e., substitution of sugar-sweetened beverages with NSS beverages) can partly overcome these methodological limitations and provide more consistent results. For example, results from the Harvard Pooling Project of Diet and Coronary Disease Substitution analyses suggested that replacing SSBs with NSS beverages might be associated with a lower risk of developing coronary events (Keller et al, 2020).

A systematic review and meta-analysis by the Diabetes and Nutrition Study Group (DNSG) of the European Association for the Study of Diabetes (EASD) included prospective observational studies using substitution and change analyses that minimize reverse causality and residual confounding from incomplete adjustment of confounders and behavior clustering, providing evidence that is more robust and biologically plausible (Lee et al, 2022). Prevalent or baseline analyses of NSS exposure cannot capture the intended replacement strategy of the substitution of SSBs with NSS beverages and are susceptible to reverse causation, resulting in an underestimation of the intended cardiometabolic benefits. This systematic review and meta-analysis of 14 prospective cohort studies (416,830 participants) found that **the intended substitution of SSBs with NSS beverages was associated with lower body weight and lower risk of incident obesity, coronary heart disease, CVD and total mortality, with no adverse associations across other outcomes** (Lee et al, 2022). These findings confirm that NSS are not associated with higher, but rather, with a lower risk in important cardiometabolic outcomes in the intended substitution for SSBs, comparable with outcomes for water, and are in line with the evidence from systematic reviews and meta-analyses of RCTs of intermediate cardiometabolic risk factors (McGlynn et al, 2022; Rios-Leyvraz and Montez, 2022).

Importantly, for a NSS to be approved for use on the market, it must first undergo a thorough safety assessment by the competent food safety authority such as the Joint Food and Agriculture Organisation (FAO)/ World Health Organization (WHO) Expert Committee on Food Additives (JECFA), the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA). These regulatory bodies have extensively evaluated all kinds of studies examining potential side effects and, on a basis of a wealth of data confirming also that there is no mechanistic evidence that supports potential effects on NCDs, have consistently confirmed that all approved NSS are safe and do not cause cancer (Magnuson et al, 2016).

Collectively, cancer epidemiology research does not support a relationship between NSS intake and an increased risk of cancer. The WHO review that informed the draft WHO guideline found no significant associations between NSS use and several types of cancer or cancer mortality in meta-analysis of prospective cohort studies (Rios-Leyvraz and Montez, 2022). The WHO review reported a positive association between saccharin intake and bladder cancer based on meta-analyses of case-control studies (very low certainty evidence), which were decades old, with important limitations and serious risk of bias, and have been reviewed before by regulatory authorities. Importantly, the safety and lack of carcinogenicity of all NSS is confirmed by food safety authorities around the world following extensive safety assessment reviews of the collective evidence from both cancer epidemiological and carcinogenicity studies, which have not been considered in the WHO study or, overall, in the draft guideline.

C. Use of non-sugar sweeteners in pregnancy is safe

As presented above, the safety of NSS has been consistently confirmed by food safety bodies worldwide including the Joint Expert Scientific Committee on Food Additives of the United Nations Food and Agriculture Organization (FAO) and of the World Health Organization (WHO), the European Food Safety Authority, and the US Food and Drug Administration. **These agencies confirm that NSS are safe including during pregnancy and lactation.** For the safety evaluation of the individual NSS, the food safety bodies review all available data from reproductive, prenatal, and developmental toxicity studies and a breadth of tests for possible effects on mating, reproductive performance, fertility, gestational length and outcomes, skeletal and organ development, and neonatal growth and development, as well as observational data on NSS use in pregnancy.

Observational data suggesting an association between NSS consumption in pregnancy and risk of preterm birth (Halldorsson et al, 2010) have also been reviewed by EFSA. In a statement published in 2011, EFSA concluded that *“there is no evidence available to support a causal relationship between the consumption of artificially sweetened soft drinks and preterm delivery”* (EFSA, 2011b).

D. Missing data and evidence not considered in the draft WHO guideline

The benefit of non-sugar sweeteners use in tooth mineralisation is important given that dental caries is one of the most common global noncommunicable diseases

The draft WHO guideline failed to consider the collective evidence examining the effect on NSS on tooth mineralization, and hence their role in dental caries, which is amongst the most common NCDs globally (FDI, 2015). Despite excluding the majority of relevant published studies, the WHO review that supported the development of the draft guideline supports a beneficial effect of NSS on dental health (Rios-Leyvraz & Montez, 2022). In a scientific opinion in 2011, the European

Food Safety Authority (EFSA) reviewed all available evidence and concluded that **“there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralisation by decreasing tooth demineralisation if consumed instead of sugars”** (EFSA, 2011a). Based on this scientific opinion from EFSA, the European Commission authorised the health claim that the consumption of foods containing NSS instead of sugar contributes to the maintenance of tooth mineralisation (Commission Regulation (EU) No 432/2012). Additionally, there are United States FDA claims³³ allowed for non-fermentable carbohydrates such as the sugars D-tagatose and isomaltulose, sucralose, sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, and erythritol, along with hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of these (FDA, 2006). Noncariogenic carbohydrate sweeteners do not promote dental caries as they are slowly metabolized by bacteria resulting in a rate and amount of acid production significantly less than seen with sucrose or other fermentable carbohydrates. This in turn does not cause the loss of important minerals from tooth enamel.

In addition, a large battery of studies supports that the consumption of sugar-free chewing gum sweetened with non-fermentable NSS provides anti-cariogenic benefits. Reviewing the available evidence, the EFSA confirmed in its Scientific Opinions that sugar-free chewing gum helps reduce oral dryness, maintain tooth mineralisation, and neutralise plaque acids (EFSA, 2009). Plaque acids are a risk factor in the development of dental caries (EFSA 2010). A recent systematic review and meta-analysis also confirmed that chewing sugar-free gum may reduce the further development of dental caries (Newton et al, 2020).

While the intake of dietary sugars is a well-established hazard in relation to dental caries in humans (WHO, 2015; EFSA, 2022), by being non-fermentable and non-cariogenic ingredients, NSS can contribute to good dental health when used in place of sugar (FDI policy statement, 2008). According to the FDI World Dental Federation, eating a well-balanced diet that is low in sugar and chewing sugar-free gum, sweetened with NSS, after meals and snacks when brushing is not possible, are amongst the key recommendations for good oral health (FDI, 2015). Not acknowledging this well-established benefit of NSS use in dental health is a risk to public health efforts to improve oral health given the high prevalence of dental caries and related conditions such as gum disease and tooth loss globally. There is a failure in these draft guidelines to consider the resulting oral health impacts and to achieve an alignment with the WHO draft global strategy on tackling oral diseases based in the 2030 Agenda (WHA74.5)^{34 35}.

Strong evidence supports that consumption of non-sugar sweeteners induces a lower blood glucose rise after their consumption when used instead of sugar

The draft WHO guideline did not consider data from a wealth of RCTs confirming the lower rise of post-prandial blood glucose levels when NSS are consumed instead of sugars (EFSA, 2011a). Based on this scientific opinion by EFSA, in an authorised health claim in the EU Register of nutrition and health claims, it is recognised that **‘the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods’** (Commission Regulation (EU) No 432/2012). In addition, several systematic reviews have confirmed that NSS, by themselves, do not affect glycaemia and insulin levels post-prandially (Tucker and Tan, 2017; Nichol et al, 2018; Greyling et al, 2020) or in the long-term (Lohner et al, 2020). The absence of glycaemic effect of NSS, and the lower spike

³³ [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-E/section-101.80#p-101.80\(c\)\(2\)\(ii\)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-E/section-101.80#p-101.80(c)(2)(ii))

³⁴ https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_7-en.pdf#page=25

³⁵ https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R5-en.pdf

in postprandial blood glucose they cause when used instead of sugars, makes NSS a useful dietary aid for people with diabetes who need to manage their carbohydrate and sugars intake.

The draft WHO guideline states that *“Assessing the health effects of NSS on individuals with pre-existing diabetes was beyond the scope of this guideline”*. However, not considering the needs of people living with diabetes, which represents approximately 10% of the global population, is an important shortcoming of this draft guideline. In fact, the WHO recommendation suggesting not to use non-sugar sweeteners as a means for weight control might be **confusing to people living with diabetes, especially when diabetes related organisations including the American Diabetes Association (ADA) and Diabetes UK support the use of NSS for diabetes management**.

Health organisations globally recognise that NSS can be safely used to replace sugar in the nutritional management of diabetes (Franz et al, 2017; Diabetes UK, 2018; Evert et al, 2019). For example, both the American Diabetes Association (ADA) and the US Academy of Nutrition and Dietetics (AND), in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of NSS has the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners and without compensation by intake of additional calories from other food sources (Franz et al, 2017; Evert et al, 2019). Also, the latest Diabetes UK Position Statement on low/ no calorie sweeteners (LNCS) concludes that: *“LNCS are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes”* (Diabetes UK, 2018).

References:

1. ACHIPIA. Chronic dietary exposure assessment on sweeteners in food consumed by the Chilean population, 2021, Available online: https://www.achipia.gob.cl/wp-content/uploads/2021/06/2021_ACHIPIA_Informe-EED-Cronica-Edulcorantes-MINSAL-ACHIPIA_Nueva-Version_final-con-abstract-English.pdf
2. Alexander PE, Brito JP, Neumann I, Gionfriddo MR, Bero L, Djulbegovic B, Stoltzfus R, Montori VM, Norris SL, Schünemann HJ, Guyatt GH. World Health Organization strong recommendations based on low-quality evidence (study quality) are frequent and often inconsistent with GRADE guidance. *J Clin Epidemiol.* 2016 Apr;72:98-106
3. Appleton KM, Tuorila H, Bertenshaw EJ, de Graaf C, Mela DJ. Sweet taste exposure and the subsequent acceptance and preference for sweet taste in the diet: systematic review of the published literature. *Am J Clin Nutr.* 2018 Mar 1;107(3):405-419
4. Appleton KM, Rajska J, Warwick SM, Rogers PJ. No effects of sweet taste exposure at breakfast for 3 weeks on pleasantness, desire for, sweetness or intake of other sweet foods: a randomised controlled trial. *Br J Nutr.* 2021 Jun 25:1-11.
5. Appleton KM. Repeated exposure to and subsequent consumption of sweet taste: Reanalysis of test meal intake data following the repeated consumption of sweet vs non-sweet beverages. *Physiol Behav.* 2021 Feb 1;229:113221.
6. Ashwell M, Gibson S, Bellisle F, Buttriss J, Drewnowski A, Fantino M, Gallagher AM, de Graaf K, Gosciniy S, Hardman CA, Laviada-Molina H, López-García R, Magnuson B, Mellor D, Rogers P, Rowland I, Russell W, Sievenpiper J, la Vecchia C. Expert consensus on low calorie sweeteners: facts, research gaps and suggested actions. *Nutr Res Rev.* 2020 Jun;33(1):145-154
7. Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J, Vist GE, Falck-Ytter Y, Meerpohl J, Norris S, Guyatt GH. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol.* 2011 Apr;64(4):401-6
8. Barraj LM, Bi X, Murphy MM, Scrafford CG, Tran NL. Comparisons of Nutrient Intakes and Diet Quality among Water-Based Beverage Consumers. *Nutrients.* 2019 Feb 1;11(2):314
9. Barraj L, Scrafford C, Bi X, Tran N. Intake of low and no-calorie sweeteners (LNCS) by the Brazilian population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess.* 2021 Feb;38(2):181-194
10. Barraj L, Bi X, Tran N. Screening level intake estimates of low and no-calorie sweeteners in Argentina, Chile, and Peru. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess.* 2021 Dec;38(12):1995-2011
11. Bellisle F. Intense Sweeteners, Appetite for the Sweet Taste, and Relationship to Weight Management. *Curr Obes Rep.* 2015 Mar;4(1):106-110
12. Bernabe E, Marcenes W, Hernandez CR, Bailey J, Abreu LG, Alipour V, et al. GBD 2017 Oral Disorders Collaborators. Global, Regional, and National Levels and Trends in Burden of Oral Conditions from 1990 to 2017: A Systematic Analysis for the Global Burden of Disease 2017 Study. *J Dent Res.* 2020 Apr;99(4):362-373
13. Blackburn GL, Kanders BS, Lavin PT, Keller SD, Whatley J. The effect of aspartame as part of a multidisciplinary weight-control program on short-and long-term control of body weight. *Am J Clin Nutr.* 1997 Feb;65(2):409-418
14. Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. *Plast Reconstr Surg.* 2011 Jul;128(1):305-310
15. Catenacci VA, Pan Z, Thomas JG, Ogden LG, Roberts SA, Wyatt HR, Wing RR, Hill JO. Low/no calorie sweetened beverage consumption in the National Weight Control Registry. *Obesity (Silver Spring).* 2014 Oct;22(10):2244-51
16. Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health
17. de Ruyter JC, Olthof MR, Seidell JC, Katan MB. A trial of sugar-free or sugar-sweetened beverages and body weight in children. *N Engl J Med.* 2012 Oct;367(15):1397-1406
18. de Ruyter JC, Katan MB, Kuijper LD, Liem DG, Olthof MR. The effect of sugar-free versus sugar-sweetened beverages on satiety, liking and wanting: An 18 month randomized double-blind trial in children. *PlosOne.* 2013 Oct;8(10):e78039
19. Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>
20. Dietary Guidelines Advisory Committee (DGAC) 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. Available at: <https://doi.org/10.52570/DGAC2020>

21. Drewnowski A, Rehm CD. Consumption of low-calorie sweeteners among U.S. adults is associated with higher Healthy Eating Index (HEI 2005) scores and more physical activity. *Nutrients*. 2014 Oct;6(10):4389-403
22. Drewnowski A, Rehm CD. The use of low-calorie sweeteners is associated with self-reported prior intent to lose weight in a representative sample of US adults. *Nutr Diabetes*. 2016 Mar;6(3):e202
23. ECDC, Coronavirus disease 2019 (COVID-19) in the EU/EEA and the UK, 8 April 2020, <https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-rapid-risk-assessment-coronavirus-disease-2019-eighth-update-8-april-2020.pdf>
24. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum and dental and oral health, including gum and tooth protection and strength (ID 1149), plaque acid neutralisation (ID 1150), maintenance of tooth mineralisation (ID 1151), reduction of oral dryness (ID 1240), and maintenance of the normal body weight (ID 1152) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. *EFSA Journal* 2009;7(9):1271. [20 pp.]. Available online: <https://doi.org/10.2903/j.efsa.2009.1271>
25. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific opinion on the substantiation of a health claim related to sugar-free chewing gum and reduction of tooth demineralisation which reduces the risk of dental caries pursuant to Article 14 of Regulation (EC) No 1924/2006. *EFSA Journal* 2010;8(10):1775 [13 pp.]. Available online: <https://doi.org/10.2903/j.efsa.2010.1775>
26. EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to intense sweeteners and contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299), reduction of post-prandial glycaemic responses (ID 4298), maintenance of normal blood glucose concentrations (ID 1221, 4298), and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal* 2011a;9(6):2229. [26 pp.]. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>
27. European Food Safety Authority; EFSA Statement on the scientific evaluation of two studies related to the safety of artificial sweeteners. *EFSA Journal* 2011b;9(2):2089. [16 pp.]. doi:10.2903/j.efsa.2011.2089. Available online: www.efsa.europa.eu/efsajournal
28. EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Bohn T, Castenmiller J, de Henauw S, Hirsch-Ernst KI, Knutsen HK, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Peláez C, Pentieva K, Siani A, Thies F, Tsabouri S, Adan R, Emmett P, Galli C, Kersting M, Moynihan P, Tappy L, Ciccolallo L, de Sesmaisons-Lecarré A, Fabiani L, Horvath Z, Martino L, Muñoz Guajardo I, Valtueña Martínez S and Vinceti M, 2022. Scientific Opinion on the tolerable upper intake level for dietary sugars. *EFSA Journal* 2022;20(2):7074, 337 pp. <https://doi.org/10.2903/j.efsa.2022.7074>
29. Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. *Diabetes Care*. 2019 May;42(5):731-754
30. Food and Drug Administration, HHS. Food labeling: health claims; dietary noncariogenic carbohydrate sweeteners and dental caries. Final rule. *Fed Regist*. 2006 Mar 29;71(60):15559-64
31. FDI Policy Statement: Sugar substitutes and their role in caries prevention. Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden. Available online: <https://www.fdiworlddental.org/sugar-substitutes-and-their-role-caries-prevention>
32. FDI World Dental Federation. The Challenge of Oral Disease – A call for global action. The Oral Health Atlas. 2nd ed. Geneva. 2015. Available online: <https://www.fdiworlddental.org/oral-health-atlas>
33. Franz MJ, MacLeod J, Evert A, Brown C, Gradwell E, Handu D, Reppert A, Robinson M. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. *J Acad Nutr Diet* 2017 Oct;117(10):1659-79
34. Gibson S, Drewnowski J, Hill A, Raben B, Tuorila H, Windstrom E. Consensus statement on benefits of low calorie sweeteners. *Nutrition Bulletin* 2014;39(4):386-389
35. Gibson SA, Horgan GW, Francis LE, Gibson AA, Stephen AM. Low Calorie Beverage Consumption Is Associated with Energy and Nutrient Intakes and Diet Quality in British Adults. *Nutrients*. 2016 Jan;8(1):9
36. González-Monroy C, Gómez-Gómez I, Olarte-Sánchez CM, Motrico E. Eating Behaviour Changes during the COVID-19 Pandemic: A Systematic Review of Longitudinal Studies. *Int J Environ Res Public Health*. 2021 Oct 22;18(21):11130

37. Greyling A, Appleton KM, Raben A, Mela DJ. Acute glycemic and insulinemic effects of low-energy sweeteners: a systematic review and meta-analysis of randomized controlled trials. *Am J Clin Nutr* 2020 Oct 1;112(4):1002-1014
38. Halldorsson TI, Strøm M, Petersen SB, Olsen SF. Intake of artificially sweetened soft drinks and risk of preterm delivery: a prospective cohort study in 59,334 Danish pregnant women. *Am J Clin Nutr*. 2010 Sep;92(3):626-33
39. IDF Diabetes Atlas, 10th Edition. 2021. Available at: https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf
40. Katan MB, de Ruyter JC, Kuijper LD, Chow CC, Hall KD, Olthof MR. Impact of Masked Replacement of Sugar-Sweetened with Sugar-Free Beverages on Body Weight Increases with Initial BMI: Secondary Analysis of Data from an 18 Month Double-Blind Trial in Children. *PLoS One*. 2016 Jul 22;11(7):e0159771.
41. Keller A, O'Reilly EJ, Malik V, Buring JE, Andersen I, Steffen L, Robien K, Männistö S, Rimm EB, Willett W, Heitmann BL. Substitution of sugar-sweetened beverages for other beverages and the risk of developing coronary heart disease: Results from the Harvard Pooling Project of Diet and Coronary Disease. *Prev Med*. 2020 Feb;131:105970
42. Laviada-Molina H, Molina-Segui F, Pérez-Gaxiola G, Cuello-García C, Arjona-Villicaña R, Espinosa-Marrón A, Martínez-Portilla RJ. Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and meta-analysis. *Obes Rev*. 2020 Jul;21(7):e13020.
43. Leahy M, Ratliff JC, Riedt CS, Fulgoni VL. Consumption of Low-Calorie Sweetened Beverages Compared to Water Is Associated with Reduced Intake of Carbohydrates and Sugar, with No Adverse Relationships to Glycemic Responses: Results from the 2001–2012 National Health and Nutrition Examination Surveys. *Nutrients*. 2017 Aug 24;9(9):928
44. Lee HY, Jack M, Poon T, Noori D, Venditti C, Hamamji S, Musa-Veloso K. Effects of Unsweetened Preloads and Preloads Sweetened with Caloric or Low-/No-Calorie Sweeteners on Subsequent Energy Intakes: A Systematic Review and Meta-Analysis of Controlled Human Intervention Studies. *Adv Nutr*. 2021 Jul 30;12(4):1481-1499
45. Lee JJ, Khan TA, McGlynn N, Malik VS, Hill JO, Leiter LA, Jeppesen PB, Rahelić D, Kahleová H, Salas-Salvadó J, Kendall CWC, Sievenpiper JL. Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages With Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies. *Diabetes Care*. 2022 Aug 1;45(8):1917-1930
46. Lobach AR, Roberts A, Rowland IR. Assessing the in vivo data on low/no-calorie sweeteners and the gut microbiota. *Food Chem Toxicol*. 2019 Feb;124:385-399
47. Lohner S, Toews I, Meerpohl JJ. Health outcomes of non-nutritive sweeteners: analysis of the research landscape. *Nutr J*. 2017 Sep 8;16(1):55
48. Lohner S, Kuellenberg de Gaudry D, Toews I, Ferenci T, Meerpohl JJ. Non-nutritive Sweeteners for Diabetes Mellitus. *Cochrane Database Syst Rev*. 2020 May 25;5:CD012885. doi: [10.1002/14651858.CD012885.pub2](https://doi.org/10.1002/14651858.CD012885.pub2)
49. Mac Giolla Phadraig C, van Harten MT, Diniz-Freitas M, Limeres Posse J, Faulks D, Dougall A, Diz Dios P, Daly B. The impact of COVID-19 on access to dental care for people with disabilities: a global survey during the COVID-19 first wave lockdown. *Med Oral Patol Oral Cir Bucal*. 2021 Nov;26(6):e770–e777
50. Magnuson BA, Carakostas MC, Moore NH, Poulos SP, Renwick AG. Biological fate of low-calorie sweeteners. *Nutr Rev*. 2016 Nov;74(11):670-689
51. Maloney NG, Christiansen P, Harrold JA, Halford JCG, Hardman CA. Do low-calorie sweetened beverages help to control food cravings? Two experimental studies. *Physiol Behav*. 2019 Sep 1;208:112500
52. Martínez X, Zapata Y, Pinto V, et al. Intake of Non-Nutritive Sweeteners in Chilean Children after Enforcement of a New Food Labeling Law that Regulates Added Sugar Content in Processed Foods. *Nutrients*. 2020 May 29;12(6):1594
53. Martyn D, Darch M, Roberts A, Lee HY, Yaqiong Tian N, Kaburagi N, Belmar P. Low-/No-Calorie Sweeteners: A Review of Global Intakes. *Nutrients*. 2018 Mar 15;10(3):357
54. Martyn D, Darch M, Floyd S, Ngo K, Fallah S. Low- and no-calorie sweetener intakes in the Brazilian population estimated using added sugar substitution modelling. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*. 2022 Feb;39(2):215-228
55. McGlynn ND, Khan TA, Wang L, Zhang R, Chiavaroli L, Au-Yeung F, Lee JJ, Noronha JC, Comelli EM, Blanco Mejia S, Ahmed A, Malik VS, Hill JO, Leiter LA, Agarwal A, Jeppesen PB, Rahelić D, Kahleová H, Salas-Salvadó J, Kendall CWC, Sievenpiper JL. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages With Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. *JAMA Network Open* 2022 Mar 1;5(3):e222092
56. Mela DJ, McLaughlin J, Rogers PJ. Perspective: Standards for Research and Reporting on Low-Energy ("Artificial") Sweeteners. *Adv Nutr*. 2020 May 1;11(3):484-491

57. Mennella JA, Bobowski NK. The sweetness and bitterness of childhood: Insights from basic research on taste preferences. *Physiol Behav.* 2015 Dec 1;152:502-507
58. Miller PE, Perez V. Low-calorie sweeteners and body weight and composition: a meta-analysis of randomized controlled trials and prospective cohort studies. *Am J Clin Nutr.* 2014 Sep;100(3):765-777
59. Movahedian M, Golzan SA, Ashtary-Larky D, Clark CCT, Asbaghi O, Hekmatdoost A. The effects of artificial- and stevia-based sweeteners on lipid profile in adults: a GRADE-assessed systematic review, meta-analysis, and meta-regression of randomized clinical trials. *Crit Rev Food Sci Nutr.* 2021 Dec 9;1-17. doi: 10.1080/10408398.2021.2012641. Epub ahead of print
60. Newton JT, Awojobi O, Nasseripour M, Warburton F, Di Giorgio S, Gallagher JE, Banerjee A. A systematic review and meta-analysis of the role of sugar-free chewing gum in dental caries. *JDR Clin Trans Res.* 2020 Jul;5(3):214-223
61. Nichol AD, Holle MJ, An R. Glycemic impact of non-nutritive sweeteners: a systematic review and meta-analysis of randomized controlled trials. *Eur J Clin Nutr.* 2018 Jun;72(6):796-804
62. Normand M, Ritz C, Mela D, Raben A. Low-energy sweeteners and body weight: a citation network analysis. *BMJ Nutr Prev Health.* 2021 Apr 1;4(1):319-332.
63. Patel L, Alicandron G, La Vecchia C. Low-calorie beverage consumption, diet quality and cardiometabolic risk factor in British adults. *Nutrients.* 2018 Sep 7;10(9):1261
64. Peters JC, Beck J, Cardel M, Wyatt HR, Foster GD, Pan Z, Wojtanowski AC, Vander Veur SS, Herring SJ, Brill C, Hill JO. The effects of water and non-nutritive sweetened beverages on weight loss and weight maintenance: A randomized clinical trial. *Obesity (Silver Spring).* 2016 Feb;24(2):297-304
65. Pham H, Phillips LK, Jones KL. Acute Effects of Nutritive and Non-Nutritive Sweeteners on Postprandial Blood Pressure. *Nutrients.* 2019 Jul 25;11(8):1717.
66. Piernas C, Tate DF, Wang X & Popkin BM. Does diet-beverage intake affect dietary consumption patterns? Results from the Choose Healthy Options Consciously Everyday (CHOICE) randomized clinical trial. *Am J Clin Nutr.* 2013 Mar;97(3):604-611
67. Public Health England (PHE) 2015. Sugar reduction: The evidence for action. Annexe 5: Food Supply. Available online: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/470176/Annexe_5_Food_Supply.pdf
68. Pyrogianni V, La Vecchia C. Letter by Pyrogianni and La Vecchia Regarding Article, "Artificially Sweetened Beverages and Stroke, Coronary Heart Disease, and All-Cause Mortality in the Women's Health Initiative". *Stroke.* 2019 Jun;50(6):e169
69. Richardson MB, Williams MS, Fontaine KR, Allison DB. The development of scientific evidence for health policies for obesity: why and how? *Int J Obes (Lond).* 2017 Jun;41(6):840-848
70. Rios-Leyvraz M, Montez J (World Health Organization). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization (WHO) 2022. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO
71. Rogers PJ, Hogenkamp PS, de Graaf C, Higgs S, Lluch A, Ness AR, Penfold C, Perry R, Putz P, Yeomans MR, Mela DJ. Does low-energy sweetener consumption affect energy intake and body weight? A systematic review, including meta-analyses, of the evidence from human and animal studies. *Int J Obes (Lond.)* 2016 Mar;40(3):381-94
72. Rogers PJ. The role of low-calorie sweeteners in the prevention and management of overweight and obesity: evidence v. conjecture. *Proc Nutr Soc.* 2018 Aug;77(3):230-238
73. Rogers PJ, Ferriday D, Irani B, Hei Hoi JK, England CY, Bajwa KK, Gough T. Sweet satiation: Acute effects of consumption of sweet drinks on appetite for and intake of sweet and non-sweet foods. *Appetite.* 2020 Jun 1;149:104631.
74. Rogers PJ, Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes (Lond.).* 2021 Mar;45(3):464-478
75. Serra-Majem L, Raposo A, Aranceta-Bartrina J, Varela-Moreiras G, Logue C, Laviada H, et al. Ibero-American Consensus on Low- and No-Calorie Sweeteners: Safety, nutritional aspects and benefits in food and beverages. *Nutrients.* 2018 Jun 25;10(7):818
76. Sievenpiper JL, Khan TA, Ha V, Viguioliouk E, Auyeung R. The importance of study design in the assessment of non-nutritive sweeteners and cardiometabolic health. *CMAJ.* 2017 Nov 20;189(46):E1424-E1425
77. Silva Monteiro L, Kulik Hassan B, Melo Rodrigues PR, Massae Yokoo E, Sichieri R, Alves Pereira R. Use of table sugar and artificial sweeteners in Brazil: National Dietary Survey 2008-2009. *Nutrients.* 2018 Mar 1;10(3):295
78. Spill MK, English LK, Raghavan R, Callahan E, Güngör D, Kingshapp B, Spahn J, Stoody E, Obbagy J. Perspective: USDA Nutrition Evidence Systematic Review Methodology: Grading the Strength of Evidence in Nutrition- and Public Health-Related Systematic Reviews. *Adv Nutr.* 2022 Aug 1;13(4):982-991

79. Stennett M, Tsakos G. The impact of the COVID-19 pandemic on oral health inequalities and access to oral healthcare in England. *Br Dent J*. 2022 Jan;232(2):109–114
80. Tennant DR. Estimation of exposures to non-nutritive sweeteners from consumption of tabletop sweetener products: a review. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*. 2019 Mar;36(3):359-365
81. Tennant DR, Vlachou A. Potential consumer exposures to low/no calorie sweeteners: a refined assessment based upon market intelligence on use frequency, and consideration of niche applications. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*. 2019 Aug;36(8):1173-1183
82. Toews I, Lohner S, Küllenberg de Gaudry D, Sommer H, Meerpohl JJ. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies. *BMJ*. 2019 Jan 2;364:k4718
83. Tucker RM, Tan SY. Do non-nutritive sweeteners influence acute glucose homeostasis in humans? A systematic review. *Physiol Behav*. 2017 Dec 1;182:17-26
84. World Health Organization (WHO). Handbook for guideline development, 2nd ed. World Health Organization; 2014. <https://apps.who.int/iris/handle/10665/145714>
85. World Health Organization (WHO). Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015. <https://www.who.int/publications/i/item/9789241549028>
86. World Health Organization (WHO) European Regional Obesity Report 2022. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NC-SA 3.0 IGO. <https://apps.who.int/iris/bitstream/handle/10665/353747/9789289057738-eng.pdf>
87. Wittekind A, Higgins K, McGale L, Schwartz C, Stamataki NS, Beauchamp GK, Bonnema A, Dussort P, Gibson S, de Graaf C, Halford JCG, Marsaux CFM, Mattes RD, McLaughlin J, Mela DJ, Nicklaus S, Rogers PJ, Macdonald IA. A workshop on 'Dietary Sweetness-Is It an Issue?'. *Int J Obes (Lond)*. 2018 Apr;42(4):934-938
88. Yeung AWK, Wong NSM. How Does Our Brain Process Sugars and Non-Nutritive Sweeteners Differently: A Systematic Review on Functional Magnetic Resonance Imaging Studies. *Nutrients*. 2020 Sep 30;12(10):3010

Survey response 2

General information

Family/last name
Tayés
Given/first name
Leonel
Organization/affiliation
Cámara Guatemalteca de Alimentos y Bebidas
Sector
Private sector
Sector [Other]
Country
Guatemala

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Observaciones y comentarios ","comment":"La C\u00e1mara Guatemala Guatemalteca de Alimentos y Bebidas por este medio env\u00eda sus comentarios para que puedan ser tomados en cuenta por la OMS. ","size":"204.634765625","name":"Observaciones%20CGAB%20-%20Uso%20de%20Edulcorantes%20sin%20Azucar%2010.08.2022.pdf","filename":"fu_ckvts3qifpcc2sj","ext":"pdf" }]

Guatemala, 10 de agosto de 2022

Ref. Pautas de la OMS: Uso de edulcorantes sin azúcar.

Estimado señor/a:

La Cámara Guatemalteca de Alimentos y Bebidas -CGAB- es una asociación civil no lucrativa, creada para representar a nivel nacional y regional a la industria de alimentos y bebidas en temas que impulsen su desarrollo y competitividad, así como proponer y apoyar en la elaboración de políticas, estrategias y normativas nacionales e internacionales, que fortalezcan a la industria. En la actualidad contamos con 49 socios, nacionales e internacionales que están dispuestos a proporcionar un entorno favorable de negocios con responsabilidad social y ambiental.

La CGAB apoya los esfuerzos de la OMS en promover dietas saludables. Sin embargo, respetuosamente consideramos que la OMS reconsidere sus prioridades generales. En el 2018, la Declaración Política de la Reunión de Alto Nivel de la ONU sobre las ENT pidió al sector privado que “fortalezca su compromiso” de hacer más esfuerzos por reformular los alimentos y las bebidas para reducir el uso excesivo de sales, azúcares y grasas.

Como industria hemos atendido a dicho llamado de la ONU, y durante los últimos años se han intensificado significativamente los esfuerzos por reformular las bebidas para reducir los azúcares agregados, confiando en una herramienta clave de reformulación como lo son los edulcorantes bajos en calorías. Sin embargo, la OMS simultáneamente ha ido emitiendo pautas preliminares que tienen como objetivo suprimir la reformulación que las empresas han estado elaborando, las cuales económica, técnica y científicamente representan un alcance significativo.

Dichas pautas preliminares de la OMS están basadas en evidencia de baja certeza y en inquietudes de seguridad, lo que como industria nos preocupa tanto, ya que este tipo de recomendaciones corren el riesgo de socavar las prioridades claves de la OMS, establecidas por los estados miembros.

Un ejemplo de dicho socavamiento la baja certeza relacionada con la diabetes y salud dental, la autoridad Europea de Seguridad Alimentaria ha indicado que “hay suficiente información científica para respaldar las afirmaciones de que los edulcorantes intensos, como todos los sustitutos del azúcar, mantienen la mineralización dental al disminuir la desmineralización si se consumen en lugar de azúcares”.

Aunque la OMS indique que las personas con diabetes están excluidas de estas pautas, esta declaración sin tratamiento previo ignora las implicaciones del mundo real de emitir

pautas para las personas de todo el mundo. Cuando la OMS emite recomendaciones generales como “no use edulcorantes sin azúcar para controlar el peso”, eso confundirá a las personas, ya sea que tengan o no diabetes. En el mundo real, las personas adoptan los titulares, no la letra pequeña. Y para aquellos que viven con diabetes, los edulcorantes bajos en calorías y sin calorías son una parte integral del control de la diabetes.

En ese sentido, se puede interpretar que las recomendaciones de la OMS sobre el uso de edulcorantes sin azúcar es una recomendación “condicional” o “débil” reflejada la evidencia de la baja certeza.

Otro aspecto a considerar es que los estados miembros esperan que las pautas de la OMS se basen en análisis científicos sólidos y no en ciencia de baja certeza que provoque inquietudes en la seguridad

Como se indicó anteriormente, la recomendación de la OMS en este Borrador de las pautas es “condicional” o débil, porque se basa en evidencia de certeza general baja. Nos preocupan las implicaciones generales de que la OMS, en la que los países de todo el mundo confían como la “regla de oro” para el asesoramiento científico, desarrolle pautas de políticas basadas en evidencia de baja calidad.

Por tanto, apreciamos el esfuerzo de la OMS por brindar orientación a los responsables de formular políticas sobre edulcorantes sin azúcar. Sin embargo, creemos que cualquier orientación debe estar fundamentada en los principios de la política basada en la ciencia, exhibir coherencia en la política y seguir la hoja de ruta de las prioridades de salud recientes establecidas por los Estados miembros. Nos preocupa que la decisión de basar las pautas en evidencia de baja calidad pueda, en última instancia, llevar a los Estados miembros a promulgar una legislación que potencialmente ponga en peligro los resultados positivos de la salud pública.

Correo: asistente.regulacion@cgab.org.gt

Survey response 3

General information

Family/last name
Rodriguez
Given/first name
Ana Marcela
Organization/affiliation
ALAIAB
Sector
Private sector
Sector [Other]
Country
Costa Rica

Comments on the draft guideline

Summary of evidence
The evidence, the recommendations and supporting information and other comments on the Draft WHO guideline of Non Sugar Sweeteners (NSS) were already uploaded at the bottom of the page.
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"ALAIAB Comments to WHO Draft Guideline on use of Non-Sugar Sweeteners (NSS)","comment":"ALAIAB is the the Alliance of Food and Beverage Associations in Latin America. The comments uploaded are in Spanish.","size":"1235.7275390625","name":"Observaciones%20ALAIAB%20NSS%20Guideline%20WHO.pdf","filename":"fu_6src3edfidjfrew","ext":"pdf" }]



Observaciones de Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas ALAIAB sobre el BORRADOR de las Guías de OMS sobre el Uso de Edulcorantes sin Azúcar

La Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas (ALAIAB), es una asociación empresarial, formalmente establecida y sin fines de lucro, conformada por las más importantes asociaciones representativas de la industria de alimentos y bebidas de América Latina¹.

Somos una institución regional que busca diversos fines, entre los cuales podemos destacar: i. la representación de este sector productivo en los diversos foros públicos y privados, de carácter internacional, que requieran una interacción técnica, política o científica con la industria de alimentos y bebidas, ii. la promoción de marcos normativos y regulatorios equilibrados, razonables y basados en la ciencia, iii. el fortalecimiento de la competitividad global y el clima de negocios de la industria de alimentos y bebidas, mediante valores como la sostenibilidad, económica, social y ambiental y iv. el intercambio de experiencias en la promoción de estilos de vida saludable y demás iniciativas que incidan positivamente en el bienestar de los consumidores.

ALAIAB apoya los esfuerzos de la OMS por promover dietas saludables. Sin embargo, respetuosamente solicita que la OMS reconsidere sus prioridades generales y regrese a la coherencia de políticas basadas en la ciencia, al proporcionar orientación a las partes interesadas en sus esfuerzos por alcanzar los Objetivos de Desarrollo Sostenible de la ONU para 2030.

En 2015, cuando la ONU adoptó por primera vez los Objetivos Globales, el llamado a la acción exigió un compromiso global intensivo en apoyo de la implementación de todos los objetivos y metas, reuniendo a los Gobiernos, el sector privado, la sociedad civil, el sistema de las Naciones

¹ **Organizaciones empresariales miembros de ALAIAB:** **Argentina:** Coordinadora de Productores de Alimentos (COPAL) y la Cámara de Industriales de Alimentos (CIPA); **Uruguay:** Cámara de Industriales de Alimentos (CIALI); **Paraguay:** Cámara de Empresas Paraguayas de Alimentos (CEPALI) y la Cámara de Alimentos y Bebidas de Paraguay CABE; **Chile:** Asociación de Empresas de Alimentos (Chilealimentos) y Alimentos y Bebidas de Chile (ABChile); **Brasil:** Asociación Brasileña de las Industrias de Alimentación (ABIA) y Asociación Brasileña de Bebidas Refrescantes y No Alcohólicas (ABIR); **Perú:** Asociación de la Industria de Bebidas y Refrescos no Alcohólicos (ABRESA) y Sociedad Nacional de Industriales (SNI); **Colombia:** Gremial de Alimentos y Gremial de Bebidas de la Asociación Nacional de Empresarios (ANDI-ALIMENTOS y ANDI-BEBIDAS); **Venezuela:** Cámara Venezolana de la Industria de Alimentos (CAVIDEA); **Ecuador:** Asociación Nacional de Fabricantes de Alimentos (ANFAB) y la Asociación de Industriales de Bebidas no Alcohólicas (AIBE); **Costa Rica:** Cámara Costarricense de la Industria Alimentaria (CACIA); **Guatemala:** Cámara de Industria de Guatemala (CIG) y la Cámara Guatemalteca de Alimentos y Bebidas (CGAB); **México:** Consejo Mexicano de la Industria de Consumo Masivo (CONMEXICO) y la Asociación Mexicana de Refrescos y Aguas Carbonatadas (ANPRAC); **República Dominicana:** Asociación de Industrias de Bebidas No Alcohólicas de República Dominicana. (ASIBENAS).



Unidas y otros actores y movilizandolos recursos disponibles”.² De particular interés, uno de esos recursos específicamente destacados por el sistema de la ONU, es la capacidad de reformulación de la industria de alimentos y bebidas. En 2018, la Declaración Política de la Reunión de Alto Nivel de la ONU sobre las ENT pidió al sector privado que “fortalezca su compromiso” de hacer más esfuerzos por reformular los alimentos y las bebidas para reducir el uso excesivo de sales, azúcares y grasas.³

Nuestra industria ha atendido este llamado de la OMS y del sistema de Naciones Unidas. Durante los últimos años, nuestro sector ha intensificado significativamente los esfuerzos por innovar sus procesos productivos, orientados a atender una gran cantidad de necesidades nutrimentales de la población, particularmente aquellas que requieren una reducción de dichos nutrientes. El desarrollo tecnológico y la capacidad de adaptación de la industria, ha permitido avances significativos, especialmente en el campo de la reducción de calorías por contenido de azúcar añadido, donde hemos contado con una herramienta clave, como lo son los edulcorantes bajos en calorías.

Identificación de la Preocupación:

Dicho lo anterior, es importante manifestar el amplio sentido de confusión que se ha generado, a partir de los criterios expuestos por la OMS en materia de edulcorantes bajos en calorías, puesto que, emite recomendaciones tendientes a evitar el uso de edulcorantes no calóricos. No obstante, según expone la misma OMS, **su criterio está basado en evidencia de baja certeza, con respecto a la eficacia de los edulcorantes no calóricos como herramienta** para controlar el peso o reducir el riesgo de enfermedades no transmisibles.

Como declaró el Secretario General de la ONU, Antonio Guterres, en el Foro Político de Alto Nivel de la ONU 2022, “el mundo está en serios problemas, al igual que los Objetivos de Desarrollo Sostenible”. La misma OMS reconoció que el mundo no está “encaminado para alcanzar los Objetivos de Desarrollo Sostenible 3,4 (SDG target 3.4), para reducir las muertes prematuras por ENT, y ningún país está logrando los nueve objetivos voluntarios establecidos en el Plan de Acción Global para la Prevención y el Control de las ENT 2013-2030”.⁴

² “Transformación de nuestro mundo: la Agenda para el Desarrollo Sostenible 2030”, Resolución adoptada por la Asamblea General el 25 de septiembre de 2015, A/RES/70/1 en los párrafos 39 y 60. (énfasis añadido)

³ Consulte la Reunión de Alto Nivel de la ONU 2018 sobre la Declaración Política sobre ENT, A-73-L-2-EN en OP 44, disponible en <https://digitallibrary.un.org/record/1645265?ln=en>.

⁴ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).

Solicitamos que la OMS revise este borrador en el contexto de las Hojas de Ruta recientes de la ONU de Alto Nivel (que, en particular han dejado de citar en su borrador, haciendo referencia solo a las Reuniones de Alto Nivel de la ONU de 2011 y 2014 sobre las ENT, omitiendo completamente la Reunión de Alto Nivel de la ONU de 2018 sobre las ENT). Creemos en el valor de estas Hojas de Ruta de la ONU. Estas son las prioridades establecidas con los aportes de los Estados Miembros para ayudar a establecer el camino hacia los Objetivos Globales, a diferencia de las recomendaciones recientes del comité de la OMS. Si los borradores que emanan de los comités dentro de las agencias son incoherentes (y se basan en evidencia de baja calidad) y no son consistentes con las directivas generales de la política establecidas por los Estados miembros de la ONU, entonces recomendamos encarecidamente a los líderes de la OMS que revisen dicho borrador.

1. Las recomendaciones de la OMS corren el riesgo de socavar las prioridades clave de la OMS establecidas por los estados miembros relacionadas con la diabetes y la salud dental

El pasado mes de mayo, en la 75.a Asamblea Mundial de la Salud, los Estados Miembros respaldaron una estrategia mundial histórica sobre la salud bucal, y uno de sus objetivos generales era reducir las enfermedades bucales.⁵ De manera similar, en esta misma Asamblea Mundial de la Salud, los Estados Miembros apoyaron la creación de los primeros objetivos globales para la diabetes, como parte del Pacto Mundial contra la Diabetes de la OMS.⁶ En ambos casos, estos son objetivos de prioridades de alto nivel para la OMS avalados por los Estados miembros. Dado que no hubo suficiente evidencia para revisar el impacto de los Non Sugar Sweeteners, (de aquí en adelante: NSS, en la salud oral en la revisión sistemática de Rios-Leyvraz y Montez, se recomienda encarecidamente reformular la declaración de recomendación final del NUGAG de la OMS: "La OMS sugiere que los NSS no se usen como un medio para lograr el control del peso o reducir el riesgo de enfermedades no transmisibles (recomendación condicional)". Para garantizar la mejor comprensión, comunicación e interpretación de la recomendación final, se sugiere mencionar solo los hallazgos específicos en la revisión sistemática y el metanálisis y no generalizar todas las ENT.

Los edulcorantes bajos en calorías y sin calorías son una herramienta importante para apoyar la salud bucal y el control de la diabetes. Con respecto a la salud bucal, se reconoce que debido a que los edulcorantes bajos en calorías y sin calorías no son fermentables

⁵ Consulte <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

⁶ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

por las bacterias bucales, pueden contribuir a una buena salud bucal.⁷ Como indicó la Autoridad Europea de Seguridad Alimentaria, “hay suficiente información científica para respaldar las afirmaciones de que los edulcorantes intensos, como todos los sustitutos del azúcar, mantienen la mineralización dental”.⁸

Hay 3.500 millones de casos de caries dental en todo el mundo, lo que resulta en enfermedad periodontal (de las encías) y, finalmente, pérdida de dientes, lo que convierte a las enfermedades bucales en las ENT más comunes. Sin embargo, estas condiciones bucales se pueden prevenir casi por completo; en parte por la reducción de azúcares libres (FDI, 2015; OMS, 2015). Para reducir los azúcares libres, las NSS se utilizan en las reformulaciones de productos. Los beneficios para la salud bucal proporcionados por NSS son ingredientes críticos en la goma de mascar sin azúcar, la higiene y los productos bucales para el cuidado personal. Debe destacarse en el documento final de la guía de la OMS que hubo publicaciones que destacan los beneficios de la NSS para la salud oral, y que se necesita más investigación en esta área para realizar un metanálisis adecuado en el futuro.

Aunque la OMS dice que las personas con diabetes están excluidas de las Guías en discusión, esta declaración sin tratamiento previo ignora las implicaciones del mundo real de emitir Guías para todas las personas. Cuando la OMS emite recomendaciones generales como “no use edulcorantes sin azúcar para controlar el peso”, esto tiende a ser confuso, ya sea que las personas tengan o no diabetes, ya que la mayoría de las personas adoptan los titulares, no la letra pequeña. Y para aquellos que viven con diabetes, los edulcorantes bajos en calorías y sin calorías son una parte integral de su control.

Por ejemplo, la UE permite una declaración de salud específica relacionada con edulcorantes bajos en calorías y sin calorías y niveles de glucosa: *“El consumo de alimentos que contienen edulcorantes intensos en lugar de azúcar induce un menor aumento de la glucosa en sangre después de su consumo en comparación con los alimentos que contienen azúcar”*.⁹ **Las organizaciones de salud a nivel mundial reconocen que los edulcorantes bajos en calorías y sin calorías pueden utilizarse de manera**

⁷ Declaración de la política de FDI: Sustitutos del azúcar y su función en la prevención de caries. Adoptado por la Asamblea General del FDI, 26 de septiembre de 2008, Estocolmo, Suecia

⁸ EFSA, Opinión científica sobre la justificación de afirmaciones de salud relacionadas con edulcorantes intensos. EFSA Journal 2011;9(6):2229. Disponible en línea: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

⁹ Regulación de la Comisión (UE) n.º 432/2012 del 16 de mayo de 2012 que establece una lista de reclamaciones de salud permitidas hechas sobre alimentos, que no sean aquellas que se refieren a la reducción del riesgo de enfermedad y al desarrollo y la salud de los niños

segura para reemplazar el azúcar en el manejo nutricional de la diabetes.¹⁰ Por ejemplo, tanto la Asociación Americana de Diabetes (American Diabetes Association, ADA)¹¹ como la Academia de Nutrición y Dietética (Academy of Nutrition and Dietetics, AND)¹² de los EE. UU., en sus recomendaciones nutricionales para la diabetes tipo 1 y tipo 2, concluyen que el uso de edulcorantes bajos en calorías y sin calorías tiene el potencial de reducir la ingesta general de calorías y carbohidratos si se sustituyen por edulcorantes calóricos y sin compensación por la ingesta de calorías adicionales de otras fuentes de alimentos. Además, la última declaración de posición de Diabetes UK sobre edulcorantes bajos en calorías y sin calorías concluye que: *“Se ha demostrado que los edulcorantes bajos en calorías o sin calorías son seguros y pueden usarse como parte de una estrategia para adultos y niños en el control del peso y la diabetes”*.¹⁰

Nuevamente, observamos que la recomendación de la OMS sobre el uso de edulcorantes sin azúcar en estas pautas preliminares es una recomendación “condicional” o débil, lo que significa que se basa en evidencia de baja certeza. Solicitamos que los estados miembros revisen la necesidad de una recomendación tan débil a la luz de las prioridades existentes de la OMS establecidas por los estados miembros, como las relacionadas con el Pacto de la Diabetes y la Estrategia global sobre salud bucal.

2. Los estados miembros deben esperar que las pautas de la OMS se basen en la ciencia más sólida, no en ciencia de “baja certeza”

Como ya se indicó anteriormente, la recomendación de la OMS en este Borrador es “condicional” o débil, porque se basa en evidencia de certeza general baja. Nos preocupan las implicaciones generales de que la OMS, ente en cual los países de todo el mundo confían como la “regla de oro” para el asesoramiento científico, desarrolle pautas de políticas basadas en evidencia de baja calidad. Observamos que estas guías preliminares

¹⁰ Diabetes UK. El uso de edulcorantes bajos en calorías o sin calorías. Declaración de posición (actualizada en diciembre de 2018). Disponible en: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹¹ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. “Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report”. Diabetes Care. mayo de 2019;42(5):731-754;

¹² Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

tienen implicaciones debido a la dependencia de esta “evidencia de baja certeza”. Se podría ver a futuro a los Estados Miembros desarrollar una legislación que realmente no cumpla con los objetivos de salud pública para reducir los azúcares agregados en la dieta. Recomendamos encarecidamente a la OMS que vuelva al uso de las mejores prácticas en el desarrollo de pautas.

Observamos con preocupación que la OMS no confió en ciencia más sólida, disponible para desarrollar este borrador. La OMS se ha basado en gran medida en estudios observacionales, que no pueden establecer una relación de causa y efecto, y, como concluyó la OMS en última instancia, proporcionan evidencia de una baja calidad.

Nos sorprende que la OMS haya marginado su propio metaanálisis de ensayos controlados aleatorizados (ECA), que son la “regla de oro” en nutrición e investigación clínica, al desarrollar estas pautas. A principios de este año, la OMS publicó un metaanálisis de los ECA que demostró un beneficio modesto pero significativo para la pérdida de peso (entre otros beneficios) en adultos, lo que refuerza los hallazgos de una revisión basada en evidencia realizada a principios de 2019 por la OMS.¹³ Estamos desconcertados porque la propia evaluación de la OMS que reconoce la evidencia de ensayos clínicos de certeza moderada a alta que muestran efectos beneficiosos o una ausencia de efectos perjudiciales por el consumo de endulzantes sin azúcar (en la grasa corporal y la circunferencia de la cintura, peso corporal, IMC, glucosa en ayunas, hemoglobina glicosilada, presión arterial sistólica, presión arterial diastólica, colesterol HDL), fue desestimada a favor de la evidencia observacional de certeza muy baja a baja (conocida por sufrir de confusión residual y causalidad inversa) que finalmente sirvió como base para las Recomendaciones condicionales en este Borrador.

Los beneficios de los edulcorantes bajos en calorías y sin calorías están respaldados por una gran cantidad de ensayos controlados aleatorizados a corto y largo plazo en seres humanos, bien realizados y que proporcionan evidencia de alta calidad. No considerar la evidencia colectiva sobre los efectos en la salud de los edulcorantes sin azúcar ni traducir con precisión la totalidad de la evidencia disponible en una recomendación en vista de la jerarquía de la evidencia científica, puede obstaculizar los esfuerzos de salud pública para reducir el consumo excesivo de azúcar y abordar la obesidad.

¹³ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). *Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis*. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. Licencia: CC BY-NC-SA 3.0 IGO; “Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J. “Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies” BMJ 2019; 364: k4718 doi:10.1136/bmj. k4718)



Por tanto,

Apreciamos el esfuerzo de la OMS por brindar orientación a los responsables de formular políticas sobre edulcorantes sin azúcar. Sin embargo, creemos que cualquier orientación debe estar fundamentada en los principios de la política basada en la ciencia, exhibir coherencia en la política y seguir la hoja de ruta de las prioridades de salud recientes establecidas por los Estados miembros.

Igualmente se hace un respetuoso llamado a evitar recomendaciones basadas en documentos que la misma OMS reconoce como evidencia de baja calidad, puesto que, en última instancia, esto puede llevar a los Estados miembros a promulgar políticas contraproducentes para la misma salud pública, al mismo tiempo que se genere un espacio innecesario a la inseguridad jurídica y la conflictividad ideológica alrededor de un tema que nos debe unir a todos los sectores como es el combate a la malnutrición.

Agradecemos la oportunidad de enviar estos comentarios. Háganos saber si tiene alguna pregunta o necesita información adicional.

Muy cordialmente,

Marcela Rodríguez Jiménez
Secretaría Técnica
Alianza Latinoamericana de Asociaciones de la Industria de Alimentos y Bebidas
ALAIAB

Survey response 4

General information

Family/last name
Loatman
Given/first name
Katherine
Organization/affiliation
International Council of Beverages Associations
Sector
Private sector
Sector [Other]
Country
United States of America

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Comments from the International Council of Beverages Associations on WHO Draft Guidelines on Non Sugar Sweeteners","comment":"Please see the attached comments from ICBA. Thank you.","size":"307.693359375","name":"FINALICBA%20Comments%20on%20WHO%20Draft%20Guidelines%20on%20Non%20Sugar%20Sweeteners7.27.22%20%28ID%2041721%29.pdf","filename":"fu_tw9drb2fufkau87","ext":"pdf" }]



July 27, 2022

VIA Email (NFS@WHO.int)

Re: DRAFT WHO Guideline: Use of Non-Sugar Sweeteners

Dear Sir or Madam:

The International Council of Beverages Associations (“ICBA”) is pleased to submit these comments on WHO’s Draft Guideline on the Use of Non-Sugar Sweeteners (the “Draft Guideline”).¹ As discussed below in these comments, although ICBA supports WHO’s efforts to promote healthy diets, ICBA respectfully requests that WHO reconsider overall priorities and return to science-based policy coherence when providing guidance to stakeholders in its efforts to achieve the UN Sustainable Development Goals by 2030.

In 2015, when the UN first adopted the Global Goals, the call for action mandated an intensive global engagement in support of implementation of all the Goals and targets, bringing together Governments, *the private sector*, civil society, the United Nations system and other actors and *mobilizing all available resources*.² Of particular interest, one of those resources specifically highlighted by the UN system is the food and beverage industry’s ability to reformulate. In 2018, the Political Declaration of the UN High Level Meeting on NCDs called upon the private sector to “strengthen its commitment” to make further efforts to reformulate foods and beverages to reduce the excessive use of salts, sugars and fats.³ As discussed in the attached Annex, our industry has heeded this call

¹ ICBA is an international non-governmental organization established in 1995 that is the voice of the global non-alcoholic beverage industry. The members of ICBA include national and regional beverage associations as well as international beverage companies that operate in more than 200 countries and territories and produce, distribute, and sell a variety of non-alcoholic sparkling and still beverages, including soft drinks, sports drinks, energy drinks, bottled waters, flavored and/or enhanced waters, ready-to-drink teas and coffees, 100 percent fruit or vegetable juices, nectars and juice drinks, and dairy-based beverages.¹ ICBA holds special consultative status with the UN Economic and Social Council and has been a recognized observer and well-respected stakeholder at the Codex Alimentarius (“Codex”) Commission for over twenty years.

² “Transforming our world: the 2030 Agenda for Sustainable Development,” Resolution adopted by the General Assembly on 25 September 2015, A/RES/70/1 at paras. 39 and 60. (emphasis added)

³ See 2018 UN High Level Meeting on NCDs Political Declaration, A-73-L-2-EN at OP 44, available at <https://digitallibrary.un.org/record/1645265?ln=en>.

from the UN, and over the past years and significantly stepped up our efforts to reformulate our beverages to reduce added sugars, relying on a key tool of reformulation -- low-calorie sweeteners -- in order to do so.

However, while we are making this robust effort, WHO is simultaneously issuing Draft Guidelines that seek to suppress this important reformulation tool from our toolbox. WHO acknowledges these Draft Guidelines are 1) based on low-certainty evidence and 2) not based on safety concerns. We are, frankly, concerned about this apparent policy u-turn. As UN Secretary General Antonio Guterres stated at this year's 2022 UN High Level Political Forum, "[t]he world is in deep trouble – and so too are the Sustainable Development Goals." Of particular interest to WHO's goals, WHO itself acknowledged that the world is "off track to achieve SDG target 3.4, to reduce premature deaths from NCDs, and no country is achieving all nine voluntary targets set out in the Global Action Plan for the Prevention and Control of NCDs 2013-2030."⁴

Why then would WHO issue Draft Guidelines with advice for the general population with advice based on evidence of "low certainty overall"? **We request that WHO review this Draft Guideline in the context of recent higher-level UN roadmaps** (which notably, they have neglected to cite in their draft, referring only to the dated 2011 and 2014 UN High Level Meetings on NCDs, omitting entirely the 2018 UN High-Level Meeting on NCDs). We believe in the value of these UN roadmaps – these are the priorities established with Member State input to help set the path toward the Global Goals, as opposed to the recent WHO committee recommendations. If Draft Guidelines that emanate from committees within agencies are incoherent (and based on low quality evidence) and inconsistent with the overall policy directives set by UN Member States, then we strongly encourage WHO leadership to revisit the Guidelines themselves.

I. The WHO Recommendations Risk Undercutting Key WHO Priorities Established by Member States Related to Diabetes and Dental Health

This past May, at the 75th World Health Assembly, the Member States endorsed a **landmark global strategy on oral health**, with one of the overarching goals being to reduce oral disease.⁵ Similarly, at this same World Health Assembly, the Member States supported the creation of the **first-ever global targets for diabetes**, as part of WHO's Global Diabetes Compact.⁶ In both of these instances, these are high-level priorities goals for WHO endorsed by the Member States.

Low- and no-calorie sweeteners are an important tool in supporting oral health and in diabetes management. With regard to oral health, it is well-recognized that excessive intake of sugar can contribute to dental caries. Because low- and no-calorie sweeteners are non-fermentable by oral

⁴ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).

⁵ See <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

⁶ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

bacteria, they can contribute to good oral health when used in place of sugar.⁷ As the European Food Safety Authority stated, “there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralization by decreasing tooth demineralization if consumed instead of sugars”⁸

Although WHO simply says that people with diabetes are excluded from these Guidelines, this naïve statement ignores the real-world implications of issuing guidelines to people around the world. When WHO issues blanket recommendations such as “don’t use non-sugar sweeteners for weight control,” that will confuse people – whether or not they have diabetes. In the real world, people embrace headlines, not fine print. And for those who live with diabetes, low- and no- calorie sweeteners are an integral part of diabetes management.

For example, the EU allows a specific health claim related to low- and no-calorie sweeteners and glucose levels: *‘the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods.’*⁹ **Health organizations globally recognize that low- and no- calorie sweeteners can be safely used to replace sugar in the nutritional management of diabetes.**¹⁰ For example, both the American Diabetes Association (ADA)¹¹ and the US Academy of Nutrition and Dietetics (AND)¹², in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of low- and no-calorie sweeteners have the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners and without compensation by intake of additional calories from other food sources. Also, the latest Diabetes UK Position Statement on low- and no-calorie sweeteners

⁷ FDI Policy Statement: Sugar substitutes and their role in caries prevention. Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden

⁸ EFSA, Scientific opinion on the substantiation of health claims related to intense sweeteners. EFSA Journal 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

⁹ Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health

¹⁰ Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹¹ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019 May;42(5):731-754;

¹² Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

concludes that: “LNCs are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes”.¹⁰

Further, it is interesting to note that the 2020 U.S. Dietary Guidelines Advisory Committee (DGAC) acknowledge that low- and no-calorie sweetened beverages are “a useful aid in weight management in adults,” noting that added sugars intakes could be greatly reduced by consuming low- and no-calorie sweetened reformulated versions of foods and beverages”¹³

We again note that the WHO Recommendation on the use of non-sugar sweeteners in these Draft Guidelines is a “conditional” or weak recommendation, meaning it is based on evidence of low certainty. We request that Member States review the need for such a weak recommendation in light of existing Member State-established WHO priorities, such as those related to the Diabetes Compact and the Global Strategy on Oral Health.

II. Member States Should Expect WHO Guidelines to Be Grounded in the Strongest Science, Not Science of “Low Certainty”

As noted above, WHO’s recommendation in this Draft Guideline is “conditional,” or weak, because it is based on evidence of overall low certainty. We are concerned about the overall implications of WHO – whom countries around the world rely upon as the “gold standard” for scientific advice – developing policy guidelines based on low-quality evidence. We note that these Draft Guidelines have real-world implications: because of reliance on this “low-certainty evidence,” we may see Member States develop legislation which runs afoul of public health goals to reduce added sugars in the diet. We strongly encourage WHO to return to the use of best practices in developing guidelines – with strong science as the foundation, the guidelines will be more than “evidence-informed.”

We note with concern that WHO did not rely on the strongest available science to develop these Guidelines. WHO has relied heavily on observational studies, which cannot establish a cause-and-effect relationship – and, as WHO ultimately concluded, provide evidence of a low quality. We are puzzled that WHO marginalized its own meta-analysis of randomized controlled trial (RCTs), which are the “gold standard” in nutrition and clinical research, when developing this Guideline. Earlier this year, WHO published a meta-analysis of the RCTs that demonstrated a modest but significant weight loss benefit (among other benefits) in adults, reinforcing findings from

¹³2020 U.S. Dietary Guidelines Advisory Committee Report(https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf). pp. 633, 636, 180, 691 of the 835 page pdf document. Accessed July 21, 2022. (Moreover, the US Dietary Guidelines Committee further stated “Plain water has been recommended to displace other energy-yielding beverages in the diet to dilute the energy density of the diet, reduce total energy intake, and aid weight management. The success of this strategy has not been established and warrants further study.”)

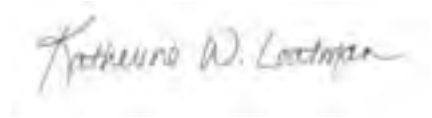
an earlier 2019 WHO-commissioned evidence-based review.¹⁴ We are flummoxed as to why WHO's own assessment acknowledging the moderate-to-high certainty clinical trial evidence showing either beneficial effects or an absence of detrimental effects from non-sugar sweetener consumption (on body fatness and waist circumference, body weight, BMI, fasting glucose, glycated hemoglobin, systolic blood pressure, diastolic blood pressure, and HDL cholesterol),¹⁵ was dismissed in favor of the very low to low certainty observational evidence (known to suffer from residual confounding and reverse causality) that ultimately served as the basis for the Conditional Recommendations in these Draft Guideline.

The benefits of low- and no-calorie sweeteners when used in place of sugars are supported by a wealth of well-conducted, acute, short- and longer-term randomized controlled trials in humans, which provide high quality evidence. Failing to consider the collective evidence on the health effects of non-sugar sweeteners and to accurately translate the totality of available evidence into a recommendation in view of the hierarchy of scientific evidence, may hinder public health efforts to reduce excess sugars intake and to tackle obesity.

III. Conclusion

In conclusion, we appreciate WHO's effort to provide guidance to policymakers on non-sugar sweeteners. However, we believe that any guidance must be grounded in principles of science-based policy, exhibit policy coherence and follow the roadmap of recent health priorities established by Member States. We are concerned that the decision to base guidelines on low-quality evidence may ultimately lead Member States to enact legislation that potentially jeopardizes positive public health outcomes. We thank you for the opportunity to submit these comments. Please let us know if you have any questions or require additional information.

Respectfully submitted,



Katherine W. Loatman
Executive Director

¹⁴ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO; "Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J J. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies BMJ 2019; 364 :k4718 doi:10.1136/bmj.k4718)

¹⁵ See Annex 6 'GRADE Evidence Profiles' in the Draft Guidelines (see p.57)

Annex
The Global Beverage Industry's Sugar Reduction Pledges

ICBA and its members have long been supportive of meaningful, science-based efforts to help consumers make informed food and beverage choices toward healthful diets and we have a strong track record of leaning in with robust leadership initiatives. For example, our industry has made voluntary commitments regarding responsible marketing, marketing to children, and beverages offered in schools. Furthermore, the ICBA membership supports science-based interpretative front-of-package nutrition labeling, as we agree that executed well it is a useful tool for helping people make informed dietary choices as well as incentivizing companies to innovate and reformulate.¹⁶ The beverage industry has been working hard to reformulate beverages to reduce sugar, offer more lower- and no-calorie options, and make smaller package sizes more widely available. Around the globe, our industry is implementing and publicly reporting on sugar reduction commitments, through an array of public-private partnerships. **Importantly, non-sugar sweeteners are a key tool in the success of these sugar reduction commitments.** We offer just a few examples:

- In June 2018, the **Australian Beverages Council** committed to a 20 percent reduction in sugar across the beverage industry's portfolio by 2025. As of 2021, the third progress report demonstrated a 16% reduction in sugar had been achieved, showing that the industry was well on track to achieve its overall goal.¹⁷
- In November 2018, the **Brazilian Ministry of Health and the Brazilian food and beverage associations** signed a Memorandum of Understanding to establish national goals for sugar reduction. The agreement outlines a series of commitments to be undertaken by the food and beverage sector to help reduce Brazilians' sugar intake to less than 10% of total daily calories consumed, including reducing sugar in key categories such as sugar-sweetened beverages, confectioneries, and other foods.
- In partnership with the **Conference Board of Canada**, the Canadian Beverage Association and its membership have committed to reducing beverage calories consumed per person by 20 percent by 2025. A report prepared by The Conference Board of Canada shows that through product and packaging innovations, beverage calories consumed by Canadians has dropped by 16% between 2014 and 2020, and the industry is on track to meet the 20% reduction goal by 2025. That means that since 2004 there has been almost a 30 percent reduction in calories.¹⁸

¹⁶ ICBA, "The Global Non-Alcoholic Beverage Industry Supports Science-Based Front-of-Package Interpretative Labeling to Support Consumer Health" (June 23, 2021), available at <https://icba-bigtrees3.amazonaws.com/files/resources/icbainterpretativelabelingpositionfinal.pdf>.

¹⁷ See Statement by Australian Beverages Council available at <https://www.australianbeverages.org/non-alcoholic-beverages-industry-sugar-reduction-report-exceeds-target/>

¹⁸ The Conference Board of Canada, "Counting the Calories, Canadian's Consumption of High-Calorie Beverages Continues to Decline" (August 2018), *available at*

- In 2020 in **Mexico**, the members of **ANPRAC**, the national beverage association, pledged to reduce calories in their products an additional 20% by 2024 by reformulating more than 50 products, and by increasing their portfolio of reduced or non-caloric products to 70%.
- In 2014, in partnership with the Alliance for a Healthier Generation, America's leading beverage companies joined forces in a landmark agreement to decrease beverage calories in the American diet by 20 percent per person by 2025. Keybridge, an independent evaluator, has monitored and measured the progress annually. From 2014 to 2020, average beverage calories per person fell by 10.0%, halfway to the 20% calorie reduction goal that was set for 2025. The annual decline has accelerated every year since 2016, with the largest single year decline (-5.0%) coming in 2020. The most important trends in terms of impact on calories has been the shift toward low- and no-calorie beverages, including water and sparkling waters. This trend has accelerated every year since 2016 as consumers increasingly select lower calorie-versions of all beverage types.
- Earlier this month, the **European soft drink association**, UNESDA, issued a press release communicating that the soft drinks industry has reduced sugar by 17.7% since 2015 and also, the sector's progress against its new commitment to reduce added sugars by another 10% by 2025 as part of the pledge submitted last year under the Farm to Fork Strategy's EU Code of Conduct on Responsible Food Business and Marketing Practices. This new pledge will bring our sector's total average added sugar reduction in Europe to 33% by 2025 (baseline 2000).
- Inspired by the series of three consecutive UNESDA sugar reduction commitments at EU level, 14 of their national members across Europe have made national sugar/calorie reduction commitments, and many have already reported notable achievements, for example:
 - The **Austrian** soft drink sector is working toward reducing average added sugars in its drinks by 15% by 2025 (baseline 2019);
 - The **Belgian** soft drink industry achieved in 2020 a 20% reduction in sugar (baseline 2012);
 - The **Dutch** soft drink industry achieved in 2020 a 26.7% reduction in calories (baseline 2012);
 - The **French** soft drink sector has achieved a 9.8% reduction in sugars between 2010 and 2018, building on their commitment for a 5% reduction between 2010 and 2015;

<https://www.conferenceboard.ca/press/newsrelease/2018/08/09/counting-the-calories-canadians-consumption-of-high-calorie-beverages-continues-to-decline?AspxAutoDetectCookieSupport=1> (last accessed May 29, 2019).

- The **German** soft drink sector has committed to make a 15% reduction by 2025 in calories from the beverages it puts on the market (baseline 2015);
- The **Italian** soft drink sector has already achieved a 20% reduction in sugar and calories between 2009 and 2016 and has made a commitment for an additional 10% reduction in sugar by 2022 (baseline 2020). It is noteworthy that the Italian soft drink sector reduced sugar by 27% between 2009 and 2019;
- In **Latvia**, the soft drink sector aims to reduce average added sugars in its beverages by 20% by 2030 (baseline 2015);
- The **Portuguese** soft drink industry achieved in 2020 a 30.5% reduction in calories (baseline 2013) and in 2019 announced an additional reduction of 10% by 2022 (baseline 2019);
- In **Spain**, the soft drinks industry has reduced added sugars by 43% and in May this year announced a new 10% reduction pledge that will bring total sugar reduction to 53% by 2025 (baseline 2005); and
- The **Swedish** soft drink sector is committed to delivering a further 15% reduction in average added sugars by 2025 (baseline 2019).

Survey response 5

General information

Family/last name
Lamonaca
Given/first name
Sara
Organization/affiliation
FoodDrinkEurope
Sector
Private sector
Sector [Other]
Country
Belgium

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"FoodDrinkEurope comments on WHO draft Guidelines on non-sugar sweeteners","comment":"","size":"142.3701171875","name":"FoodDrinkEurope%20comments%20on%20WHO%20draft%20Guidelines%20on%20non-sugar%20sweeteners%20%28August%202022%29.pdf","filename":"fu_p6e8wgd2a4nafwd","ext":"pdf" }]

August 2022

FoodDrinkEurope comments on draft WHO guideline on use of non-sugar sweeteners

FoodDrinkEurope appreciates the opportunity to provide comments to the WHO online public consultation on the draft guideline on use of non-sugar sweeteners (NSS).

FoodDrinkEurope would like to raise its concerns about the limited and low-quality evidence that underpins the 'conditional' draft WHO recommendation. NSS have been extensively studied for their safety and rigorously tested by national and international bodies prior to the approval for use and consumption. The totality and weight of the evidence does not support the statement reached in the draft guideline. NSS can be beneficial and are part of safe and valuable endorsed strategies for short-term weight management, blood glucose management and dental health.

Any guidance must be grounded in principles of science-based policy, exhibit policy coherence and follow the roadmap of recent health priorities established by WHO member countries. We are concerned that the decision to base guidelines on low-quality scientific evidence may ultimately lead WHO member countries to adopt legislation that potentially jeopardises positive public health outcomes. It will also have a disincentivising effect on food product reformulation.

Role of NSS in weight management, glucose control and other benefits

The role of NSS in reducing energy (calorie) intake and in assisting with modest weight loss has been confirmed in numerous studies and systematic reviews ^{1 2 3 4 5 6}, including the WHO study on the health effects of the use of NSS that contributed to informing the draft WHO guideline ⁷.

It is therefore surprising that the benefit of using NSS as a way to reduce calories intake, and in turn, to assist in weight management, is not acknowledged in the WHO recommendation suggesting against using NSS for weight control.

Longer-term randomised controlled trials (RCTs), - with a duration up to 2 years, studying the impact of low/no calorie sweeteners on weight control are also supportive of their useful role in weight management ^{8 9 10}. Importantly, observational data provide inconsistent and unreliable evidence about the association between NSS and obesity, as observational research in this field is prone to reverse causality, meaning that "a positive association between non-nutritive sweeteners consumption and weight gain in observational studies may be the consequence of and not the reason for overweight and obesity", as also recognised in WHO-supported studies ¹¹.

Experts have expressed concerns about the weight that should be placed on observational data exploring the association between NSS and obesity when data from sustained RCTs are available ¹². By design, observational studies cannot establish a cause-and-effect relationship and provide evidence of low quality. It is well documented that prospective cohort studies are also at a high risk of residual confounding and reverse causality, as higher consumers of NSS may choose these products because they are at greater risk for adverse cardiometabolic outcomes ¹³. This is also recognised in the reviews supported by the WHO: results of observational studies on the health effects of NSS should be interpreted with caution, and attention should be focused on plausible residual confounding as well as reverse causality ^{14 15}.

Weight control and especially long-term weight loss maintenance has been proven to be very challenging to individuals living with overweight and obesity. While NSS are not a quick solution for weight loss, they can be a useful dietary tool, as they provide low-calorie options for consumers.

NSS are safe and confirmed as such by global food safety authorities

The statement in the WHO draft guideline on the undesirable effects from long-term use of NSS is based on limited, low-quality evidence from observational studies ¹⁶. It contradicts the aligned position taken by regulatory authorities around the world that confirmed the safety of NSS, even among vulnerable populations such as pregnant women and children. All NSS have undergone an extensive and rigorous safety evaluation processes by international and national regulatory food safety bodies, both before and after their approval for use in the market. The FAO/ WHO Joint Expert Committee on Food Additives (JECFA) ¹⁷, the US Food and Drug Administration (FDA)¹⁸ and the European Food Safety Authority (EFSA) ¹⁹, have confirmed the safety of all approved NSS as food additives. There is an extensive body of evidence from both animal models and human studies which supports the safety of NSS for the general population including the elderly, children, pregnant and lactating women, within Acceptable Daily Intake (ADI) limits.

Furthermore, there is an ongoing review process to ensure that any new information on safety on NSS is re-evaluated e.g.: the EFSA re-evaluation of sweeteners is ongoing since 2018. The re-evaluation programme of food additives that were already permitted in the European Union before 20 January 2009 has been set up under Regulation (EU) No 257/2010 establishing a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 on food additives. Regulation (EU) No 257/2010 also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information.

In addition, results from meta-analyses of RCTs ²⁰ confirmed that NSS have no adverse impact on cardiometabolic risk factors, including glucose and insulin levels, blood lipids and blood pressure. In the presence of higher-quality evidence from RCTs, low certainty evidence from observational studies should be interpreted with caution.

The WHO draft guideline on use of non-sugar sweeteners may confuse consumers

The draft guideline states that assessing the health effects of NSS on individuals with pre-existing diabetes was beyond the scope of this guideline, and therefore this recommendation is possibly not relevant for individuals with diabetes²¹. However, NSS can be a useful dietary tool for people with diabetes who need to manage their carbohydrate and sugars intake. Failing to consider the needs of those living with diabetes, consisting approximately 10% of the global population, is an important shortcoming of this draft guideline.

In fact, the WHO recommendation suggesting not to use NSS as a means for weight control might even be confusing to people living with diabetes, especially when diabetes and nutrition-related organisations globally support the use of NSS for diabetes management, such as the American Diabetes Association, the US Academy of Nutrition and Dietetics and Diabetes UK. For example, both the American Diabetes Association (ADA)²² and the US Academy of Nutrition and Dietetics (AND)²³, in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of NSS has the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners and without compensation by intake of additional calories from other food sources. Also, the latest Diabetes UK Position Statement on NSS concludes that: “low/no calorie sweeteners are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes”²⁴.

We trust that our comments will be duly considered in the revision of the draft guideline. We thank you for your kind consideration and remain at your disposal for any additional information or clarifications you may need.

¹ Miller PE, Perez V. Low-calorie sweeteners and body weight and composition: a meta-analysis of randomized controlled trials and prospective cohort studies. *Am J Clin Nutr.* 2014 Sep;100(3):765-77. doi: 10.3945/ajcn.113.082826. Epub 2014 Jun 18. PMID: 24944060; PMCID: PMC4135487.

² Rogers PJ, Hogenkamp PS, de Graaf C, Higgs S, Lluch A, Ness AR, Penfold C, Perry R, Putz P, Yeomans MR, Mela DJ. Does low-energy sweetener consumption affect energy intake and body weight? A systematic review, including meta-analyses, of the evidence from human and animal studies. *Int J Obes (Lond).* 2016 Mar;40(3):381-94. doi: 10.1038/ijo.2015.177. Epub 2015 Sep 14. PMID: 26365102; PMCID: PMC4786736.

³ Laviada-Molina H, Molina-Segui F, Pérez-Gaxiola G, Cuello-García C, Arjona-Villicaña R, Espinosa-Marrón A, Martínez-Portilla RJ. Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and meta-analysis. *Obes Rev.* 2020 Jul;21(7):e13020. doi: 10.1111/obr.13020. Epub 2020 Mar 25. PMID: 32216045.

⁴ Lee HY, Jack M, Poon T, Noori D, Venditti C, Hamamji S, Musa-Veloso K. Effects of Unsweetened Preloads and Preloads Sweetened with Caloric or Low-/No-Calorie Sweeteners on Subsequent Energy Intakes: A Systematic Review and Meta-Analysis of Controlled Human Intervention Studies. *Adv Nutr.* 2021 Jul 30;12(4):1481-1499. doi: 10.1093/advances/nmaa157. PMID: 33439973; PMCID: PMC8321874.

⁵ Rogers PJ, Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes (Lond).* 2021 Mar;45(3):464-478. doi: 10.1038/s41366-020-00704-2. Epub 2020 Nov 9. Erratum in: *Int J Obes (Lond).* 2021 May 27;: PMID: 33168917.

⁶ McGlynn ND, Khan TA, Wang L, Zhang R, Chiavaroli L, Au-Yeung F, Lee JJ, Noronha JC, Comelli EM, Blanco Mejia S, Ahmed A, Malik VS, Hill JO, Leiter LA, Agarwal A, Jeppesen PB, Rahelic D, Kahleová H, Salas-Salvadó J, Kendall CWC, Sievenpiper JL. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-

- Sweetened Beverages With Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. JAMA Netw Open. 2022 Mar 1;5(3):e222092. doi: 10.1001/jamanetworkopen.2022.2092. PMID: 35285920.
- ⁷ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO
- ⁸ Blackburn GL, Kanders BS, Lavin PT, Keller SD, Whatley J. The effect of aspartame as part of a multidisciplinary weight-control program on short- and long-term control of body weight. Am J Clin Nutr. 1997 Feb;65(2):409-18. doi: 10.1093/ajcn/65.2.409. PMID: 9022524.
- ⁹ de Ruyter JC, Olthof MR, Seidell JC, Katan MB. A trial of sugar-free or sugar-sweetened beverages and body weight in children. N Engl J Med. 2012 Oct 11;367(15):1397-406. doi: 10.1056/NEJMoa1203034. Epub 2012 Sep 21. PMID: 22998340.
- ¹⁰ Peters JC, Beck J, Cardel M, Wyatt HR, Foster GD, Pan Z, Wojtanowski AC, Vander Veur SS, Herring SJ, Brill C, Hill JO. The effects of water and non-nutritive sweetened beverages on weight loss and weight maintenance: A randomized clinical trial. Obesity (Silver Spring). 2016 Feb;24(2):297-304. doi: 10.1002/oby.21327. Epub 2015 Dec 26. PMID: 26708700; PMCID: PMC4744961.
- ¹¹ Lohner S, Toews I, Meerpohl JJ. Health outcomes of non-nutritive sweeteners: analysis of the research landscape. Nutr J. 2017 Sep 8;16(1):55. doi: 10.1186/s12937-017-0278-x. PMID: 28886707; PMCID: PMC5591507.
- ¹² Mela DJ, McLaughlin J, Rogers PJ. Perspective: Standards for Research and Reporting on Low-Energy ("Artificial") Sweeteners. Adv Nutr 2020;11(3):484-491
- ¹³ Sievenpiper JL, Khan TA, Ha V, Viguiouk E, Auyeung R. The importance of study design in the assessment of non-nutritive sweeteners and cardiometabolic health. A letter in response to Azad et al study in CMAJ. CMAJ 2017; 189(46):E1424-E1425
- ¹⁴ Lohner S, Toews I, Meerpohl JJ. Health outcomes of non-nutritive sweeteners: analysis of the research landscape. Nutr J. 2017 Sep 8;16(1):55. doi: 10.1186/s12937-017-0278-x. PMID: 28886707; PMCID: PMC5591507.
- ¹⁵ Toews I, Lohner S, Küllenberg de Gaudry D, Sommer H, Meerpohl JJ. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies. BMJ. 2019 Jan 2;364:k4718. doi: 10.1136/bmj.k4718. Erratum in: BMJ. 2019 Jan 15;364:l156. PMID: 30602577; PMCID: PMC6313893.
- ¹⁶ Draft WHO guideline: use of non-sugar sweeteners. <https://www.who.int/news-room/articles-detail/online-public-consultation-draft-guideline-on-use-of-non-sugar-sweeteners>
- ¹⁷ JECFA: <http://apps.who.int/food-additives-contaminants-jecfadatabase/search.aspx?fc=66>
- ¹⁸ FDA: <https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm397725.htm>
- ¹⁹ EFSA: <https://www.efsa.europa.eu/en/topics/topic/sweeteners>
- ²⁰ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO
- ²¹ Draft WHO guideline: use of non-sugar sweeteners. <https://www.who.int/news-room/articles-detail/online-public-consultation-draft-guideline-on-use-of-non-sugar-sweeteners>
- ²² Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen S, Urbanski PB, Yancy WS Jr. Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019 May;42(5):731-754. doi: 10.2337/dci19-0014. Epub 2019 Apr 18. PMID: 31000505; PMCID: PMC7011201.
- ²³ Franz MJ, MacLeod J, Evert A, Brown C, Gradwell E, Handu D, Reppert A, Robinson M. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. J Acad Nutr Diet. 2017 Oct;117(10):1659-1679. doi: 10.1016/j.jand.2017.03.022. Epub 2017 May 19. PMID: 28533169.
- ²⁴ Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>

Survey response 6

General information

Family/last name
Cardozo
Given/first name
Gislene
Organization/affiliation
BIAD - Brazilian Association of the Food Industry for Special Purposes and Similars
Sector
Other
Sector [Other]
trade association
Country
Brazil

Comments on the draft guideline

Summary of evidence

Regarding the benefits of sweeteners of low/no calorie sweeteners in weight control, ABIAD – Brazilian Association of the Food Industry for special purposes and similars, makes the following considerations:

The helpful role of low/no calorie sweeteners in reducing energy (calorie) intake and in assisting with modest weight loss when used to replace sugars has been confirmed in numerous studies and systematic reviews,⁵⁻¹⁰ including the WHO study that informed the draft WHO guideline.³ In fact, in the WHO meta-analysis of RCTs, the gold standard in nutrition and clinical research, Rios-Leyvraz & Montez showed that low/no calorie sweeteners' use results in reductions in sugars and calorie intakes and in modest but significant weight loss in adults.³ It is therefore surprising that the benefit of using low/no calorie sweeteners as a way to reduce excess sugars and calories intake, and in turn, to assist in weight management, is not acknowledged in the WHO recommendation suggesting against using non-sugar sweeteners for weight control.

Longer-term RCTs with a duration up to 2 years studying the impact of low/no calorie sweeteners on weight control are also supportive of their useful role in weight management.^{11,12,13} Importantly, observational data provide inconsistent and unreliable evidence about the association between low/no calorie sweeteners and obesity, as observational research in this field is prone to reverse causality, meaning that "a positive association between NNS [non-nutritive sweeteners] consumption and weight gain in observational studies may be the consequence of and not the reason for overweight and obesity.", as also recognised in WHO-supported studies.¹⁴

Experts have expressed concern about the weight that should be placed on observational data exploring the association between low/no calorie sweeteners and obesity when data from sustained RCTs are available.¹⁵ By design, observational studies cannot establish a cause-and-effect relationship and provide evidence of low quality, as recognised in the WHO handbook for guideline development.¹⁶ It is well documented that prospective cohort studies are also at a high risk of residual confounding and reverse causality, as higher consumers of low/no calorie sweeteners may choose these products because they are at greater risk for adverse cardiometabolic outcomes and not the other way around.¹⁷ This is also recognised in the reviews supported by the WHO: results of observational studies on the health effects of low/no calorie sweeteners should be interpreted with caution, and attention should focus on plausible residual confounding as well as reverse causality.^{14,18}

In contrast, a body of evidence based on RCTs is rated as being of higher quality and thus RCTs are the preferred source of evidence for measuring the effects of interventions related to measurable health outcomes such as body weight. Comprehensive systematic reviews and meta-analyses of RCTs are supportive of the beneficial role of low/no calorie sweeteners, as sugars substitutes in calorie and sugar reduction, and in turn, in weight loss.⁵⁻¹⁰ In fact, some studies have also found that this beneficial effect is greater in people with overweight or obesity, who need to manage their body weight.^{7,18} The benefit of replacing added sugars with low/no calorie sweeteners in reducing calorie intake in the short-term and aiding in weight management is also supported by a systematic review by the US Dietary Guideline Advisory Committee of the Dietary Guidelines for Americans, 2020-2025.¹⁹

Weight control and especially long-term weight loss maintenance has been proven to be very challenging to individuals living with overweight and obesity. While low/no calorie sweeteners are not a magic bullet in weight loss, they can be a useful dietary tool in providing wider options for sweet-tasting foods and beverages with fewer calories and sugars and help people living with obesity to adhere to an overall higher quality diet while trying to manage their body weight.

REFERENCES

3. World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO

5. Miller PE & Perez V. Low-calorie sweeteners and body weight and composition: a meta-analysis of randomized controlled trials and prospective cohort studies. *Am J Clin Nutr* 2014; 100(3): 765-777

6. Rogers PJ, Hogenkamp PS, de Graaf C, Higgs S, Lluch A, Ness AR, et al. Does low-energy sweetener consumption affect energy intake and body weight? A systematic review, including meta-analyses, of the evidence from human and animal studies. *Int J Obes* 2016; 40(3): 381-94

7. Laviada-Molina H, Molina-Segui F, Pérez-Gaxiola G, et al. Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and meta-analysis. *Obesity Reviews* 2020;21(7):e13020

8. Lee HY, Jack M, Poon T, Noori D, Venditti C, Hamamji S, Musa-Veloso K. Effects of Unsweetened Preloads and Preloads Sweetened with Caloric or Low-/No-Calorie Sweeteners on Subsequent Energy Intakes: A Systematic Review and Meta-Analysis of Controlled Human Intervention Studies. *Adv Nutr*. 2021 Jul 30;12(4):1481-1499

9. Rogers PJ and Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes* 2021; 45(3): 464-478

-
10. McGlynn ND, Khan TA, Wang L, et al. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages With Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. *JAMA Network Open* 2022;5(3):e222092
 11. Blackburn GL, Kanders BS, Lavin PT, Keller SD, & Whatley J. The effect of aspartame as part of a multidisciplinary weight-control program on short-and long-term control of body weight. *Am J Clin Nutr* 1997; 65(2): 409–418
 12. de Ruyter JC, Olthof MR, Seidell JC, & Katan MB. A trial of sugar-free or sugar-sweetened beverages and body weight in children. *N Engl J Med* 2012; 367(15): 1397–1406
 13. Peters JC, Beck J, Cardel M, Wyatt HR, Foster GD, Pan Z, . . . Hill JO. The effects of water and non-nutritive sweetened beverages on weight loss and weight maintenance: A randomized clinical trial. *Obesity (Silver Spring)* 2016; 24(2): 297-304
 14. Lohner S, Toews I, Meerpohl JJ. Health outcomes of non-nutritive sweeteners: analysis of the research landscape. *Nutr J*. 2017 Sep 8;16(1):55
 15. Mela DJ, McLaughlin J, Rogers PJ. Perspective: Standards for Research and Reporting on Low-Energy (“Artificial”) Sweeteners. *Adv Nutr* 2020;11(3):484-491
 16. World Health Organization. (2014). WHO handbook for guideline development, 2nd ed. World Health Organization. <https://apps.who.int/iris/handle/10665/145714>
 17. Sievenpiper JL, Khan TA, Ha V, Vigiouk E, Auyeung R. The importance of study design in the assessment of non-nutritive sweeteners and cardiometabolic health. A letter in response to Azad et al study in *CMAJ*. *CMAJ* 2017; 189(46):E1424-E1425
 18. Toews I, Lohner S, Ku?llenberg de Gaudry D, Sommer H, Meerpohl JJ. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies. *BMJ* 2019;364:k4718
 19. Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC
-

Evidence to recommendations
<p>ABIAD does not agree with the understanding contained in the draft of the WHO Guideline on some of the cited evidence that supports the Guideline's recommendation, for example, regarding to safety and effect of the use of sweeteners on cardiometabolic health, as explained below.</p> <p>Food safety authorities around the world have repeatedly and consistently confirmed the safety of low/no calorie sweeteners, including during pregnancy. In fact, for a low/no calorie sweetener to be approved for use on the market, it must first undergo a thorough safety assessment by the competent food safety authority assessing all the available literature, including but not limited to the data reviewed by WHO as evidence from short-term RCTs in humans, animal and in-vitro data are also assessed. Such scientific regulatory bodies include the Joint Expert Scientific Committee on Food Additives (JECFA) of the United Nations Food & Agriculture Organization (FAO) and of the World Health Organization (WHO)², the European Food Safety Authority (EFSA)²⁹ and the US Food and Drug Administration (FDA).³⁰</p> <p>Based on very low quality evidence, the draft WHO guideline points to “potential undesirable effects from long-term use in the form of increased risk of type 2 diabetes, cardiovascular diseases, and mortality in adults. Limited evidence suggests potential undesirable effects in the form of increased risk of preterm birth with NSS use during pregnancy.”¹ However, this statement is based solely on very low to low evidence from observational studies, which are at risk of residual confounding and reverse causality, as acknowledged in this guideline. Importantly, and contrary to observational findings, results from meta-analyses of RCTs, including in the recent WHO study, confirm that low/no calorie sweeteners have no adverse impact on cardiometabolic risk factors, including glucose and insulin levels, blood lipids and blood pressure.^{3,10,31} In fact, a recent systematic review of RCTs found potential cardiometabolic health benefits when low/no calorie sweetened beverages are used to replace sugars.¹⁰</p> <p>REFERENCES</p> <p>1. Draft WHO guideline: use of non-sugar sweeteners. https://www.who.int/news-room/articles-detail/online-public-consultation-draft-guideline-on-use-of-non-sugar-sweeteners</p> <p>2. http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/</p> <p>3. World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. https://apps.who.int/iris/handle/10665/353064. License: CC BY-NC-SA 3.0 IGO</p> <p>10. McGlynn ND, Khan TA, Wang L, et al. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages With Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. <i>JAMA Network Open</i> 2022;5(3):e222092</p> <p>29. http://www.efsa.europa.eu/en/topics/topic/sweeteners</p> <p>30. https://www.fda.gov/food/food-additives-petitions/high-intensity-sweeteners</p> <p>31. Movahedian M, Golzan SA, Ashtary-Larky D, Clark CCT, Asbaghi O, Hekmatdoost A. The effects of artificial- and stevia-based sweeteners on lipid profile in adults: a GRADE-assessed systematic review, meta-analysis, and meta-regression of randomized clinical trials. <i>Crit Rev Food Sci Nutr</i>. 2021 Dec 9:1-17. doi: 10.1080/10408398.2021.2012641. Epub ahead of print</p>
Recommendations and supporting information
<p>The draft recommendation on use of non-sugar sweeteners is a conditional recommendation. Conditional recommendations are those recommendations for which the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences or when the anticipated net benefits are small. This decision was based on the assessment of the available evidence as overall low certainty in the recent WHO systematic review that supported today's draft guideline.³ However, this study examined only a fraction of the available literature and missed to assess strong evidence from RCTs examining the impact of low/no calorie sweeteners on postprandial glycaemia and in tooth mineralisation.</p> <p>REFERENCE</p> <p>3. World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. https://apps.who.int/iris/handle/10665/353064. License: CC BY-NC-SA 3.0 IGO</p>

Other comments

Moreover, ABIAD emphasizes that the draft guideline states that assessing the health effects of non-sugar sweeteners on individuals with pre-existing diabetes was beyond the scope of this guideline, and therefore this recommendation possibly is not relevant for individuals with diabetes.¹ However, low/no calorie sweeteners are a useful dietary aid for people with diabetes who need to manage their carbohydrate and sugars intake and missing to consider the needs of patients living with diabetes, consisting approximately 10% of the global population, is an important shortcoming of this draft guideline. In fact, the WHO recommendation suggesting not to use non-sugar sweeteners as a means for weight control might even be confusing to people living with diabetes, especially when diabetes and nutrition-related organisations support the use of low/no calorie sweeteners for diabetes management.

Based on the scientific opinion of the European Food Safety Authority,⁴ in an authorised health claim in the EU Register of nutrition and health claims, it is recognised that 'the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods' (Commission Regulation (EU) No 432/2012).²⁰ Also, several reviews have confirmed that low/no calorie sweeteners, by themselves, do not affect glycaemia and insulin levels post-prandially.^{21,22} The absence of glycaemic effect of low/no calorie sweeteners, and the lower spike in postprandial blood glucose they cause when used instead of sugars, makes them a useful dietary aid for people with diabetes who need to manage their carbohydrate and sugars intake. Health organisations globally recognise that low/no calorie sweeteners can be safely used to replace sugar in the nutritional management of diabetes.²³⁻²⁵ For example, both the American Diabetes Association (ADA)²⁴ and the US Academy of Nutrition and Dietetics (AND)²⁵, in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of low/no calorie sweeteners has the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners and without compensation by intake of additional calories from other food sources. Also, the latest Diabetes UK Position Statement on low/ no calorie sweeteners (LNCS) concludes that: "LNCS are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes.

Another point to be highlighted is that the excess intake of dietary sugars is a recognised hazard in relation to dental caries in humans.^{26,27} In contrast, by being non-fermentable by oral bacteria, low/no calorie sweeteners can contribute to good dental health, when used in place of sugar.²⁸ EFSA supports in the respective scientific opinions that "there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralisation by decreasing tooth demineralisation if consumed instead of sugars".⁴ The draft WHO guideline missed to consider the totality of evidence confirming this well-established benefit of low/no calorie sweeteners use in dental health, which was in fact also supported by evidence reviewed in WHO's own study. This is concerning because dental caries is amongst the most widespread non-communicable disease.

The benefits of low/no calorie sweeteners when used in place of sugars are supported by a wealth of well conducted, acute, short- and longer-term randomised controlled trials in humans, which provide high quality evidence.³² Failing to consider the collective evidence on the health effects of non-sugar sweeteners and to accurately translate the totality of available evidence into a recommendation in view of the hierarchy of scientific evidence, may hinder public health efforts to reduce excess sugars intake and to tackle obesity.

Considering all the scientific evidences described above, ABIAD has serious concerns on the conditional recommendation that low- and no-calorie sweeteners should not be used as a means of achieving weight control or reducing risk of non-communicable diseases. Considering the relevance and global impact that the guidelines may have it is our view that such recommendations should be supported by strong evidence and not be based on data with "low evidence of certainty". Low- and no-calorie sweeteners have been proven to support body weight and blood glucose management, and also to help in the calorie and sugar reduction being an important tool in the reduction of added sugars consumption whose importance is very well recognized by the WHO.

We really appreciate the opportunity to participate in this very important Public Consultation and hope that our contributions will be useful.

REFERENCES

1. Draft WHO guideline: use of non-sugar sweeteners. <https://www.who.int/news-room/articles-detail/online-public-consultation-draft-guideline-on-use-of-non-sugar-sweeteners>

4. EFSA. Scientific opinion on the substantiation of health claims related to intense sweeteners. EFSA Journal 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

20. Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and Health

21. Nichol AD, Holle MJ, An R. Glycemic impact of non-nutritive sweeteners: a systematic review and meta-analysis of randomized controlled trials. Eur J Clin Nutr 2018;72:796-804

22. Greyling A, Appleton KM, Raben A, Mela DJ. Acute glycemic and insulinemic effects of low-energy sweeteners: a systematic review and meta-analysis of randomized controlled trials. Am J Clin Nutr 2020 Oct 1;112(4):1002-1014

-
23. Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>
24. Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. *Diabetes Care*. 2019 May;42(5):731-754
25. Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. *Journal of the Academy of Nutrition and Dietetics* 2017;117(10):1659-79
26. WHO Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015
27. EFSA NDA Panel, 2022. Scientific Opinion on the Tolerable Upper Intake Level for dietary sugars (EFSA-Q-2016- 00414). *EFSA Journal* 2022;20(2):7074. doi:10.2903/j.efsa.2022.7074
28. FDI Policy Statement: Sugar substitutes and their role in caries prevention. Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden
32. Ashwell M, Gibson S, Bellisle F, Buttriss J, Drewnowski A, Fantino M, Gallagher AM, de Graaf K, Goscinny S, Hardman CA, Laviada-Molina H, López-García R, Magnuson B, Mellor D, Rogers P, Rowland I, Russell W, Sievenpiper J, la Vecchia C. Expert consensus on low calorie sweeteners: facts, research gaps and suggested actions. *Nutr Res Rev*. 2020 Jun;33(1):145-154

Upload comments

Survey response 7

General information

Family/last name
Sibson
Given/first name
Victoria
Organization/affiliation
First Steps Nutrition Trust
Sector
Non-governmental agency
Sector [Other]
Country
United Kingdom

Comments on the draft guideline

Summary of evidence
Clear and concise. Thank you.
Evidence to recommendations
Clear, important, proportionate and achievable. Thank you. Additional suggestions on potential government actions, reflecting on the UK context (informed by FSNT 2019 report Sweeteners report and observations of current policy and practice as outlined below). <ul style="list-style-type: none">• Explicit mention that Governments should consider discouraging the addition of NNS as a part of product reformulation.• Governments should consider monitoring and reporting of NNS use in food production.• Governments should collect data on NNS consumption (intakes and dietary sources beyond NNS soft drinks) among infants, young children, pregnant and breastfeeding women through national dietary surveys. A current focus in policy and practice in the UK in the food/nutrition sector is tackling the marketing of High saturated Fat, Salt and Sugar (HFSS) foods/drinks and reducing their consumption. This focus is primarily among adolescents and adults, with little in the way of action on infants and young children. While this is important, First Steps Nutrition Trust's concern is that this is happening in the absence of any associated efforts to consider the possibly perverse effects this may have in terms of increased use and consumption of NNS and also inadvertent promotion of highly processed foods and drinks. For example in early 2022 the DHSC launched a 'Food scanner' App which is being widely promoted to families and through schools, and which suggests 'healthier' swaps for HFSS foods and drinks, and these swaps include, for example, NNS fizzy drinks, which are given a 'good choice' label. It should be noted that there are currently no public health or dietary recommendations which make explicit mention of the level of processing of foods, which we believe is an important limitation in the context in which actions may be needed to reduce NNS consumption alongside free sugar consumption.
Recommendations and supporting information
Suggest that additional gaps in the evidence to be addressed by future research should include: <ul style="list-style-type: none">• The impact of NNS beverages on the oral health of infants and young children• The impact of NNS consumption in infancy and early childhood on the child's palate and sweet preference in later life.

Other comments
<p>We feel it would be of value to consider alongside health outcomes of NSS consumption, their effects on taste preferences, if sufficient data are available. Two studies which contain some data on this are:</p> <p>Goran M.I., Plows J.F., Ventura E.E. (2018) Effects of consuming sugar and alternative sweeteners during pregnancy on maternal and child health: evidence for a secondhand sugar effect. <i>Proc Nutr Soc</i>, 78 (3), 262-271.</p> <p>Zhang G.H., Chen M.L., Liu S.S., Zhan Y.H., Quan Y. et al (2011). Effects of mother's dietary exposure to acesulfame-k in pregnancy or lactation on the adult offspring's sweet preferences. <i>Chemical Senses</i>, 38 (9), 763-770.</p>
Upload comments

Survey response 8

General information

Family/last name
OKUNLOLA
Given/first name
OMOLARA
Organization/affiliation
STANDARDS ORGANISATION OF NIGERIA/RETIRED AS A STANDARD OFFICER IN AREAS OF FOOD AND AGRICULTURE
Sector
Government
Sector [Other]
Country
Nigeria

Comments on the draft guideline

Summary of evidence
In the short term, the reported weight loss and reduced BMI in the randomised controlled trial did not take attribution for individuals undergoing weight reduction programmes into account. It is critical to confirm if the analysis considered the issue of attribution.
Evidence to recommendations
No comment
Recommendations and supporting information
No comment
Other comments
<p>Sub-Saharan Africa, particularly Nigeria, should be included in future work on the guideline revision. Though it is commendable that WHO conditionally recommends that non sugar sweeteners should not be used to achieve weight control or reduce the risk of non-communicable diseases (conditional recommendation), research outcomes should also consider anthropometry results (i.e., weight loss and BMI) from various national food consumption surveys. Such additional analysis is necessary for countries where most children aged 6-59 months, adolescents aged 10-29 years, and adults aged 30-39 years experience stunted growth or are underweight.</p> <p>Furthermore, due to the high temperatures caused by climate change in Sub-Sahara Africa, non sugar sweetened drinks and beverages are consumed by the public for hydration. The effect on long-term use of non sugar sweetened drinks may be related to prospective cohort studies that show an increase in BMI and accompanying cardiovascular illnesses.</p>
Upload comments

Survey response 9

General information

Family/last name
Weikel
Given/first name
Karen
Organization/affiliation
Bonumose, Inc.
Sector
Private sector
Sector [Other]
Country
United States of America

Comments on the draft guideline

Summary of evidence
<p>The WHO draft guideline on the use of non-sugar sweeteners explicitly excludes natural caloric sweeteners (p.3) such as Tagatose. Tagatose is not mentioned a single time in the draft guideline (although 2 Allulose studies are referenced, 1 of which was excluded from analysis).</p> <p>Tagatose consumption has not been associated with any of the negative health outcomes potentially linked with non-sugar sweetener intake.</p> <p>Tagatose alone has minimal glycemic impact and with other carbohydrates reduces postprandial glucose and insulin excursions (Donner et al, 1999; Boesch et al, 2001). Tagatose has a significant positive effect on additional intermediate markers of T2D such as fasting glucose, HbA1c and blood lipid levels (Ensor et al, 2014; Ensor et al, 2015). It promotes a healthy microbiome, both reducing risk for dental caries and promoting the growth of beneficial gut bacteria (Bertelsen et al, 1999; Hasibul et al, 2018; Mayumi et al, 2021). Albeit a monosaccharide, tagatose resembles dietary fiber in many ways including its caloric value (which is less than 40% that of sucrose) primarily attributable to Tagatose being consumed by beneficial gut bacteria and producing short chain fatty acids.</p> <p>Bertelsen H, Jensen BB, Buemann B. D-tagatose, a novel low-calorie bulk sweetener with prebiotic properties. <i>World Rev Nutr Diet</i> 1999; 85: 98–109.</p> <p>Boesch C, Ith M, Jung B, Bruegger K, Erban S, Diamantis I, Kreis R, Bär A. Effect of oral D-tagatose on liver volume and hepatic glycogen accumulation in healthy male volunteers. <i>Regul Toxicol Pharmacol</i>. 2001 33(2):257-67.</p> <p>Donner TW, Wilber JF, Ostrowski D. D-tagatose, a novel hexose: acute effects on carbohydrate tolerance in subjects with and without type 2 diabetes. <i>Diabetes Obes Metab</i>. 1999 Sep;1(5):285-91.</p> <p>Ensor M, Williams J, Smith R, Banfield A, Lodder RA. Effects of Three Low-Doses of D-Tagatose on Glycemic Control Over Six Months in Subjects with Mild Type 2 Diabetes Mellitus Under Control with Diet and Exercise. <i>J Endocrinol Diabetes Obes</i>. 2014, 2(4):1057.</p> <p>Ensor M, Banfield AB, Smith RR, Williams J, Lodder RA. Safety and Efficacy of D-Tagatose in Glycemic Control in Subjects with Type 2 Diabetes. <i>J Endocrinol Diabetes Obes</i>. 2015, 3(1): 1065.</p> <p>Hasibul K, Nakayama-Imaohji H, Hashimoto M, Yamasaki H, Ogawa T, Waki J, Tada A, Yoneda S, Tokuda M, Miyake M, Kuwahara T. D-Tagatose inhibits the growth and biofilm formation of <i>Streptococcus mutans</i>. <i>Mol Med Rep</i>. 2018 Jan;17(1):843-851. doi: 10.3892/mmr.2017.8017.</p> <p>Mayumi S, Kuboniwa M, Sakanaka A, Hashino E, Ishikawa A, Ijima Y, Amano A. Potential of Prebiotic D-Tagatose for Prevention of Oral Disease, <i>Front Cell Infect Microbiol</i>. 2021 Nov 5;11:767944. doi: 10.3389/fcimb.2021.767944. eCollection 2021.</p>
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments

Survey response 10

General information

Family/last name
Grit
Given/first name
Christine
Organization/affiliation
FNLI
Sector
Private sector
Sector [Other]
Country
Netherlands

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"FNLI nss WHO","comment":"","size":"223.7001953125","name":"FNLI%20nss%20WHO.docx","filename":"fu_4jkg6rna5rqpgyv","ext":"docx"}]]

Comments by the FNLI (Dutch Food, Drink and Groceries Association) on the draft WHO guideline on use of non-sugar sweeteners (nss)

The FNLI appreciates it that we can provide comments to the WHO online public consultation on the draft guideline on use of non-sugar sweeteners (nss).

The FNLI is very concerned about the limited as well as the low-quality of the evidence that underpins this draft WHO recommendation. In our view it seems to be rather unwise to recommend governments to not base their health policies on sound scientific principles as 'even the WHO doesn't care about the evidence anymore'. Eventually this could lead to policies just being executed that will not lead to healthier populations. Especially in the case of nss which have been extensively studied for their safety and also tested prior to the approval for use and consumption. The statement in the Draft guideline "WHO suggests that NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases" is not supported by the quality and weight of the evidence while the consequences, whether the recommendation is conditional or not, may be huge. In countries with no existing scientific bodies of their own, such recommendations might be followed up regardless. Basing guidance on low quality evidence (and it is not the first time this happens) may ultimately lead WHO member countries to adopt legislation that possibly jeopardises health outcomes. Also, such advice does not help people (for whom the guidance eventually is meant) who should or wish to lose weight and maintain that loss. Nss can be helpful and are part of safe and valuable endorsed strategies for (short-term) weight management, blood glucose management and dental health.

Role of nss in weight management, glucose control and other benefits.

The role of nss in reducing energy (kilojoules) intake and in assisting modest weight loss has been conformed in numerous studies and reviews^{iiiiivvvvii}. Take note that the WHO systematic review and meta-analysis to base the guidance on, is included in this list. It surprises us that the positive aspects of using nss as a way to reduce the intake of kilojoules as well as assisting in weight management has not been acknowledged in the guideline. At all.

Longer-term randomized controlled trials (RCTs), - with a duration up to 2 years studying the impact of low/no calorie on weight control are also supportive of their useful role in weight management^{viiiix}. Noteworthy is the fact that observational data provide inconsistent and unreliable evidence about the relationship between nss and obesity as observational data can be prone to reverse causality. Something which is well-known in so-called Clinical Case-Control Epidemiological studies, meaning that "a positive association between the consumption of nss and weight gain may be the consequence of and not the reason for overweight and obesity". This proneness towards reverse causality has also been recognized in WHO-supported studies^{xi}. Higher users of nss may choose these products because they are already obese and/or (personal addition) at greater risk for adverse cardiometabolic outcomes^{xii}.

Weight control and especially long-term weight loss maintenance has been proven to be very challenging to individuals living with overweight and obesity. It is not for no reason that most governments would rather prevent weight gain from happening! Nss are obviously not a quick solution for weight loss but they can be a useful tool.

Nss are safe and confirmed as such by global safety authorities.

This guidance is not about safety but about long -term health outcomes. However it easily can be interpreted as such and in that way contradicts the position taken by regulatory authorities around the world that confirmed the safety of nss, even among vulnerable populations and children. Furthermore, in the EU the EFSA re-evaluates all additives, including sweeteners periodically.

It is a great pity that the draft guideline has not taken the health effects of nss on individuals with pre-existing diabetes into account. This recommendation is possibly not relevant for individuals with diabetes. This means that the needs of approximately 10% of the global population are not considered.

For good order: most diabetes and nutrition related bodies support the use of nss. Naturally, with some caution but acknowledging the potential in helping these people. The Dutch Health Council has published her Advice for people suffering from Diabetes Type II on the 16th of November 2021 and was altogether more nuanced^{xiii}.

We trust that you will consider our comments in the revision of the draft guideline. We thank you for your kind consideration and remain at your disposal for any additional information or clarifications.

ⁱ Laviada-Molina H., Molina-Segui F., et al., Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and Meta-Analysis. *Obesity Reviews* 2020 Juli; 21 (7): e13020.

ⁱⁱ Lee H.Y., Jack M., Effects of unsweetened Preloads and Preloads Sweetened with Caloric or low-/no-calorie Sweeteners on Subsequent Energy Intakes: A systematic Review and Meta-Analysis of Controlled human Intervention Studies. *Advanced Nutrition* 2021 Juli 30; 12 (4): pp. 1481-1489.

ⁱⁱⁱ McGlynn N.D., Khan T.A., et al., Association of Low- and No-calorie Sweetened Beverages as a replacement for Sugar Sweetened Beverages with Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-Analysis. *J of the American Medical Association Network Open*. 2022 March 1; 5 (3): e222092.

^{iv} World Health Organisation.- Rios-Legras M., Montez J. (2022) Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. Possible to download from WHO website.

^v Rogers P.J., Appleton K.M., The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *International J of Obesity*. 2021 March; 45 (3): pp. 464-478. Erratum in: *International J of Obesity*. 2021 May 27; PMID: 33168917.

^{vi} Miller P.E., Perez V., Low-calorie sweeteners and body weight and composition: a meta analysis of randomized controlled trials and prospective cohort studies. *American J of Clinical Nutrition* 2014 September; 100(3): pp. 765-777.

^{vii} Rogers P.J., Hogenkamp P.S., et al., Does low-energy sweetener consumption affect energy intake and body weight? A systematic review, including meta-analyses, of the evidence of human and animal studies. *International J of Obesity*. 2016 March; 40 (3): pp. 381-394.

^{viii} De Ruyter J.C., Olthof M.R., Seidell J.C., Katan M.B., A trial of sugar free or sugar-sweetened beverages and body weight in Children. *New England J of Medicine* 212 October 11; 367 (15): pp. 1397-1406.

^{ix} Blackburn G.L., Kanders B.S., et al., The effect of aspartame as part of a multidisciplinary weight-control program on short- and long term-term control of body weight. *American J of Clinical Nutrition*. 1997 February; 65 (2): pp. 409-418.

^x Peters J.C., Beck J., et al., The effects of water and non-nutritive sweetened beverages on weight loss and weight maintenance: A randomized clinical trial. *Obesity* 2016 February; 24 (2): pp. 297-304.

^{xi} Lohner S., Toews I., Meerpool J.J., Health outcomes of non-nutritive sweeteners: analysis of the research landscape. *Nutrition J*. 2017 September 8; 16 (1): 55.

^{xii} Sievenpiper J.L., Khan T.A., et al., The importance of study design in the assessment of non-nutritive sweeteners and cardiometabolic health. A letter in response to Azad Et al study in *Canadian Medical Association J*. *CMAJ* 2017; 189 (46): E1424-E1425.

^{xiii} Vaste commissie voeding van de Gezondheidsraad, Richtlijnen goede voeding bij diabetes type 2, nr. 2021/41, 16 november 2021.

Survey response 11

General information

Family/last name
ANTILLON
Given/first name
CARLOS
Organization/affiliation
CAMARA COSTARRICENSE DE INDUSTRIA ALIMENTARIA
Sector
Private sector
Sector [Other]
Country
Costa Rica

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"COMENTARIOS CACIA BORRADOR EDULCORANTES OMS","comment":"COMENTARIOS CACIA BORRADOR EDULCORANTES OMS","size":"260.7783203125","name":"COMENTARIOS%20CACIA%20Borrador%20edulcorantes%20OMS.pdf","filename":"fu_w7b5bejpu3qwsyf","ext":"pdf" }]

Posición de la Cámara Costarricense de la Industria Alimentaria ante el BORRADOR de las Guías de OMS sobre el Uso de Edulcorantes sin Azúcar

La Cámara Costarricense de la Industria Alimentaria (CACIA) al igual que muchos actores institucionales, públicos y privados, mantiene el ideal de incidir positivamente sobre el bienestar humano de nuestras comunidades; consideramos que la elaboración de políticas públicas relacionadas a la salud y bienestar debe ser transparente y consultativa – incluyendo la participación legítima de la industria y otros actores relevantes – con amplia aplicación de criterios científicos.

CACIA reconoce la realidad mundial en torno a la problemática de sobrepeso, obesidad y enfermedades crónicas no transmisibles (ECNT), motivo por el cual, apoyamos los esfuerzos de la OMS por promover dietas saludables. Sin embargo, nos preocupa que no haya coherencia al proporcionar orientación a las partes interesadas en sus esfuerzos por alcanzar los Objetivos de Desarrollo Sostenible de la ONU para 2030 y no genere sus recomendaciones basándose en la ciencia.

En 2015, cuando la ONU adoptó por primera vez los Objetivos Globales, el llamado a la acción exigió un compromiso global intensivo en apoyo de la implementación de todos los objetivos y metas, reuniendo a los Gobiernos, el sector privado, la sociedad civil, el sistema de las Naciones Unidas y otros actores y movilizando todos los recursos disponibles”.¹ De particular interés, uno de esos recursos específicamente destacados por el sistema de la ONU, es la capacidad de reformulación de la industria de alimentos y bebidas. En 2018, la Declaración Política de la Reunión de Alto Nivel de la ONU sobre las ENT pidió al sector privado que “fortalezca su compromiso” de hacer más esfuerzos por reformular los alimentos y las bebidas para reducir el uso excesivo de sales, azúcares y grasas.²

Nuestra industria ha atendido este llamado de la ONU, y durante los últimos años ha intensificado significativamente los esfuerzos por reformular y reducir los azúcares agregados, confiando en una herramienta clave de reformulación para lograrlo: los edulcorantes bajos en calorías.

¹ “Transformación de nuestro mundo: la Agenda para el Desarrollo Sostenible 2030”, Resolución adoptada por la Asamblea General el 25 de septiembre de 2015, A/RES/70/1 en los párrafos 39 y 60. (énfasis añadido)

² Consulte la Reunión de Alto Nivel de la ONU 2018 sobre la Declaración Política sobre ENT, A-73-L-2-EN en OP 44, disponible en <https://digitallibrary.un.org/record/1645265?ln=en>.

Sin embargo, mientras la industria de alimentos y bebidas realiza este esfuerzo, la OMS está emitiendo Borradores de Guías como ésta, que sin ninguna justificación científica robusta, buscan suprimir esta importante herramienta que es la reformulación. **La OMS reconoce que este borrador está basado en evidencia de baja certeza y no está basado en preocupaciones por su seguridad.** Estamos altamente preocupados por este aparente cambio de enfoque de la política. Como declaró el Secretario General de la ONU, Antonio Guterres, en el Foro Político de Alto Nivel de la ONU 2022, *“el mundo está en serios problemas, al igual que los Objetivos de Desarrollo Sostenible”*. La misma OMS reconoció que el mundo *“no está encaminado para alcanzar los Objetivos de Desarrollo Sostenible 3,4 (SDG target 3.4), para reducir las muertes prematuras por ENT, y ningún país está logrando los nueve objetivos voluntarios establecidos en el Plan de Acción Global para la Prevención y el Control de las ENT 2013-2030”*.³

¿Por qué entonces la OMS emite guías preliminares dando asesoramiento para la población general basado en evidencia de “baja certeza”? Solicitamos respetuosamente a la OMS que revise este borrador en el contexto de las Hojas de Ruta recientes de la ONU de Alto Nivel (que, en particular han dejado de citar en su borrador, haciendo referencia solo a las Reuniones de Alto Nivel de la ONU de 2011 y 2014 sobre las ENT, omitiendo completamente la Reunión de Alto Nivel de la ONU de 2018 sobre las ENT). Creemos en el valor de estas Hojas de Ruta de la ONU. Estas son las prioridades establecidas con los aportes de los Estados Miembros para ayudar a establecer el camino hacia los Objetivos Globales, a diferencia de las recomendaciones recientes del comité de la OMS. Si los borradores que emanan de los comités dentro de las agencias son incoherentes (y se basan en evidencia de baja calidad) y no son consistentes con las directivas generales de la política establecidas por los Estados miembros de la ONU, entonces recomendamos encarecidamente a los líderes de la OMS que revisen dicho borrador.

1. Las recomendaciones de la OMS corren el riesgo de socavar las prioridades clave de la OMS establecidas por los Estados miembros relacionadas con la diabetes y la salud dental.

El pasado mes de mayo, en la 75.^a Asamblea Mundial de la Salud, los Estados Miembros respaldaron una estrategia mundial histórica sobre la salud bucal, y uno de sus objetivos generales era reducir las enfermedades bucales.⁴ De manera

³ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).

⁴ Consulte <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

similar, en esta misma Asamblea Mundial de la Salud, los Estados Miembros apoyaron la creación de los primeros objetivos globales para la diabetes, como parte del Pacto Mundial contra la Diabetes de la OMS.⁵ En ambos casos, estos son objetivos de prioridades de alto nivel para la OMS avalados por los Estados miembros.

Los edulcorantes bajos en calorías y sin calorías son una herramienta importante para apoyar la salud bucal y el control de la diabetes. Con respecto a la salud bucal, se reconoce que debido a que los edulcorantes bajos en calorías y sin calorías no son fermentables por las bacterias bucales, pueden contribuir a una buena salud bucal.⁶ Como indicó la Autoridad Europea de Seguridad Alimentaria, *“hay suficiente información científica para respaldar las afirmaciones de que los edulcorantes intensos, como todos los sustitutos del azúcar, mantienen la mineralización dental”*.⁷

Aunque la OMS dice que las personas con diabetes están excluidas de las Guías en discusión, esta declaración sin tratamiento previo ignora las implicaciones del mundo real de emitir Guías para todas las personas. Cuando la OMS emite recomendaciones generales como ***“no use edulcorantes sin azúcar para controlar el peso”***, ***esto tiende a ser confuso***, ya sea que las personas tengan o no diabetes, ya que la mayoría de las personas adoptan los titulares, no la letra pequeña. Y para aquellos que viven con diabetes, los edulcorantes bajos en calorías y sin calorías son una parte integral de su control.

Por ejemplo, la UE permite una declaración de salud específica relacionada con edulcorantes bajos en calorías y sin calorías y niveles de glucosa: *“El consumo de alimentos que contienen edulcorantes intensos en lugar de azúcar induce un menor aumento de la glucosa en sangre después de su consumo en comparación con los alimentos que contienen azúcar”*.⁸ **Las organizaciones de**

⁵ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

⁶ Declaración de la política de FDI: Sustitutos del azúcar y su función en la prevención de caries. Adoptado por la Asamblea General del FDI, 26 de septiembre de 2008. Estocolmo, Suecia

⁷ EFSA, Opinión científica sobre la justificación de afirmaciones de salud relacionadas con edulcorantes intensos. EFSA Journal 2011;9(6):2229. Disponible en línea: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

⁸ Regulación de la Comisión (UE) n.º 432/2012 del 16 de mayo de 2012 que establece una lista de reclamaciones de salud permitidas hechas sobre alimentos, que no sean aquellas que se refieren a la reducción del riesgo de enfermedad y al desarrollo y la salud de los niños

salud a nivel mundial reconocen que los edulcorantes bajos en calorías y sin calorías pueden utilizarse de manera segura para reemplazar el azúcar en el manejo nutricional de la diabetes.⁹ Por ejemplo, tanto la Asociación Americana de Diabetes (American Diabetes Association, ADA)¹⁰ como la Academia de Nutrición y Dietética (Academy of Nutrition and Dietetics, AND)¹¹ de los EE. UU., en sus recomendaciones nutricionales para la diabetes tipo 1 y tipo 2, concluyen que el uso de edulcorantes bajos en calorías y sin calorías tiene el potencial de reducir la ingesta general de calorías y carbohidratos si se sustituyen por edulcorantes calóricos y sin compensación por la ingesta de calorías adicionales de otras fuentes de alimentos. Además, la última declaración de posición de Diabetes UK sobre edulcorantes bajos en calorías y sin calorías concluye que: *“Se ha demostrado que los edulcorantes bajos en calorías o sin calorías son seguros y pueden usarse como parte de una estrategia para adultos y niños en el control del peso y la diabetes”*.¹⁰

La recomendación de la OMS sobre el uso de edulcorantes sin azúcar en estas pautas preliminares es una recomendación “condicional” o débil, lo que significa que se basa en evidencia de baja certeza. Solicitamos que los estados miembros revisen la necesidad de una recomendación tan débil a la luz de las prioridades existentes de la OMS establecidas por los Estados miembros, como las relacionadas con el Pacto de la Diabetes y la Estrategia global sobre salud bucal.

2. Los estados miembros deben esperar que las pautas de la OMS se basen en la ciencia más sólida, no en ciencia de “baja certeza”.

⁹ Diabetes UK. El uso de edulcorantes bajos en calorías o sin calorías. Declaración de posición (actualizada en diciembre de 2018). Disponible en: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹⁰ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. “Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report”. Diabetes Care. mayo de 2019;42(5):731-754;

¹¹ Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

Como ya se indicó anteriormente, la recomendación de la OMS en este Borrador es “condicional” o débil, porque se basa en evidencia de baja certeza. Nos preocupan las implicaciones generales de que la OMS, ente en el cual los países de todo el mundo confían como la “regla de oro” para el asesoramiento científico, desarrollen pautas de políticas basadas en evidencia de baja calidad y legislaciones que realmente no cumplan con los objetivos de salud pública para reducir los azúcares agregados en la dieta. Recomendamos encarecidamente a la OMS que vuelva al uso de las mejores prácticas en el desarrollo de recomendaciones a los Estados miembros, como la utilización de la ciencia más sólida para desarrollar este borrador. **La OMS se ha basado en gran medida en estudios observacionales, que no pueden establecer una relación de causa y efecto, y, como concluyó la OMS en última instancia, proporcionan evidencia de una baja calidad.**

Nos sorprende que la OMS haya marginado su propio metaanálisis de ensayos controlados aleatorizados (ECA), que son la “regla de oro” en nutrición e investigación clínica, al desarrollar estas pautas. A principios de este año, la OMS publicó un metaanálisis de los ECA que demostró un beneficio modesto pero significativo para la pérdida de peso (entre otros beneficios) en adultos, lo que refuerza los hallazgos de una revisión basada en evidencia realizada a principios de 2019 por la OMS.¹² Estamos desconcertados porque la propia evaluación de la OMS que reconoce la evidencia de ensayos clínicos de certeza moderada a alta que muestran efectos beneficiosos o una ausencia de efectos perjudiciales por el consumo de endulzantes sin azúcar (en la grasa corporal y la circunferencia de la cintura, peso corporal, IMC, glucosa en ayunas, hemoglobina glicosilada, presión arterial sistólica, presión arterial diastólica, colesterol HDL),¹³ fue desestimada a favor de la evidencia observacional de certeza muy baja a baja (conocida por sufrir de confusión residual y causalidad inversa) que finalmente sirvió como base para las recomendaciones condicionales en este Borrador.

Los beneficios de los edulcorantes bajos en calorías y sin calorías están respaldados por una gran cantidad de ensayos controlados aleatorios a corto y

¹² World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). *Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis*. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. Licencia: CC BY-NC-SA 3.0 IGO; “Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J. “Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies” BMJ 2019; 364 :k4718 doi:10.1136/bmj.k4718)

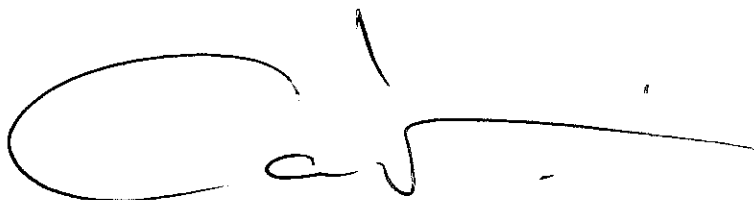
largo plazo en seres humanos, bien realizados y que proporcionan evidencia de alta calidad. No considerar la evidencia colectiva sobre los efectos en la salud de los edulcorantes sin azúcar ni traducir con precisión la totalidad de la evidencia disponible en una recomendación en vista de la jerarquía de la evidencia científica, puede obstaculizar los esfuerzos de salud pública para reducir el consumo excesivo de azúcar y abordar la obesidad.

Conclusión

Apreciamos el esfuerzo de la OMS por brindar orientación a los responsables de formular políticas sobre edulcorantes sin azúcar, sin embargo, creemos que cualquier orientación debe estar fundamentada en la ciencia, mostrar coherencia en la política y seguir la hoja de ruta de las prioridades de salud recientes establecidas por los Estados miembros.

Por lo anterior, CACIA muy respetuosamente solicita a la OMS revisar este borrador en el contexto de las Hojas de Ruta recientes de la ONU de Alto Nivel, ya que, basar las recomendaciones en evidencia de baja calidad puede, en última instancia, llevar a los Estados miembros a promulgar una legislación que potencialmente ponga en peligro los resultados positivos de la salud pública.

Con muestras de consideración,

A handwritten signature in black ink, appearing to read 'C. Antillón Morera', with a long horizontal stroke extending to the right.

Carlos Antillón Morera

Cámara Costarricense de Industria Alimentaria

Survey response 12

General information

Family/last name
THOMPSON
Given/first name
Jennifer
Organization/affiliation
Australian Industry Group (Ai GroupP
Sector
Other
Sector [Other]
Industry Associationi
Country
Australia

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
<input type="text"/>

Ai GROUP SUBMISSION

**Response on the draft WHO
guideline on use of non-sugar
sweeteners**

AUGUST 2022



About Australian Industry Group

The Australian Industry Group (Ai Group) is a peak industry association in Australia which, along with its affiliates, represents the interests of more than 60,000 businesses in an expanding range of sectors: manufacturing, engineering, construction, automotive, food, transport, information technology, telecommunications, call centres, labour hire, printing, defence, mining equipment and supplies, airlines, health and other industries. The businesses which we represent employ more than one million people. Ai Group members operate small, medium and large businesses. Ai Group is closely affiliated with many other employer groups and directly manages a number of those organisations.

The Ai Group represents the Australian and New Zealand confectionery industry through its Confectionery Sector, representing manufacturers of chocolate, sugar and gum confectionery; suppliers of ingredients, machinery, packaging materials and services to the industry, and wholesaler and distributor firms. The Ai Group has approximately 120 confectionery sector members. Major confectionery manufacturing plants are principally located in New South Wales, Tasmania and Victoria, including in a number of regional locations (eg Ballarat and Lithgow) and in South Australia, Western Australia, Queensland and New Zealand.

Australian Industry Group Confectionery Sector contact for this submission

Jennifer Thompson – Ai Group Confectionery Sector – Technical & Regulatory Manager

Telephone: 0418 223170 or 03 9867 0181

Email: jennifer.thompson@aigroup.com.au

Submission : Response on the draft WHO guideline on use of non-sugar sweeteners

The Australian Industry Group (Ai Group) Confectionery Sector welcomes the opportunity to comment on the draft WHO guideline on use of non-sugar sweeteners.

The submission is made in consultation with our Australasian confectionery industry members.

Summarising Statement

The WHO has established a draft recommendation on use of non-sugar sweeteners (NSS) *“to provide evidence-informed guidance on the use of NSS by consumers”*. It is further stated that *“The recommendation in this guideline can be used by policymakers and programme managers to address NSS use in their populations through a range of policy actions and public health interventions”*.

To the end, the WHO has suggested (conditional recommendation) that non-sugar sweeteners (NSS) not be used as a means of achieving weight control or reducing risk of non-communicable disease.

This conditional recommendation for non-sugar sweeteners (NSS) not to be used is based on limited, low-quality evidence. Although there are some observational studies linked to undesired health effects, the totality of the evidence and the weight of the evidence does not support the statement reached in the WHO Draft Guideline.

Previously, WHO determined the relationship between free sugars intake and body weight (low and moderate quality evidence) and dental caries (very low and moderate quality evidence) which led to the strong recommendation to reduce “the intake of free sugars throughout the life course”. Implementation of the conditional recommendation not to use NSS is contradictory to the existing aim to reduce free sugars and will not contribute to a reduction in morbidity and mortality. This WHO guidance on the use of NSS will effectively have a very significant impact on the ability to reduce sugars levels in food and drink products via product reformulation, and it can be expected that consequently sugars levels in foods and drinks will continue to increase, very likely also leading to confusion amongst consumers and food operators alike. NSS are a useful option for manufacturers to help make products with less sugar and less energy, while being palatable.

NSS have been extensively studied for their safety and rigorously tested by national and international bodies prior to the approval for use and consumption. NSS are a part of a safe and valuable endorsed strategy to replace sugars, with benefits in short term weight management, blood glucose management, dental health and other positive health outcomes.

Summary of Evidence

Totality of the science and weight of evidence does not support the WHO guideline on NSS use

The statement in the WHO draft guideline on the undesirable effects from long-term use of NSS, is based on limited, low-quality evidence from observational studies¹ which are at-risk of residual confounding and reverse causality as acknowledged in the guideline. This statement contradicts the aligned position taken by regulatory authorities around the world that confirmed the safety of NSS, even among vulnerable populations such as pregnant women and children.

In addition, results from meta-analyses of randomized controlled trials (RCTs) in the study² confirmed that NSS have no adverse impact on cardiometabolic risk factors, including glucose and insulin levels, blood lipids and blood pressure. In the presence of higher-quality evidence from RCTs, low certainty evidence from observational studies should be interpreted with caution.

The authors mentioned that results of observational studies^{2, 3, 4} on the health effects of NSS should be interpreted with focus on plausible residual confounding as well as reverse causality (“a positive association between NSS consumption and weight gain in observational studies may be the consequence of response to health issues such as obesity and not the reason for overweight and obesity.”). Most of the observational studies adjusted from BMI but not body weight. Human fluid requirements are directly related to body weight (35-45mL per kg body weight), not BMI. All but two of the included observational studies were confounded by this factor. It is not scientifically robust to group such a diverse set of molecules together on the basis of sweetness, given that NSS are all digested, absorbed, metabolised and excreted differently.

In terms of the congruency of cohort studies with in-vitro and animal models, it is important to note also that these models usually involved lifelong feeding of specific NSS at greater than Acceptable Daily Intake (ADI) amounts in pure form. Australian data has shown that most consumers have less than 10% of the ADI which is in the dilute form (requirement of Food Standards Australia New Zealand, Standard 1.3.1-5)⁵. Therefore, results of most animal studies are not relevant to free-living humans.

Finally, NSS use in personal care and hygiene products (eg toothpaste and mouthwash) or pharmaceutical products were not considered, thereby not capturing all sources. As such, these results should not be used as the key evidence as basis for the conditional recommendation in WHO draft guidelines.

Role of NSS in weight management, glucose control, dental health and other positive benefits

When NSS are used to replace sugars, they result in lower-sugar foods and beverages that can be useful dietary tools in three ways: to lower energy intake when there is excess sugar intake; for diabetes meal planning; and for nutritional strategies for dental health.

The best-quality evidence from meta-analyses of randomized controlled trials (RCT), as assessed in Rios-Leyvraz and Montez², confirmed that consuming NSS led to a significant energy reduction when compared to sugars, which may support short-term weight loss without affecting overall glucose control and other cardiometabolic risk factors.

The WHO draft guideline on use of NSS only looked at medium and long-term effects of NSS on cardiometabolic health and hence does not acknowledge the NSS' short-term benefits. It is important to point out that, the short-term benefits of NSS used in place of sugars, such as in post-prandial blood glucose control and in dental health, should also be considered when evaluating NSS overall role in the diet.

A few RCTs on the issues of dental health were included in the draft NSS Guideline, but their importance was greatly downplayed. This is in contrast to the strong emphasis in the WHO Guideline: Sugars intake for adults and children where the results of the Moynihan and Kelly systematic review⁶ that formed the basis for the 10% and 5% of energy recommendations was given huge weighting, despite the authors acknowledging that *"the evidence was judged to be of very low quality"*. Given this, we question why a separate, more comprehensive systematic review was not undertaken investigating the effect of NSS on dental caries. Furthermore, limited data identified by Rios Leyvraz and Montez in their systematic review and meta-analysis² which showed a dental health benefit, was not considered in supporting a recommendation to use NSS instead of free sugars.

Globally, 537 million, approximately 1 in 10 adults, are living with diabetes⁷. NSS are a beneficial dietary tool for those with diabetes. The availability of the approved NSS has made possible a wider range of lower sugar products that can provide a larger choice for people with diabetes. By discouraging reformulation with NSS, the draft WHO recommendation may negatively influence the availability of food and drink choices for those people with diabetes, unintentionally impeding efforts to limit the intake of sugars. While the recommendation may not be relevant to people with diabetes, a very probable undesirable effect of the recommendation on this community must be well-thought out. Maintaining the assurance in NSS as a helpful alternative to sugar is crucial for people living with diabetes.

There are 3.5 billion cases of dental caries, subsequent periodontal (gum) disease and ensuing tooth loss globally making oral diseases the most prevalent non-communicable disease (NCD). The draft WHO guideline on use of NSS did not consider the available scientific data evaluating the health benefits of NSS on dental health (tooth mineralization) when NSS are consumed instead of sugars. Not including the benefits of NSS for oral health is a lost opportunity and a

misalignment with the global NCD agenda, where the WHO has recommended to reduce the intake of free sugars to below 5% of total energy to have additional oral health benefits. The recent WHO global strategy on oral health, adopted at the World Health Assembly in May 2022 further points to the importance of addressing oral health. It is therefore essential to consider the potential undesirable effect of not including oral health in the draft guideline on the global effort to address NCDs. The oral health benefits provided by NSS are critical ingredients in sugar-free chewing gum, hygiene, and personal care oral products. It should be strongly highlighted in the final WHO guideline document that there were some publications highlighting the oral health benefits of NSS, and that more research is needed.

These many health benefits have been recognised by the European Food Safety Authority (EFSA)⁸. In 2011, the EFSA Panel on Nutrition, Novel Foods and Food Allergens concluded that there was sufficient scientific evidence to support the claims that intense sweeteners led to a lower rise in blood sugar levels after meals if consumed instead of sugars and maintained tooth mineralisation. NSS are not fermentable by oral bacteria, they cannot contribute to or promote dental decay. Along with good dental hygiene, dentists may recommend NSS as a way to help prevent tooth decay, if consumed instead of sugars, as part of a balanced diet to decrease tooth demineralization⁹.

NSS are safe and confirmed as such by global food safety authorities

All NSS have undergone an extensive safety evaluation process by international and national regulatory food safety bodies both before and after their approval for use in the market. The FAO/ WHO Joint Expert Committee on Food Additives (JECFA)¹⁰, the US Food and Drug Administration (FDA)¹¹ and EFSA¹² have confirmed the safety of all approved NSS as food additives. All legally authorized sweeteners, under food additives, are safe for consumption under the established maximum use levels in the defined food categories.

There is an extensive body of evidence from both animal models and human studies that support the safety of NSS for the general population including the elderly, children, pregnant and lactating women, within Acceptable Daily Intake (ADI) limits. Furthermore, there is an ongoing review process to ensure that any new information on safety on NSS is re-evaluated.

Evidence to Recommendations

Role of NSS in relation to nutrition and public health policy

Reduction in the intake of 'free sugars' and 'added sugars' is being recommended around the world to reduce the risk of obesity, which is a major public health concern¹³. A number of health policies acknowledge NSS consumption as a useful strategy to reduce sugars intake, including a systematic review by the US Dietary Guideline Advisory Committee of the Dietary Guidelines for Americans, 2020-2025¹⁴, as well as Public Health England¹⁵. Governments around

the world are trying to tackle the problem of rising rates of obesity and diabetes, along with dental diseases. NSS are a critical tool that, along with exercise and a healthy diet, can help consumers achieve their dietary and weight management goals.

Being several hundred times sweeter than sugar, they are used in minute amounts to confer the desired level of sweetness, while contributing very little or no energy at all to the foods and drinks they are used in. This offers one major advantage to food manufacturers to fulfil consumers taste expectation and, ultimately, consumers: providing sweet taste whilst eliminating or substantially reducing the energy from sugars in a food or drink.

WHO draft guideline on use of non-sugar sweeteners may confuse consumers

WHO recommends not to use NSS as a means for weight control which will bring confusion to consumers who want to manage their sugars and carbohydrate intake, especially if they refer to diabetes and nutrition-related organizations such as Diabetes UK¹⁶, they do support the use of NSS for energy intake reduction and diabetes management¹⁶⁻¹⁸.

From a public health policy perspective, a key undesirable effect of the WHO recommendation would be the potential discouragement of the industry's sugar reduction effort. This in turn could have a negative impact on the availability of lower sugar and no sugar food and drink options on the market, limit consumer choice and hinder individuals' efforts to reduce their free sugars intake.

Conclusion

NSS have been extensively studied for their safety and rigorously tested by national and international bodies prior to the approval for use and consumption. The WHO conditional recommendation for non-sugar sweeteners (NSS) not to be used is based on limited, low-quality evidence. Although there are some observational studies linked to undesired health effects, the totality of the evidence and the weight of the evidence does not support the statement reached in the draft Guideline. Implementation of the conditional recommendation not to use NSS is contradictory to the existing aim to reduce free sugars and will not contribute to a reduction in morbidity and mortality.

Reduction in the intake of 'free sugars' and 'added sugars' is being recommended around the world to reduce the risk of obesity, which is a major public health concern¹⁹. Governments around the world are trying to tackle the problem of rising rates of obesity and diabetes, along with dental diseases. NSS are a critical tool that, along with exercise and a healthy diet, can help consumers achieve their dietary and weight management goals. NSS are a part of a safe and valuable endorsed strategy to replace sugars, benefitting in short term weight management, blood glucose management, dental health and other positive health outcomes.

Public policy should be developed exclusively on the foundation of the highest quality and most comprehensive evidence. It is counter to public health to base dietary recommendations on poor-quality evidence, and neglect higher quality research from RCTs supporting beneficial effects of NSS use on reduced energy intake, weight, glucose control, and dental health.

Reference:

1. Draft WHO guideline: use of non-sugar sweeteners. <https://www.who.int/news-room/articles-detail/online-publicconsultation-draft-guideline-on-use-of-non-sugar-sweeteners>
2. World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO
3. Toews I, Lohner S, Ku?llenberg de Gaudry D, Sommer H, Meerpohl JJ. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies. *BMJ* 2019;364:k4718
4. Lohner S, Toews I & Meerpohl JJ. Health outcomes of non-nutritive sweeteners: analysis of the research landscape. *Nutr J* 2017;16(1):55
5. Australia New Zealand Food Standards Code: www.foodstandards.gov.au
6. Moynihan PJ and Kelly SAM (2014) Effect on Caries of Restricting Sugars Intake, *J Dent Res*. 93(1):8-18
7. IDF, 2015
8. EFSA. Scientific opinion on the substantiation of health claims related to intense sweeteners. *EFSA Journal* 2011;9(6):2229.: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>
9. Roberts MW, Wright JT (2012), Nonnutritive, Low Caloric Substitutes for Food Sugars: Clinical Implications for Addressing the Incidence of Dental Caries and Overweight/Obesity, *International Journal of Dentistry*.
10. JECFA: <http://apps.who.int/food-additives-contaminants-jecfadatabase/search.aspx?fc=66>
11. USFDA: <https://www.fda.gov/food/ingredientpackaginglabeling/foodadditivesingredients/ucm397725.htm>
12. EFSA: <https://www.efsa.europa.eu/en/topics/topic/sweeteners>
13. WHO Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015
14. Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC

15. Public Health England (2015) Sugar reduction: the evidence for action. PHE publications gateway number 2015391. [https:// www.gov.uk/government/publications/sugar-reduction-from-evidence-into-action](https://www.gov.uk/government/publications/sugar-reduction-from-evidence-into-action) (accessed August 2019)
16. Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>
17. Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. *Diabetes Care*. 2019 May;42(5):731-754
18. Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. *Journal of the Academy of Nutrition and Dietetics* 2017;117(10):1659-79
19. WHO Guideline: Sugars intake for adults and children. Geneva: World Health Organization; 2015

Survey response 13

General information

Family/last name
Schmidtke
Given/first name
Andrea
Organization/affiliation
Obesity Policy Coalition
Sector
Non-governmental agency
Sector [Other]
Country
Australia

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"","comment":"","size":"183.28125","name":"Call%20for%20comment%20WHO%20guideline%20on%20NNS%20-%20O PC%20Submission.pdf","filename":"fu_vqsg5xketi688jy","ext":"pdf"}]]



Call for comment: draft WHO guideline on use of non-sugar sweeteners

Obesity Policy Comments on the draft guideline August 2022

The Obesity Policy Coalition (OPC) is an Australian public health advocacy partnership between Cancer Council Victoria, VicHealth and the Global Centre for Preventative Health and Nutrition at Deakin University; a World Health Organization (WHO) Collaborating Centre for Obesity Prevention. The OPC advocates for evidence-based policy and regulatory change to address overweight, obesity and unhealthy diets in Australia, particularly among children.

The OPC welcomes the development of the draft WHO guideline on use of non-sugar sweeteners (the Guideline) and acknowledges the important role of the WHO in supporting and guiding policy in efforts to reduce sugars intake and promote healthy diets.

Summary of evidence

The OPC supports the summary of evidence presented in the Guideline and the recently published WHO systematic review and meta-analysis on the health effects of non-sugar sweeteners that underpins the Guidelineⁱ (the Review). The Review, and supporting literature, clearly show links between non-sugar sweeteners and adverse health outcomes. We note however, that much of the literature is funded or affiliated with the food industry. As there is a clear conflict of interest in this literature, we caution its inclusion in WHO's decision making process.

In addition to the evidence base presented in the Review we note a recent publication that assessed the global, regional, and country income category trends in added sugar and non-sugar sweetener sales globally.ⁱⁱ In this study, it was found that the sale of non-sugar sweeteners (and by proxy consumption) in both food and beverages is increasing globally and, in most regions and country income categories. Of particular concern, the study found that the sweetness of the packaged food supply increased over time. Additionally, regions with more sugar-related policy actions had a significant increase in the volume of non-sugar sweetener quantities from beverage sales ($r=0.68$, $p=0.04$).

There is also a growing body of literature that links non-sugar sweeteners to issues outside metabolic harms:

- habitual non-sugar sweetener consumption may contribute to shifting population taste preferences towards sweeter palates.ⁱⁱⁱ
- non-sugar sweeteners are used exclusively in ultra-processed foods (UPFs), defined as industrial formulations which typically contain processed food substances.^{iv} UPFs are markers of poor diets^v and have known adverse health^{vi} and environmental^{vii,viii} impacts. UPFs which contain non-sugar sweeteners often carry health claims, including 'low sugar', and thus receive a 'health halo' and potentially displace nutritious whole foods from the diet.

Evidence to recommendations

The OPC strongly supports the translation of the evidence to recommendations. We also appreciate the obvious consideration for the nuance within and between sweetener types. We hope that the inclusion of all sweeteners in this recommendation reduces the apparent 'health halo' that is given to foods that promote claims of 'low sugar' or the addition of a 'natural sweetener' (including stevia).

Recommendations and supporting information

The OPC strongly supports the recommendation included in the draft guideline. **We strongly agree with the WHO draft position NOT to recommend non-sugar sweeteners to control weight OR to reduce the risk of non-communicable disease for the general population.** In particular, the evidence provided demonstrates that not only do non-sugar sweeteners lack efficacy to reduce the risk of non-communicable disease, or to control weight; they in fact contribute to the development of these adverse health outcomes. As such, these additives are not a 'fit for purpose' solution to public health risks related to diet.

There is content in the Guideline regarding the need to promote minimally processed, nutritious, whole foods, which we feel is imperative to sustain public health improvements. We argue that this should be given stronger prominence in the guideline.

Other comments

With a growing focus on free sugars in public health and the media, and a number of policy actions recommended and, in many countries, implemented to reduce their consumption, there has been an increasing reliance from manufacturers to add non-sugar sweeteners to their ultra-processed products. In Australia, and many other countries, there has been rapid and increasing approvals by food regulation authorities to increase the type and amount of non-sugar sweeteners in a growing variety of food and drinks.^{ix} We hope this recommendation will be useful for food regulators and governments when considering such policy actions and applications in the future.

ⁱ Rios-Leyvraz M, Montez J, World Health Organization. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis.

ⁱⁱ Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. *Public Health Nutrition*.:1-39.

ⁱⁱⁱ Rios-Leyvraz M, Montez J, Organization WH. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. 2022.

^{iv} Monteiro CA, Cannon G, Levy RB, Moubarac J-C, Louzada ML, Rauber F, et al. Ultra-processed foods: what they are and how to identify them. *Public health nutrition*. 2019;22(5):936-41.

^v Marchese L, Livingstone KM, Woods JL, Wingrove K, Machado P. Ultra-processed food consumption, socio-demographics and diet quality in Australian adults. *Public Health Nutrition*. 2022;25(1):94-104.

^{vi} Elizabeth L, Machado P, Zinöcker M, Baker P, Lawrence M. Ultra-processed foods and health outcomes: a narrative review. *Nutrients*. 2020;12(7):1955.

-
- ^{vii} Leite FHM, Khandpur N, Andrade GC, Anastasiou K, Baker P, Lawrence M, et al. Ultra-processed foods should be central to global food systems dialogue and action on biodiversity. *BMJ Global Health*. 2022;7(3):e008269.
- ^{viii} Anastasiou K, Baker P, Hadjikakou M, Hendrie GA, Lawrence M. A conceptual framework for understanding the environmental impacts of ultra-processed foods and implications for sustainable food systems. *Journal of Cleaner Production*. 2022 Jul 21:133155.
- ^{ix} Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. *Public Health Nutrition*.:1-39.

Survey response 14

General information

Family/last name
Bharadwaj
Given/first name
Agastya
Organization/affiliation
Australian Government Department of Health and Aged Care
Sector
Government
Sector [Other]
Country
Australia

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Australia's Written Submission - Draft Guideline on use of non-sugar sweeteners","comment":"","size":"21.0712890625","name":"Australia%27s%20Written%20Submission%20-%20Draft%20Guideline%20on%20use%20of%20non-sugar%20sweeteners.docx","filename":"fu_k996kzwht69pcrs","ext":"docx" }]

Online public consultation: Draft guideline on use of non-sugar sweeteners- Comments from Australia

Australia welcomes the opportunity to provide a submission to the online public consultation on the draft guideline on use of non-sugar sweeteners. Our comments on the draft guideline are outlined below.

General comments:

- We note that the guideline is likely to raise questions and potential concerns about the safety assessments conducted by Joint FAO/WHO Expert Committee on Food Additives (JECFA). As JECFA is established as a joint FAO/WHO committee, ideally, those sweeteners for which health concerns have been raised by new studies should be prioritised for an updated assessment by JECFA. However, the WHO (2022) systematic review assessed non-sugar sweeteners as a class, and this approach does not allow for the identification of potential health concerns that may be attributable to a specific sweetener.
- The title use of non-sugar sweeteners should be clarified to align with the scope of the evidence assessment and recommendation i.e. Guidance on use of Non-Sugar Sweeteners (NSS) as a means for achieving weight control. This would provide clarity and re-iterate that the guidance is not intended to provide alternative safety guidance to assessments undertaken by JECFA.
- The document notes the physiological and metabolic impact of NSS differ between specific sweeteners, however, considers evidence and makes recommendations for NSS collectively. **Comment:** There may be benefit for further guidance (possibly at a later date) around individual NSS if some provide greater benefits/risks than others. This would help member states/food companies make more specific recommendations and reformulation decisions going forward.

Introduction (Section 1)

- We note that the guideline was developed in accordance with the WHO evidence-informed guideline development process outlined in the *WHO Handbook for Guideline Development*. It is stated that because of the complex nature of the guideline topic and rapidly evolving evidence base, the guideline was developed over several, successive meetings of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health, beginning in 2016. The rapidly evolving evidence base raises the question of the anticipated timeframe for a future update of the guideline.
 - **Comment:** It is noted that this issue is discussed under the section “Updating the guideline” (page 47). It is suggested that a cross-reference to this information is added to this section.
- The scope section notes this guideline is an extension of other guidelines particularly related to sugars. The WHO guideline development process includes consideration of additional, potentially mitigating factors. This is explained in the footnote to include considerations related to: *the priority of the problem that the recommendation addresses; values and preference related to the recommendation in different settings; the cost of the options available to public health officials and program managers in different settings, feasibility and acceptability of implementing the recommendations in different settings; and the potential impact on equity and human rights.*

- **Comment:** There is little comment on how feasible it is for the various stakeholders to utilise this recommendation and link to existing interventions around sugar. Some guidance on this could be included.
- It is stated that the recommendations and other elements of the guideline will hopefully support the 2030 Agenda on Sustainable Development and achieving the Sustainable Development Goals (SDGs), including Goal 2 of Zero Hunger. However, there is no discussion of how the guideline could potentially support this goal.

Summary of Evidence (Section 3)

- It is stated that “A systematic review...identified 283 unique studies, including 50 randomized controlled trials, 97 prospective cohort studies, and 47 case-control studies assessing cancer outcomes”. The nature of the remaining 89 studies (to make up 283 in total) is not mentioned, however this information is provided in the WHO (2022) systematic review on the health effects of the use of non-sugar sweeteners.
 - **Comment:** For clarity, it is suggested that this information is incorporated into the guideline.
- It is stated that some studies could not be meta-analysed. It is suggested that the reason(s) for this are described in the guideline.
- Based on results from randomised, controlled trials in children, the certainty in the evidence for a beneficial effect on body weight, waist circumference, and body fat mass was considered to be moderate (Table 2). The overall certainty in the available evidence for outcomes in children was considered to be very low. **Comment:** It is suggested that there is some discussion of how this very low overall certainty was derived.
- On page 31 it is stated that “...it can be difficult for some [individuals] to switch from free sugars to NSS”. It is suggested that additional information is provided on this point, particularly evidence indicating the prevalence of this difficulty.
- The discussion on reverse causation is important and the explanation of the analysis to exclude those already at high risk of disease at baseline is very valuable in understanding the risks and relationships between NSS use and risk of non-communicable disease.
- Noting this section has information on the effects of NSS consumption amongst pregnant women, the document would benefit from some discussion on the consumption of NSS amongst lactating women and any associated impacts on their babies.
- The sub-section ‘NCDs and mortality’ could benefit from comparisons between NSS and equivalent amounts of sugar if available. Simply stating higher intakes of NSS result in higher risk of Type-2-Diabetes, Cardiovascular Disease and all-cause mortality neglects the fact that most individuals/countries introduce NSS as a substitute to sugar, which has significant impacts on risk factors for Type-2-Diabetes, Cardiovascular Disease and all-cause mortality.
- It is stated several times that “GRADE assessments for each outcome can be found in Annex 1”. The GRADE assessments are at Annex 6.
- Minor typo at the bottom of page 30, “significant impact on the observations associations” should be “significant impact on the observed associations”.

Evidence to recommendations (Section 4)

- This section notes the recommendation/intervention is a ‘dietary goal’ and a suggestion to exclude NSS in the diet. The recommendation is focused on not using NSS as a means of weight loss. This section discusses health benefits, this link could be made clearer.

- It is stated that “The overall certainty in the evidence was considered low and is based on undesirable effects of non-sugar sweetener use on prioritized health outcomes observed in prospective cohort studies which were individually considered to be very low to low.”
 - **Comment:** This statement could cause confusion. Whether the observed effects are undesirable or not is irrelevant to the assessment of certainty in the evidence.
 - **Comment:** It is also noted that this statement on overall certainty does not account for certainty in the evidence from randomised, controlled trials. It is suggested that such information is included.
- As the recommendation does not provide any guidance on how the proposed audience of policy makers, health professionals, scientists, industry, educators etc should utilise the guidance (dietary goal). There is a risk that this guidance will result in messaging to consumers which will create confusion and fear. The recommendation section notes this is a conditional recommendation meaning there is uncertainty that the desirable consequences of the recommendation will outweigh the undesirable consequences. This should be acknowledged in the discussion.
- In the rationale for the recommendation on not using NSS as a means of achieving weight control or reducing NCD risk, it states the NUGAG Subgroup on Diet and Health noted that ‘there were no identified undesirable effects or other mitigating factors that would argue against not using NSS’. **Comment:** This statement is very confusing as there are many double negatives in this sentence which makes it difficult to understand.

Recommendation and supporting information (Section 5)

- We note that the recommendation “suggests” that NSS not be used, and the recommendation is “conditional”. Because of the lack of certainty in the recommendation, we consider it to have negligible practical value. Moreover, the recommendation may result in undesirable health outcomes for some individuals, i.e. those who have reduced their sugars intake due to the use of non-sugar sweeteners may stop using them, resulting in increased sugars intake and associated adverse health outcomes.
- In the context of the short duration (several months or less) of most randomised, controlled trials on non-sugar sweeteners, it is stated on page 41 that “...weight loss and maintenance of a healthy weight must be sustained over the long-term to have a meaningful impact on health...”. **Comment:** It is suggested that some discussion or definition of “long-term” is included (noting that maintenance of a healthy weight over a lifetime is clearly the most desirable scenario and reducing sugars intake over the long-term through use of non-sugar sweeteners may aid the achievement of this goal).
- In the rationale for the recommendation on not using NSS as a means of achieving weight control or reducing NCD risk, it states the NUGAG Subgroup on Diet and Health noted that ‘there were no identified undesirable effects or other mitigating factors that would argue against not using NSS’. **Comment:** This statement is very confusing as there are many double negatives in this sentence which makes it difficult to understand.
 - **Comment:** Does this statement extend to replacing NSS with sugar? An obvious undesirable effect of the recommendation is that people will revert from using NSS to using sugar, therefore the Group should be clear on their position here and elsewhere in the document stating that where external sweeteners are used, sugar is preferred over NSS (or otherwise).
 - **Comment:** The recommendation needs to be contextualised in relation to use of sugar to be helpful and practical.

Dissemination, Translation and implementation, and Monitoring and evaluation (Section 6, 7 and 8)

- This section would benefit from comparison with the WHO Guideline: sugars intake for adults and children. For example, consideration of the evidence and the strength of the evidence on NSS vs sugar, where should Member States focus their efforts to improve health outcomes.
- Careful messaging of the recommendation and underlying evidence base is required. Some of the statements related to the evidence summaries may cause alarm for consumers. For example, it could be understood that the guideline recommends not consuming NSS due to increased risk of NCDs, mortality and pre-term birth when consumed in pregnancy. This is when consumed with the ADIs set by JECFA.
 - More consideration needs to be given to how this recommendation will be communicated. It is possible that disseminating guidelines such as this which are based on predominantly based on low and very low certainty evidence may affect trust and credibility of the broader suite of WHO guidelines and result in less attention and importance being given WHO guidelines, including those with stronger evidence. **Comment:** We therefore urge careful consideration for how this guideline is to be published and disseminated to maintain the trust and credibility of the WHO.
- It may be more suitable that this document be published as a research summary and additional dietary guidance attached to the WHO sugars Guideline. This could reference the systematic literature review, with recommendations for where further research could be undertaken, rather than publishing this as a formal guideline, given the potential for it to impact trust and credibility of the broader suite of WHO Guidelines.
- Monitoring and evaluation section suggests broad adoption of the guideline across all countries despite the lack of suggested ways to implement the recommendation. This has potential for confusion among member states.

Research gaps and future initiatives and Updating the guideline (Section 9 and 10)

- This section includes a comprehensive summary of further research needed. If relevant in the scope of a guideline, it would be useful to include further details noting specifically what should be included. This will ensure that any future studies in this area contain the evidence needed to be able to make more informed conclusions and increase the rating of the evidence used. For example, it is noted that more robust exposure assessments are needed within studies but doesn't explicitly note what data or evidence should be collected or generated.

Survey response 15

General information

Family/last name
La Vecchia
Given/first name
Carlo
Organization/affiliation
University of Milan, I
Sector
Academic/research
Sector [Other]
Country
Italy

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"","comment":"","size":"14.736328125","name":"COMMENTS%20ON%20THE%20WHO%20DRAFT%20GUIDELINE.docx","filename":"fu_3n7cbibpzabhku4","ext":"docx"}]

COMMENTS ON THE WHO DRAFT GUIDELINE: USE OF NON-SUGAR SWEETENERS (NSS).

In the draft WHO guideline, “**WHO suggests that NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases (conditional recommendation)**”.

This conditional (**based on evidence of low certainty**) WHO recommendation is essentially based on the findings from observational (cohort) studies providing information on potential long term use, though only a proportion of observational studies have repeated measures of exposure to NSS.

Observational studies are exposed to a series of biases, and can hardly prove very modest associations, i.e. relative risks of the order of 1.1 to 1.3, as those listed in Table 1 of the Guidelines. Observational studies are exposed to from the usual information, selection, follow-up participation biases, etc. More important the key issue here is **reverse causation**, i.e. overweight and obese subjects tend to use more frequently NSS, and this may apply – apart from diabetics – to subjects at high risk of vascular disease, i.e. those with hypertension, hypercholesterolemia, etc.

The evidence from observational cohort studies is inconsistent with that from randomized clinical trials (RCT) which indicate moderate but consistent favourable effects of NSS on measures of body weight and consequently indicators of metabolic and cardio-metabolic risk.

The evidence from long-term observational studies on NSS frequently lacking repeated measurement of exposure is therefore hardly interpretable, if at all interpretable, and its use as a basis of the WHO Guidelines is consequently open to criticism.

It is also inconsistent with data of observational studies with repeated exposure measurements, which allowed analysis of change or substitution of NSS over time (Lee et al, 2022). The overall evidence from a meta-analysis of the 14 prospective studies providing such information on exposure follow-up indicate no unfavourable cardio-metabolic effect of NSS and, if anything, a modest cardio-metabolic benefit of substitution for NSS. This is consistent with the key findings from RCTs.

Reference

Lee JJ, Khan TA, McGlynn N, Malik VS, Hill JO, Leiter LA, Jeppesen PB, Rahelić D, Kahleová H, Salas-Salvadó J, Kendall CWC, **Sievenpiper JL**. *Diabetes Care*. 2022 Aug 1;45(8):1917-1930. doi: 10.2337/dc21-2130 [Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages With Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies](#). -2130

Carlo La Vecchia, M.D.
Professor of Medical Statistics and Epidemiology
Dept. of Clinical Sciences and Community Health
Università degli Studi di Milano (“La Statale”)
Via Celoria, 22
20133 Milano - Italy
carlo.lavecchia@unimi.it

CLV is member of the ISA Scientific Advisory Panel

Survey response 16

General information

Family/last name
de Graaf
Given/first name
kees
Organization/affiliation
wageningen University and Research
Sector
Academic/research
Sector [Other]
Country
Netherlands

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"comment on WHO on NNS by Kees de Graaf","comment":"","size":"13.2158203125","name":"Comment%20of%20WHO%20guidelines%20on%20NNS%20august%202022%20by%20Kees%20de%20Graaf%20Wageningen%20University.docx","file name":"fu_8g9kz93g4yw2hjr","ext":"docx" }]

Comment of WHO guidelines on NNS august 2022 by Kees de Graaf Wageningen University

Summary of evidence

The evidence pyramid indicates that systematic reviews of RCT have the highest weight for recommendations. This is especially true for NNS where in observational studies on the relation between NNS use and body weight there is a serious risk of reverse causality. Table 28 – 30 which report the outcome of RCT's clearly indicates that the use of NNS to replace sugar helps to moderate energy intake and body weight. Why is this not acknowledged in the conclusion ?

Evidence to recommendations

The report misses a number of recent complete meta-analyses of observational studies, animal studies, short human RCT's, and long term human RCT's (Rogers et al, Int J Obes 2016; Rogers and Appleton, Int J Obes 2021). These meta-analyses show that NNS use to replace sugar help to reduce energy intake, both in adults and in children. In the meta-analysis of the WHO (ref 189), the report cites the only long term RCT done in children with this aim, but it dilutes with another study that was not aimed at the effect of NNS on body weight.

Recommendations and Supporting information

This report seems to have a bias against the use of low energy sweeteners (see e.g. Mela D, Is there an academic bias against low energy sweeteners; Nutrient 2022). For example, when discussing the mechanisms of NNS in paragraph six on page 30 -31, all type of physiological mechanisms come up, but the report forget to mention a review and systematic meta-analysis of studies on the effects of NNS on glucose and insulin metabolism (Greyling et al Am J Clin Nutr 2020). NNS have no effect on glucose or insulin.

The WHO review Figure 31 -34 shows that NNS help to reduce sugar intake, which is in line with WHO recommendations. Why is this reported in the conclusions.

On page 35 on feasibility, the report talks about the feasibility of taxing the use of NNS . Why is that in the light of the results of the RCT's on body weight

Other comments

Sweet taste is one of the most enjoyable sensations in human life. Food enjoyment is part of a high quality of life/health. NNS can help with this.

Survey response 17

General information

Family/last name
Appleton
Given/first name
Katherine
Organization/affiliation
Bournemouth University
Sector
Academic/research
Sector [Other]
Country
United Kingdom

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"WHO consultation response - Appleton","comment":"","size":"18.0078125","name":"WHO%20consultation.docx","filename":"fu_6rxueh8x3a68bpf","ext":"docx"}]]

WHO: Conditional recommendation on NSS: Public consultation
Prof. Katherine M Appleton, Bournemouth University, UK.

The WHO are proposing a conditional recommendation that NSS not be used as a means of achieving weight control or reducing risk of non-communicable diseases. I suggest this recommendation is premature, based on the (lack of) evidence that is currently available. The recommendation is based largely on a recent WHO commissioned systematic review of the health effects of NSS (1), which reports 'This systematic review of a large number of RCTs, prospective cohort studies and case-control studies found that NSS use results in a small reduction in body weight and BMI in adults, as assessed in RCTs (*low* certainty evidence) without significant effects on other measures of adiposity or cardiometabolic health, including fasting glucose, insulin, blood lipids and blood pressure (*very low* to *high* certainty evidence). p.43.'

Firstly, the vast majority of the evidence provided is rated by the authors using the GRADE system as 'low' or 'very low certainty' (see Annex 7), with a few results reported as 'moderate certainty', although none of those in Annex 7 are reported as 'high certainty'. The authors have also not downgraded evidence based on number of studies and notably most of the results that are considered of 'moderate certainty' are based on very few studies and very few participants. There is clear potential for bias when limited studies are considered (2). Downgrading based on low numbers of studies/participants would create a situation here where most if not all the evidence on which the proposed recommendations are based would be considered of 'low' or 'very low certainty'. No recommendations should be based on low or very low certainty evidence.

Secondly, the evidence suggests a small benefit for weight control – an effect that is reported also in other systematic reviews of the same topic (3,4), as stated by Rios-Leyvraz & Montez. This benefit is then disregarded, based on the suggestion that cohort studies provide weaker evidence of this benefit, that RCTs may not reflect the realistic situation, and that small benefit is meaningless for long term health. Regarding the first point, RCTs are considered top of the hierarchy of evidence (2), and weaker evidence should not over-rule this or, as above, be used to provide a recommendation. Regarding the second point, some of these trials are very long, so arguably become realistic, but importantly, the authors have no evidence here of any bias. On page 47 of their review, they discuss some possible scenarios where the consumption of NSS may not result in reduced body weight in the real world, but they fail to discuss the comparable situation where NSS can aid body weight reductions, e.g. when NSS replace sugar, despite the evidence of a benefit in their review. The evidence for NSS consumed as part of a calorie controlled diet is weaker, but only four studies are provided here, three of which suggest a benefit, and only two of these used NSS in place of sugars. Regarding the third point, plenty of evidence now suggests that overweight results gradually over time from small increases in energy intake relative to energy expenditure (e.g. 5). While weight reduction can be harder to achieve than weight gain, small reductions in energy intake (relative to energy expenditure) are suggested and even recommended to aid weight control (5). Again, no evidence is provided by the authors or the WHO to suggest that small reductions in energy intake over time may not be beneficial, or would be disadvantageous, to warrant a recommendation that NSS not be used.

Thirdly, and equally importantly, no evidence is provided that 'No identified undesirable effects or other mitigating factors would argue against not using NSS' (WHO draft guideline, p. 8.). Again, a recommendation can not be given based on a lack of evidence. Furthermore, the primary intended use of NSS within the food supply is to provide a pleasurable taste in the absence of energy, and undesirable effects due to a lack of pleasure within the diet are found in the literature (e.g. 6). I am not aware of a systematic review of the literature on pleasure, but considering the maintenance of dietary palatability to be a primary purpose of NSS, this evidence would need to be gathered before a comment on undesirable effects of not using NSS can be made. Evidence of the effects of removing NSS from habitual users is also notably absent from consideration by the WHO.

Further evidence on the potential positive and negative effects of NSS in realistic scenarios is needed before evidence-based recommendations can be made.

References

1. Rios-Leyvraz M, Montez J. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. Geneva: World Health Organization; 2022. Licence: [CC BY-NC-SA 3.0 IGO](#).
2. Higgins JPT, Green S. Cochrane handbook for systematic reviews of interventions. 5.1 edn. Chichester, UK: The Cochrane Collaboration & John Wiley & Sons, Ltd; 2011.
3. Laviada-Molina H, Molina-Segui F, Pérez-Gaxiola G, Cuello-García C, Arjona-Villicaña R, Espinosa-Marrón A, et al. Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: systematic review and meta-analysis. *Obes Rev*. 2020;21:e13020. doi: 10.1111/obr.13020.
4. Rogers PJ, Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes (Lond)*. 2021;45:464–78. doi: 10.1038/s41366-020-00704-2.
5. Hill JO, Wyatt HR, Peters JC. Energy balance and obesity. *Circulation* 2012;126:126-32. doi: 10.1161/CIRCULATIONAHA.111.087213.
6. Appleton KM, McGowan L. The relationship between restrained eating and poor psychological health is moderated by pleasure normally associated with eating. *Eating Behav*. 2006;7:342-347. <https://doi.org/10.1016/j.eatbeh.2005.11.008>.

Survey response 18

General information

Family/last name
Mackintosh
Given/first name
Anne-Marie
Organization/affiliation
Australian Food and Grocery Council
Sector
Other
Sector [Other]
Food Industry
Country
Australia

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Letter from the AFGC ","comment":"","size":"466.5859375","name":"AFGC%20letter_Draft%20WHO%20guideline%20us e%20of%20non-sugar%20sweeteners%20%28NSS%29_Final.pdf","filename":"fu_rq8jrg2vrz7nm56","ext":"pdf" }]

12 August 2022

Public consultation on the WHO draft guideline on use of non-sugar sweeteners (NNS)

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink, and grocery manufacturing industry. The membership of the AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 60 percent of the gross dollar value of the processed food, beverage, and grocery products sectors in Australia.

On 15 July 2022, the World Health Organization (WHO) published its draft guideline ('the guideline') on the use of non-sugar sweetenersⁱ aiming to provide guidance on their intake for the general population, especially regarding their impact on weight control and non-communicable diseases.

The AFGC welcomes the opportunity to comment on the *Public consultation on the WHO draft guideline on use of non-sugar sweeteners*. The consultation document has been reviewed and the comments below relate to this specific document.

In response to the consultation, the AFGC has had the opportunity to review the positionⁱⁱ to this consultation of the International Sweeteners Association (ISA). The AFGC strongly supports the ISA's and other industry positions and shares the concerns that the ISA has described in detail about the limited and low-quality evidence that underpins the 'conditional' draft WHO recommendation.

Comments

1. Evidence supports the useful role of low/no calorie/no kilojoule sweeteners in weight control

Concerns are raised about the limited and low-quality evidence that underpins the 'conditional' draft WHO recommendation.

- Evidence from higher quality research reviewed recently by WHOⁱⁱⁱ supports the useful role of low/no calorie sweeteners in sugar and energy reduction and, in turn, in weight loss. It is therefore surprising that this benefit is not acknowledged in the WHO recommendation suggesting no role for NSS in weight control.
- The totality and weight of the evidence does not support the statement reached in the draft guideline. i.e. NSS can be beneficial and are part of safe and valuable endorsed strategies for short-term weight management, blood glucose management (reduced postprandial glycaemia) and dental health (reduction of dental caries and increased tooth mineralisation).
- Observational data provide inconsistent and unreliable evidence about the association between NSS and obesity, as observational research in this field is prone to reverse causality, meaning that "a positive association between non-nutritive sweeteners consumption and weight gain in observational studies may be the consequence of and not the reason for overweight and obesity". By design, observational studies cannot establish a cause-and-effect relationship and provide evidence of low quality.
- Prospective cohort studies are also at a high risk of residual confounding and reverse causality, as higher consumers of NSS may choose these products because they are at greater risk for adverse cardiometabolic outcomes.

- Weight control and long-term weight loss maintenance is challenging to individuals living with overweight and obesity. NSS can be a useful dietary tool in providing wider options for sweet-tasting foods and beverages with less calories/kilojoules and sugars and help people living with obesity to follow a higher quality dietary pattern while trying to manage their body weight.

2. The WHO recommendation may be confusing to people with diabetes

The guideline states that assessing the health effects of NSS on individuals with pre-existing diabetes is beyond its scope, and therefore this recommendation is not relevant for people with diabetes. This is confusing and does not align with other authorities and NGOs' positions that low/no calorie sweeteners are a useful dietary aid for people with diabetes who are required to manage their carbohydrate and sugars intake.

- Based on the scientific opinion of the European Food Safety Authority (EFSA) in an authorised health claim in the EU Register of nutrition and health claims, it is recognised that '*the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods*' (Commission Regulation (EU) No 432/2012).^{iv} The absence of glycaemic effect of low/no calorie sweeteners, and the lower spike in postprandial blood glucose they cause when used instead of sugars, makes them a useful dietary aid for people with diabetes who need to manage their carbohydrate and sugars intake.
- Diabetes and nutrition-related organisations support the use of low/no calorie sweeteners for diabetes management. e.g., American Diabetes Association (ADA)^v and the US Academy of Nutrition and Dietetics^{vi}, and Diabetes UK Position Statement on low/ no calorie sweeteners ^{vii}.

3. The role of low/no calorie sweeteners in dental health is important and well-established

The guideline does not recognise the totality of evidence of the well-established benefit of low/no calorie sweeteners use in dental health. The implications of this, is that it may hinder public health efforts to reduce excess sugars intake and to tackle obesity.

- The excess intake of dietary sugars is a recognised contributor to dental caries in humans. Low/no calorie sweeteners can contribute to good dental health, when used in place of sugar, as they are non-fermentable by oral bacteria.
- EFSA supports in the respective scientific opinions^{viii} that "*there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralisation by decreasing tooth demineralisation if consumed instead of sugars*".

4. Reformulation and the role of industry

In 2018 the political declaration from the United Nations High-Level Meeting (HLM) on Non-Communicable Diseases (NCDs) called upon the private sector to "strengthen its commitment" to make further efforts to reformulate foods and beverages to reduce the excessive use of salts, sugars and fats in order to achieve the Sustainable Development Goal (SDG) 3.4.^{ix}

Industry has responded by reformulating products to provide healthier options, and the use of NSS is a useful option for food and beverage manufacturers to help make products with less sugar and fewer calories, while being palatable.

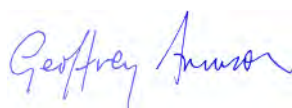
The WHO recommendation that "NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases" is inconsistent with the approach to addressing NCDs to which Member States have committed, of which sugar reduction via reformulation is critical.

The benefits of low/no calorie sweeteners when used in place of sugars are supported by a wealth of well conducted, acute, short- and longer-term randomised controlled trials in humans, which provide high quality evidence.

From a public health policy perspective, a key undesirable effect of the WHO recommendation would be the potential discouragement of the industry's sugar reduction effort and its contribution to Member States efforts to deliver on their commitments. This in turn could have a negative impact on the availability of lower sugar and no sugar food and drink options on the market, limit consumer choice and hinder individuals' efforts to reduce their free sugars intake.

The AFGC respectfully requests that WHO re-draft the guideline to include the totality of the evidence base including the WHO's commissioned studies from 2019 and 2022; acknowledges and gives regard to the roadmap for supporting reformulation by the private sector; and follow science-based policy to support Member States in achieving SDG 3.4.

Yours sincerely



Geoffrey Annison, PhD
Deputy CEO

ⁱ Draft WHO guideline: use of non-sugar sweeteners. <https://www.who.int/news-room/articles-detail/online-public-consultation-draft-guideline-on-use-of-non-sugar-sweetener>

ⁱⁱ International Sweeteners Association. [The WHO recommendation for non-sugar sweeteners use is not supported by the collective evidence - International Sweeteners Association](#) downloaded 12/8/22

ⁱⁱⁱ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO

^{iv} Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

^v Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019 May;42(5):731-754

^{vi} Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

^{vii} Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>

^{viii} EFSA. Scientific opinion on the substantiation of health claims related to intense sweeteners. EFSA Journal 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

^{ix} 1 See 2018 UN High Level Meeting on NCDs Political Declaration, A-73-L-2-EN at OP 44, available at <https://digitallibrary.un.org/record/1645265?ln=en> .

Survey response 19

General information

Family/last name
Barclay
Given/first name
Alan
Organization/affiliation
Alan Barclay (self employed)
Sector
Academic/research
Sector [Other]
Country
Australia

Comments on the draft guideline

Summary of evidence

The summary of evidence in the draft WHO guideline on use of non-sugar sweeteners (draft WHO guideline) is based on the systematic review and meta-analyses (SRMA) of Rios-Leyvraz and Montez (1), and is comprehensive and adequately reflects Rios-Leyvraz and Montez (1) results and conclusions. The section on interpreting the evidence also reflects Rios-Leyvraz and Montez (1), however, their interpretation of the evidence is not as comprehensive as it should be given the importance of the issue.

Randomised controlled trials

Rios-Leyvraz and Montez analysis and conclusions on data from randomised controlled trials (RCTs) are consistent with those from other recent SRMA's (2-4). The evidence supports the conclusion that higher intakes of non-sugar sweeteners (NSSs) result in a modest reduction in body weight (~0.7 kg) in the short-medium term. The conclusion that any changes in weight are due to energy restriction is also as expected and consistent with food regulators assessments of the individual NSSs.

The results from the RCTs are also consistent with the findings of the WHO sponsored SRMA of RCTs by Te Morenga et al (5) that forms part of the evidence base for the WHO Guideline: Sugars intake for adults and children (6), which determined that reducing dietary sugars (mostly added sugars) decreases body weight by a similarly modest 0.8 kg in the short-term (all included RCTs were ≤ 8 months duration).

The congruence between the two datasets is to be as expected – the effect of dietary sugars on body weight is modest, due in part to their relatively low energy density (≤16.5 kJ/g)(7), and therefore replacing them with NSS will have a modest effect on body weight, through modest energy reduction (-569 kJ/day).

Observational studies

Overarching issues

A fundamental flaw shared with a large proportion of the included observational studies is that while NSS share the same organoleptic property of sweetness, their molecular structure and consequently digestion, absorption, metabolism and excretion are all significantly different. It is therefore highly questionable whether they should all be lumped in together as if they are all “one and the same” in individual observational studies, let alone in meta-analyses.

It is also important to point out that despite their intense sweetness in pure form, in foods and beverages consumed by humans, NSSs are found in minute quantities. In most nations, food regulations permit only the amount equivalent to the sweetness of sucrose, or other nutritive sweeteners, to be added to any food or beverage intended for human consumption (e.g., Australia and New Zealand Food Standards Code 1.3.1—5 Limitation on use of intense sweeteners (8)). To achieve this, in most foods and beverages, they are diluted with either water, dietary fibres, polyols or maltodextrins, with the exact bulking agent varying significantly between different foods and beverages.

Additionally, NSS are used in a range of non-food products (e.g., cosmetics and pharmaceuticals), and these sources are not captured, and/or are not adjusted for, in most of the observational studies.

Finally, when assessing association for dietary exposures against the Bradford Hill criteria for assessing causation, it is generally recommended that summary relative risks be ≤0.83 or ≥1.20, P

Evidence to recommendations
<p>For the reasons discussed above, the evidence from observational studies is likely to be significantly confounded and therefore should not be used as the primary rationale for not recommending non-sugar sweeteners (NSSs) for the general population.</p> <p>The results from randomised controlled trials (RCTs) assessing the effects of NSSs on weight are based on short-medium term data and are not high quality overall. However, they are consistent with the data from RCTs on body weight (1) that forms part of the evidence base for the WHO Guideline: Sugars intake for adults and children (2). Given the primary benefit of using NSS instead of nutritive sweeteners is to reduce energy intake, and that the energy contribution of sugars is relatively low (≤ 16.5 kJ/g)(3), the modest beneficial effect on weight demonstrated in RCTs is to be expected, and should not be overlooked.</p> <p>While the data included in the Rios-Leyvraz and Montez systematic review and meta-analyses (SRMA) (4) are limited, they do indicate that replacement of added sugars with NSSs is beneficial for dental health, overall. The Moynihan and Kelly systematic review (5) that forms the basis for the 10% and 5% of energy recommendations for the WHO Guideline: Sugars intake for adults and children (2), noted that “the evidence was judged to be of very low quality”, yet their data were used to set the recommended intake for free sugars. Given the role of NSSs as a replacement for added sugars, the evidence base should be evaluated consistently and the recommendations should be complimentary, based on science, not ideology.</p> <p>Finally, the recommendations overlook the social and cultural aspects of eating and drinking. Food is not medicine; it is far more important than that. People eat and drink a wide range of foods and beverages for a variety of reasons, including hunger, hydration, enjoyment and social participation in a broad variety of events (e.g., birthdays, funerals, religious festivals, weddings, etc...). NSS foods and beverages have a role in assisting people to reduce the energy density of their diet while providing enjoyment (sweetness) without detrimentally affecting their dental health. It’s naïve to think that people will only want to drink water at these events, or only have naturally sweetened beverages and foods. NSS drinks are often consumed where alcoholic beverages may not be an ideal alternative or are socially prohibited (e.g., age, religious beliefs). The likely effect of not recommending the use of NSSs instead of nutritive sweeteners is an increase in nutritive sweetener consumption (6) and potentially even alcoholic beverage consumption (7).</p> <p>References:</p> <ol style="list-style-type: none"> 1. Te Morenga LA, Howatson AJ, Jones RM, Mann J. Dietary sugars and cardiometabolic risk: systematic review and meta-analyses of randomized controlled trials of the effects on blood pressure and lipids. <i>AmJClinNutr</i>. 2014;100(1):65-79. 2. World Health Organisation. Guideline: Sugars intake for adults and children. 2015. 3. Elia M, Cummings JH. Physiological aspects of energy metabolism and gastrointestinal effects of carbohydrates. <i>EurJClinNutr</i>. 2007;61 Suppl 1:S40-74.:S40-S74. 4. World Health Organisation, Rios-Leyvraz M, Montez J. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. Geneva: World Health Organization; 2022 2022. 5. Moynihan PJ, Kelly SA. Effect on caries of restricting sugars intake: systematic review to inform WHO guidelines. <i>JDentRes</i>. 2014;93(1):8-18. 6. Phelan S, Lang W, Jordan D, Wing RR. Use of artificial sweeteners and fat-modified foods in weight loss maintainers and always-normal weight individuals. <i>IntJObes(Lond)</i>. 2009;33(10):1183-90. 7. Powell LM, Leider J. Impact of the Seattle Sweetened Beverage Tax on substitution to alcoholic beverages. <i>PLoS one</i>. 2022;17(1):e0262578.
Recommendations and supporting information
<p>The draft recommendation “WHO suggests that NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases” is not consistent with the higher quality evidence from RCTs about weight, overemphasises the quality and importance of observational, in vitro and animal data, and completely overlooks the role of NSSs in dental health. It appears to be based on ideology rather than science. Therefore, it is at odds with the evidence and rationale for the WHO Guideline: Sugars intake for adults and children (1). It also ignores the hedonic, social and cultural roles of foods and beverages in the diets of humans and naïvely suggests that people will switch to unsweetened alternatives.</p> <p>References:</p> <ol style="list-style-type: none"> 1. World Health Organisation. Guideline: Sugars intake for adults and children. 2015.

Other comments
<p>The WHO Guideline: Sugars intake for adults and children (1) advises children and adults to reduce added and free sugars. However, sweetness is one of the 5 basic tastes (i.e., Sweet, Salty, Sour, Bitter and Umami) and is preferred by most humans from birth, because human breast milk and its analogues are sweet (2). It is important to note that a preference for sweetness should not be conflated with addiction (3).</p> <p>The draft recommendation “WHO suggests that NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases” is of course unlikely in itself have any effect on individuals preference for sweet foods and drinks.</p> <p>It will however have an effect on government policy and food industry. If through coercion or regulation, the use of NSSs is curtailed in the food supply, the most likely replacement will be nutritive sweeteners.</p> <p>Therefore, it is likely that the outcome of this draft WHO guideline will not be a reduction in peoples preference for sweet foods and drinks but an increase in the consumption of nutritive sweeteners.</p> <p>References:</p> <ol style="list-style-type: none">1. World Health Organisation. Guideline: Sugars intake for adults and children. 2015.2. Fidler Mis N, Braegger C, Bronsky J, Campoy C, Domellöf M, Embleton ND, et al. Sugar in Infants, Children and Adolescents: A Position Paper of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition. J Pediatr Gastroenterol Nutr. 2017;65(6):681-96.3. Greenberg D, St Peter JV. Sugars and Sweet Taste: Addictive or Rewarding? Int J Environ Res Public Health. 2021;18(18).
Upload comments

Survey response 20

General information

Family/last name
Parker
Given/first name
Geoff
Organization/affiliation
Australian Beverages Council Limited
Sector
Private sector
Sector [Other]
Country
Australia

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"Australian Beverages Council comments on WHO draft guideline on NSS","comment":"","size":"598.736328125","name":"Australian%20Beverages%20Council%20comments%20on%20WHO%20Draft%20Guideline%20on%20Use%20of%20Non-Sugar%20Sweeteners%20Final%2012082022.pdf","filename":"fu_idgh7efmj6q3dic","ext":"pdf"}]]

12 August 2022

Via email: NFS@WHO.int

Re: Call for comment: draft WHO guideline on the use of non-sugar sweeteners

Dear Sir or Madam,

The Australian Beverages Council Limited (ABCL) is pleased to submit comments on the World Health Organisation (WHO) *Draft Guideline on the Use of Non-Sugar Sweeteners*.

The ABCL is the leading peak body representing 95 per cent of the non-alcoholic beverages industry's volume and is the only dedicated sector representative in Australia. Our members include large, medium, small and micro- beverage manufacturers, and make a substantial AUD\$7+ billion contribution to the Australian economy each year. The industry is responsible and responsive, listening to consumers, working in partnership with government and providing thought leadership on a range of important matters including sugar reduction, nutrition information labelling and responsible marketing and advertising.

We recognise the many complex and nutrition-related issues impacting the global community (such as overweight and obesity), and it is critical that all stakeholders, including industry, engage in multi-sectoral dialogue to develop holistic and long-lasting solutions, based on robust science. With that regard, the ABCL engages with allied associations worldwide as a member of the International Council of Beverage Associations (ICBA). The ABCL also acts as secretariat to the ICBA Asia-Pacific Group (APAC). Through this global network, we continue to advocate for the drinks industry's efforts in Australia to provide consumers with low- and no-sugar options via reformulation as the key tool.

The non-alcoholic beverages industry recognises WHO's role in promoting healthy diets to reduce the prevalence of non-communicable diseases (NCDs). In 2018 the political declaration from the United Nations (UN) High-Level Meeting (HLM) on NCDs called upon the private sector to "strengthen its commitment" to make further efforts to reformulate foods and beverages to reduce excessive use of salts, sugars, and fats, to achieve the Sustainable Development Goal (SDG) 3.4¹. We also note WHO's recently commissioned review on health effects of non-sugar sweetener (NSS) use² demonstrated a modest but significant weight loss benefit (among other benefits) in adults. This outcome is based on moderate to high certainty evidence-based studies and reinforces the findings from WHO's 2019 review³.

Importance of non-sugar sweeteners as a key tool for sugar reduction in beverages

The beverage (and food) industry has been relying on NSS to support sugar reduction efforts for decades. A 2020 study⁴ into sales of sugar-sweetened beverages in Australia showed that over a 22-year period this reformulation agenda has resulted in a decrease in sugar from drinks over that time

¹ See 2018 UN High Level Meeting on NCDs Political Declaration, A-73-L-2-EN at OP 44, available at <https://digitallibrary.un.org/record/1645265?ln=en>

² World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization.

³ Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J J. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies BMJ 2019; 364 :k4718.

⁴ Shrapnel W.S., Butcher B.E. Sales of Sugar-Sweetened Beverages in Australia: A Trend Analysis from 1997 to 2018. Nutrients. 2020;12:1016. <https://www.mdpi.com/2072-6643/12/4/1016>

equivalent to 127 grams of sugar per person per year. To bring speed and scale to this agenda in 2018 the industry launched its [sugar reduction pledge](#), which as of 2021 has delivered a 16 per cent reduction in sugar across signatories' portfolios⁵ which represent a total industry volume coverage of approximately 70 per cent. This is just one example of industry-led voluntary initiatives in the Australian market. There are many examples from other markets worldwide.

Beyond this market the beverages industry is increasingly using a range of NSS as a key tool to reduce sugar, including in many developing and low- and middle-income countries (LMICs). The industry across the Asia Pacific region and beyond is only able to rely on NSS in a favourable regulatory environment which must be underpinned by the latest *quality* evidence regards safety and additional health benefits.

Issues with the current draft guideline

The draft guideline's key recommendation "WHO suggests that NSS not be used as a means of achieving weight control or reducing risk of non-communicable diseases" is a conditional recommendation⁶ based on evidence of overall low certainty. From an industry perspective, this is not adequate for a guideline of this importance.

Despite a clear roadmap mandate from the UN to support reformulation efforts by the private sector to help achieve the SDG 3.4, WHO has issued a recommendation in conflict with its own commissioned studies with moderate-high certainty findings into the benefit of NSS use⁷.

It is our view that issuing a guideline as such based on low quality evidence will have adverse consequences for local public health efforts to reduce the prevalence of diet-related disease, particularly in LMICs, and will create confusion for consumers relying on NSS to reduce sugar from their diet.

Our concerns are captured in detail in the ICBA's comments submitted to the WHO on 26 July, 2022 (Appendix 1). The ABCL fully supports the ICBA's submission as a representation of the global non-alcoholic beverages industry's views on the draft guideline, of which we request WHO to carefully consider.

Conclusion

Thank you for considering the ABCL's comments and concerns regarding the *WHO Draft Guideline on Use of Non-Sugar Sweeteners*. We appreciate WHO's efforts to provide guidance to policymakers on the use of NSS, however we believe that any guidance must be based on the most current and highest quality evidence available and therefore the ABCL respectfully requests the draft guideline be reassessed and redrafted taking into account such evidence. Further, the draft guideline must reference the UN's 2018 HLM on NCDs and specifically, the important role that the private sector must play to reformulate products with excess sugar (and sodium, saturated fat).

⁵ KMPG. Sugar Reduction Pledge by the Australian non-alcoholic beverage industry. *Aggregation report for the year ended December 2021*. 2022.


⁶ *Conditional* recommendations are those recommendations for which the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences or when the anticipated net benefits are small. Policymaking related to conditional recommendations therefore may require substantial debate and involvement of various stakeholders.

⁷ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization.
<https://apps.who.int/iris/handle/10665/353064>.



For further information or any questions pertaining to the contents of this letter, please do not hesitate to contact me via email at geoff@ausbev.org.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Geoff Parker', written in a cursive style.

Geoff Parker
Chief Executive Officer





July 26, 2022

VIA Email (NFS@WHO.int)

Re: DRAFT WHO Guideline: Use of Non-Sugar Sweeteners

Dear Sir or Madam:

The International Council of Beverages Associations (“ICBA”) is pleased to submit these comments on WHO’s Draft Guideline on the Use of Non-Sugar Sweeteners (the “Draft Guideline”).¹ As discussed below in these comments, although ICBA supports WHO’s efforts to promote healthy diets, ICBA respectfully requests that WHO reconsider overall priorities and return to science-based policy coherence when providing guidance to stakeholders in its efforts to achieve the UN Sustainable Development Goals by 2030.

In 2015, when the UN first adopted the Global Goals, the call for action mandated an intensive global engagement in support of implementation of all the Goals and targets, bringing together Governments, *the private sector*, civil society, the United Nations system and other actors and *mobilizing all available resources*.² Of particular interest, one of those resources specifically highlighted by the UN system is the food and beverage industry’s ability to reformulate. In 2018, the Political Declaration of the UN High Level Meeting on NCDs called upon the private sector to “strengthen its commitment” to make further efforts to reformulate foods and beverages to reduce the excessive use of salts, sugars and fats.³ As discussed in the attached Annex, our industry has heeded this call

¹ ICBA is an international non-governmental organization established in 1995 that is the voice of the global non-alcoholic beverage industry. The members of ICBA include national and regional beverage associations as well as international beverage companies that operate in more than 200 countries and territories and produce, distribute, and sell a variety of non-alcoholic sparkling and still beverages, including soft drinks, sports drinks, energy drinks, bottled waters, flavored and/or enhanced waters, ready-to-drink teas and coffees, 100 percent fruit or vegetable juices, nectars and juice drinks, and dairy-based beverages.¹ ICBA holds special consultative status with the UN Economic and Social Council and has been a recognized observer and well-respected stakeholder at the Codex Alimentarius (“Codex”) Commission for over twenty years.

² “Transforming our world: the 2030 Agenda for Sustainable Development,” Resolution adopted by the General Assembly on 25 September 2015, A/RES/70/1 at paras. 39 and 60. (emphasis added)

³ See 2018 UN High Level Meeting on NCDs Political Declaration, A-73-L-2-EN at OP 44, available at <https://digitallibrary.un.org/record/1645265?ln=en>.

from the UN, and over the past years and significantly stepped up our efforts to reformulate our beverages to reduce added sugars, relying on a key tool of reformulation -- low-calorie sweeteners -- in order to do so.

However, while we are making this robust effort, WHO is simultaneously issuing Draft Guidelines that seek to suppress this important reformulation tool from our toolbox. WHO acknowledges these Draft Guidelines are 1) based on low-certainty evidence and 2) not based on safety concerns. We are, frankly, concerned about this apparent policy u-turn. As UN Secretary General Antonio Guterres stated at this year's 2022 UN High Level Political Forum, "[t]he world is in deep trouble – and so too are the Sustainable Development Goals." Of particular interest to WHO's goals, WHO itself acknowledged that the world is "off track to achieve SDG target 3.4, to reduce premature deaths from NCDs, and no country is achieving all nine voluntary targets set out in the Global Action Plan for the Prevention and Control of NCDs 2013-2030."⁴

Why then would WHO issue Draft Guidelines with advice for the general population with advice based on evidence of "low certainty overall"? **We request that WHO review this Draft Guideline in the context of recent higher-level UN roadmaps** (which notably, they have neglected to cite in their draft, referring only to the dated 2011 and 2014 UN High Level Meetings on NCDs, omitting entirely the 2018 UN High-Level Meeting on NCDs). We believe in the value of these UN roadmaps – these are the priorities established with Member State input to help set the path toward the Global Goals, as opposed to the recent WHO committee recommendations. If Draft Guidelines that emanate from committees within agencies are incoherent (and based on low quality evidence) and inconsistent with the overall policy directives set by UN Member States, then we strongly encourage WHO leadership to revisit the Guidelines themselves.

I. The WHO Recommendations Risk Undercutting Key WHO Priorities Established by Member States Related to Diabetes and Dental Health

This past May, at the 75th World Health Assembly, the Member States endorsed a **landmark global strategy on oral health**, with one of the overarching goals being to reduce oral disease.⁵ Similarly, at this same World Health Assembly, the Member States supported the creation of the **first-ever global targets for diabetes**, as part of WHO's Global Diabetes Compact.⁶ In both of these instances, these are high-level priorities goals for WHO endorsed by the Member States.

Low- and no-calorie sweeteners are an important tool in supporting oral health and in diabetes management. With regard to oral health, it is well-recognized that excessive intake of sugar can contribute to dental caries. Because low- and no-calorie sweeteners are non-fermentable by oral

⁴ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).

⁵ See <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

⁶ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

bacteria, they can contribute to good oral health when used in place of sugar.⁷ As the European Food Safety Authority stated, “there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralization by decreasing tooth demineralization if consumed instead of sugars”⁸

Although WHO simply says that people with diabetes are excluded from these Guidelines, this naïve statement ignores the real-world implications of issuing guidelines to people around the world. When WHO issues blanket recommendations such as “don’t use non-sugar sweeteners for weight control,” that will confuse people – whether or not they have diabetes. In the real world, people embrace headlines, not fine print. And for those who live with diabetes, low- and no- calorie sweeteners are an integral part of diabetes management.

For example, the EU allows a specific health claim related to low- and no-calorie sweeteners and glucose levels: *‘the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods.’*⁹ **Health organizations globally recognize that low- and no- calorie sweeteners can be safely used to replace sugar in the nutritional management of diabetes.**¹⁰ For example, both the American Diabetes Association (ADA)¹¹ and the US Academy of Nutrition and Dietetics (AND)¹², in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of low- and no-calorie sweeteners have the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners and without compensation by intake of additional calories from other food sources. Also, the latest Diabetes UK Position Statement on low- and no-calorie sweeteners

⁷ FDI Policy Statement: Sugar substitutes and their role in caries prevention. Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden

⁸ EFSA, Scientific opinion on the substantiation of health claims related to intense sweeteners. EFSA Journal 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

⁹ Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health

¹⁰ Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹¹ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019 May;42(5):731-754;

¹² Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

concludes that: “LNCs are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes”.¹⁰

Further, it is interesting to note that the 2020 U.S. Dietary Guidelines Advisory Committee (DGAC) acknowledge that low- and no-calorie sweetened beverages are “a useful aid in weight management in adults,” noting that added sugars intakes could be greatly reduced by consuming low- and no-calorie sweetened reformulated versions of foods and beverages”¹³

We again note that the WHO Recommendation on the use of non-sugar sweeteners in these Draft Guidelines is a “conditional” or weak recommendation, meaning it is based on evidence of low certainty. We request that Member States review the need for such a weak recommendation in light of existing Member State-established WHO priorities, such as those related to the Diabetes Compact and the Global Strategy on Oral Health.

II. Member States Should Expect WHO Guidelines to Be Grounded in the Strongest Science, Not Science of “Low Certainty”

As noted above, WHO’s recommendation in this Draft Guideline is “conditional,” or weak, because it is based on evidence of overall low certainty. We are concerned about the overall implications of WHO – whom countries around the world rely upon as the “gold standard” for scientific advice – developing policy guidelines based on low-quality evidence. We note that these Draft Guidelines have real-world implications: because of reliance on this “low-certainty evidence,” we may see Member States develop legislation which runs afoul of public health goals to reduce added sugars in the diet. We strongly encourage WHO to return to the use of best practices in developing guidelines – with strong science as the foundation, the guidelines will be more than “evidence-informed.”

We note with concern that WHO did not rely on the strongest available science to develop these Guidelines. WHO has relied heavily on observational studies, which cannot establish a cause-and-effect relationship – and, as WHO ultimately concluded, provide evidence of a low quality. We are puzzled that WHO marginalized its own meta-analysis of randomized controlled trial (RCTs), which are the “gold standard” in nutrition and clinical research, when developing this Guideline. Earlier this year, WHO published a meta-analysis of the RCTs that demonstrated a modest but significant weight loss benefit (among other benefits) in adults, reinforcing findings from

¹³2020 U.S. Dietary Guidelines Advisory Committee Report(https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf). pp. 633, 636, 180, 691 of the 835 page pdf document. Accessed July 21, 2022. (Moreover, the US Dietary Guidelines Committee further stated “Plain water has been recommended to displace other energy-yielding beverages in the diet to dilute the energy density of the diet, reduce total energy intake, and aid weight management. The success of this strategy has not been established and warrants further study.”)

an earlier 2019 WHO-commissioned evidence-based review.¹⁴ We are flummoxed as to why WHO's own assessment acknowledging the moderate-to-high certainty clinical trial evidence showing either beneficial effects or an absence of detrimental effects from non-sugar sweetener consumption (on body fatness and waist circumference, body weight, BMI, fasting glucose, glycated hemoglobin, systolic blood pressure, diastolic blood pressure, and HDL cholesterol),¹⁵ was dismissed in favor of the very low to low certainty observational evidence (known to suffer from residual confounding and reverse causality) that ultimately served as the basis for the Conditional Recommendations in these Draft Guideline.

The benefits of low- and no-calorie sweeteners when used in place of sugars are supported by a wealth of well-conducted, acute, short- and longer-term randomized controlled trials in humans, which provide high quality evidence. Failing to consider the collective evidence on the health effects of non-sugar sweeteners and to accurately translate the totality of available evidence into a recommendation in view of the hierarchy of scientific evidence, may hinder public health efforts to reduce excess sugars intake and to tackle obesity.

III. Conclusion

In conclusion, we appreciate WHO's effort to provide guidance to policymakers on non-sugar sweeteners. However, we believe that any guidance must be grounded in principles of science-based policy, exhibit policy coherence and follow the roadmap of recent health priorities established by Member States. We are concerned that the decision to base guidelines on low-quality evidence may ultimately lead Member States to enact legislation that potentially jeopardizes positive public health outcomes. We thank you for the opportunity to submit these comments. Please let us know if you have any questions or require additional information.

Respectfully submitted,

/S/

Katherine W. Loatman
Executive Director

¹⁴ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. License: CC BY-NC-SA 3.0 IGO; "Toews I, Lohner S, K Allenberg de Gaudry D, Sommer H, Meerpohl J J. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies BMJ 2019; 364 :k4718 doi:10.1136/bmj.k4718)

¹⁵ See Annex 6 'GRADE Evidence Profiles' in the Draft Guidelines (see p.57)

Annex
The Global Beverage Industry's Sugar Reduction Pledges

ICBA and its members have long been supportive of meaningful, science-based efforts to help consumers make informed food and beverage choices toward healthful diets and we have a strong track record of leaning in with robust leadership initiatives. For example, our industry has made voluntary commitments regarding responsible marketing, marketing to children, and beverages offered in schools. Furthermore, the ICBA membership supports science-based interpretative front-of-package nutrition labeling, as we agree that executed well it is a useful tool for helping people make informed dietary choices as well as incentivizing companies to innovate and reformulate.¹⁶ The beverage industry has been working hard to reformulate beverages to reduce sugar, offer more lower- and no-calorie options, and make smaller package sizes more widely available. Around the globe, our industry is implementing and publicly reporting on sugar reduction commitments, through an array of public-private partnerships. **Importantly, non-sugar sweeteners are a key tool in the success of these sugar reduction commitments.** We offer just a few examples:

- In June 2018, the **Australian Beverages Council** committed to a 20 percent reduction in sugar across the beverage industry's portfolio by 2025. As of 2021, the third progress report demonstrated a 16% reduction in sugar had been achieved, showing that the industry was well on track to achieve its overall goal.¹⁷
- In November 2018, the **Brazilian Ministry of Health and the Brazilian food and beverage associations** signed a Memorandum of Understanding to establish national goals for sugar reduction. The agreement outlines a series of commitments to be undertaken by the food and beverage sector to help reduce Brazilians' sugar intake to less than 10% of total daily calories consumed, including reducing sugar in key categories such as sugar-sweetened beverages, confectioneries, and other foods.
- In partnership with the **Conference Board of Canada**, the Canadian Beverage Association and its membership have committed to reducing beverage calories consumed per person by 20 percent by 2025. A report prepared by The Conference Board of Canada shows that through product and packaging innovations, beverage calories consumed by Canadians has dropped by 16% between 2014 and 2020, and the industry is on track to meet the 20%

¹⁶ ICBA, "The Global Non-Alcoholic Beverage Industry Supports Science-Based Front-of-Package Interpretative Labeling to Support Consumer Health" (June 23, 2021), available at <https://icba-bigtree.s3.amazonaws.com/files/resources/icbainterpretativelabelingpositionfinal.pdf>.

¹⁷ See Statement by Australian Beverages Council available at <https://www.australianbeverages.org/non-alcoholic-beverages-industry-sugar-reduction-report-exceeds-target/>

reduction goal by 2025. That means that since 2004 there has been almost a 30 percent reduction in calories.¹⁸

- In 2020 in **Mexico, the members of ANPRAC**, the national beverage association, pledged to reduce calories in their products an additional 20% by 2024 by reformulating more than 50 products, and by increasing their portfolio of reduced or non-caloric products to 70%.
- In 2014, in partnership with the Alliance for a Healthier Generation, America's leading beverage companies joined forces in a landmark agreement to decrease beverage calories in the American diet by 20 percent per person by 2025. Keybridge, an independent evaluator, has monitored and measured the progress annually. From 2014 to 2020, average beverage calories per person fell by 10.0%, halfway to the 20% calorie reduction goal that was set for 2025. The annual decline has accelerated every year since 2016, with the largest single year decline (-5.0%) coming in 2020. The most important trends in terms of impact on calories has been the shift toward low- and no-calorie beverages, including water and sparkling waters. This trend has accelerated every year since 2016 as consumers increasingly select lower calorie-versions of all beverage types.
- Earlier this month, **the European soft drink association, UNESDA**, issued a press release communicating that the soft drinks industry has reduced sugar by 17.7% since 2015 and also, the sector's progress against its new commitment to reduce added sugars by another 10% by 2025 as part of the pledge submitted last year under the Farm to Fork Strategy's EU Code of Conduct on Responsible Food Business and Marketing Practices. This new pledge will bring our sector's total average added sugar reduction in Europe to 33% by 2025 (baseline 2000).
- Inspired by the series of three consecutive UNESDA sugar reduction commitments at EU level, 14 of their national members across Europe have made national sugar/calorie reduction commitments, and many have already reported notable achievements, for example:
 - The **Austrian** soft drink sector is working toward reducing average added sugars in its drinks by 15% by 2025 (baseline 2019);
 - The **Belgian** soft drink industry achieved in 2020 a 20% reduction in sugar (baseline 2012);
 - The **Dutch** soft drink industry achieved in 2020 a 26.7% reduction in calories (baseline 2012);

¹⁸ The Conference Board of Canada, "Counting the Calories, Canadian's Consumption of High-Calorie Beverages Continues to Decline" (August 2018), *available at* <https://www.conferenceboard.ca/press/newsrelease/2018/08/09/counting-the-calories-canadians-consumption-of-high-calorie-beverages-continues-to-decline?AspxAutoDetectCookieSupport=1> (last accessed May 29, 2019).

- The **French** soft drink sector has achieved a 9.8% reduction in sugars between 2010 and 2018, building on their commitment for a 5% reduction between 2010 and 2015;
- The **German** soft drink sector has committed to make a 15% reduction by 2025 in calories from the beverages it puts on the market (baseline 2015);
- The **Italian** soft drink sector has already achieved a 20% reduction in sugar and calories between 2009 and 2016 and has made a commitment for an additional 10% reduction in sugar by 2022 (baseline 2020). It is noteworthy that the Italian soft drink sector reduced sugar by 27% between 2009 and 2019;
- In **Latvia**, the soft drink sector aims to reduce average added sugars in its beverages by 20% by 2030 (baseline 2015);
- The **Portuguese** soft drink industry achieved in 2020 a 30.5% reduction in calories (baseline 2013) and in 2019 announced an additional reduction of 10% by 2022 (baseline 2019);
- In **Spain**, the soft drinks industry has reduced added sugars by 43% and in May this year announced a new 10% reduction pledge that will bring total sugar reduction to 53% by 2025 (baseline 2005); and
- The **Swedish** soft drink sector is committed to delivering a further 15% reduction in average added sugars by 2025 (baseline 2019).

Survey response 21

General information

Family/last name
BENSON
Given/first name
Helen
Organization/affiliation
UNESDA Soft Drinks Europe
Sector
Private sector
Sector [Other]
Country
Belgium

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"","comment":"","size":"197.8798828125","name":"UNESDA_WHO%20NSS%20draft%20guideline_12%20August%202022.pdf","filename":"fu_hg7pbvi9i9g4dki","ext":"pdf"}]

12 August 2022

WHO Draft Guideline on the Use of Non-Sugar Sweeteners – public consultation

UNESDA Soft Drinks Europe hereby expresses its full support and endorsement of the respective submissions to the present consultation from our umbrella associations, the International Council of Beverage Associations ('ICBA'), and FoodDrinkEurope.

UNESDA fully shares the concerns expressed by ICBA and FoodDrinkEurope with regard to the limited and low-quality evidence that underpins the 'conditional' draft WHO recommendation.

Non-sugar sweeteners have been extensively studied for their safety and rigorously tested by national and international bodies prior to the approval for use and consumption. They can be beneficial and are part of safe and valuable endorsed strategies, especially for short-term weight management and blood glucose management. As explained by FoodDrinkEurope and ICBA, the totality and weight of the evidence does not support the statement reached in the draft guideline.

Any guidance must be grounded in principles of science-based policy, exhibit policy coherence and follow the roadmap of recent health priorities established by WHO member countries. We are concerned that the decision to base guidelines on low-quality scientific evidence may ultimately lead WHO member countries to adopt legislation that potentially jeopardises positive public health outcomes. It may also risk having a disincentivising effect on food product reformulation.

*For further information, please contact Helen Benson, Regulatory & Scientific Affairs, UNESDA
hbenson@unesda.eu*

Survey response 22

General information

Family/last name
HODAC
Given/first name
Nicholas
Organization/affiliation
UNESDA
Sector
Private sector
Sector [Other]
Country
Belgium

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"","comment":"","size":"197.8798828125","name":"UNESDA_WHO%20NSS%20draft%20guideline_12%20August%202022.pdf","filename":"fu_t9cpm365id89pqs","ext":"pdf" }]

12 August 2022

WHO Draft Guideline on the Use of Non-Sugar Sweeteners – public consultation

UNESDA Soft Drinks Europe hereby expresses its full support and endorsement of the respective submissions to the present consultation from our umbrella associations, the International Council of Beverage Associations ('ICBA'), and FoodDrinkEurope.

UNESDA fully shares the concerns expressed by ICBA and FoodDrinkEurope with regard to the limited and low-quality evidence that underpins the 'conditional' draft WHO recommendation.

Non-sugar sweeteners have been extensively studied for their safety and rigorously tested by national and international bodies prior to the approval for use and consumption. They can be beneficial and are part of safe and valuable endorsed strategies, especially for short-term weight management and blood glucose management. As explained by FoodDrinkEurope and ICBA, the totality and weight of the evidence does not support the statement reached in the draft guideline.

Any guidance must be grounded in principles of science-based policy, exhibit policy coherence and follow the roadmap of recent health priorities established by WHO member countries. We are concerned that the decision to base guidelines on low-quality scientific evidence may ultimately lead WHO member countries to adopt legislation that potentially jeopardises positive public health outcomes. It may also risk having a disincentivising effect on food product reformulation.

*For further information, please contact Helen Benson, Regulatory & Scientific Affairs, UNESDA
hbenson@unesda.eu*

Survey response 23

General information

Family/last name
Leeds
Given/first name
Anthony R
Organization/affiliation
Total Diet & Meal Replacements (TDMR) Europe
Sector
Private sector
Sector [Other]
Country
United Kingdom

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"","comment":"","size":"124.5556640625","name":"TDMR%20Europe%20-%20Submission%20to%20WHO%20consultati on%20on%20use%20of%20non-sugar%20sweeteners%20-%202012082022.pdf","filename":"fu_yksdg58c4zcx9u6","ext":"pdf"}]]



TDMR Europe's response to consultation on draft guideline on use of non-sugar sweeteners

This submission is made by Total Diet & Meal Replacements (TDMR) Europe, the European trade body for manufacturers and distributors of total diet replacements (TDRs) and meal replacements (MRPs) for weight control.

TDRs, which include very low-calorie diets (VLCDs) and low-calorie diets (LCDs), are specifically formulated programmes that are based around formula foods that replace the whole of the daily diet. These formula foods are nutritionally balanced with key vitamins, minerals, high quality protein, essential fats, and fibre, and are designed to replace conventional foods for a period usually no more than 8 to 12 weeks duration to facilitate optimal weight loss. This is followed by stepped reintroduction of conventional food to achieve a conventional food weight maintenance programme. MRPs are products presented as a replacement for one or more meals of the daily diet. They are used alongside conventional food, as part of an energy restricted diet, to facilitate and maintain weight loss.

Sweeteners are crucial to ensure a low enough energy content and palatability in formula foods

There is a technological need to add sweeteners to both TDR and MRP as the products are expressly formulated for consumers who wish to manage their weight. The products' composition is subject to strict composition rules¹ including energy requirements between 200 and 250 Kcal for MRPs and 600 to 1,200 Kcal for TDRs (total daily amount). In order to comply with these requirements and allow individuals to lose and manage their weight, the use of sweeteners is essential.

Sweeteners also ensure the maintenance of palatability for the average consumer. Without sweeteners, manufacturers would need to add sugar to the formulation of these products to obtain a reasonable taste for consumers. This would defeat the purpose of these products which are intended to help overweight individuals lose weight and maintain weight loss in a safe and effective way.

The safety of sweeteners has been confirmed by the European Food Safety Authority (EFSA)

Sweeteners are regulated substances which are subject to safety evaluation prior to market authorisation. In the EU, the EFSA evaluates the safety of sweeteners and provides advice on their use before the EU institutions regulate them. In addition, EFSA is currently undertaking a review of all authorised sweeteners² and has so far not identified any major safety concern for any of the re-evaluated food additives.

TDRs and MRPs play a crucial role in the public health objective of reversing obesity rates

The steep increase over the past decades of overweight and obesity in Europe is an alarming trend. Obesity is not only associated with reduced life expectancy and many diseases, including cancer, type 2 diabetes, coronary heart disease, stroke and asthma, but also results in severe healthcare cost across the continent.

TDRs and MRPs have been available for several decades, providing an effective and safe way of helping people with overweight and obesity to lose weight. Total Diet Replacement products and MRPs have been shown in gold-standard randomised clinical trials to deliver sufficient weight loss (10-15kg) to give diabetes remission or diabetes prevention, improved symptoms and quality of life in osteoarthritis, reduced and sustained cardiovascular risk reduction, reduced severity of obstructive sleep apnoea and improved sleep duration and

¹ In the EU, **TDRs** are regulated under the EU Food for Specific Groups Regulation (Regulation No 609/2013) and Commission Delegated Regulation (EU) 2017/1798 as regards the specific compositional and information requirements for TDR for weight control. Under this legislative framework, the composition of TDRs is strictly regulated where the energy provided shall not be less than 2 510 kJ (600 kcal) and shall not exceed 5 020 kJ (1 200 kcal) for the total daily ration. **MRPs** fall within the Nutrition and Health Claims Regulation framework (Commission Regulation (EU) 2016/1413) which permits two health claims for these products and lays down that the energy content of MRPs shall not be less than 200 kcal (840 kJ) and shall not exceed 250 kcal (1 046 kJ) per meal. In the UK, the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulation 1997, which remains to apply in the Great Britain - Northern Ireland has to align with the EU following the Northern Ireland protocol -, states that the energy provided by TDRs shall not be less than 3360 kJ (800 kcal) and shall not exceed 5040 kJ (1 200 kcal) for the total daily ration. The UK allows use of products below 800 calories, for which companies usually apply CODEX Standard 203-1995 for very low calorie diets.

² According to Regulation (EC) No 1333/2008, food additives that were permitted for use in the EU before 20th January 2009 need to be re-evaluated by EFSA. As a result, EFSA is conducting a systematic re-evaluation of authorised food additives and is issuing scientific opinions on these food additives.



sleep quality in people with obesity. Proven to be effective and cost-effective in primary care, community settings and in specialist centres weight loss with TDR delivers reduced use of medications for diabetes and high blood pressure. TDR based diabetes remission programmes have been rolled out in the United Kingdom and in other centres in the Middle East and in South-East Asia. Full scale national diabetes remission programmes are planned for countries such as Malaysia with the highest regional rates for diabetes.

Backed up by extensive scientific research³⁴⁵⁶⁷, the successful use of TDRs and MRPs has the potential to deliver a significant reduction of the incidence of obesity-related conditions, with consequent reduced public spending.

We ask the WHO to recognise that the use of sweeteners remains essential in TDRs and MRPs for weight control.

³ Kent, S., Aveyard, P., Astbury, N., Mihaylova, B. and Jebb, S.A. (2019), Is Doctor Referral to a Low-Energy Total Diet Replacement Program Cost-Effective for the Routine Treatment of Obesity? *Obesity*, 27: 391-398. <https://doi.org/10.1002/oby.22407>

⁴ Lean MEJ et al Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised Trial *The Lancet* 2018 [391, p541-5](https://doi.org/10.1016/S0140-6736(18)31261-2); [https://doi.org/10.1016/S0140-6736\(18\)31261-2](https://doi.org/10.1016/S0140-6736(18)31261-2)

⁵ Lean MEJ et al 2019 Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. *Lancet Diabetes and Endocrinology* Online March 6, 2019 [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(19\)30068-3/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(19)30068-3/fulltext)

⁶ Zhu, R., Larsen, T., Fogelholm, M., Poppitt, S., Vestenot, P., & Silvestre, M. et al. (2021). Dose-Dependent Associations of Dietary Glycemic Index, Glycemic Load, and Fiber With 3-Year Weight Loss Maintenance and Glycemic Status in a High-Risk Population: A Secondary Analysis of the Diabetes Prevention Study PREVIEW. *Diabetes Care* 2021;44:1-10. doi: 10.2337/dc20-3092

⁷ Raben A et al 2020 PREVIEW - Results from a 3-year randomised 2 x 2 factorial multinational trial investigating the role of protein, glycemic index and physical activity for prevention of type-2 diabetes. *Diabetes Obes Metab*. 2021;23:324-337. doi:10.1111/dom.14219

Survey response 24

General information

Family/last name
Griffiths
Given/first name
James
Organization/affiliation
Council for Responsible Nutrition (CRN)
Sector
Other
Sector [Other]
Non-Governmental Organization (NGO)
Country
United States of America

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"2022-08-14; CRN COMMENTS TO WHO NUGAG on NSS","comment":"","size":"194.7529296875","name":"2022-08-14 %20FINAL%20LETTER%20TO%20WHO%20NUGAG%20-%20NSS.pdf","filename":"fu_ptj3rcvasg3egnw","ext":"pdf" }]

August 14, 2022

VIA ELECTRONIC SUBMISSION

To : WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health

Re: Draft WHO Guideline on Use of Non-Sugar Sweeteners

Dear WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health,

The Council for Responsible Nutrition (CRN)¹ is the leading trade association for the dietary supplement and nutritional products industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements, many of which are multinational and already actively exporting and selling ingredients, finished products and services globally.

CRN respectfully submits these comments to the WHO Nutrition Guidance Expert Advisory Group (NUGAG) Subgroup on Diet and Health, in response to the published “Draft Guideline on Use of Non-Sugar Sweeteners (NSS), “to provide evidence-informed guidance on the use of NSS by consumers”.

As a Board-certified toxicologist practicing in the field of nutrition safety, I address my comments towards the following issue.

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our [member companies](#) manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN’s Code of Ethics. Learn more about us at www.crnusa.org.

As a global authority in public health, dedicated to addressing non-communicable diseases (NCDs), the WHO attempts to support its Member States by providing evidence-informed guidelines. **Public policy should be developed exclusively on the foundation of the highest quality and most comprehensive evidence.**

A weakness of the draft WHO guideline on the use of non-sugar sweeteners (NSS) is **NOT considering the differences among individual NSS**, despite acknowledging that each NSS “*has a unique chemical structure, which is reflected in different sweetness intensities, organoleptic properties, and routes of processing in the body*”². Further the definition of non-sugar sweeteners (NSS) can be confusing, as different jurisdictions and regulatory agencies include and exclude certain compounds which are broadly non-sugar sweeteners, but may also be termed “low-calorie sweeteners” and/or “non-nutritive sweeteners” (NNS). NSS is overly all-encompassing, as it would capture all future sweetening agents that simply do not include sugar, but may in and of themselves be perfectly appropriate.

The draft WHO guideline states that: “*The overall certainty in the evidence was considered low and is based on undesirable effects of NSS use on prioritized health outcomes observed in prospective cohort studies which were individually considered to be very low to low.*” **It is counter to public health to base dietary recommendations on poor-quality evidence, and neglect higher quality research from randomized controlled trials (RCTs) supporting beneficial effects of NSS use on reduced energy intake, weight, glucose control, and dental health.**

While recognized that the safety of NSS is assessed by food safety agencies, including the Joint Expert Scientific Committee on Food Additives (JECFA) of the United Nations Food and Agriculture Organization (FAO) and of the World Health Organization (WHO), the European Food Safety Authority (EFSA)³, and the US Food and Drug Administration (FDA), it is also stated that “*there is no clear consensus on whether NSS are effective for long-term weight loss or if they are linked to other long-term health effects at habitual intakes within the ADI*”. With this statement the draft WHO guideline brings into question the safety of NSS. This is inconsistent with the safety evaluation of all approved NSS and outside of the scope of the WHO NUGAG Subgroup. **It is therefore important that this lack of alignment between WHO bodies is addressed as this**

² Magnuson BA, Carakostas MC, Moore NH, Poulos SP, & Renwick AG. Biological fate of low-calorie sweeteners. *Nutr Rev* 2016; 74(11): 670-689

³ EFSA NDA Panel, 2022. Scientific Opinion on the Tolerable Upper Intake Level for dietary sugars (EFSA-Q-2016- 00414). *EFSA Journal* 2022;20(2):7074. doi:10.2903/j.efsa.2022.7074

inconsistency can lead to confusion. For example, the WHO Oral Health Guidelines include use of fluoridated toothpaste, which include NSS to mask the metallic taste of fluoride. Since most toothpastes contain NSS, the oral health guidelines for preservation of good oral health from WHO may be in conflict with these WHO draft guidelines. This is worrisome, and may be interpreted to cause confusion with regards to oral products, including sugarfree gum.

As regulated ingredients, NSS are used in very small amounts to provide sweet taste with fewer or virtually no calories, with the amount of NSS used in such food and drink products determined by their acceptable daily intake, to ensure we cannot overconsume them.

In summary, CRN has the following statements in response to the “Draft WHO Guideline on Use of Non-Sugar Sweeteners”

1. Public health policy **MUST** be developed exclusively on the foundation of the highest quality and most comprehensive scientific evidence.
2. Public health recommendations **MUST** consider the differences among individual NSS.
3. Public health recommendations **CANNOT** be based on poor-quality evidence, neglecting higher quality research from randomized controlled trials (RCTs) supporting beneficial effects of NSS use on reduced energy intake, weight, glucose control, and dental health.
4. Public health recommendations from WHO **MUST** be in alignment amongst all WHO bodies as inconsistency leads to confusion.

Without clarity and firm reliance on the best available science, the “Draft WHO Guideline on Use of Non-Sugar Sweeteners” **DO NOT** provide evidence-informed guidance on the use of NSS by consumers.

Respectfully submitted,



James C Griffiths, Ph.D., DABT, CFS, FRSB

Senior Vice President, International and Scientific Affairs
Council for Responsible Nutrition

Survey response 25

General information

Family/last name
Hung
Given/first name
Estella
Organization/affiliation
Office for Health Improvement and Disparities
Sector
Government
Sector [Other]
Country
United Kingdom

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"WHO consultation on NSS comments from OHID","comment":"","size":"21.34765625","name":"WHO%20consultation%20on%20NSS%20comments%20%28OHID%20FINAL%29.docx","filename":"fu_jtjxyib63t8xbyj","ext":"docx" }]

overall clarity, considerations and implications for adaptation and implementation of the guideline, context and setting-specific issues that have not yet been captured, and any errors of fact or missing data.

UK position on sugar and non-nutritive sweeteners (NNS)

UK government advice on non-nutritive sweeteners (NNS) is based on recommendations from the Scientific Advisory Committee for Nutrition (SACN) and the Food Standards Agency (FSA) advisory committees (that is, in relation to food safety). WHO advice is also taken into account in establishing such recommendations.

In the UK, NNS have been considered by the FSA committees in relation to safety. A proposal on NNS was considered by SACN as part of its horizon scan in June 2022. Details of this discussion will be published in the minutes of the meeting in due course. Papers for this meeting are available [here](#).

There was insufficient time for SACN to consider and respond to the consultation on the WHO draft guideline on non-sugar sweeteners (NSS) since its publication in July 2022.

UK government advice on a healthy, balanced diet is encapsulated in the UK's national food guide, [The Eatwell Guide](#). The Eatwell Guide shows the proportions in which different types of foods should be consumed to have a well-balanced and healthy diet, to help meet nutrient requirements and reduce the risk of chronic disease.

Recommendations on reducing free sugars are based on findings from [SACN's report 'Carbohydrates and Health' \(2015\)](#). The report concluded that:

- Prospective cohort studies indicate that higher consumption of sugars and sugars containing foods and beverages is associated with a greater risk of dental caries.
- Prospective cohort studies indicate that greater consumption of sugars-sweetened beverages is associated with increased risk of type 2 diabetes mellitus.
- Randomised controlled trials conducted in adults indicate that increasing or decreasing the percentage of total dietary energy as sugars when consuming an ad libitum diet leads to a corresponding increase or decrease in energy intake.
- Reduction in the percentage of dietary energy as sugars was achieved in these trials either through the substitution of other macronutrient components or by replacing sugars with non-caloric sweeteners.
- Randomised controlled trials conducted in children and adolescents indicate that consumption of sugars-sweetened beverages, as compared with non-calorically sweetened beverages, results in greater weight gain and increases in body mass index.
- With the proposed reduction in the population intake of free sugars, their contribution toward recommended total carbohydrate intake should be replaced by starches, sugars contained within the cellular structure of foods and, for those who consume dairy products, by lactose naturally present in milk and milk products. The complete replacement of energy derived from free sugars by these carbohydrate sources would only apply to those people who are a healthy body mass index (BMI) and in energy balance. In those who are overweight, the reduction of free sugars would be part of a strategy to decrease energy intake.

Evidence within the draft WHO guideline on non-sugar sweeteners (NSS)

The draft WHO guideline on non-sugar sweeteners (NSS) appears to corroborate the findings of SACN in relation to diets high in free sugars ([SACN, 2015](#)). While the draft WHO guideline is clearly written, the recommendation that NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases may be too strong given the limitations of the evidence base including possible concerns regarding study design and reverse causality.

The WHO draft guideline recognises that the systematic review suggests a higher compared to lower intake of NSS had no long-term benefit on measure of body fatness in adults or children and potential undesirable effects from long term use in relation to type 2 diabetes and cardiovascular disease. It noted however, that these results are largely from observational studies with concern of reverse

causality and that there is low or very low certainty in these findings. It is further noted that sensitivity analysis of the overall diet relates to baseline diet.

The draft guideline also acknowledges that there are limitations in the design of the primary studies (RCTs and observational studies) included in the systematic review. Most studies utilised NSS-containing beverages and there may be differences in mechanisms of actions compared with foods. In addition, only 4 RCTs specifically replaced sugars-sweetened beverages with NSS alternatives, which may further limit the interpretation of the evidence. There was limited, if any, evidence of wider dietary factors that may impact body weight and non-communicable disease risk. As such the results of the analysis may be considered inconclusive in relation to the role of NSS consumption in food and beverages while moving towards a healthy dietary pattern.

It is unclear whether a hierarchy of evidence approach alongside GRADE was used in drawing conclusions. The draft guideline appears to give equal weight to RCTs and observational studies, which appears to reflect the opinion as to the benefit or otherwise of NSS from the steering group considerations. There is limited interpretation of evidence on the possible adverse effects from non-use of NSS – which may exacerbate weight gain and associated ill-health.

Given the low and very low certainty evidence, concerns about study design and potential for reverse causality, the draft guideline may go too far in suggesting that NSS should not be used as a means of achieving weight control or reducing risk of non-communicable diseases. Until there is further evidence, WHO may wish to consider redrafting their recommendations to reflect the limited evidence and perhaps recommend more appropriate research designs that take account of wider dietary issues across both food and drinks.

Implications of the Draft WHO guideline

It is generally accepted that reducing free sugars is associated with reduced body weight and BMI in adults and that similar associations are likely to be seen in children. It is also generally accepted that replacing free sugars with NSS in the diet is likely to result in reduced energy intake, which results in reduction in body weight.

The evidence that informed the WHO draft guideline appears to corroborate this at least in the short term. However, the use of NSS should not be considered a magic bullet for reducing energy intake, as intake of free sugars is just one of several factors that impacts body weight and BMI. Therefore, addressing intake of free sugars through use of NSS alone will not be a long-term effective mechanism for achieving healthy population weight and the further impact on diet related health. This also appears to be borne out by the WHO draft guideline.

The guideline states that NSS is not an essential component of the diet and that there is limited evidence of no effect on health outcomes in longer term observational studies. However, this may not provide sufficient evidence that NSS may not help to contribute to improvements in overall diet through a reduction in free sugars intake.

While moving populations to healthier dietary patterns is fully supported, it would be unfortunate to discount the large reductions in intakes of free sugars that some approaches have already achieved. The draft guideline acknowledges a perception that NSS- and sugars-sweetened beverages tend to be consumed alongside other 'unhealthy' foods and appears to assume that removal of the beverage would remove the consumption of the associated foods. Yet, no evidence has been presented to support this perspective.

While the UK government, along with other governments, continue to recommend that free sugars are replaced by starchy foods, sugars contained within the cellular structure of foods, and for those who consume dairy products, lactose naturally present in milk and milk products, it is also important to reflect that this also maintains the energy content of the whole diet. Thus, this approach alone will have limited impact on some weight-related health outcomes.

Given the limited evidence, it remains appropriate to recommend dietary patterns that lower intakes of free sugars, saturated fats and salt, choosing foods that help to achieve a healthy dietary pattern and not simply rely on one component of the diet (for example, simply swapping free sugars for NSS).

Survey response 26

General information

Family/last name
Mann
Given/first name
Richard F.
Organization/affiliation
International Chewing Gum Association
Sector
Private sector
Sector [Other]
Country
United States of America

Comments on the draft guideline

Summary of evidence
Please see uploaded comments
Evidence to recommendations
Please see uploaded comments
Recommendations and supporting information
Please see uploaded comments
Other comments
Please see uploaded comments
Upload comments
[[{"title":"Comments of the International Chewing Gum Association","comment":"","size":"150.486328125","name":"ICGA%20COMMENTS%20SUBMITTED%20TO%20WHO.pdf","filename":"fu_j3kxjwx37dxd","ext":"pdf"}]]



INTERNATIONAL CHEWING GUM ASSOCIATION

C/O KELLER AND HECKMAN LLP • 1001 G STREET, N.W. • WASHINGTON D.C. 20001 • USA • www.gumassociation.org • icga@gumassociation.org

August 14, 2022

Via Electronic Mail

NFS@WHO.int

Re: WHO Draft Guideline: Use of Non-Sugar Sweeteners

Dear Sir or Madam:

The International Chewing Gum Association (ICGA) is grateful for the opportunity to submit these comments on the WHO Draft Guideline on Use of Non-Sugar Sweeteners. ICGA, headquartered in Washington, DC, is the association of the world's leading producers of chewing gum, chewing gum base, and the ingredients used in these foods. The majority of chewing gum products sold throughout the world are sugar-free, and, accordingly, contain a variety of non-sugar sweeteners ("NSS") that are used for both sweetening and other performance enhancing functions. Accordingly, our industry has a substantial interest in the outcome of WHO's guidance regarding these substances.

As an active participant and recognized observer organization in the Joint FAO/WHO Codex Alimentarius program, ICGA has established a history of support for sound, science-based food standards and dietary guidelines, focused on providing consumers with foods that serve their nutritional needs, as well as foods that are known to provide specific health benefits. In our view, the WHO Draft Guideline on Use of Non-Sugar Sweeteners could make improvements in both regards.

WHO expressly acknowledges the weakness of the scientific support for the Draft Recommendation, which is qualified as "Conditional", while at the same time pointing to significant gaps that are not even addressed, including the role of non-sugar sweeteners in promoting dental health and reducing certain risk factors of dental caries – a disease of major global health significance. As such, the WHO Draft Guideline is a missed opportunity to take a positive step in line with the World Health Assembly's recently adopted resolution setting forth a Global Strategy on Oral Health, intended to inform the development of a global action plan on oral health, including a framework for tracking progress with clear measurable targets to be achieved by 2030.

I. WHO'S EVIDENTIARY BASIS FOR THE DRAFT GUIDELINE IS ACKNOWLEDGED TO BE OF VERY LOW CERTAINTY.

The crux of the WHO Draft Guideline is as follows:

"WHO suggests that NSS (non-sugar sweeteners) not be used as a means of achieving weight control or reducing risk of noncommunicable diseases."

Essentially, WHO, as a leading and influential health authority, is making a pronouncement that non-sugar sweeteners should not be used, either alone or as ingredients in a broad range of food products, despite acknowledging that –

1. The recommendation is "conditional" on NSS use for which "the WHO guideline development group is uncertain that the desirable consequences of implementing the recommendation outweigh the undesirable consequences";
2. Non-sugar sweeteners have been determined to be safe at specified levels "by authoritative bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA)" and are regulated at the international level in the Codex alimentarius Commission's General Standard on Food Additives;
3. The draft recommendation "is based on evidence of low certainty overall";
4. There is a lack of certainty about the overall balance of desirable and undesirable effects associated with long-term effects of NSS use for reducing non-communicable disease risk;
5. Further research is needed to achieve a better understanding of the effects of non-sugar sweeteners intake from foods and beverages on oral health, including dental caries across all age groups, from young children to adults.

The draft WHO Guideline includes policy suggestions to lower or stop the consumption of NSS, including marketing restrictions, fiscal policies, and nutrition labelling. The desirable and undesirable impacts of the proposed policies, including their feasibility, acceptability and resource implications should be better evaluated before making a final recommendation. As developing public policy should be done on the basis of the best quality and most comprehensive evidence, it is vital that any ultimate suggestions are supported by a robust evidentiary basis.

II. THE WHO DRAFT GUIDELINE DOES NOT CONSIDER THE CONTRIBUTION OF NON-SUGAR SWEETENERS TO DENTAL HEALTH.

In 2015, WHO recommended reduction of the intake of free sugars to below 5 percent of total energy on the basis of the resulting benefit to oral health.¹ Sweeteners are an essential tool in these sugar reduction efforts, especially in the case of sugar-free chewing gum. Yet the NUGAG reviews excluded sugar alcohols and low-calorie sugars² which are known to have oral health benefits. Instead, the 2019 and 2022 literature reviews only focused on acesulfame K, aspartame, advantame, cyclamates, neotame, saccharin, sucralose, stevia and stevia derivatives. By limiting the sweeteners in the systematic review, not all of the oral health evidence could be properly evaluated for an opinion on oral health. Clearly this oversight is a major concern. In its recently adopted Draft Global Strategy on Oral Health, the World Health Assembly noted that globally, there were estimated to be more than 3.5 billion cases of oral diseases and other oral conditions in 2017, most of which are preventable. WHA further noted that for the last three decades, the combined global prevalence of dental caries (tooth decay), periodontal (gum) disease and tooth loss has remained unchanged at 45 percent – a figure that is higher than the prevalence of any other noncommunicable disease.

In the interest of public health, it is imperative that any recommendation regarding sweetener use be based on the science in its totality and interpreted based on its hierarchy and weight. **ICGA respectfully suggests a wider review on non-fermentable carbohydrates, often sweeteners, be performed for their oral health benefits due to the prevalence of this NCD.**

It is important that any guideline that WHO ultimately issues relating to non-sugar sweeteners not lose sight of the pivotal role of these substances in positively contributing to dental health and the reduction of risk of dental caries, particularly when used as ingredients in sugar-free chewing gum. Numerous studies associating sugar-free chewing gum containing non-sugar sweeteners (as well as other sweeteners) have demonstrated a material impact on the prevention of dental caries and overall promotion of dental health. Yet, as noted above, the Draft Guideline was based on a review that excluded sugar alcohols and low-calorie sugars, and considered only human studies, despite the wealth of available *in vitro* data relating to the synergistic effect of NSS and sugar alcohols. **Any assessment of sweeteners – including sugar alcohols and low-calorie sugars -- is incomplete without balancing the associated risks and benefits that they provide, particularly when the benefits are so pronounced and can be**

¹ World Health Organization at <https://www.who.int/publications/i/item/9789241549028>.

² See page 4, footnote 1.

**achieved with only a minimal impact on the overall consumption of the
aforementioned sweeteners.**

The contribution of non-sugar sweeteners to dental health has been recognized for decades by leading food safety and regulatory authorities. In 1996, the U.S. Food and Drug Administration (US-FDA) officially authorized a health claim associating foods sweetened with “non-cariogenic carbohydrate sweeteners” with the reduction of risk of dental caries.³ US-FDA reviewed 15 published studies on the relationship between sugar alcohols and plaque acid production⁴ and 17 published studies on the relationship between sugar alcohols and dental caries,⁵ several of which involved the administration of sugar-free chewing gum to study participants. Ultimately, the agency determined that a claim associating consumption of sugar-free foods sweetened with non-cariogenic carbohydrate sweeteners and dental health was supported by “significant scientific agreement”, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles), among experts qualified by scientific training and experience to evaluate such claims.⁶ Non-cariogenic carbohydrate sweeteners do not promote dental caries as they are slowly metabolized by bacteria resulting in a rate and amount of acid production significantly less than seen with sucrose or other fermentable carbohydrates. This in turn does not cause the loss of important minerals from tooth enamel. It is important to note that these non-cariogenic carbohydrate sweeteners are used in combination with NSS to deliver the taste and functional attributes of sugar-free chewing gum.

Separately, the European Union regulatory authorities have reviewed the published scientific evidence through two distinctive processes by virtue of the EU regulatory framework⁷ adopted in 2006, and have approved a number of health claims

³ 61 *Fed. Reg.* 43433, *et seq.* (August 23, 1996). FDA specifically listed as “non-cariogenic carbohydrate sweeteners” D-tagatose and isomaltulose, sucralose, sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, and erythritol, along with hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of these.

⁴ See Table 1 to Proposed Rule, “Food Labeling, Health Claims; Sugar Alcohols and Dental Caries,” 60 *Fed. Reg.* 37507, 37531-37539 (July 20, 1995).

⁵ See Table 2 to Proposed Rule, “Food Labeling, Health Claims; Sugar Alcohols and Dental Caries,” 60 *Fed. Reg.* 37507, 37540-37549 (July 20, 1995).

⁶ *Id.*

⁷ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended and consolidated in 2014. See <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1924>.

associating sugar-free chewing gum with dental health benefits.⁸ This approval was based on several European Food Safety Authority (EFSA) scientific opinions issued in 2009 and in 2011, which addressed the substantiation for health claims in relation to sugar-free chewing gum and dental and oral health.⁹ EFSA concluded that a cause and effect relationship had been established between the consumption of sugar-free chewing gum and plaque acid neutralization, maintenance of tooth mineralization, and reduction of oral dryness, all of which are beneficial to human health. In parallel, EFSA issued three separate opinions, two of which concluded that a cause-and-effect relationship had been established between the consumption of sugar-free chewing gum and (a) the reduction of tooth demineralization and (b) neutralizing plaque acid, both of which reduce the risk of developing dental caries.¹⁰

⁸ European Commission. 2012a. Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health Text with EEA relevance. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0432&from=EN>.

⁹ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum and dental and oral health, including gum and tooth protection and strength (ID 1149), plaque acid neutralisation (ID 1150), maintenance of tooth mineralisation (ID 1151), reduction of oral dryness (ID 1240), and maintenance of the normal body weight (ID 1152) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal 2009; 7(9):1271. [20 pp.]. doi:10.2903/j.efsa.2009.1271. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/1271> Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum sweetened with xylitol and plaque acid neutralisation (ID 485), maintenance of tooth mineralisation (ID 486, 562, 1181), reduction of dental plaque (ID 485, 3085), and defence against pathogens in the middle ear (ID 561, 1180) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011; 2011;9(6):2266. doi: <https://doi.org/10.2903/j.efsa.2011.2071>. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/2266>.

Scientific Opinion on the substantiation of health claims related to sugar-free chewing gum with carbamide and plaque acid neutralisation (ID 1153) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011 ; 2011;9(4):2071. doi: <https://doi.org/10.2903/j.efsa.2011.2071>. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/2071>.

¹⁰ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to sugar-free chewing gum and reduction of tooth demineralisation which reduces the risk of dental caries pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1775. [13 pp.]. doi:10.2903/j.efsa.2010.1775. Available online: www.efsa.europa.eu/efsajournal.htm EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to sugar-free chewing gum and neutralisation of plaque acids which reduces the risk of dental caries pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1776. [13 pp.]. doi:10.2903/j.efsa.2010.1776. Available online: <https://www.efsa.europa.eu/en/efsajournal/pub/1776>.

Those two health claims were subsequently approved in 2011 as permitted health claims in all European Union Member States.^{11, 12}

In 2011, EFSA issued an additional opinion, recognizing the role of sugar-free chewing gum containing fluoride and the maintenance of tooth mineralization, building on the previous EFSA opinions on the demonstrated relationship between food sources of fluoride and maintenance of tooth mineralization on the one hand and sugar-free chewing gum and maintenance of tooth mineralization on the other.¹³ Both were approved in 2012. Health claims associating sugar-free foods including sugar-free chewing gum and improved dental health have been approved in Canada¹⁴, Switzerland¹⁵, Japan¹⁶, and other countries.

The oral care benefits of chewing sugar-free chewing gum are also recognized by the World Dental Federation (FDI). In its 2015 report, entitled “Oral Health Worldwide”, the FDI specifically recommended sugar-free chewing gum as a simple and effective way for families and individuals to improve their oral health, alongside other equally essential oral care behaviors such as brushing teeth twice daily and using fluoride toothpaste.¹⁷ Similarly, the oral care benefits of chewing sugar-free chewing gum are recognized by national dental associations and experts around the

¹¹ Commission Regulation (EU) No 665/2011 of 11 July 2011 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk. See <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0665>.

¹² A third approved health claim associating chewing gum sweetened with 100% xylitol and reduction of the risk of dental caries by reducing dental plaque was approved in 2009, based on an EFSA opinion issued in 2008. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R1024:EN:NOT>; See also EFSA opinion at <http://www.efsa.europa.eu/en/efsajournal/doc/852.pdf>.

¹³ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to sugar-free chewing gum with fluoride and maintenance of tooth mineralisation (ID 1154) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2072. [13 pp.]. doi:10.2903/j.efsa.2011.2072. Available online: www.efsa.europa.eu/efsajournal.

¹⁴ [Summary of Health Canada's Assessment of a Health Claim about Sugar-Free Chewing Gum and Dental Caries Risk Reduction - Canada.ca](#).

¹⁵ [AS 2012 6811 - Verordnung des EDI über die Kennzeichnung und Anpreisung von Lebensmitteln \(LKV\) \(admin.ch\)](#)

¹⁶ [Ministry of Health, Labour and Welfare: Food with Health Claims, Food for Special Dietary Uses, and Nutrition Labeling \(mhlw.go.jp\)](#).

¹⁷ [2015_wohd-whitepaper-oral_health_worldwide.pdf \(fdiworlddental.org\)](#) at 20.

world, including the United States¹⁸, Australia¹⁹, the United Kingdom²⁰, France²¹, China,²² Germany²³, and Malaysia.²⁴

Studies conducted over the past decade have confirmed and strengthened several decades of previous evidence associating consumption of sugar-free chewing gum with dental health benefits, including reduction of risk of dental caries, adjustment of plaque acids, and support of tooth remineralization.²⁵ Yet these studies were not captured in the review leading to the Draft Guideline.

In addition, published articles analyzing multiple studies and databases uniformly support the role of sugar-free chewing gum in addressing major dental health issues.²⁶ Chewing sugar-free gum is emerging as a possible adjunct to existing

¹⁸American Dental Association: [Chewing Gum - American Dental Association \(mouthhealthy.org\)](https://www.mouthhealthy.org/en/az-topics/gum).

¹⁹ Australian Dental Association: [Sugar & Nutrition \(ada.org.au\)](https://www.ada.org.au/health-topics/sugar-nutrition).

²⁰ British Oral Health Foundation: [Sugar free chewing gum - Oral Health Foundation \(dentalhealth.org\)](https://www.dentalhealth.org/health-topics/sugar-free-chewing-gum).

²¹ Union Français Pour La Sante Bucco-Dentaire: [Focus Chewing gum without sugars - UFSBD](https://www.ufsbd.org/fr/la-sante-bucco-dentaire).

²² [The economic benefits of increased sugar-free chewing gum in China: a budget impact analysis - PMC \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/31111111/).

²³ [Full article: Elevating the use of sugar-free chewing gum in Germany: cost saving and caries prevention \(tandfonline.com\)](https://www.tandfonline.com/doi/full/10.1080/13643153.2019.1644444).

²⁴ [Oral Care Product : Chewing Gum - PORTAL MyHEALTH](https://www.portalmyhealth.com/oral-care-product/chewing-gum).

²⁵ See, e.g., Saheer P A, Parmar P, Majid SA, Bashyam M, Kousalya PS, Marriette TM, "Effect of sugar-free chewing gum on plaque and gingivitis among 14–15-year-old school children: A randomized controlled trial," *Indian J Dent Res* 2019;30:61-6 (reduction in clinical parameters such as plaque, gingival, and bleeding score, suggesting preventive potential of sugar-free chewing gum); Aluckal E, Ankola AV, "Effectiveness of xylitol and polyol chewing gum on salivary streptococcus mutans in children: A randomized controlled trial," *Indian J Dent Res* 2018;29:445-9 (suggestion that xylitol-containing chewing gums as an adjunct to regular home care preventive procedures may prevent dental caries); Vantipalli UK, Avula SSJ, Enuganti S, Bandi S, Kakarla P, Kuravadi RV, "Effect of three commercially available chewing gums on salivary flow rate and pH in caries-active and caries-free children: An *in vivo* study," *J Indian Soc Pedod Prev Dent*. 2017 Jul-Sep;35(3):254-259 (suggestion that chewing sugar-free gums in both caries-active and caries-free children may aid in reducing the incidence of dental caries); Dong Y, Yin W, Hu D, Zhang X, Xu L, Dodds WJ, Tian M., "Remineralization of early caries by chewing sugar-free gum: a clinical study using quantitative light-induced fluorescence," *Am J Dent*. 2014 Dec;27(6):291-5 (suggestion that regular chewing of sugar-free gum can help to arrest and reverse early caries lesions after 4, 8 and 12 weeks); Kumar S, Sogi SH, Indushekar KR, "Comparative evaluation of the effects of xylitol and sugar-free chewing gums on salivary and dental plaque pH in children," *J Indian Soc Pedod Prev Dent*. 2013 Oct-Dec;31(4):240-4 (suggestion that xylitol helps to reduce tooth decay).

²⁶ See, e.g., Newton JT, Awojobi O, Nasseripour M, Warburton F, Di Giorgio S, Gallagher JE, Banerjee A., "A Systematic Review and Meta-Analysis of the Role of Sugar-Free Chewing Gum in

prevention strategies²⁷ through mechanisms such as its stimulation of saliva, mechanical plaque control, as well as acting as a carrier for agents facilitating remineralization (calcium, phosphate, fluoride) and bacteriostatic ingredients, supporting homeostasis in the oral plaque biofilm.²⁸ A systematic review further suggests that the use of sugar-free chewing gum may contribute to prevent and control dental caries in children.²⁹ **We respectfully submit that WHO should not issue such a significant and influential guideline without reviewing the full panoply of data supporting the contribution of non-sugar sweeteners to the reduced risk of one of the major noncommunicable diseases.**

ICGA further notes that the COVID-19 pandemic has negatively impacted access to dental preventative care and treatments and widened inequities in oral care access specifically in children, older populations, and those with disabilities.³⁰ Accordingly, it is more important than ever that nutrition guidelines and other messaging from health and nutrition authorities be based on a full assessment of dietary risk factors associated with dental disease and opportunities to address such risks, particularly

Dental Caries,” JDR Clin Trans Res. 2020 Jul;5(3):214-223 (chewing SFG reduces caries increment in comparison to nonchewing controls); Parker-Groves D, “Should dentists recommend sugar-free chewing gum to help prevent decay?” Evid Based Dent. 2020 Sep;21(3):88 (use of SFG appears to have a significant effect in reducing the incidence of caries, compared to those who do not or use other sugar-free alternatives); Dodds MW, “The oral health benefits of chewing gum,” J Ir Dent Assoc. 2012 Oct-Nov;58(5):253-61 (sugar-free chewing gum has a place as an additional mode of dental disease prevention to be used in conjunction with the more traditional preventive methods); Mickenautsch S, Leal SC, Yengopal V, Bezerra AC, Cruvinel V, “Sugar-free chewing gum and dental caries: a systematic review,” J Appl Oral Sci. 2007 Apr;15(2):83-8 (sugar-free chewing gum has a caries-reducing effect).

²⁷ Wessel, S.W., van der Mei, H.C., Maitra, A., Dodds, M.W., Busscher, H.J. “Potential benefits of chewing gum for the delivery of oral therapeutics and its possible role in oral healthcare.” Expert Opinion on Drug Delivery. 2016; 13(10), 1421–1431.

²⁸ Marsh P.D. “Dental plaque: biological significance of a biofilm and community life-style.” Journal of Clinical Periodontology. 2005;32 Suppl 6:7-15.

²⁹ Newton, J.T., Awojobi, O., Nasseripour, M., Warburton, F, Di Giorgio, S., Gallagher, J.E., Banerjee, A.A. “Systematic Review and Meta-Analysis of the Role of Sugar-Free Chewing Gum in Dental Caries.” JDR Clinical & Translational Research. 2020; Jul;5(3):214-223.

³⁰ : <https://pubmed.ncbi.nlm.nih.gov/35091614/> Stennett, M., & Tsakos, G. (2022). “The impact of the COVID-19 pandemic on oral health inequalities and access to oral healthcare in England.” *British dental journal*, 232(2), 109–114. <https://doi.org/10.1038/s41415-021-3718-0>; <https://pubmed.ncbi.nlm.nih.gov/34414999/> Mac Giolla Phadraig, C., van Harten, M. T., Diniz-Freitas, M., Limeres Posse, J., Faulks, D., Dougall, A., Diz Dios, P., & Daly, B. (2021); “The impact of COVID-19 on access to dental care for people with disabilities: a global survey during the COVID-19 first wave lockdown.” *Medicina oral, patologia oral y cirugia bucal*, 26(6), e770–e777. <https://doi.org/10.4317/medoral.24742>.

when dental disease is acknowledged as the most prevalent non-communicable disease.

Indeed, in the pandemic context that global public health groups must continue to navigate, making conflicting scientific recommendations is not beneficial to the public's trust of our scientific processes and institutions. This would be the case if the WHO NUGAG final opinion were to continue featuring the final statement "...that NSS not be used as a means of... reducing risk of noncommunicable diseases (conditional recommendation)" and not consider how oral health could be interpreted as one of those NCDs in the draft WHO recommendation. Therefore, the final WHO NUGAG recommendation statement should ensure that understanding, communication and interpretation of the final recommendation is accurate. **ICGA respectfully suggests that the recommendation mention only the specific findings in the systematic review and meta-analysis and not generalize to all NCDs.**

Additionally, neither the draft WHO guideline, nor the systematic review by Rios-Leyvraz and Montez, examined data regarding NSS use in medications, personal care, and hygiene products. Therefore, there is no scientific support for the remark on page 11 of the draft that "NSS-free versions of these items, when readily obtainable, can be considered." In fact, as the WHO Draft Guideline points out, these hygiene products, along with sugar-free chewing gum, contain NSS in small amounts to make them more palatable which encourages their use for oral health benefits. A remark should not be made without scientific evidence to support it, or without considering the public health impacts such a recommendation would have on compliance and adherence to well established routines such as utilizing fluoridated toothpastes or chewing sugar-free chewing gum after meals. **On this basis, ICGA respectfully suggests that the comments about medications, hygiene, and personal care items be removed from the final recommendation.**

Like non-fermentable and non-cariogenic ingredients, NSS can contribute to good dental health when used in place of sugar.³¹ According to the FDI World Dental Federation, eating a well-balanced diet that is low in sugar and chewing sugar-free chewing gum, sweetened with NSS, after meals and snacks when brushing is not possible, are amongst the key recommendations for good oral health.³² Not acknowledging this well-established benefit of NSS use on dental health is counter to public health efforts to improve oral health given the high prevalence of dental caries and related conditions such as gum disease and tooth loss. An undesirable

³¹ FDI Policy Statement: "Sugar substitutes and their role in caries prevention." Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden.

³² "The Challenge of Oral Disease – A Call For Global Action." The Oral Health Atlas. 2nd ed. Geneva. 2015.

effect of the WHO NSS recommendation would discourage consumers from selecting lower sugar options, blunt the industry's sugar reduction efforts, and reduce options in the market which can lower the fermentable carbohydrates in the food supply with resulting oral health benefits.

III. THE DRAFT GUIDELINE DOES NOT CONSIDER THE ECONOMICS OF CARIES TREATMENT.

A recent analysis of published data conducted on behalf of the non-profit Alliance for a Cavity-Free Future estimated a global economic burden of \$245 billion for combined direct and indirect costs of caries treatment.³³ As an adjunct to other routine oral hygiene measures, regular use of sugar-free chewing gum may have relevant economic advantages with high savings on health expenditures. For example, published health economic analyses estimate annual savings of up to £8.2 million on dental treatments in the UK,³⁴ considerable savings on mandatory health insurance in Germany³⁵ for a total of hundreds of millions of euros across the world translating into reduced financial burdens for governments and individuals.³⁶ The economic impacts are an additional aspect which the WHO NUAGAG Subgroup on Diet and Health should consider in the resource implications section before making their final recommendation, especially in regards to oral health.

IV. THE DRAFT GUIDELINE SHOULD BE REVISED.

For all of these reasons, ICGA respectfully submits that the WHO Draft Guideline and its draft Conditional Recommendation should be revised to fully address the relationship of non-sugar sweeteners and dental health, and, in particular, the scientific evidence linking foods containing non-sugar sweeteners with the reduction of risk factors leading to dental caries and other oral diseases.

We further suggest that the draft Guideline acknowledge in greater detail the weaknesses found in the cited scientific evidence in relation to observational studies

³³ Claxton L., Taylor M., Kay E. "Oral health promotion: the economic benefits to the NHS of increased use of sugarfree gum in the UK." *British Dental Journal*. 2016; 220(3): 121 DOI: <https://www.nature.com/articles/sj.bdj.2016.94>.

³⁴ Newton, J.T., Awojobi, O., Nasseripour, M., Warburton, F, Di Giorgio, S., Gallagher, J.E., Banerjee, A.A. "Systematic Review and Meta-Analysis of the Role of Sugar-Free Chewing Gum in Dental Caries." *JDR Clinical & Translational Research*. 2020; Jul;5(3):214-223.

³⁵ Zimmer S., Spyra A, Kreimendahl F. "Elevating the use of sugar-free chewing gum in Germany: cost saving and caries prevention." *Acta Odontologica Scandinavica*. 2018. 76:6, 407-414.

³⁶ Rychlik R, Kreimendahl F, Blaich C, Calache H, Garcia-Godoy F, Kay E, Si Y, Zilberman D, Zimmer S. "A global approach to assess the economic benefits of increased consumption of sugar-free chewing gum." *American Journal of Dentistry*. 2017. Vol. 30(2), 77-83.

(scored low and very low) and randomized control trials (scored moderate), to avoid unintended ramifications that could have significant long term health implications.

* * *

ICGA thanks WHO for this opportunity and stands ready to work cooperatively in the further development of this important Guideline.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard F. Mann", with a stylized flourish at the end.

Richard F. Mann
Counsel to the
International Chewing Gum Association

Survey response 27

General information

Family/last name
Kendall
Given/first name
Karima
Organization/affiliation
Calorie Control Council
Sector
Other
Sector [Other]
Association
Country
United States of America

Comments on the draft guideline

Summary of evidence
Evidence to recommendations

Recommendations and supporting information

As a general comment, CCC strongly disagrees with the conditional recommendation that non-sugar sweeteners should not be used as a means of achieving weight control or reducing risk of non-communicable diseases. Given the impact of guidelines issued by WHO on regulatory, labeling and policy decisions globally, which will no doubt cascade down to healthcare professionals, food manufacturers and consumers, such recommendations should not be based primarily on prospective data with “low evidence of certainty” and should meet a threshold higher than “conditional”. Formulating recommendations that are not supported by strong scientific evidence is inappropriate and could unnecessarily deter the public from personal choice and potentially beneficial dietary options. Non-sugar sweeteners have been proven to assist in body weight and blood glucose management, as well as calorie and sugar reduction. Non-sugar sweeteners are a tool that, along with exercise and a healthy diet, can help individuals achieve their dietary and weight management goals, as well as WHO’s “strong” recommendation to reduce added sugars consumption. Discouraging the use of non-sugar sweeteners is not in line with the scientific evidence and has the potential to negatively impact public health.

The Use of Non-Sugar Sweeteners Has Been Proven Effective in Body Weight Management

We appreciate the Subgroup on Diet and Health’s acknowledgment of the evidence for reductions in body weight, BMI and sugar and caloric intake as a result of non-sugar sweetener consumption. However, the report’s caveat of “evidence of minor weight loss or reduced BMI over several months or less as observed in the randomized controlled trials without additional evidence of long-term impact, does not represent a health benefit” diminishes the significance of the role of these ingredients in weight management. Obesity is a multifactorial condition, with various approaches and tools available to address the issue. (1) The term “meaningful impact”, which is used in the Subgroup’s note that “weight loss and maintenance of a healthy weight must be sustained over the long-term”, is subjective and may have a different definition depending on the situation or specific individual. Meaningful impact with regard to the use of non-sugar sweeteners could also relate to weight management as opposed to only weight reduction. Consumers want and need safe and effective options when it comes to managing or potentially reducing their weight. Along with exercise and a balanced diet, non-sugar sweeteners are critical tools that can help consumers achieve their dietary and weight management goals. While we recognize studies evaluating the effects of non-sugar sweeteners on weight management vary in design and duration, the consistency of positive associations between beverages containing non-sugar sweeteners and weight management is noted across the body of evidence, which includes randomized clinical trials (RCTs), the gold standard of evidence, and raises the level of confidence in these findings. (2–5) For reasons difficult to understand, the WHO favors findings from prospective cohort trials to support the draft guideline, despite the well-known limitations associated with population studies. This is especially concerning given the findings of a recently published systematic review and meta-analysis of prospective cohort studies which sought to mitigate the effects of reverse causality and residual confounding typically seen in observational studies. (6) Through the utilization of change analyses of repeated measures of intake and substitution analyses to synthesize the association of non-sugar sweetened beverage intake with cardiometabolic outcomes, the authors report that an increase in non-sugar sweetened beverage intake was associated with lower body weight. Given these results, it would seem that the prevailing issue is not the lack of evidence regarding the efficacy of non-sugar sweeteners in weight management, but rather the limitations of the methods used. The characterization of the evidence reviewed as “low certainty” stops short of definitively highlighting these ingredients as sustainable tools in weight management. Though additional rigorous, long-term investigations would be helpful, the current evidence has repeatedly substantiated the benefits of non-sugar sweeteners in weight management.

Non-Sugar Sweeteners Should Be Recognized as a Tool to Help Achieve Reductions in Calories and Added Sugars

The draft guideline notes that the conditional recommendation should be “considered in the context of WHO recommendations to reduce free sugars intake and other guidance promoting healthy diets, including WHO guidance on dietary fat, carbohydrates, sodium and potassium.” (7) The WHO Subgroup’s own 2015 Guideline on Sugars Intake for Adults and Children included the “strong” recommendation that “individuals consume less than 10% of their total calories from free sugars (also known as added sugars),” (8) National Health and Nutrition Examination Survey (NHANES) data from 2015-2016 (9) suggests that over half of American adults exceed the recommended daily amount for added sugars, accounting for almost 270 calories/day (>13% percent of total calories) on average, according to the 2020-2025 Dietary Guidelines for Americans (DGAs). (10) Further, a 2017 summary and review of the available data from representative nation-wide surveys in the European Member States concerning the various characteristics of sugar intakes in children and adults reported that added sugars contributed 7 to 11% of total energy intake in adults and represented an even higher proportion of children’s energy intake at 11 to 17%. (11) With beverages noted in all three reports as a major source of dietary added sugar, the Subgroup’s hypothesis that “simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected”, (7) is unsubstantiated. Substituting sugar-sweetened beverages with those containing non-sugar sweeteners should be recognized as a safe and effective way for consumers to reduce added sugars in the diet. (5)

While water is always a good choice, the note in the draft guideline suggesting that, “messaging about potable water as a preferred replacement for sugar-sweetened beverages and as a mode of hydration generally can be incorporated into public health communications and food-based dietary guidelines”, (7) could potentially give way to unintended public health consequences (i.e., no change or increased consumption of food and beverages containing added sugar). As such, the validity of the rationale contained in the draft guidance stating there are “no identified undesirable effects or other mitigating factors that would argue against not using NSS” (7) is questionable. Further, substantial evidence shows that consuming beverages containing non-sugar sweeteners not only helps individuals manage their weight and has been shown in clinical trials to be no different than water when it comes to weight loss, but also their intended substitution for sugar-sweetened beverages is associated with improvements in body weight and cardiometabolic risk factors without any evidence of harm. (12-14)

Non-Sugar Sweeteners Are Associated with Lower Risk of Non-Communicable Diseases (NCDs)

Careful consideration of possible reverse causality and residual confounders is required when seeking to interpret the findings of prospective cohort studies investigating potential associations between non-sugar sweetener use and NCD risk. The aforementioned systematic review and meta-analysis, which implemented both change and substitution analyses, also reported that the substitution of beverages containing non-sugar sweeteners for sugar-sweetened beverages was associated with lower incidence of coronary heart disease, cardiovascular disease mortality and total mortality, with no adverse associations across other outcomes. (6) Still, the evidence should be considered in totality and include findings from well-designed and robust RCTs. A recent systematic review and network analysis of such trials, which applied substitution analyses, reported that the substitution of beverages containing non-sugar sweeteners or water for sugar-sweetened beverages resulted in reductions in body weight and improvements in cardiometabolic risk factors. (13) These findings not only align with those reported in other systematic reviews and meta-analyses, which have allowed for the interpretation of results by comparator, they add to the body of existing evidence that substantiate the intended benefit of non-sugar sweeteners as sugar substitutions.

Evidence indicates that non-sugar sweeteners do not raise blood glucose or insulin levels and, when used to replace sugar, can help lower carbohydrate intake, (15-17) which is especially important for those managing pre-diabetes and diabetes. When considered in totality with the findings of the aforementioned network analysis, for adults with overweight or obesity who are at risk for or have diabetes, beverages containing non-sugar sweeteners are useful tools for blood glucose management and are a viable sugar-sweetened beverage replacement strategy. (13) To recommend against their use not only unnecessarily removes an important consumer choice, but as mentioned above, may lead to unintended consequences, which is particularly troubling for those living with diabetes who may misinterpret this guideline as being applicable to them.

Lastly, there is no evidence of a plausible mechanism to support potential effects of non-sugar sweeteners on the incidence of NCD. (18) There is a large body of evidence, which includes the systematic review of RCTs, indicating a lack of plausible mechanisms of how non-sugar sweeteners could increase the risk of obesity, diabetes and cardiovascular diseases in humans, as they do not negatively affect risk factors such as blood pressure, blood lipids, glycemia, or body weight. (13,19-22)

Non-Sugar Sweeteners Provide Oral Health Benefits

Though the Global Burden of Disease Collaborative Network notes “untreated dental caries in permanent teeth as the most common health condition”, (23) and the WHO’s own 2015 Guideline on Sugars Intake in Adults and Children cites dental caries as “critical in relation to free sugars intake”, (8) the effects of non-sugar sweetener intake and oral health were not analyzed in the draft guideline. In addition to evidence of desirable effects of these ingredients and dental caries, authorities such as the European Food Safety Authority (EFSA) state, “there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralization by decreasing tooth demineralization if consumed instead of sugars”. (24) As free sugar consumption is recognized as one of the leading modifiable risk factors for dental caries by WHO, (25) global-reaching guidelines should align and explicitly state the benefits of non-sugar sweeteners in this area.

References:

1. Ashwell MA, Gibson S, Bellisle F, Buttriss J, Drewnowski A, Fantino M, Gallagher AM, de Graaf K, Gosciny S, Hardman CA, Laviada-Molina H, López-García R, Magnuson B, Mellor D, Rogers P, Rowland I, Russell W, Sievenpiper J, la Vecchia C. Expert Consensus on Low-Calorie Sweeteners: Facts, Research Gaps and Suggested Actions. *Nutr Res Rev.* 2020; 33(1): 1-10.
2. Miller PE, Perez V. Low-Calorie Sweeteners and Body Weight and Composition: A Meta-Analysis of Randomized Controlled Trials and Prospective. 2014;(3):765-777. doi:10.3945/ajcn.113.082826.1
3. Peters JC, Beck J, Cardel M, et al. The Effects of Water and Non-Nutritive Sweetened Beverages on Weight Loss and Weight Maintenance: A Randomized Clinical Trial. *Obesity.* 2016;24(2):297-304. doi:10.1002/oby.21327
4. Rogers PJ. The Role of Low-Calorie Sweeteners in the Prevention and Management of Overweight and Obesity: Evidence v. Conjecture. *Proc Nutr Soc.* 2017. doi:10.1017/S0029665117004049
5. Rogers PJ and Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes* 2020. <https://doi.org/10.1038/s41366-020-00704-2>
6. Lee JJ, Khan TA, McGlynn N, et al. Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages with Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies. *Diabetes Care.* 2022 Aug 1;45(8):1917-1930. doi: 10.2337/dc21-2130. PMID: 35901272.
7. WHO Draft Guidance on Use of Non-Sugar Sweeteners (2022) NSS guideline_DRAFT_PC July 2022.pdf (who.int)
8. WHO Guideline: “Sugars Intake for Adults and Children” (2015). http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/
9. Bowman SA, Clemens JC, Friday JE, LaComb RP, Paudel D, and Shimizu M. Added Sugars in Adults’ Diet: What We Eat in America, NHANES 2015-2016. Food Surveys Research Group. Dietary Data Brief No. 24. October 2019
10. U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).
11. Azaïs-Braesco V, Sluik D, Maillot M, Kok F, Moreno LA. A review of total & added sugar intakes and dietary sources in Europe. *Nutr J.* 2017 Jan 21;16(1):6. doi: 10.1186/s12937-016-0225-2. PMID: 28109280; PMCID: PMC5251321.
12. Peters JC, et al. The Effects of Water and Non-Nutritive Sweetened Beverages on Weight Loss and Weight Maintenance: A Randomized Clinical Trial. *Obesity (Silver Spring).* 2016; 24: 297-304
13. McGlynn ND, Khan TA, Wang L, et al. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages with Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. *JAMA Netw*

Open. 2022;5(3):e222092. doi:10.1001/jamanetworkopen.2022.2092

14. De Ruyter, J. C., Olthof, M. R., Seidell, J. C., & Katan, M. B. (2012). A Trial of Sugar-Free or Sugar-Sweetened Beverages and Body Weight in Children. *New England Journal of Medicine*, 367(15), 1397–1406.
 15. Lohner S, Kuellenberg de Gaudry D, Toews I, Ferenci T, Meerpohl JJ. Non-nutritive Sweeteners for Diabetes Mellitus. *Cochrane Database of Systematic Reviews* 2020 May 25;5:CD012885. Doi 10.1002/14651858.CD012885.pub2
 16. Nichol, A. D., Holle, M. J., & An, Ruopeng. (2018). Glycemic impact of non-nutritive sweeteners: a systematic review and meta-analysis of randomized controlled trials. *European Journal of Clinical Nutrition*. <https://doi.org/10.1038/s41430-018-0170-6>
 17. Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. *Diabetes Care*. 2019 May;42(5):731-754.
 18. Pyrogianni V and La Vecchia C. Letter by Pyrogianni and La Vecchia Regarding Article, “Artificially Sweetened Beverages and Stroke, Coronary Heart Disease, and All-Cause Mortality in Women’s Health Initiative”. *Stroke* 2019;50(6):e169
 19. Pham H, Phillips LK, Jones KL. Acute Effects of Nutritive and Non-Nutritive Sweeteners on postprandial Blood Pressure. *Nutrients*. 2019 Jul 25;11(8):1717
 20. Toews I, Lohner S, Kullenberg de Gaudry D, Sommer H, Meerpohl JJ. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomized and non-randomised controlled trials and observational studies. *BMJ* 2019;364:K4718
 21. Greyling A, Appleton KM, Raben A, Mela DJ. Acute glycemic and insulinemic effects of low-energy sweeteners: a systematic review and meta-analysis of randomized controlled trials. *Am J Clin Nutr* 2020 Oct 1;112(4):1002-1014
 22. Movahedian M, Golzan SA, Ashtary-Larky D, Clark CCT, Asbaghi O, Hekmatdoost A. The effects of artificial- and stevia-based sweeteners on lipid profile in adults: a GRADE-assessed systematic review, meta-analysis, and meta-regression of randomized clinical trials. *Crit Rev Food Sci Nutr*. 2021 Dec 9:1-17. Doi: 10.1080/10408398.2021.2012641. Epub ahead of print
 23. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019). Seattle: Institute of Health Metrics and Evaluation (IHME); 2020. Available from <http://ghdx.healthdata.org/gbd-results-tool>.
 24. European Food Safety Authority. Scientific Opinion on the Substantiation of Health Claims Related to Intense Sweeteners. *EFSA Journal* 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>
 25. World Health Organization. Oral Health Fact Sheet. Available at <https://www.who.int/news-room/fact-sheets/detail/oral-health>
-

Other comments
<p>CCC urges WHO to consider the importance of communicating accurate information on the evidence reviewed in the formation of the guideline. As safety assessment is not within the scope of work of WHO NUGAG Subgroup on Diet and Health and the draft guideline explicitly states that it is not intended as a safety assessment of non-sugar sweeteners, it is important that Subgroup commentary and the resulting recommendation are not worded in a way that suggests otherwise. Because the evidence reviewed in the draft guideline is inadequate for such assessment, the safety of non-sugar sweeteners should be reiterated as established by various international government and regulatory agencies including but not limited to EFSA (26-28), the United States Food and Drug Administration (29), Public Health England (30), Food Standards Australia and New Zealand (31) and Health Canada. (32) As many of these organizations require a demonstration of need before the safety of an additive is examined, it is important to highlight the general acceptance of non-sugar sweeteners in reformulation as replacements for sugar, as well as the benefits demonstrated in the body of scientific evidence. As indicated in the draft guideline, WHO guidelines are meant to be considered in the context of one another, and therefore consumers will benefit from a better understanding of the importance of reducing caloric intake, particularly from added sugars, and achieving a balanced diet and how non-sugar sweeteners and low-calorie ingredients can aid in achieving this goal.</p> <p>Finally, there is a lack of harmonization between this WHO draft guideline and the recommendations of several leading diabetes organizations, such as the American Diabetes Association, Diabetes Canada and Diabetes UK, all of which acknowledge the benefits of non-sugar sweetener use for those living with diabetes, including calorie and carbohydrate reduction and blood glucose management. (33-35) Finalizing a recommendation that seemingly contradicts and overlooks the scientific evidence and recommendations from global authorities could lead to questions in WHO's credibility and defeat the purpose of the guideline altogether.</p> <p>In closing, CCC appreciates the WHO NUGAG Subgroup on Diet and Health's consideration of our comments on the draft Guideline on Non-Sugar Sweeteners. These ingredients remain an important and beneficial tool in helping consumers manage not only their sugars and calorie intakes, but also their weight and certain chronic conditions. It is critical that the final Guideline reflect this understanding so as to offer regulators, clinicians and consumers more practical options in meeting recommendations for sugar reduction.</p> <p>References:</p> <ol style="list-style-type: none"> 26. European Food Safety Authority. "Aspartame" https://www.efsa.europa.eu/en/efsajournal/pub/3496 27. European Food Safety Authority. "Steviol Glycosides" https://www.efsa.europa.eu/en/efsajournal/pub/1537 28. European Food Safety Authority. "Sucralose" https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out68_en.pdf 29. United States Food and Drug Administration. "High Intensity Sweeteners permitted for use in the United States" https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm397725.htm 30. Public Health England (2017) Sugar Reduction: Achieving the 20% A technical report outlining progress to date, guidelines for industry, 2015 baseline levels in key foods and next steps. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/604336/Sugar_reduction_achieving_the_20_.pdf 31. Food Standards Australia and New Zealand. "Sweeteners" http://www.foodstandards.gov.au/consumer/additives/intensesweetener/Pages/default.aspx 32. Health Canada. "The Safety of Sugar Substitutes" https://www.canada.ca/en/health-canada/services/healthy-living/your-health/food-nutrition/safety-sugarsubstitutes.html 33. American Diabetes Association. 5. Facilitating Behavior Change and Well-being to Improve Health Outcomes: Standards of Medical Care in Diabetes-2020. Diabetes Care. 2020 Jan;43(Suppl 1):S48-S65. doi: 10.2337/dc20-S005. PMID: 31862748. 34. Diabetes Canada Clinical Practice Guidelines Expert Committee, Sievenpiper JL, Chan CB, Dworatzek PD, Freeze C, Williams SL. Nutrition Therapy. Can J Diabetes. 2018 Apr;42 Suppl 1:S64-S79. doi: 10.1016/j.cjcd.2017.10.009. Erratum in: Can J Diabetes. 2019 Mar;43(2):153. PMID: 29650114. 35. Dyson PA, Twenefour D, Breen C, et al. Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes. Diabet Med. 2018 May;35(5):541-547. doi: 10.1111/dme.13603. PMID: 29443421.
Upload comments
<pre>[{"title":"Calorie Control Council Comments on NUGAG Draft Guideline on Use of Non-Sugar Sweeteners","comment":"","size":"214.3056640625","name":"CCC%20Final%20Comments%20on%20WHO%20NUGAG%20NSS%20Guidance%208122022.pdf","filename":"fu_pw74tkjrms6yanm","ext":"pdf" }]</pre>

CCC Comments on Draft WHO Guideline on Non-Sugar Sweeteners

The Calorie Control Council (CCC) is an international association representing manufacturers and end-users of low- and no-calorie ingredients, foods and beverages, including manufacturers and suppliers of non-sugar sweeteners (also referred to by CCC as “low- and no-calorie sweeteners”). CCC promotes open dialogue among its members, scientific and governmental organizations, health professionals and consumer groups on the benefits and appropriate use of low- and no-calorie ingredients, foods and beverages. CCC is pleased to provide the following comments on the draft WHO Guideline on Non-Sugar Sweeteners.

As a general comment, CCC strongly disagrees with the conditional recommendation that non-sugar sweeteners should not be used as a means of achieving weight control or reducing risk of non-communicable diseases. Given the impact of guidelines issued by WHO on regulatory, labeling and policy decisions globally, which will no doubt cascade down to healthcare professionals, food manufacturers and consumers, such recommendations should not be based primarily on prospective data with “low evidence of certainty” and should meet a threshold higher than “conditional”. Formulating recommendations that are not supported by strong scientific evidence is inappropriate and could unnecessarily deter the public from personal choice and potentially beneficial dietary options. Non-sugar sweeteners have been proven to assist in body weight and blood glucose management, as well as calorie and sugar reduction. Non-sugar sweeteners are a tool that, along with exercise and a healthy diet, can help individuals achieve their dietary and weight management goals, as well as WHO’s “strong” recommendation to reduce added sugars consumption. Discouraging the use of non-sugar sweeteners is not in line with the scientific evidence and has the potential to negatively impact public health.

The Use of Non-Sugar Sweeteners Has Been Proven Effective in Body Weight Management

We appreciate the Subgroup on Diet and Health’s acknowledgment of the evidence for reductions in body weight, BMI and sugar and caloric intake as a result of non-sugar sweetener consumption. However, the report’s caveat of “evidence of minor weight loss or reduced BMI over several months or less as observed in the randomized controlled trials without additional evidence of long-term impact, does not represent a health benefit” diminishes the significance of the role of these ingredients in weight management. Obesity is a multifactorial condition, with various approaches and tools available to address the issue.¹ The term “meaningful impact”, which is used in the Subgroup’s note that “weight loss and maintenance of a healthy weight must be sustained over the long-term”, is subjective and may have a different definition depending on the situation or specific individual. Meaningful impact with regard to the use of non-sugar sweeteners could also relate to weight management as opposed to only weight reduction. Consumers want and need safe and effective options when it comes to managing or potentially reducing their weight. Along with exercise and a balanced diet, non-sugar sweeteners are critical tools that can help consumers achieve their dietary and weight management goals. While we recognize studies evaluating the effects of non-sugar sweeteners on weight management vary in design and duration, the consistency of positive associations between beverages containing non-sugar sweeteners and weight management is noted across the body of evidence, which includes randomized clinical trials (RCTs), the gold standard of evidence, and raises the level of confidence in these findings.²⁻
⁵ For reasons difficult to understand, the WHO favors findings from prospective cohort trials to support the draft guideline, despite the well-known limitations associated with population studies. This is

especially concerning given the findings of a recently published systematic review and meta-analysis of prospective cohort studies which sought to mitigate the effects of reverse causality and residual confounding typically seen in observational studies.⁶ Through the utilization of change analyses of repeated measures of intake and substitution analyses to synthesize the association of non-sugar sweetened beverage intake with cardiometabolic outcomes, the authors report that an increase in non-sugar sweetened beverage intake was associated with lower body weight. Given these results, it would seem that the prevailing issue is not the *lack* of evidence regarding the efficacy of non-sugar sweeteners in weight management, but rather the limitations of the methods used. The characterization of the evidence reviewed as “low certainty” stops short of definitively highlighting these ingredients as sustainable tools in weight management. Though additional rigorous, long-term investigations would be helpful, the current evidence has repeatedly substantiated the benefits of non-sugar sweeteners in weight management.

Non-Sugar Sweeteners Should Be Recognized as a Tool to Help Achieve Reductions in Calories and Added Sugars

The draft guideline notes that the conditional recommendation should be “considered in the context of WHO recommendations to reduce free sugars intake and other guidance promoting healthy diets, including WHO guidance on dietary fat, carbohydrates, sodium and potassium.”⁷ The WHO Subgroup’s own 2015 Guideline on Sugars Intake for Adults and Children included the “strong” recommendation that “individuals consume less than 10% of their total calories from free sugars (also known as added sugars),”⁸ National Health and Nutrition Examination Survey (NHANES) data from 2015-2016⁹ suggests that over half of American adults exceed the recommended daily amount for added sugars, accounting for almost 270 calories/day (>13% percent of total calories) on average, according to the 2020-2025 Dietary Guidelines for Americans (DGAs).¹⁰ Further, a 2017 summary and review of the available data from representative nation-wide surveys in the European Member States concerning the various characteristics of sugar intakes in children and adults reported that added sugars contributed 7 to 11% of total energy intake in adults and represented an even higher proportion of children’s energy intake at 11 to 17%.¹¹ With beverages noted in all three reports as a major source of dietary added sugar, the Subgroup’s hypothesis that “simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected”,⁷ is unsubstantiated. Substituting sugar-sweetened beverages with those containing non-sugar sweeteners should be recognized as a safe and effective way for consumers to reduce added sugars in the diet.⁵

While water is always a good choice, the note in the draft guideline suggesting that, “messaging about potable water as a preferred replacement for sugar-sweetened beverages and as a mode of hydration generally can be incorporated into public health communications and food-based dietary guidelines”,⁷ could potentially give way to unintended public health consequences (i.e., no change or increased consumption of food and beverages containing added sugar). As such, the validity of the rationale contained in the draft guidance stating there are “no identified undesirable effects or other mitigating factors that would argue against not using NSS”⁷ is questionable. Further, substantial evidence shows that consuming beverages containing non-sugar sweeteners not only helps individuals manage their weight and has been shown in clinical trials to be no different than water when it comes to weight loss,

but also their intended substitution for sugar-sweetened beverages is associated with improvements in body weight and cardiometabolic risk factors without any evidence of harm. ¹²⁻¹⁴

Non-Sugar Sweeteners Are Associated with Lower Risk of Non-Communicable Diseases (NCDs)

Careful consideration of possible reverse causality and residual confounders is required when seeking to interpret the findings of prospective cohort studies investigating potential associations between non-sugar sweetener use and NCD risk. The aforementioned systematic review and meta-analysis, which implemented both change and substitution analyses, also reported that the substitution of beverages containing non-sugar sweeteners for sugar-sweetened beverages was associated with lower incidence of coronary heart disease, cardiovascular disease mortality and total mortality, with no adverse associations across other outcomes. ⁶ Still, the evidence should be considered in totality and include findings from well-designed and robust RCTs. A recent systematic review and network analysis of such trials, which applied substitution analyses, reported that the substitution of beverages containing non-sugar sweeteners or water for sugar-sweetened beverages resulted in reductions in body weight and improvements in cardiometabolic risk factors. ¹³ These findings not only align with those reported in other systematic reviews and meta-analyses, which have allowed for the interpretation of results by comparator, they add to the body of existing evidence that substantiate the intended benefit of non-sugar sweeteners as sugar substitutions.

Evidence indicates that non-sugar sweeteners do not raise blood glucose or insulin levels and, when used to replace sugar, can help lower carbohydrate intake, ¹⁵⁻¹⁷ which is especially important for those managing pre-diabetes and diabetes. When considered in totality with the findings of the aforementioned network analysis, for adults with overweight or obesity who are at risk for or have diabetes, beverages containing non-sugar sweeteners are useful tools for blood glucose management and are a viable sugar-sweetened beverage replacement strategy. ¹³ To recommend against their use not only unnecessarily removes an important consumer choice, but as mentioned above, may lead to unintended consequences, which is particularly troubling for those living with diabetes who may misinterpret this guideline as being applicable to them.

Lastly, there is no evidence of a plausible mechanism to support potential effects of non-sugar sweeteners on the incidence of NCD. ¹⁸ There is a large body of evidence, which includes the systematic review of RCTs, indicating a lack of plausible mechanisms of how non-sugar sweeteners could increase the risk of obesity, diabetes and cardiovascular diseases in humans, as they do not negatively affect risk factors such as blood pressure, blood lipids, glycemia, or body weight. ^{13,19-22}

Non-Sugar Sweeteners Provide Oral Health Benefits

Though the Global Burden of Disease Collaborative Network notes “untreated dental caries in permanent teeth as the most common health condition”, ²³ and the WHO’s own 2015 Guideline on Sugars Intake in Adults and Children cites dental caries as “critical in relation to free sugars intake”, ⁸ the effects of non-sugar sweetener intake and oral health were not analyzed in the draft guideline. In addition to evidence of desirable effects of these ingredients and dental caries, authorities such as the European Food Safety Authority (EFSA) state, “there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralization by decreasing tooth demineralization if consumed instead of sugars”. ²⁴ As free sugar consumption is recognized as one of

the leading modifiable risk factors for dental caries by WHO,²⁵ global-reaching guidelines should align and explicitly state the benefits of non-sugar sweeteners in this area.

Communication Without Context is Misleading

CCC urges WHO to consider the importance of communicating accurate information on the evidence reviewed in the formation of the guideline. As safety assessment is not within the scope of work of WHO NUGAG Subgroup on Diet and Health and the draft guideline explicitly states that it is not intended as a safety assessment of non-sugar sweeteners, it is important that Subgroup commentary and the resulting recommendation are not worded in a way that suggests otherwise. Because the evidence reviewed in the draft guideline is inadequate for such assessment, the safety of non-sugar sweeteners should be reiterated as established by various international government and regulatory agencies including but not limited to EFSA²⁶⁻²⁸, the United States Food and Drug Administration²⁹, Public Health England³⁰, Food Standards Australia and New Zealand³¹ and Health Canada.³² As many of these organizations require a demonstration of need before the safety of an additive is examined, it is important to highlight the general acceptance of non-sugar sweeteners in reformulation as replacements for sugar, as well as the benefits demonstrated in the body of scientific evidence. As indicated in the draft guideline, WHO guidelines are meant to be considered in the context of one another, and therefore consumers will benefit from a better understanding of the importance of reducing caloric intake, particularly from added sugars, and achieving a balanced diet and how non-sugar sweeteners and low-calorie ingredients can aid in achieving this goal.

Finally, there is a lack of harmonization between this WHO draft guideline and the recommendations of several leading diabetes organizations, such as the American Diabetes Association, Diabetes Canada and Diabetes UK, all of which acknowledge the benefits of non-sugar sweetener use for those living with diabetes, including calorie and carbohydrate reduction and blood glucose management.³³⁻³⁵ Finalizing a recommendation that seemingly contradicts and overlooks the scientific evidence and recommendations from global authorities could lead to questions in WHO's credibility and defeat the purpose of the guideline altogether.

In closing, CCC appreciates the WHO NUGAG Subgroup on Diet and Health's consideration of our comments on the draft Guideline on Non-Sugar Sweeteners. These ingredients remain an important and beneficial tool in helping consumers manage not only their sugars and calorie intakes, but also their weight and certain chronic conditions. It is critical that the final Guideline reflect this understanding so as to offer regulators, clinicians and consumers more practical options in meeting recommendations for sugar reduction.

References:

1. Ashwell MA, Gibson S, Bellisle F, Buttriss J, Drewnowski A, Fantino M, Gallagher AM, de Graaf K, Gosciniy S, Hardman CA, Laviada-Molina H, López-García R, Magnuson B, Mellor D, Rogers P, Rowland I, Russell W, Sievenpiper J, la Vecchia C. Expert Consensus on Low-Calorie Sweeteners: Facts, Research Gaps and Suggested Actions. *Nutr Res Rev.* 2020; 33(1): 1-10.
2. Miller PE, Perez V. Low-Calorie Sweeteners and Body Weight and Composition: A Meta-Analysis of Randomized Controlled Trials and Prospective. 2014;(3):765-777. doi:10.3945/ajcn.113.082826.1

3. Peters JC, Beck J, Cardel M, et al. The Effects of Water and Non-Nutritive Sweetened Beverages on Weight Loss and Weight Maintenance: A Randomized Clinical Trial. *Obesity*. 2016;24(2):297-304. doi:10.1002/oby.21327
4. Rogers PJ. The Role of Low-Calorie Sweeteners in the Prevention and Management of Overweight and Obesity: Evidence v. Conjecture. *Proc Nutr Soc*. 2017. doi:10.1017/S0029665117004049
5. Rogers PJ and Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes* 2020. <https://doi.org/10.1038/s41366-020-00704-2>
6. Lee JJ, Khan TA, McGlynn N, et al. Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages with Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies. *Diabetes Care*. 2022 Aug 1;45(8):1917-1930. doi: 10.2337/dc21-2130. PMID: 35901272.
7. WHO Draft Guidance on Use of Non-Sugar Sweeteners (2022) [NSS guideline_DRAFT_PC July 2022.pdf \(who.int\)](#)
8. WHO Guideline: “Sugars Intake for Adults and Children” (2015). http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/
9. Bowman SA, Clemens JC, Friday JE, LaComb RP, Paudel D, and Shimizu M. Added Sugars in Adults’ Diet: What We Eat in America, NHANES 2015-2016. Food Surveys Research Group. Dietary Data Brief No. 24. October 2019
10. U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).
11. Azaïs-Braesco V, Sluik D, Maillot M, Kok F, Moreno LA. A review of total & added sugar intakes and dietary sources in Europe. *Nutr J*. 2017 Jan 21;16(1):6. doi: 10.1186/s12937-016-0225-2. PMID: 28109280; PMCID: PMC5251321.
12. Peters JC, et al. The Effects of Water and Non-Nutritive Sweetened Beverages on Weight Loss and Weight Maintenance: A Randomized Clinical Trial. *Obesity (Silver Spring)*. 2016; 24: 297-304
13. McGlynn ND, Khan TA, Wang L, et al. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages with Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2022;5(3):e222092. doi:10.1001/jamanetworkopen.2022.2092
14. De Ruyter, J. C., Olthof, M. R., Seidell, J. C., & Katan, M. B. (2012). A Trial of Sugar-Free or Sugar-Sweetened Beverages and Body Weight in Children. *New England Journal of Medicine*, 367(15), 1397–1406.
15. Lohner S, Kuellenberg de Gaudry D, Toews I, Ferenci T, Meerpohl JJ. Non-nutritive Sweeteners for Diabetes Mellitus. *Cochrane Database of Systematic Reviews* 2020 May 25;5:CD012885. Doi 10.1002/14651858.CD012885.pub2
16. Nichol, A. D., Holle, M. J., & An, Ruopeng. (2018). Glycemic impact of non-nutritive sweeteners: a systematic review and meta-analysis of randomized controlled trials. *European Journal of Clinical Nutrition*. <https://doi.org/10.1038/s41430-018-0170-6>
17. Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. *Diabetes Care*. 2019 May;42(5):731-754.
18. Pyrogianni V and La Vecchia C. Letter by Pyrogianni and La Vecchia Regarding Article, “Artificially Sweetened Beverages and Stroke, Coronary Heart Disease, and All-Cause Mortality in Women’s Health Initiative”. *Stroke* 2019;50(6):e169

19. Pham H, Phillips LK, Jones KL. Acute Effects of Nutritive and Non-Nutritive Sweeteners on postprandial Blood Pressure. *Nutrients*. 2019 Jul 25;11(8):1717
20. Toews I, Lohner S, Kullenberg de Gaudry D, Sommer H, Meerpohl JJ. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomized and non-randomised controlled trials and observational studies. *BMJ* 2019;364:K4718
21. Greyling A, Appleton KM, Raben A, Mela DJ. Acute glycemc and insulinemic effects of low-energy sweeteners: a systematic review and meta-analysis of randomized controlled trials. *Am J Clin Nutr* 2020 Oct 1;112(4):1002-1014
22. Movahedian M, Golzan SA, Ashtary-Larky D, Clark CCT, Asbaghi O, Hekmatdoost A. The effects of artificial- and stevia-based sweeteners on lipid profile in adults: a GRADE-assessed systematic review, meta-analysis, and meta-regression of randomized clinical trials. *Crit Rev Food Sci Nutr*. 2021 Dec 9:1-17. Doi: 10.1080/10408398.20212012641. Epub ahead of print
23. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019). Seattle: Institute of Health Metrics and Evaluation (IHME); 2020. Available from <http://ghdx.healthdata.org/gbd-results-tool>.
24. European Food Safety Authority. Scientific Opinion on the Substantiation of Health Claims Related to Intense Sweeteners. *EFSA Journal* 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>
25. World Health Organization. Oral Health Fact Sheet. Available at <https://www.who.int/news-room/fact-sheets/detail/oral-health>
26. European Food Safety Authority. "Aspartame" <https://www.efsa.europa.eu/en/efsajournal/pub/3496>
27. European Food Safety Authority. "Steviol Glycosides" <https://www.efsa.europa.eu/en/efsajournal/pub/1537>
28. European Food Safety Authority. "Sucralose" https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out68_en.pdf
29. United States Food and Drug Administration. "High Intensity Sweeteners permitted for use in the United States" <https://www.fda.gov/food/ingredientpackaginglabeling/foodadditivesingredients/ucm397725.htm>
30. Public Health England (2017) Sugar Reduction: Achieving the 20% A technical report outlining progress to date, guidelines for industry, 2015 baseline levels in key foods and next steps. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/604336/Sugar_reduction_achieving_the_20_.pdf
31. Food Standards Australia and New Zealand. "Sweeteners" <http://www.foodstandards.gov.au/consumer/additives/intensesweetener/Pages/default.aspx>
32. Health Canada. "The Safety of Sugar Substitutes" <https://www.canada.ca/en/health-canada/services/healthy-living/your-health/food-nutrition/safety-sugarsubstitutes.html>
33. American Diabetes Association. 5. Facilitating Behavior Change and Well-being to Improve Health Outcomes: *Standards of Medical Care in Diabetes-2020*. *Diabetes Care*. 2020 Jan;43(Suppl 1):S48-S65. doi: 10.2337/dc20-S005. PMID: 31862748.
34. Diabetes Canada Clinical Practice Guidelines Expert Committee, Sievenpiper JL, Chan CB, Dworatzek PD, Freeze C, Williams SL. Nutrition Therapy. *Can J Diabetes*. 2018 Apr;42 Suppl 1:S64-S79. doi: 10.1016/j.jcjd.2017.10.009. Erratum in: *Can J Diabetes*. 2019 Mar;43(2):153. PMID: 29650114.

35. Dyson PA, Twenefour D, Breen C, et al. Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes. *Diabet Med*. 2018 May;35(5):541-547. doi: 10.1111/dme.13603. PMID: 29443421.

Survey response 28

General information

Family/last name
Castro
Given/first name
Igor
Organization/affiliation
ABIR - Associação Brasileira das Indústrias de Refrigerantes e de Bebidas Não Alcoólicas
Sector
Other
Sector [Other]
Non-governmental Association
Country
Brazil

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"ABIR comments on the public consultation","comment":"","size":"1565.6923828125","name":"Contribuic%C7a%CC%83o%20ABIR%20-%20OMS%20-%20CP%20Diretriz%20Educorantes.pdf","filename":"fu_4y58jmu3wkfsgjd","ext":"pdf" }]



Brasília, 08 de agosto de 2022.

VIA E-mail (NFS@WHO.int)

Assunto: MINUTA da Diretriz da OMS: uso de adoçantes sem açúcar

Prezados:

A Associação Brasileira das Indústrias de Refrigerantes e de Bebidas Não Alcoólicas (“ABIR”) tem o prazer de enviar esses comentários sobre a minuta da diretriz da OMS sobre o uso de adoçantes sem açúcar (a “Minuta da Diretriz”).¹ Conforme discutido abaixo nestes comentários, embora a ABIR apoie os esforços da OMS para promover dietas saudáveis, a ABIR respeitosamente **solicita que a OMS reconsidere as prioridades gerais e retorne à coerência política baseada na ciência**, ao orientar as partes interessadas em seus esforços para alcançar os Objetivos de Desenvolvimento Sustentável da ONU até 2030.

Em 2015, quando a ONU adotou pela primeira vez os Objetivos Globais, o chamado à ação exigiu intensivo envolvimento global em apoio à implementação de todos os objetivos e metas, reunindo governos, *o setor privado*, a sociedade civil, o sistema das Nações Unidas e outros atores, *mobilizando todos os recursos disponíveis*.² De particular interesse, um desses recursos especificamente destacados pelo sistema da ONU é a capacidade de reformulação do setor de alimentos e bebidas. Em 2018, a declaração política do Encontro de Alto Nível da ONU sobre NCDs (Non-Communicable Diseases, Doenças não transmissíveis) convocou o setor privado a “fortalecer seu compromisso” de se esforçar mais para reformular alimentos e bebidas e reduzir o uso excessivo de sais, açúcares e

¹ A ABIR é uma organização brasileira não governamental, fundada em 1950, sendo a voz do setor brasileiro de bebidas não alcoólicas, detendo 90% do share do mercado. As associadas da ABIR incluem empresas nacionais e regionais de bebidas, bem como fabricantes internacionais de bebidas que operam em mais de 200 países e produzem, distribuem e vendem diversas bebidas não alcoólicas com e sem gás, como refrigerantes, bebidas esportivas, energéticos, águas engarrafadas, águas aromatizadas e/ou aprimoradas, chás e cafés prontos para beber, sucos integrais de frutas ou vegetais, néctares e bebidas à base de soja e bebidas lácteas.¹

² “Transformando Nosso Mundo: A Agenda 2030 para o Desenvolvimento Sustentável”, resolução adotada pela Assembleia Geral em 25 de setembro de 2015, A/RES/70/1 nos parágrafos 39 e 60 (grifo nosso).

gorduras.³ Conforme discutido no Anexo, nosso setor tem atendido a essa chamada da ONU e, nos últimos anos, intensificou significativamente os esforços para reformular as bebidas e reduzir a adição de açúcares, contando com uma ferramenta-chave de reformulação para isso: adoçantes de baixa caloria.

E, ainda assim, enquanto fazemos esse esforço satisfatório e robusto, a OMS simultaneamente emite uma minuta de diretriz que busca suprimir essa importante ferramenta de reformulação de nossa caixa de ferramentas, enquanto reconhece que essa minuta de diretriz é 1) baseada em evidências “de baixa certeza” e 2) não baseada em preocupações de segurança. Estamos, francamente, preocupados com essa aparente reviravolta política. Como o secretário geral da ONU, Antonio Guterres, declarou no Fórum Político de Alto Nível da ONU em 2022, “[o] mundo tem profundos problemas, assim como os Objetivos de Desenvolvimento Sustentável”. De particular interesse para as metas da OMS, a própria entidade reconheceu que o mundo está “longe de atingir a meta de ODS 3.4, para reduzir mortes prematuras por NCDs, e nenhum país está atingindo as nove metas voluntárias estabelecidas no Plano de Ação Global para Prevenção e Controle de NCDs 2013-2030”.⁴

Por que então a OMS emitiria uma minuta de diretriz para a população geral, com conselhos baseados em evidências de “baixa certeza geral”? **Solicitamos que a OMS analise essa Minuta de Diretriz no contexto dos recentes roteiros de nível superior da ONU** (que, notavelmente, não foram citados em sua minuta de diretriz, que se refere apenas aos Encontros de Alto Nível da ONU de 2011 e 2014 sobre NCDs, omitindo inteiramente o Encontro de Alto Nível da ONU de 2018). Acreditamos no valor desses roteiros da ONU, que definem as prioridades com contribuição dos estados membros para ajudar a definir o caminho em direção aos Objetivos Globais, em oposição às recentes recomendações do comitê da OMS. Se as Minutas de Diretrizes que emanam de comitês dentro das agências forem incoerentes (e baseadas em evidências de baixa qualidade) e inconsistentes com as diretrizes gerais das políticas estabelecidas pelos estados membros da ONU, então incentivamos fortemente a liderança da OMS a reavaliar as próprias diretrizes.

I. As recomendações da OMS podem prejudicar as prioridades da OMS estabelecidas pelos estados membros em relação ao diabetes e à saúde dentária

No último mês de maio, na 75^a Assembleia Mundial da Saúde, os estados membros endossaram a **estratégia global de referência sobre saúde bucal**, com um dos objetivos principais sendo reduzir as doenças bucais.⁵ Da mesma forma, nessa mesma Assembleia Mundial da Saúde, os

³ Para a declaração política sobre NCDs, consulte a Reunião de Alto Nível da ONU de 2018, A-73-L-2-EN em OP 44, disponível em <https://digitallibrary.un.org/record/1645265?ln=en>.

⁴ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).

⁵ Consulte <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

estados membros apoiaram a criação das **primeiras metas globais para o diabetes**, como parte do Pacto Global contra Diabetes da OMS.⁶ Em ambos os casos, essas metas são prioridades de alto nível para a OMS, endossadas pelos estados membros.

Adoçantes com pouca ou nenhuma caloria são uma ferramenta importante para apoiar a saúde bucal e o controle do diabetes. Com relação à saúde bucal, é bem reconhecido que a ingestão excessiva de açúcar pode contribuir para a formação de cáries. Como os adoçantes com pouca ou nenhuma caloria não são fermentáveis por bactérias orais, podem contribuir para uma boa saúde bucal quando usados no lugar do açúcar.⁷ Como a Autoridade Europeia de Segurança Alimentar declarou, “há informações científicas suficientes para apoiar as alegações de que adoçantes intensos, como todos os substitutos do açúcar, mantêm a mineralização dental e diminuem a desmineralização dental se consumidos em vez de açúcares”⁸

Embora a OMS simplesmente diga que pessoas com diabetes estão excluídas dessas diretrizes, essa declaração ingênua ignora as implicações reais de emitir diretrizes para pessoas em todo o mundo. Quando a OMS emite recomendações gerais, como “não use adoçantes sem açúcar para o controle do peso”, isso confundirá as pessoas – independentemente de terem diabetes ou não. No mundo real, as pessoas levam em conta o que dizem as manchetes, não as letras miúdas. Além disso, para as pessoas que têm diabetes, os adoçantes com pouca ou nenhuma caloria são parte integrante do controle do diabetes.

Por exemplo, a UE permite uma declaração de saúde específica, relacionada a adoçantes e níveis de glicose de baixa e nenhuma caloria: “*o consumo de alimentos contendo adoçantes intensos em vez de açúcar induz a um aumento menor da glicose no sangue após o consumo, em comparação com alimentos que contêm açúcar*”.⁹ **Organizações de saúde de todo o mundo reconhecem que adoçantes com pouca ou nenhuma caloria podem ser usados com segurança para substituir o açúcar no controle nutricional do diabetes.**¹⁰ Por exemplo, a Associação Americana de Diabetes (American

⁶ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

⁷ Declaração de política da FDI (Federação Odontológica Internacional): Substitutos do açúcar e seu papel na prevenção da cárie. Adotada pela Assembleia Geral da FDI, 26 de setembro de 2008, Estocolmo, Suécia

⁸ EFSA, Parecer científico sobre a fundamentação das alegações de saúde relacionadas a adoçantes intensos. EFSA Journal 2011;9(6):2229. Disponível on-line: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

⁹ Regulamento da Comissão (UE) N.º 432/2012, de 16 de maio de 2012, estabelecendo uma lista de alegações sobre saúde que são permitidas para alimentos, exceto aquelas referentes à redução do risco de doenças e ao desenvolvimento e saúde das crianças

¹⁰ Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Atualizada em dezembro de 2018). Disponível em: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and

Diabetes Association, ADA)¹¹ e a Academia de Nutrição e Dietética (Academy of Nutrition and Dietetics) dos EUA¹², em suas recomendações nutricionais para diabetes tipo 1 e tipo 2, concluem que o uso de adoçantes com pouca ou nenhuma caloria pode reduzir a ingestão geral de calorias e carboidratos, se usados em substituição a adoçantes calóricos e sem compensação pela ingestão de calorias adicionais de outras fontes alimentares. Além disso, a mais recente Declaração de Posição sobre Diabetes no Reino Unido sobre adoçantes com pouca ou nenhuma caloria conclui que: *“Adoçantes com pouca ou nenhuma caloria se provaram seguros e podem ser usados como parte de uma estratégia para adultos e crianças no controle do peso e diabetes”*.¹⁰

Além disso, é interessante notar que o Comitê Consultivo de Diretrizes Dietéticas (Dietary Guidelines Advisory Committee, DGAC) dos EUA, reconheceu em 2020 que bebidas adoçadas com pouca ou nenhuma caloria são “um auxílio útil no controle do peso em adultos”, observando que a ingestão de açúcares adicionados pode ser bastante reduzida por versões reformuladas de alimentos e bebidas com pouca ou nenhuma caloria”.¹³

Novamente, observamos que a Recomendação da OMS sobre o uso de adoçantes sem açúcar nessa Minuta de Diretriz é uma recomendação “condicional” ou fraca, o que significa que é baseada em evidências de baixa certeza. Solicitamos que os estados membros analisem a necessidade de uma recomendação tão fraca, em vista das atuais prioridades estabelecidas pela OMS, como as relacionadas ao Pacto sobre Diabetes e à Estratégia Global sobre Saúde Bucal.

II. Os estados membros devem esperar que as diretrizes da OMS sejam fundamentadas na ciência mais forte, não na ciência de “baixa certeza”

Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹¹ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019 May;42(5):731-754;

¹² Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹³2020 U.S. Dietary Guidelines Advisory Committee Report(https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf). pp. 633, 636, 180, 691 das 835 páginas do documento em pdf. Acessado em 21 de julho de 2022. (Além disso, o Comitê de Diretrizes Dietéticas dos EUA declarou ainda que “foi recomendado que a água pura substituísse outras bebidas que produzem energia para diluir a densidade energética da dieta, reduzir a ingestão total de energia e ajudar no controle do peso. O sucesso dessa estratégia não foi comprovado e requer estudo adicional”).)

Conforme observado acima, a recomendação da OMS nessa Minuta de Diretriz é “condicional” ou fraca, porque é baseada em evidências de baixa certeza geral. Estamos preocupados com as implicações gerais da OMS – em quem os países de todo o mundo confiam como o “padrão-ouro” para aconselhamento científico – desenvolver diretrizes políticas com base em evidências de baixa qualidade. Observamos que essa Minuta de Diretriz tem implicações reais: devido à dependência nessas “evidências de baixa incerteza”, podemos ver os estados-membros aprovarem leis que, na verdade, estarão em conflito com as metas de saúde pública para reduzir o açúcar em dietas. Incentivamos fortemente a OMS a voltar ao uso das melhores práticas no desenvolvimento de diretrizes, pois tendo a ciência sólida como base, as diretrizes serão mais do que “fundamentadas por evidências”.

Observamos com preocupação que a OMS não confiou na ciência mais sólida disponível para desenvolver essas diretrizes. A OMS confiou fortemente em **estudos observacionais, que não podem estabelecer uma relação de causa e efeito** e, como a OMS concluiu, fornecem evidências de baixa qualidade.

Surpreende-nos que a OMS marginalize sua própria metanálise de estudos controlados e randomizados (RCTs), que são o “padrão-ouro” em nutrição e pesquisa clínica, ao desenvolver essa Diretriz. No início deste ano, a OMS publicou uma metanálise dos RCTs que demonstrou um benefício modesto, mas significativo, na perda de peso (entre outros benefícios) em adultos, reforçando os achados de uma revisão baseada em evidências encomendada pela OMS em 2019.¹⁴ Ficamos perplexos com o motivo pelo qual a avaliação da própria OMS, reconhecendo as evidências dos estudos clínicos com certeza moderada a alta que mostram efeitos benéficos ou ausência de efeitos prejudiciais do consumo de adoçantes sem açúcar (sobre a gordura corporal e circunferência da cintura, peso corporal, IMC, glicose em jejum, hemoglobina glicada, pressão arterial sistólica, pressão arterial diastólica, colesterol HDL),¹⁵ foi dispensada em favor de evidências observacionais de certeza muito baixa a baixa (que se sabe sofrer de confusão residual e causalidade inversa) que, por fim, serviu como base para as recomendações condicionais nessa Minuta de Diretriz.

Os benefícios dos adoçantes com pouca ou nenhuma caloria, quando usados no lugar dos açúcares, são comprovados por diversos ensaios clínicos bem conduzidos e agudos, a curto e a longo prazo, em humanos, fornecendo evidências de alta qualidade. Desconsiderar as evidências coletivas sobre os efeitos dos adoçantes sem açúcar na saúde e traduzir com precisão a totalidade das evidências

¹⁴ Organização Mundial de Saúde, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. Organização Mundial de Saúde. <https://apps.who.int/iris/handle/10665/353064>. Licença: CC BY-NC-SA 3.0 IGO; “Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J. Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies BMJ 2019; 364 :k4718 doi:10.1136/bmj.k4718)

¹⁵ Consulte o Anexo 6 “Perfis de evidências do sistema GRADE” na Minuta de Diretriz (consulte a pág. 57)

disponíveis em uma recomendação, diante da hierarquia de evidências científicas, pode prejudicar os esforços de saúde pública em reduzir o excesso de ingestão de açúcares e combater a obesidade.

III. Conclusão

Apreciamos o esforço da OMS em orientar os formuladores de políticas sobre adoçantes sem açúcar. No entanto, acreditamos que qualquer orientação deve ser fundamentada nos princípios da política baseada na ciência, demonstrar coerência com a política e seguir o roteiro recente de prioridades de saúde, estabelecido pelos estados membros. Estamos preocupados que a decisão de basear diretrizes em evidências de baixa qualidade possa, em última análise, levar os estados membros a promulgar leis que potencialmente coloquem os resultados positivos para a saúde pública em risco. Agradecemos a oportunidade de enviar esses comentários. Entre em contato conosco se tiver alguma dúvida ou precisar de informações adicionais.

Respeitosamente,

Igor Von Broesigke Castro

Assessor Técnico

Associação Brasileira das Indústrias de Refrigerantes e de Bebidas Não Alcoólicas

E-mail: icastro@abir.org.br

Anexo

Compromisso com a redução de açúcar pelo setor de alimentos e bebidas no Brasil

Há muito tempo, a ABIR e suas associadas apoiam esforços significativos e baseados na ciência para ajudar os consumidores a fazer escolhas fundamentadas sobre alimentos e bebidas orientadas a dietas saudáveis, e temos um forte histórico de apoio com iniciativas de liderança robustas. Por exemplo, nosso setor assumiu compromissos voluntários com relação a marketing responsável, marketing para crianças e bebidas oferecidas em escolas. Além disso, as associadas da ABIR apoiam a rotulagem frontal sobre nutrição, com base na ciência, já que concordamos que, se bem executada, é uma ferramenta útil para ajudar as pessoas a fazer escolhas alimentares fundamentadas, bem como incentivar as empresas a inovar e reformular. O setor de bebidas trabalha arduamente para reformular as bebidas e reduzir o açúcar, oferecer mais opções com menos ou sem calorias, e disponibilizar amplamente embalagens menores. Nosso setor está implementando e relatando publicamente os compromissos para redução de açúcar no Brasil, por meio de uma parceria público-privada. **É importante ressaltar que os adoçantes sem açúcar são uma ferramenta fundamental para o sucesso desses compromissos de redução do açúcar.**

Em novembro de 2018, o **Ministério da Saúde do Brasil e as associações de alimentos e bebidas do país** assinaram um **Termo de Compromisso** para estabelecer metas nacionais para a redução do açúcar. O acordo prevê uma série de compromissos assumidos pelo setor de alimentos e bebidas para ajudar a reduzir a ingestão de açúcar dos brasileiros a menos de 10% do total diário de calorias consumidas, incluindo a redução do açúcar em categorias importantes, como bebidas adoçadas com açúcar, doces e outros alimentos.

Survey response 29

General information

Family/last name
Erdélyi-Sipos
Given/first name
Alíz
Organization/affiliation
Hungarian Dietetic Association (HAD)
Sector
Non-governmental agency
Sector [Other]
Country
Hungary

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"MDOSZ comments","comment":"","size":"59.990234375","name":"MDOSZ_WHO_ENG%20.pdf","filename":"fu_euxf6dmh76k5sdw","ext":"pdf" }]

Position of the National Association of Hungarian Dietitians on the WHO draft directive on the use of sweeteners

WHO recommends that sweeteners should not be used as a tool for weight control or to reduce risk of non-communicable diseases (conditional recommendation).

The International Sweetener Association (ISA) has issued a statement in response to this WHO publication, in which it has collected a range of scientific evidence showing that reduced/zero energy sweeteners:

- They are safe within the established acceptable daily intake (ADI).
- They can help adults and children to reduce their energy intake, making them a useful tool for weight management when used as part of a varied and balanced diet and healthy lifestyle instead of sugar;
- For diabetics, they offer an important alternative to sugar as they do not affect blood sugar levels;
- They do not contribute to tooth decay and their use instead of sugar actually "helps maintain tooth mineralization"

We agree with all of these above statements considering daily practice. While it is true that there is conflicting research on the effects of sweeteners on weight loss in the draft directive, it is important to note that the results may be influenced by a number of factors (e.g. the diet of people consuming sweetened products may contain more processed, higher fat and therefore higher energy products), it is difficult to look specifically at the effects of sweeteners alone.

We agree with the efforts of the WHO to avoid/reduce excessive consumption of sweeteners/sweetener products, but in our opinion the appropriate way to do this is not to phase out sweeteners or tax sweetener products, but to increase knowledge of nutrition science, healthy eating, prevention, education. If, during weight loss courses and counselling sessions led by a registered dietitian, high sugar intake is identified as the cause of overweight/obesity, we consider it professionally correct to recommend the moderate use of sweeteners instead of sugar. Of course, it is important to guide patients towards good health habits and to emphasize that sugar-free products cannot be consumed in unlimited quantities, but in daily therapeutic dietetic practice we have found that they can contribute to weight reduction when incorporated in small quantities into the diet.

According to the draft guideline, the assessment of the health effects of sugar-free sweeteners on individuals with diabetes was not within the scope of this guideline and therefore this recommendation is probably not relevant for people with diabetes. The ISA regrets that the draft does not take into account the needs of patients with diabetes, who make up around 10% of the world's population. In their view, the WHO recommendation not to use energy-free sweeteners as a means of weight management may even be confusing for people with

diabetes, as medical organizations and dietetic associations support the use of these sweeteners in dietary therapy for diabetes.

Indeed, we are concerned that the draft does not address the needs of people with diabetes, for whom sweeteners are an important alternative to sugar. Considering the high proportion of obese people with type 2 diabetes, the current recommendation could lead to uncertainty among the lay public and a reduction in diet adherence.

Survey response 30

General information

Family/last name
Alexandre
Given/first name
Novachi
Organization/affiliation
ABIA - Brazilian Food Trade Association
Sector
Non-governmental agency
Sector [Other]
Country
Brazil

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Observations of the Brazilian Food Trade Association V ABIA on the DRAFT of the WHO Guidelines on the Use of Sugar-Free Sweeteners","comment":"","size":"2115.796875","name":"E-%20132-%2022%20-%20ABIA%20on%20the%20DRAFT%20of%20the%20WHO%20Guidelines%20on%20the%20Use%20of%20Sugar%20Free%20Sweeteners.pdf","filename":"fu_kei6gigjc4bhp4","ext":"pdf" }]

Re: DRAFT WHO Guideline: Use of Non-Sugar Sweeteners - Observations of the Brazilian Food Trade Association / ABIA on the DRAFT of the WHO Guidelines on the Use of Sugar-Free Sweeteners

Dear Sir or Madam:

ABIA - Brazilian Food Industry Association, an entity whose members represent 80% of food and beverage processing in Brazil and representative of the sector responsible for 1.68 million direct jobs is pleased to submit these comments on WHO's Draft Guideline on the Use of Non-Sugar Sweeteners (the "Draft Guideline").

As discussed below in these comments, although ABIA supports WHO's efforts to promote healthy diets, ABIA respectfully requests that WHO reconsider overall priorities and return to science-based policy coherence when providing guidance to stakeholders in its efforts to achieve the UN Sustainable Development Goals by 2030.

In 2015, when the UN first adopted the Global Goals, the call for action mandated an intensive global engagement in support of implementation of all the Goals and targets, bringing together Governments, the private sector, civil society, the United Nations system and other actors and mobilizing all available resources."¹

Of particular interest, one of those resources specifically highlighted by the UN system is the food and beverage industry's ability to reformulate.

In 2018, the Political Declaration of the UN High Level Meeting on NCDs called upon the private sector to "strengthen its commitment" to make further efforts to reformulate foods and beverages to reduce the excessive use of salts, sugars, and fats²

As discussed in the attached Annex, our industry has heeded this call from the UN, and over the past years and significantly stepped up our efforts to reformulate our beverages to reduce added sugars, relying on a key tool of reformulation -- low-calorie sweeteners -- in order to do so.

However, while we are making this robust effort, WHO is simultaneously issuing Draft Guidelines that seek to suppress this important reformulation tool from our toolbox. WHO acknowledges these Draft Guidelines are 1) based on low-certainty evidence and 2) not based on safety concerns.

R. Butantã, 336 • 3º andar - Pinheiros | São Paulo/SP | CEP 05424-000
+55 (11) 3030.1353 | abia.org.br

*Material de propriedade da ABIA e de uso exclusivo das empresas associadas.
Reprodução não permitida, exceto com autorização expressa da ABIA citada a fonte*

We are, frankly, concerned about this apparent policy u-turn. As UN Secretary General Antonio Guterres stated at this year's 2022 UN High Level Political Forum, "[t]he world is in deep trouble – and so too are the Sustainable Development Goals." Of particular interest to WHO's goals, WHO itself acknowledged that the world is "off track to achieve SDG target 3.4, to reduce premature deaths from NCDs, and no country is achieving all nine voluntary targets set out in the Global Action Plan for the Prevention and Control of NCDs 2013-2030."³

Why then would WHO issue Draft Guidelines for the general population with advice based on evidence of "low certainty overall"? We request that WHO review this Draft Guideline in the context of recent higher-level UN roadmaps (which notably, they have neglected to cite in their draft, referring only to the dated 2011 and 2014 UN High Level Meetings on NCDs, omitting entirely the 2018 UN High-Level Meeting on NCDs). We believe in the value of these UN roadmaps – these are the priorities established with Member State input to help set the path toward the Global Goals, as opposed to the recent WHO committee recommendations. If Draft Guidelines that emanate from committees within agencies are incoherent (and based on low quality evidence) and inconsistent with the overall policy directives set by UN Member States, then we strongly encourage WHO leadership to revisit the Guidelines themselves.

I. The WHO Recommendations Risk Undercutting Key WHO Priorities Established by Member States Related to Diabetes and Dental Health

This past May, at the 75th World Health Assembly, the Member States endorsed a landmark global strategy on oral health, with one of the overarching goals being to reduce oral disease.⁴ Similarly, at this same World Health Assembly, the Member States supported the creation of the first-ever global targets for diabetes, as part of WHO's Global Diabetes Compact.⁵ In both of these instances, these are high-level priorities goals for WHO endorsed by the Member States. Low- and no-calorie sweeteners are an important tool in supporting oral health and in diabetes management. With regard to oral health, it is well-recognized that excessive intake of sugar can contribute to dental caries. Because low- and no-calorie sweeteners are non-fermentable by oral bacteria, they can contribute to good oral health when used in place of sugar.⁶ As the European Food Safety Authority stated, "there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralization by decreasing tooth demineralization if consumed instead of sugars"⁷

Although WHO simply says that people with diabetes are excluded from these Guidelines, this naïve statement ignores the real-world implications of issuing guidelines to people around the world. When WHO issues blanket recommendations such as "don't use non-sugar sweeteners for weight control," that will confuse people – whether or not they have diabetes.

R. Butantã, 336 • 3º andar - Pinheiros | São Paulo/SP | CEP 05424-000
+55 (11) 3030.1353 | abia.org.br

*Material de propriedade da ABIA e de uso exclusivo das empresas associadas.
Reprodução não permitida, exceto com autorização expressa da ABIA, citada a fonte.*

In the real world, people embrace headlines, not fine print. And for those who live with diabetes, low- and no- calorie sweeteners are an integral part of diabetes management.

For example, the EU allows a specific health claim related to low- and no-calorie sweeteners and glucose levels: ‘the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods.’⁸ Health organizations globally recognize that low- and no- calorie sweeteners can be safely used to replace sugar in the nutritional management of diabetes.⁹ For example, both the American Diabetes Association (ADA)¹⁰ and the US Academy of Nutrition and Dietetics (AND)¹¹, in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of low- and no-calorie sweeteners have the potential to reduce overall calorie and carbohydrate intake if substituted for caloric sweeteners and without compensation by intake of additional calories from other food sources. Also, the latest Diabetes UK Position Statement on low- and no-calorie sweeteners concludes that: “LNCS are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes”.¹⁰ Further, it is interesting to note that the 2020 U.S. Dietary Guidelines Advisory Committee (DGAC) acknowledge that low- and no-calorie sweetened beverages are “a useful aid in weight management in adults,” noting that added sugars intakes could be greatly reduced by consuming low- and no-calorie sweetened reformulated versions of foods and beverages.”¹² We again note that the WHO Recommendation on the use of non-sugar sweeteners in these Draft Guidelines is a “conditional” or weak recommendation, meaning it is based on evidence of low certainty. We request that Member States review the need for such a weak recommendation in light of existing Member State-established WHO priorities, such as those related to the Diabetes Compact and the Global Strategy on Oral Health.

II. Member States Should Expect WHO Guidelines to Be Grounded in the Strongest Science, Not Science of “Low Certainty”

As noted above, WHO’s recommendation in this Draft Guideline is “conditional,” or weak, because it is based on evidence of overall low certainty. We are concerned about the overall implications of WHO – whom countries around the world rely upon as the “gold standard” for scientific advice – developing policy guidelines based on low-quality evidence. We note that these Draft Guidelines have real-world implications: because of reliance on this “low-certainty evidence,” we may see Member States develop legislation which runs afoul of public health goals to reduce added sugars in the diet. We strongly encourage WHO to return to the use of best practices in developing guidelines – with strong science as the foundation, the guidelines will be more than “evidence-informed.”

R. Butantã, 336 • 3º andar - Pinheiros | São Paulo/SP | CEP 05424-000
+55 (11) 3030.1353 | abia.org.br

*Material de propriedade da ABIA e de uso exclusivo das empresas associadas
Reprodução não permitida, exceto com autorização expressa da ABIA, citada a fonte*

We note with concern that WHO did not rely on the strongest available science to develop these Guidelines. WHO has relied heavily on observational studies, which cannot establish a cause-and effect relationship – and, as WHO ultimately concluded, provide evidence of a low quality. We are puzzled that WHO marginalized its own meta-analysis of randomized controlled trial (RCTs), which are the “gold standard” in nutrition and clinical research, when developing this Guideline.

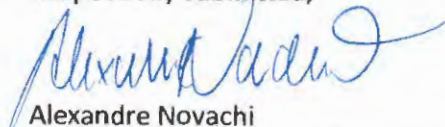
Earlier this year, WHO published a meta-analysis of the RCTs that demonstrated a modest but significant weight loss benefit (among other benefits) in adults, reinforcing findings from an earlier 2019 WHO-commissioned evidence-based review.¹³ We are flummoxed as to why WHO’s own assessment acknowledging the moderate-to-high certainty clinical trial evidence showing either beneficial effects or an absence of detrimental effects from non-sugar sweetener consumption (on body fatness and waist circumference, body weight, BMI, fasting glucose, glycated hemoglobin, systolic blood pressure, diastolic blood pressure, and HDL cholesterol),¹⁴ was dismissed in favor of the very low to low certainty observational evidence (known to suffer from residual confounding and reverse causality) that ultimately served as the basis for the Conditional Recommendations in these Draft Guideline.

The benefits of low- and no-calorie sweeteners when used in place of sugars are supported by a wealth of well-conducted, acute, short- and longer-term randomized controlled trials in humans, which provide high quality evidence. Failing to consider the collective evidence on the health effects of non-sugar sweeteners and to accurately translate the totality of available evidence into a recommendation in view of the hierarchy of scientific evidence, may hinder public health efforts to reduce excess sugars intake and to tackle obesity.

III. Conclusion

In conclusion, we appreciate WHO’s effort to provide guidance to policymakers on non-sugar sweeteners. However, we believe that any guidance must be grounded in principles of science-based policy, exhibit policy coherence and follow the roadmap of recent health priorities established by Member States. We are concerned that the decision to base guidelines on low-quality evidence may ultimately lead Member States to enact legislation that potentially jeopardizes positive public health outcomes. We thank you for the opportunity to submit these comments. Please let us know if you have any questions or require additional information.

Respectfully submitted,



Alexandre Novachi

Regulatory & Scientific Affairs Director

R. Butantã, 336 • 3º andar - Pinheiros | São Paulo/SP | CEP 05424-000
+55 (11) 3030.1353 | abia.org.br

*Material de propriedade da ABIA e de uso exclusivo das empresas associadas.
Reprodução não permitida, exceto com autorização expressa da ABIA citada a fonte*

References

- ¹ “Transformación de nuestro mundo: la Agenda para el Desarrollo Sostenible 2030”, Resolución adoptada por la Asamblea General el 25 de septiembre de 2015, A/RES/70/1 en los párrafos 39 y 60. (ênfasis añadido)
- ² Consulte la Reunión de Alto Nivel de la ONU 2018 sobre la Declaración Política sobre ENT, A-73-L-2-EN en OP 44, disponible en <https://digitallibrary.un.org/record/1645265?ln=en>.
- ³ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).
- ⁴ Consulte <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>
- ⁵ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75th-world-health-assembly>
- ⁶ Declaración de la política de FDI: Sustitutos del azúcar y su función en la prevención de caries. Adoptado por la Asamblea General del FDI, 26 de septiembre de 2008, Estocolmo, Suecia
- ⁷ EFSA, Opinión científica sobre la justificación de afirmaciones de salud relacionadas con edulcorantes intensos. EFSA Journal 2011;9(6):2229. Disponible en línea: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>
- ⁸ Regulación de la Comisión (UE) n.º 432/2012 del 16 de mayo de 2012 que establece una lista de reclamaciones de salud permitidas hechas sobre alimentos, que no sean aquellas que se refieren a la reducción del riesgo de enfermedad y al desarrollo y la salud de los niños
- ⁹ Diabetes UK. El uso de edulcorantes bajos en calorías o sin calorías. Declaración de posición (actualizada en diciembre de 2018). Disponible en: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79
- ¹⁰ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. “Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report”. Diabetes Care. mayo de 2019;42(5):731-754;
- ¹¹ Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79
- ¹² U.S. Dietary Guidelines Advisory Committee Report(https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf). pp. 633, 636, 180, 691 of the 835 page pdf document. Accessed July 21, 2022. (Moreover, the US Dietary Guidelines Committee further stated “Plain water has been recommended to displace other energy-yielding beverages in the diet to dilute the energy density of the diet, reduce total energy intake, and aid weight management. The success of this strategy has not been established and warrants further study.”)
- ¹³ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. Licencia: CC BY-NC-SA 3.0 IGO; “Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J. “Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies” BMJ 2019; 364 :k4718 doi:10.1136/bmj.k4718)

R. Butantã, 336 • 3º andar - Pinheiros | São Paulo/SP | CEP 05424-000
+55 (11) 3030.1353 | abia.org.br

Material de propriedade da ABIA e de uso exclusivo das empresas associadas.
Reprodução não permitida, exceto com autorização expressa da ABIA, citada a fonte

Survey response 31

General information

Family/last name
Páramo Ortega
Given/first name
Alicia
Organization/affiliation
Asociación Nacional de Fabricantes de Chocolates, Dulces y Similares A.C
Sector
Private sector
Sector [Other]
Country
Mexico

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
<input type="text"/>

La Asociación Nacional de Fabricantes de Chocolates, Dulces y Similares (ASCHOCO), es la asociación que agrupa al sector Chocolatero y Confitero de México, representando y abogando por las necesidades y oportunidades del gremio a nivel nacional e internacional.

Somos una institución con 85 años de trayectoria, formando alianzas y puentes de comunicación tanto en lo público como en lo privado, representando a más del 90% del sector en México.

Escribimos el presente, con el agrado de saludarles en referencia a la consulta pública sobre borrador de las Guías de OMS sobre el Uso de Edulcorantes sin Azúcar (NSS, por sus siglas en inglés).

Al respecto de este borrador, nos gustaría mencionar que, como asociación, apoyamos cualquier toma de decisión sustentada en evidencia científica sólida en el proceso de formulación de políticas públicas. Es por ello que, coincidimos en que se realice un estudio a mayor profundidad y precisión sobre la seguridad de cualquier ingrediente o aditivo que se incluya en los alimentos que se distribuyen al consumidor.

Sin embargo, consideramos prudente que se evalúe esta recomendación añadiendo la perspectiva relacionada al costo de oportunidad relacionado a la limitación del uso de estos NSS, y que aporte más información de valor y claridad en la atención y resolución a los problemas de interés público.

Lo anterior, toda vez que cualquier recomendación para restringir un ingrediente (o aditivo) requiere migrar hacia algún tipo de sustituto, ya que el uso de dicha sustancia cubre ciertas necesidades que no pueden desaparecer por restricción o limitación estas.

Fue así que cuando la industria se comprometió a realizar esfuerzos para la reducción de azúcares en los alimentos bajo el compromiso de una mejor oferta de productos al consumidor, se reformularon estos, logrando la sustitución de azúcares o reducción de estos a través de los edulcorantes no calóricos.

Con ello se logró ofrecer productos con propiedades que pudieran apoyar a lograr ciertos beneficios para el consumidor.

Asociación Nacional de Fabricantes de Chocolates, Dulces y Similares, A.C.

Manuel Ma. Contreras 133-301 Col. Cuauhtémoc, 06500, Ciudad de México Tel: 55-5546-1259
xocolatl@aschoco.org.mx www.confimex.org.mx

Sin embargo, ahora bajo la propuesta de restringir estos sustitutos, conllevaría el regreso de uso de azúcares en los productos que comercializamos, ya que la tecnología de alimentos hoy en día existente es limitada respecto a encontrar diferentes alternativas viables tecnológicamente y costeables tanto para la industria como consumidor final. Por tanto, consideramos que este aspecto debe de ser evaluado en este borrador de guías de tal forma que no genere confusión o desinformación en la población.

Es por ello, que solicitamos que además se incluya de manera previa a esta emisión de guías la evaluación particular de cada uno de estos edulcorantes, de manera que se puedan tener alternativas para la reformulación de los productos que hoy en día se comercializan, con el fin de que se puedan seguir ofreciendo productos a los consumidores acorde a sus gustos y necesidades.

Asociación Nacional de Fabricantes de Chocolates, Dulces y Similares, A.C.

Manuel Ma. Contreras 133-301 Col. Cuauhtémoc, 06500, Ciudad de México Tel: 55-5546-1259
xocolatl@aschoco.org.mx www.confimex.org.mx

 ASCHOCOAC  aschocomx  aschocomx  aschocomx-confimex

Survey response 32

General information

Family/last name
Carey
Given/first name
Clifton
Organization/affiliation
University of Colorado, School of Dental Medicine
Sector
Academic/research
Sector [Other]
Country
United States of America

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Comments on the Proposed Guideline on Non Sugar Sweeteners","comment":"See text of the letter","size":"100.93359375","name":"Comments%20Carey.pdf","filename":"fu_z45p9miwweueyfs","ext":"pdf" }]

Clifton Carey
August 12, 2022

RE: Comments on the Proposed Guideline on Non Sugar Sweeteners (NSS)

Dear W.H.O.

The WHO recommendation on NSS utilization “WHO suggests that NSS not be used as a means of achieving weight control or reducing risk of noncommunicable diseases (conditional recommendation)” is too strong and can cause great harm to the public in a number of ways.

The prevalence and incidence of dental caries is the most wide-spread disease on earth. This should be no surprise because the increase in the abundance of concentrated sugar (high fructose corn syrup) over the last decades has created the most cariogenic environment in the history of mankind. The only reason that caries is not far worse than it was 60 years ago is the combination of reduced fermentable sugars introduced via the diet through substitution of sugar with non-sugar sweeteners (NSS) along with the combination of population education on healthy habits and the advent of fluoridated topical agents such as community water fluoridation, fluoridated toothpaste, oral rinses, etc. Through this WHO recommendation dental caries will become even more prevalent leading to loss of functional dentition. Please note that tooth loss is directly related to a decrease in quality of life and has been shown to decrease life expectancy by more than a year for each tooth lost. The consequences of dental disease on systemic health are undeniable and should have been taken into account by the WHO panel as they assessed the risk of increased use of NSS versus the benefits of NSS in the general population.

- The recommendation is based on very low to low evidence assessed by the GRADE framework. This means that the recommendation is based on studies that have very high to high potential of bias.
- The recommendation is also based on evaluation of the various studies within a series of meta analyses.
 - Many meta-analyses had high heterogeneity (where the I^2 is greater than 50%) rendering the statistical outcomes as unreliable.
 - The combination of very low and low-quality studies with higher quality studies as equally valid runs the risk of introducing significant bias in the meta-analyses away from the findings of the higher quality studies. There was no effort presented where the meta-analyses calculations were performed with high quality studies (excluding the very low and low quality studies) to evaluate the impact of study quality on the conclusions reached
 - The weighting of the individual studies included in the meta-analyses are suspect. No reason is given for the weighting, see for instance Figure 6 of the meta-analysis. The weighting is wrong for study size and outcomes. Recalculated results show a HR of 1.98 (0.81 to 2.56) which is not significantly different from an HR of 1.0 (no increased or decreased risk). Obviously, the weighting of the various studies can introduce huge bias in the interpretation of the comparisons. This is but one

example, there are many more especially significant where the panel interprets the risk as substantially greater than no risk. See for example Figure 13 where the Huang 2017 study is given 30.9% weight, but it is smaller than two other studies. The weighted distribution for the studies is inconsistent with the cases or the total sample size. The conclusion is skewed as a result.

More detailed evaluations can be made, but I hope you get the message that the meta-analysis of disparate study types and outcome measures has the potential of leading to erroneous conclusions.

It is also inappropriate to ignore the broader benefits of the use of NSS for oral and systemic health while worrying about minute increases in risk ratios that are calculated as if the use of NSS was the only factor leading to that increased risk.

While it is desirable to have sufficient quality evidence to make recommendations, it is only honest to conclude that there is insufficient evidence to make recommendations against the use of NSS.

I recommend that the interest balance of NUGAG subgroup be examined for a lack of dental and pharmaceutical research professionals. The vast majority of individuals listed have expertise in nutrition and some in cancer but none in dentistry or pharmacy. In the International Standards Organization (ISO) we strive to have full representation from industry, academia, users, and interested parties to avoid decision making for the general public by unbalanced interests.

Finally, I recommend that on the basis of the above discussion that the recommendation as given be abandoned. It could be replaced with a call for quality research and the lack of evidence precludes any recommendation at this time.

Thank you for the opportunity to respond to the proposed guidelines. I am happy to discuss my observations with you.

Sincerely,

Clifton M. Carey

Survey response 33

General information

Family/last name
Macari
Given/first name
Marisa
Organization/affiliation
El Poder del Consumidor
Sector
Non-governmental agency
Sector [Other]
Country
Mexico

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"WHO Consultation Sugar alternatives","comment":"","size":"22.92578125","name":"FINAL%20WHO%20Consultation%20Sugar%20Alternatives%20EPC.docx","filename":"fu_mtht5u4em7ia5hz","ext":"docx" }]

WHO Draft Guideline: use of non-sugar sweeteners: Comments El Poder del Consumidor

We strongly support the recommendation and the rationale of this Guideline. We believe that this recommendation is based on the current scientific evidence, is in the interest of public health and has a level of clarity and detail that will enable it to be used by effectively by decision-makers in their programming and policy-development.

Evidence to recommendations

- In the sections on “balance of desirable and undesirable effects” the section of “priority of the problem and values and preferences” or the section on “equity and human rights” it might be useful to highlight the special case of children and why these recommendations are particularly important to protect the best interests of the child. For example, despite the lack of extensive evidence directly with children, the precautionary principle and protection of children’s rights would urge special consideration to protect children against any potential or yet unknown consequences of NSSs. The dimension of children’s rights is another justification for these recommendations and should be underscored.
- In the “balance of desirable and undesirable effects” section it would be useful to recognize that with the increasing stigmatization of free sugars around the world, as well as certain policies that promote a reduction in their consumption, the use of NSS in products and the food supply and reformulation will increase.^{1,2} Existing evidence shows that these increases may result in individuals overpassing “safe” levels of NSS consumption, and this will happen among children more readily and easily because of their lower tolerance.³ This is an unintended consequence of the use of NSS to replace sugars that perhaps could be *noted* here, even if these studies are beyond the scope of the Guideline. Again, throughout the document, the protection of children, could be used rightfully as a further justification for these Guidelines.
- In the sections/boxes on “feasibility” and “resource allocations” we strongly support the statement that these guidelines be incorporated into national food-based dietary guidelines, marketing and labelling policies. Furthermore, we believe it is important to mention that these guidelines can also be considered with regard to school food policies (school policies are not mentioned in these sections, even though they are mentioned in other sections they should be re-iterated here). Furthermore, this section could also mention that the nutrient profiles utilized in national policies should incorporate the ideas in this Guideline and that policies regarding health claims should also incorporate the

¹Zancheta Ricardo C, Corvalán C, Smith Taillie L, Quiral V and Reyes M (2021) Changes in the Use of Non-nutritive Sweeteners in the Chilean Food and Beverage Supply After the Implementation of the Food Labeling and Advertising Law. *Front. Nutr.* 8:773450. doi: 10.3389/fnut.2021.773450

² Rebolledo, N, Reyes, M, Popkin, BM, et al. Changes in nonnutritive sweetener intake in a cohort of preschoolers after the implementation of Chile's Law of Food Labelling and Advertising. *Pediatric Obesity*. 2022; 17(7):e12895. doi:[10.1111/ijpo.12895](https://doi.org/10.1111/ijpo.12895)

³ <https://pubmed.ncbi.nlm.nih.gov/27657125/>

recommendation in this Guideline. With regard to health claims, it is known that food reformulated to replace sugars with NSS, often use health claims and messaging that give these foods a “health halo” making the consumer think they are healthy because they contain less sugar. These Guidelines could help to ensure policies governing health claims do not allow foods with NSS to get a “health halo”.

Recommendations and supporting information

- With regard to the primary recommendation of the Guideline, we strongly support it. We urge that this recommendation remain as is to reflect current evidence and to support the implementation of nutrition policies that promote obesity and NCD prevention and protect the right to food.
- We also strongly support the retention of the final bullet in the “Remarks” box (p. 44) that highlights that because ultraprocessed foods as a category have negative effects on obesity, hypertension, diabetes, all-cause mortality, etc. simply replacing free sugars with NSS will not automatically improve the quality of a product. In other words, the product will continue to be ultraprocessed even if its source of sweetness has been altered.

Other comments

- **Human rights:** A central theme of the document should be the protection of children’s rights and the right to health. The WHO Handbook for Guideline development indicates the importance of integrating human rights into WHO Guidelines and we think in the introduction and rationale, the importance of this guideline in the protection of children’s rights, the right to health, food and water should be reiterated.
- **Non-essential quality of NSS:** We strongly support the notes of the NUGAG subgroup in the three bullets at the end of page 8 to page 9 and in particular the recognition that: NSS are non-essential elements of the diet and also that there are many alternatives to NSS that also allow a reduction of free sugars which include the consumption of unsweetened and unprocessed foods and beverages. We would, however, suggest an explicit mention of potable water in the last bullet in this section.
- **Conflict of interest:**
 - **Translation and Implementation Section:** It would be important to mention in this section that the food and ingredient industry is very strongly in favor of the use of NSSs in reformulation and successful implementation of policies at the national and sub-national level, must identify and prepare for such opposition and safeguard against such conflict of interest in their policy development.
 - **Research gaps and initiatives Section:** Considering that evidence shows that studies funded by the industry and industry groups producing and selling NSSs are less likely to

show negative relationships between NSSs and health outcomes,⁴ a note on conflict of interest in studies might be good to mention here as a potential barrier to a stronger evidence base to date. It could also be mentioned here that future research initiatives and systematic reviews on the topic of NSS should ensure they are safeguarded against conflicts of interest. This will enable an independent consensus on the topic of NSS to emerge without interference from industry-funded studies.

Survey response 34

General information

Family/last name
Lim
Given/first name
Calisa
Organization/affiliation
Food Industry Asia
Sector
Private sector
Sector [Other]
Country
Singapore

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"FIA Response WHO Draft Guidelines on Use of Non-Sugar Sweeteners","comment":"FIA Response WHO Draft Guidelines on Use of Non-Sugar Sweeteners","size":"395.0732421875","name":"220813%20FIA%20Response%20WHO%20Draft%20Guidelines%20on%20Use%20of%20Non-Sugar%20Sweeteners.pdf","filename":"fu_6gmamh xu9pdrivb","ext":"pdf" }]

FIA Response to WHO Consultation on Draft Guidelines Regarding the Use of Non-Sugar Sweeteners

Introduction

Food Industry Asia (FIA) would like to thank the World Health Organisation (WHO) for the opportunity to comment on the “Draft Guidelines on the Use of Non-Sugar Sweeteners” on behalf of the food industry in Asia through the e-consultation process.

FIA is a trade association established in Asia to represent the view of the food industry as a trusted partner for multi-stakeholder dialogue. The goal of FIA is to harness the expertise of major food and beverage companies and respond to the region's complex challenges in food safety, regulatory harmonisation and health & nutrition.

Together, we work with a broad range of stakeholders in Asia to promote the role of multi-stakeholder collaboration as a cost-effective mechanism as part of delivering positive socio-economic outcomes.

To this end, FIA is committed to working collaboratively with governments, policy makers, civil societies and academia throughout Asia, either directly or through existing local industry groups.

General Feedback

Obesity and its associated diseases are complex, multi-dimensional issues that require holistic approaches, to reduce the growing disease burden and to help create healthier food environments.

Aligned with the 2015 “[Guideline on Sugar Intake for Adults and Children](#)”, and the policy objective of reducing the overconsumption of added sugars from sugar-sweetened beverages, sugary sweets and snacks, we would like to emphasise the role of non-sugar sweeteners (NSS) as a tool for product reformulation, to deliver a wider portfolio of healthier food and beverages, containing fewer calories and added sugars. Additionally, we would like to highlight the use of NSS in maintaining oral health, in line with public health recommendations.

According to a series of studies (Annex 1) that had been carried out by FIA, in collaboration with IGD – a research organisation based in the United Kingdom, the food industry has been actively driving its reformulation commitments to reduce added sugars within their product portfolios across key Asian markets (Singapore, Malaysia, Thailand, Indonesia, India, Philippines, and China)¹.

82% of the surveyed industry sample in Asia have kickstarted their reformulation commitments in the past 4 years, using a variety of techniques to support their reformulation programmes². **80% of the sample**

¹ Food Industry Asia (FIA) has conducted a series of reformulation studies within the abovementioned Asia countries ([Singapore](#), [Malaysia](#), [Thailand](#), [Indonesia](#), [India](#), [Philippines](#) and [China](#)) from 2018 to 2021 to understand consumer perception and industry's progress and motivation towards its reformulation efforts to advance the public health agenda.

² Other approaches industry adopts to enable healthier production development/reformulation includes; (1) making a variety of changes to the recipe simultaneously to improve nutritional profile, (2) fortifying products with additional ingredients, (3) applying a new technology that supports reformulation (4) altering the cooking/production method and, (5) reducing the amount of a high calorie ingredient without making any other changes. Please refer to **Annex 1** for the regional data on industry's techniques to support their reformulation programmes.

focused its reformulation efforts on the reduction of added sugars, with 53%^A of the industry adopting lower/zero calorie sugar substitutes to support their reformulation efforts.

In fact, 72%^B of ASEAN consumers (within the abovementioned Asia countries) were receptive to products that were tweaked to include low/non-calorie sweeteners, instead of added sugars to make them healthier. **Product categories that are sweetened with NSS, are often used as a strategy by those who are overweight, obese and/or managing diabetes, as part of regulating their eating behaviours, allowing personal fulfillment of taste and choice, whilst also satisfying the longer-term goal of weight maintenance³.**

There is a need for continued support of behaviours that improve health outcomes – by encouraging product innovation and industry’s reformulation programmes, consumers are able to adjust to the changes made to the taste and flavour profiles of the reformulated product. This will also **guide consumers in maintaining the healthier food/beverage choices in the long term (as part of their diets), rather than influence a negative substitution.**

On the debate of NSS increasing one’s desire for, and intake of sweet foods, studies have found that these ingredients do not impact one’s hunger or appetite⁴. While the desire for sweetness among individuals is natural, there is a **lack of strong evidence showing that the consumption of NSS enhances a “sweet tooth”, or that NSS impact food cravings in general⁵.**

Based on the recent WHO study by [Rios-Leyvraz and Montez](#), inconsistent evidence was reported on the effects of NSS intake on measures related to sweet taste perception, **with most studies favouring the use of NSS to curb the consumption of added sugar intake⁶.**

While the draft guidelines noted that minimally processed, unsweetened foods and beverages should be the preferred choice among consumers⁷, it would not be realistic for consumers to eliminate sweetness from their diet. The liking for sweetness is both innate and universal – sweetness increases the palatability of foods and beverages, which may explain the intense liking for sweetness during childhood to ensure sufficient nutritional intake during periods of maximal growth⁸. When used to replace sugar in food and beverages, NSS allows for the personal enjoyment of sweet taste, and thus, stimulate sensory-specific satiety⁹, even as consumers grow more attentive to their dietary habits.

^A Average across abovementioned Asia countries, except for China as the questionnaire did not include the same set of industry’s methods asked to enable the development of healthier products.

^B Average across abovementioned Asia countries, except for Singapore as the questionnaire did not ask on consumers’ preference on reformulated products with low/non-calorie sweeteners.

³Ashwell M., Gallagher AM., Halford JCG., Hardman CA., Maloney NG. and Raben A. (2021). Low-calorie sweeteners in the human diet: scientific evidence, recommendations, challenges and future needs. A symposium report from the FENS 2019 conference. Journal of Nutritional Science. doi: [10.1017/ins.2020.59](https://doi.org/10.1017/ins.2020.59)

⁴ Higgins KA., Considine RV. and Mattes RD. (2018). Aspartame Consumption for 12 weeks Does Not Affect Glycemia, Appetite, or Body Weight of Healthy, Lean Adults in a Randomized Controlled Trial. Journal of Nutrition. doi: <https://doi.org/10.1093/jn/nxy021>

⁵ Appleton KM., Bertenshaw EJ., de Graaf, C., Mela DJ. and Tuorila H. (2018) Sweet taste exposure and the subsequent acceptance and preference for sweet taste in the diet: systematic review of the published literature. Am J Clin Nutr. doi: <https://doi.org/10.1093/ajcn/nqx031>

⁶ Rios-Leyvraz M. and Montez J. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. World Health Organisation. doi: <https://apps.who.int/iris/handle/10665/353064>

⁷ See [WHO draft guideline](#): “messaging about potable water as a preferred replacement for sugar-sweetened beverages and as a mode of hydration generally can be incorporated into public health communications and food-based dietary guidelines”, page 45. As argued above, it would be unrealistic for consumers to eliminate sweetness from their choice of food and beverages as throughout evolution, sweetness has had a role in human nutrition, helping to orient feeding behavior toward foods providing both energy and essential nutrients.

⁸ Mennella JA. (2014). Ontogeny of taste preferences: basic biology and implications for health. Am J Clin Nutr., 99(3): 704S-711S. doi: [10.3945/ajcn.113.067694](https://doi.org/10.3945/ajcn.113.067694).

⁹ Ingestion of sweet-tasting products induces “[sensory-specific satiety](#),” a general decrease in the attractiveness of all sweet products.

FIA firmly believes that policy interventions targeted at addressing health challenges should be **grounded on sound science where all components of the policy support the clear objective(s), to influence positive health behaviours and habits within the population and to incentivise industry's reformulation programmes/tools**. These policy interventions need to be developed through the active participation of all stakeholders, including the industry, government bodies, academia and other relevant stakeholders to advance the public health agenda.

Industry's Concerns

1. Low Certainty of Evidence on the Health Effects of Non-Sugar Sweeteners

FIA understands that while non-sugar sweeteners (NSS) is not a silver bullet towards resolving the complex issue of overweight and obesity, it serves as one of the approaches in tackling the growing disease burden.

Food safety authorities around the world have repeatedly and consistently confirmed the safety of NSS, including during pregnancy. In fact, for a NSS to be approved for use on the market, it must first undergo a thorough safety assessment by the competent food safety authorities assessing all the available literature, including but not limited to the data reviewed by WHO, whereby evidence from short-term randomised controlled trials in humans, animal and in-vitro data are also assessed.

Such scientific regulatory bodies include the Joint Expert Scientific Committee on Food Additives (JECFA)¹⁰ and the Codex Alimentarius Commission (CAC)¹¹ of the United Nations Food & Agriculture Organisation (FAO) and of the World Health Organisation (WHO), the European Food Safety Authority (EFSA)¹² and the United States Food and Drug Administration (FDA)¹³.

Evidence with regards to the safety of NSS, on an individual's overall diet and health outcomes are also consistently reaffirmed by the abovementioned, reputable food safety authorities¹⁴. **However, based on the draft guidelines, there is very low to low certainty of evidence observed in prospective cohort studies that, the use of NSS had a negative effect on prioritised health outcomes (in terms of overweight, obesity, cancer, eating behaviour).**

The [systematic and meta-analysis review by Rios-Leyvraz and Montez](#), commissioned by the WHO to inform the development of the draft guidelines, **confirmed that NSS have no adverse impact on cardiometabolic risk factors, including glucose and insulin levels, blood lipids and blood pressure¹⁵**. This is **aligned with results from other meta-analyses of randomised controlled trials (RCTs)** – a recent systematic review of RCTs **highlighted potential cardiometabolic health benefits when NSS beverages are used to replace added sugars¹⁶**.

¹⁰ United Nations Food & Agriculture Organisation. (2022). [Joint Expert Scientific Committee on Food Additives](#).

¹¹ Codex Alimentarius Commission. (2019). [Food Additives](#).

¹² European Food Safety Authority. (2022). [Sweeteners](#).

¹³ US Food and Drug Administration (2014). [High-Intensity Sweeteners](#).

¹⁴ These scientific regulatory bodies include the [Joint Expert Scientific Committee on Food Additives](#) (JECFA) of the United Nations Food & Agriculture Organisation (FAO) and of the World Health Organisation (WHO), the [European Food Safety Authority](#) (EFSA) and the [US Food and Drug Administration](#) (FDA), amidst others.

¹⁵ Asbaghi O., Ashtary-Larky D., Clark CCT., Golzan SA., Hekmatdoost A. and Movahedian M. (2021). The effects of artificial- and stevia-based sweeteners on lipid profile in adults: a GRADE-assessed systematic review, meta-analysis, and meta-regression of randomized clinical trials. Crit Rev Food Sci Nutr. doi: [10.1080/10408398.2021.2012641](#)

¹⁶ McGlynn ND., Khan TA., Wang L., et al. (2022). Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages with Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. JAMA Network Open. doi: [10.1001/jamanetworkopen.2022.2092](#)

RCTs are the gold standard in nutrition and clinical research, and is relied upon by policymakers around the world to develop evidence-based policy guidelines. As such, RCTs should be the preferred source of evidence for measuring the effects of interventions related to measurable health outcomes.

Instead, the **draft guidelines have relied heavily on the evidence derived from observational studies, which cannot establish a cause-and-effect relationship; thus, providing evidence of a low quality.** The systematic review and meta-analysis by Rios-Leyvraz and Montez have also cautioned against the limitations of observational studies and pointed to the high possibility that the reported associations are partially or largely a result of reverse causation and/or residual confounding outcomes¹⁷.

If Member States develop legislations based on a guidance founded on low-certainty evidence, this can adversely impact the public health goals to reduce added sugars in the diet and non-communicable disease prevalence within a population. We recommend that the WHO leverage the use of best practices in developing guidelines, grounded on sound science and based on the hierarchy of scientific evidence (i.e., RCTs in humans).

2. Non-Sugar Sweeteners Proven to Support Weight Management

The role of NSS in reducing energy (calorie) intake and in assisting with modest weight loss when used to replace added sugars has been confirmed and reaffirmed by numerous studies, and in systematic reviews^{18 19}. Evidence based on RCTs are also supportive of the beneficial role of NSS – in calorie reduction, sugar reduction, as well as weight loss, with some studies highlighting that this beneficial effect is greater in people living with overweight or obesity²⁰. Importantly, the meta-analysis of RCTs by Rios-Leyvraz and Montez also showed that the **use of NSS resulted in the reduction of added sugars and calorie intake in modest, but significant weight loss in adults²¹, reinforcing an earlier 2019 WHO-commissioned evidence-based review²².**

It is therefore surprising that the benefit of using **NSS as a way to reduce added sugars and calorie intake(s), and can support weight management, has not been acknowledged in the WHO draft guidelines.** Weight control, and especially long-term weight loss maintenance, has been proven to be very challenging for individuals living with overweight and obesity. While the use of NSS alone in diets is not sufficient for weight loss, they can be a critical dietary tool in providing more options for sweet-tasting foods and beverages with fewer calories and added sugars, to help people living with obesity to adhere to a better quality of living, while trying to manage their body weight.

¹⁷ According to [Rios-Leyvraz and Montez](#), further research is needed to determine whether the observed negative associations (i.e., low to very low certainty evidence on increased body weight, type 2 diabetes, cardiovascular diseases, all-cause mortality) with long-term use are genuine, or a result of reverse causation and/or residual confounding; higher consumers of NSS may choose these products because they are at greater risk for adverse cardiometabolic outcomes, **not the other way around**.

¹⁸ Miller PE. & Perez V. (2014). Low-calorie sweeteners and body weight and composition: a meta-analysis of randomised controlled trials and prospective cohort studies. *Am J Clin Nutr*. doi: [10.3945/ajcn.113.082826](#)

¹⁹ Laviada-Molina H, Molina-Segui F, Pérez-Gaxiola G, et al. (2020). Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and meta-analysis. *Obesity Reviews*. doi: [10.1111/obr.13020](#)

²⁰ Arjona-Villacaña R., Cuello-García C., Espinosa-Marrón A., Laviada-Molina H., Martínez-Portilla RJ., Molina-Segui F. and Pérez-Gaxiola G. (2020). Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and meta-analysis. *Obesity Review*. doi: [10.1111/obr.13020](#)

²¹ According to [Rios-Leyvraz and Montez](#), the short-term use of NSS resulted in reductions in sugars (approx. 39 g per day) and total energy intake (approx. 134 kcal), and in turn in small but significant decrease in body weight and adiposity, especially in adults.

²² Lohner S, Kuellenberg de Gaudry D, Toews I, Ferenci T, Meerpohl JJ. (2020). Non-nutritive Sweeteners for Diabetes Mellitus. *Cochrane Database of Systematic Reviews* 2020. doi [10.1002/14651858.CD012885.pub2](#)

3. Processed Foods can be part of a Healthy Diet

FIA is of the view that efforts to reduce added sugar intake should be implemented based on sound science, and in the context of the current food environment. Food processing has brought about the ability to transform perishable raw materials into edible, safe and nutritious foods, with the aim to ensure **food safety** (i.e., preservation and avoidance of food borne diseases), **increase palatability** (i.e., better tasting foods and access to nutrients), stability in transportation (i.e., development of supply chains), and the **production of convenient and affordable foods**²³. As such, processed foods are integral in diets across many cultures, and make up vital parts of the global food supply.

However, the draft guidelines claim that NSS are frequently used to make ‘highly processed’ low sugar or sugar-free foods, rather than encouraging fundamental shifts towards healthier dietary patterns, rich in whole foods. In reality, **a variety of foods with varying degrees of processing can fit into healthy dietary patterns**²⁴. This allows the inclusion of a broader range of foods that meet personal preferences and enjoyment, while also improving overall diet quality and ensuring adequate intakes of nutrients^{25 26}.

The abovementioned claim within the guidelines can potentially create a false perception among Member States, based on reviewed evidence/data, to make spurious recommendations²⁷, that are inaccurate and unsubstantiated, considering the role of processed foods within a population and when consumed as part of a healthy, balanced diet.

To this end, FIA believes that the draft guidelines should not be focused on the condemnation of processed foods; rather, it is about **raising the nutrition quality of packaged food products through robust reformulation programmes, while making it accessible and affordable for all**.

4. Benefits of Non-Sugar Sweeteners Related to Dental Health

The beneficial role of NSS in dental health is well established – NSS is non-cariogenic, does not cause the loss of important minerals from tooth enamel, and does not promote dental caries since the ingredient is slowly metabolised by bacteria (i.e., non-fermentable), thus resulting in a significantly less amount of acid production as compared with sucrose or other fermentable carbohydrates^{28 29}.

The WHO NUGAG group reviewed literature for NSS in Rios-Leyvraz and Montez, defined as all synthetic and naturally occurring or modified non-nutritive sweeteners that are not classified as sugars, with common examples such as *acesulfame-K*, *aspartame*, *advantame*, *cyclamates*, *neotame*, *saccharin*, *sucralose*, *stevia* and *stevia derivatives*, and excluding sugar alcohols and low-calorie sugars. Whereas the European Food Safety Authority (EFSA) noted that sufficient scientific information exists

²³ Knorr D. and Watzke H. (2019). Food Processing at a Crossroad. Front. Nutrients. 6:85. doi: [10.3389/fnut.2019.00085](https://doi.org/10.3389/fnut.2019.00085)

²⁴ Gonçalves C.B., Petrus R.R., Sobral P.J.A. and Tadini C.C. (2021). The NOVA classification system: a critical perspective in food Science. Trends Food Sci Technol. 116:603–8. doi: [10.1016/j.tifs.2021.08.010](https://doi.org/10.1016/j.tifs.2021.08.010)

²⁵ Francis L.E., Gibson A.A., Gibson S.A., Horgan G.W. And Stephen A.M. (2016). Low Calorie Beverage Consumption Is Associated with Energy and Nutrient Intakes and Diet Quality in British Adults. doi: [10.3390/nu8010009](https://doi.org/10.3390/nu8010009)

²⁶ Barraj L.M., Bi X., Murphy M.M., Tran N.L. and Scrafford C.G. (2019). Comparisons of Nutrient Intakes and Diet Quality among Water-Based Beverage Consumers. doi: <https://doi.org/10.3390/nu11020314>

²⁷ *Spurious* describes a statistical relationship between two variables that would, at first glance, appear to be causally related, but upon closer examination, only appear so by coincidence or due to the role of another, intermediary variable.

²⁸ FDI Policy Statement: Sugar substitutes and their role in caries prevention. Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden

²⁹ Birajdar SS., Gupta P., Gupta N., Natt AS., Pawar AP. & Singh HP. (2013). Role of Sugar and Sugar Substitutes in Dental Caries: A Review. ISRN Dent. doi: [10.1155/2013/519421](https://doi.org/10.1155/2013/519421)

to support the claims that NSS including *xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, D-tagatose, isomaltulose, sucralose and polydextrose* maintain tooth mineralisation by reducing tooth demineralisation resulting from acid production in plaque, caused by the fermentation of carbohydrates and is a beneficial physiological effect³⁰.

Moreover, following the scientific opinion by EFSA, the European Commission also authorised new health claims in the positive list ([Reg. EC 432/2012](#)) – “Consumption of foods/drinks containing <name of sugar replacer> instead of sugar (**) contributes to the maintenance of tooth mineralisation.”

In fact, the oral care benefits of chewing sugar-free gum are widely recognised by health authorities worldwide. These include the European Union³¹, federal health departments and bodies in Canada³², Australia³³ and Germany³⁴, and the FDI World Dental Federation³⁵.

According to a study³⁶, chewing sugar-free gum resulted in a 10 to 12-fold increase in salivary flow rate – washing away foods and neutralising plaque acids, and thus protecting the tooth enamel. Saliva also contains minerals which helps the mouth return to a normal pH level, repair damaged enamel and assist in the reduced incidence of dental caries³⁷.

By limiting the review of scientific evidence, the draft WHO NUGAG guideline failed to consider the collective evidence relating to the positive effect of NSS on tooth mineralisation, and hence their role in reducing dental caries, which is amongst the most common NCDs globally and is almost entirely preventable – with combined direct and indirect costs estimated at as much as USD 245 billion³⁸.

Not acknowledging this well-established dental benefit of NSS use is a risk to public health efforts to improve oral health given the high prevalence of dental caries and related conditions such as gum disease and loss of teeth.

The omission of oral health benefits in sugar-free chewing gum, hygiene, and personal care oral products within the draft guidelines could compromise global efforts to improve oral and dental health, should policymakers enact the WHO recommendation, in its current form. For the most accurate communication and interpretation of the guidelines, the final recommendation should only mention the findings within the systematic review and meta-analysis by Rios-Leyvraz and Montez, and not broadly speak for all NCDs.

Aligned with the adoption of [resolution WHA74.5 on oral health](#) in May 2021, and the recent publication of the [Global Strategy on Oral Health](#), FIA urges the WHO NUGAG to review the vast evidence base on the oral health benefits of NSS use within the final guidelines, alongside carrying out a meta-analysis review on NSS, and its impact on dental caries, in the future.

³⁰ European Food Safety Authority. (2011). EFSA Journal 9(6):2220. Scientific Opinion on the substantiation of health claims related to intense sweeteners and contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299), reduction of post-prandial glycaemic responses (ID 4298), maintenance of normal blood glucose concentrations (ID 1221, 4298),

³¹ European Union. (n.d.). [Register of Health and Nutrition Claims](#).

³² Health Canada. (2014). [Summary of Health Canada’s assessment of a health claim about sugar-free chewing gum and dental caries risk reduction](#).

³³ Australian Government. (2016). [Healthy Mouths Healthy Lives: Australia’s National Oral Health Plan 2015-2024](#).

³⁴ Association of the Scientific Medical Societies in Germany. (2016). [Caries prevention in permanent teeth – basic recommendations](#).

³⁵ FDI World Dental Federation. (2015). [Oral Health Worldwide](#).

³⁶ Dawes C. and Macpherson LM. (1992). Effects of nine different chewing gums and lozenges on salivary flow rate and pH. Caries Res. doi: [10.1159/000261439](#)

³⁷ Stookey GK. (2008). The effect of saliva on dental caries. J Am Dent Assoc. doi: [10.14219/jada.archive.2008.0347](#)

³⁸ Vucicik M, Listl S. An Economic perspective on the global burden of dental caries. For the ACFF Making Cavities History Taskforce, 2020.

5. Benefits of Non-Sugar Sweeteners for Diabetic Individuals

While the draft guidelines state that the recommendations are not targeted at individuals with diabetes³⁹, this can be seen as misleading to the consumer (with or without diabetes) and is a significant shortcoming in this draft guideline.

NSS is a useful dietary tool for diabetic individuals (10.5% of the global population⁴⁰) who need to manage their carbohydrate and added sugar intake, to facilitate a lower impact to blood glucose levels. WHO's recommendation for member states to not use NSS could confuse people living with diabetes, especially when diabetic and nutrition-related organisations support the use of NSS for diabetes management via the provision of food and beverage options that are lower in sugar.

Based on the scientific opinion of the [European Food Safety Authority \(EFSA\)](#), the consumption of foods containing NSS instead of sugar, induces a lower rise in blood glucose levels compared to the rise in blood glucose observed with the consumption of sugar-containing foods. Health organisations globally⁴¹ have further recognised that NSS can be safely used to replace added sugar in the nutritional management of diabetes, with the latest [Diabetes UK Position Statement](#) highlighting that NSS are shown to be safe and can be used as part of a strategy for adults and children, in the management of diabetes.

Moreover, the World Health Assembly has recently, and for the first time, developed a [draft resolution of WHA74 on diabetes](#) towards improving national diabetes responses. It would not seem justified to remove an important option to sugar reduction effort, especially with the high risk of people undiagnosed, or at risk of, type 2 Diabetes. The adoption of WHO recommendations by Member States in its policy development/revisions could also significantly reduce the availability of NSS foods and beverages if the food industry has to pull back on using high intensity sweeteners within their product portfolios. **This signifies a disservice to public health goals and contradicts industry's longstanding commitment to reduce overconsumption of added sugars among general population.**

Conclusion

FIA firmly believes that a collaborative approach involving the commitment of the government, industry and other stakeholders (public health bodies, research institutions) is required in the policy development process of tackling the rising disease burden of obesity, and its associated diseases.

In order to meet the WHO policy objective of reducing the overconsumption of added sugars within the general population, we strongly urge that the guidelines be grounded on sound science (i.e., high quality evidence base such as randomised controlled trials in humans).

The limitation and/or prohibition of the use of well-studied non-sugar sweeteners will compromise efforts to achieve WHO policy objective and contradicts established permitted usage levels guided by competent

³⁹ See [WHO draft guideline](#): "Assessing the health effects of NSS on individuals with pre-existing diabetes was beyond the scope of this guideline", page 4.

⁴⁰ Statista. (2021). [Percentage of Diabetics Worldwide](#).

⁴¹ Such organisations include Diabetes UK, the American Diabetes Association (ADA) and the US Academy of Nutrition and Dietetics (AND).

global health organisations (i.e., Codex standards), making it extremely difficult for consumers in their journey to reduce added sugars in their diets.

FIA would also like to reaffirm the benefits of non-sugar sweeteners (i.e., supporting weight management, diabetes management, dental caries prevention etc.) when used in substitution of sugars, which are supported by a wealth of well conducted, acute, short- and longer-term randomised controlled trials. Failing to consider the collective evidence on the health effects of non-sugar sweeteners and to accurately translate the totality of available evidence into a recommendation, based on the hierarchy of scientific evidence, can jeopardise the public health efforts and possible positive health outcomes, if Member States enact policies based on very low-quality evidence.



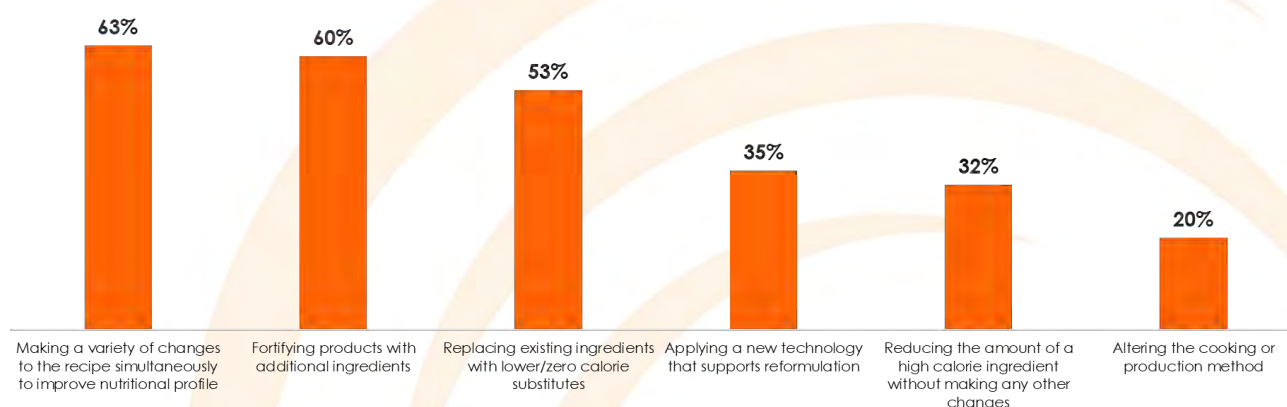
Annex 1 – FIA-IGD Reformulation Studies for Asia

The food industry has been consistently working to deliver solutions through product innovation and reformulation to nudge healthier behaviours, by improving the nutritional quality of its food and beverage products.

With innovation and reformulation efforts often carried out behind closed doors, FIA sought to understand the broad reformulation landscape of the food and beverage sector across seven markets – [Singapore](#), [Malaysia](#), [Thailand](#), [Indonesia](#), [India](#), [Philippines](#) and [China](#).

Using a purposive sampling method, the survey was completed by 139 food and drink companies[#] of varied sizes (MNCs & SMEs) operating in the abovementioned markets.

It was found that companies were using a variety of techniques to support their reformulation programmes. The most popular approaches are – making a variety of changes to a recipe simultaneously (63%), fortifying products with additional ingredients (60%), and replacing existing ingredients with lower/zero calorie substitutes (53%).



[#] As the China study was carried out using a slightly different methodology, the data is not presented here.

Survey response 35

General information

Family/last name
Chapman
Given/first name
Nancy
Organization/affiliation
Oral Health Alliance`
Sector
Non-governmental agency
Sector [Other]
Country
United States of America

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"OHA comments on WHO non-sugar sweeteners.docx","comment":"","size":"22.5634765625","name":"OHA%20comments%20on%20WHO%20non-sugar%20sweeteners.docx","filename":"fu_bxwu7uv9vymrxt6","ext":"docx" }]]

Oral Health Alliance
1150 18th Street, NW Suite 910
Washington, DC 20036
www.oralhealthalliance.org

The Oral Health Alliance, a 2030 Healthy People Champion, that represents nutrition, oral health education, and public health professional organizations, oral health providers, groups representing community, children, pregnant women, and older adults, industry, and consumer groups, submits this document to the World Health Organization *Call for Comment on the draft WHO guideline on use of non-sugar sweeteners*. The Alliance has been engaged for the past five years providing research and resources to the US Department of Agriculture and the US Department of Health and Human Services regarding the importance of oral health and nutrition in the *Healthy People 2030 Objectives*¹ the *2020-25 Dietary Guidelines for Americans*² and the recent report on *Oral Health in America: Advances and Challenges*³

Oral Health is a complex global public health problem that begins in pregnancy and extends through the lifespan. The factors contributing to poor oral health are complex and manifest differently based in large measure on socio-economic inequities. In making recommendations to promote good oral health and prevent dental caries, multifaceted and comprehensive recommendations are needed. Given the wide spectrum of individual habits, life experiences, and social environments of the world populations, any public WHO recommendation must be based on sound science and broad representation of diverse audiences. It must also consider the consequences of the specific guidance and avoid narrowing other alternatives that can also support overall public health.

The Oral Health Alliance submits these brief comments to the WHO as part of our ongoing efforts in promote preventive oral health practices. The preventive practices include brushing teeth with fluoride toothpaste, drinking fluoridated water, cleaning between teeth/flossing, chewing sugar-free gum, and avoiding frequent intake of fermentable carbohydrates

Because the OHA promotes limiting intakes of fermentable carbohydrates, it supports various dietary practices to reach that goal. One approach to reducing sugars in food and beverages has

¹ Office of Disease Prevention and Health Promotion. Oral Health. *Healthy People 2030*. U.S. Department of Health and Human Services. Available at <https://health.gov/healthypeople/search?query=oral+health>.

² U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th Edition. December 2020. Available at https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf

³ NIDCR, *Oral Health in America: Advances and Challenges*. December 2021. <https://www.nidcr.nih.gov/sites/default/files/2021-12/Oral-Health-in-America-Advances-and-Challenges.pdf#page=59>

been substituting non-sugar sweeteners that have been declared safe by the US Food and Drug Administration and the 2015 Dietary Guidelines for America⁴.

The positions the OHA takes on oral health policies have been based on rigorous review of the science. In fact, the Alliance is embarking on a scoping review of three caries prevention strategies – interdental cleaning, chewing sugar-free gum, and avoiding frequent intakes of fermentable carbohydrates. We are concerned that the oral health literature included in the WHO systematic meta-analysis that informed its guideline, “WHO Draft Guideline: Use of Non-sugar-sweeteners” is limited and may not fully represent the conclusions of the authors. Specifically, the WHO review cites Dr. Teresa Marshall’s research⁵ who has participated in the Oral Health Alliance. Her research report found children consuming sugar-free beverages and sugar-free powder at 5 years had a decreased risk of caries experience. Her data support the hypothesis that beverages that contain sucrose could be more detrimental to oral health than beverages that are sweetened with other sugars.

The WHO report includes only six oral health references and two RCTs for oral health: one on a stevia-based mouthwash and the other on stevia-based snacks. This set of studies is insufficient for a meta-analysis or conclusions related to non-sugar sweeteners and oral health; moreover in 93 pages, there is not a complete analysis of data. Non-sugar sweeteners play a part in decreasing sugar exposure within the oral cavity and the overwhelming body of research to date has concluded that the impact of reducing the exposure of the dentition to sugar positively impact natural remineralization.⁶

Submitted by Nancy Chapman, MPH, RD

nancy@oralhealthalliance.org

⁴ US Department of Agriculture and Department of Health and Human Services. 2015-2020 Dietary Guidelines for Americans. Washington, DC. December. 2015. Available at chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://health.gov/sites/default/files/2019-09/2015-2020_Dietary_Guidelines.pdf. Accessed on August 12, 2022.

⁵ Marshall T, Levy S, et al. Dental Caries and Beverage Consumption in Young Children. *Pediatrics*. Sept. 2003. Vol 112 (3): 189.

⁶ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to sugar-free chewing gum and reduction of tooth demineralisation which reduces the risk of dental caries pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1775. Available online: www.efsa.europa.eu/efsajournal.htm1

Survey response 36

General information

Family/last name
Russell
Given/first name
Cherie
Organization/affiliation
Healthy Food Systems Australia
Sector
Non-governmental agency
Sector [Other]
Country
Australia

Comments on the draft guideline

Summary of evidence

Thank you for the opportunity to contribute to this important guideline draft. We note that on page 12 of the draft, it is stated "Global trends on NSS use are unclear as NSS have yet to appreciably enter some markets and robust longitudinal intake data is not readily available for most countries outside North America, Europe and Australasia". However, since this draft was released, a study has been published (Russell et al) that assessed the global, regional, and country income category trends in added sugar and non-sugar sweetener sales globally (1). This study found that the sale of non-sugar sweeteners (and by proxy consumption) in both food and beverages is increasing globally and in most regions and country income categories. Of particular concern, the study found that the sweetness of the packaged food supply increased over time. Additionally, regions with more sugar-related policy actions had a significant increase in the volume of non-sugar sweetener from beverage sales ($r=0.68$, $p=0.04$).

Aside from this update to the evidence base, Healthy Food Systems Australia strongly supports the summary of evidence presented in the non-sugar sweetener draft guideline, underpinned by the recently published WHO systematic review and meta-analysis on the health effects of non-sugar sweeteners (2). From this review and supporting literature, there are clear links between non-sugar sweeteners and adverse health outcomes. Unfortunately, much of the literature, particularly around the impacts of habitual non-sugar sweetener intake on diet quality/energy consumption, are funded or affiliated with the food industry. As there is a clear bias for financial gain in this literature, we caution its inclusion in WHO's decision making process.

There is also a growing body of literature that links non-sugar sweeteners to issues outside metabolic harms. First, habitual non-sugar sweetener consumption may contribute to shifting population taste preferences towards sweeter palates (3). Second, non-sugar sweeteners are used exclusively in ultra-processed foods (UPFs), defined as industrial formulations which contain processed food substances and cosmetic additives (4). These products are designed to be hyper-palatable, affordable, convenient and are often marketed intensively (4). UPFs are recognised by the Food and Agriculture Organization of the United Nations (FAO) as detrimental to health. UPFs are markers of poor diets and are increasingly comprising higher proportions in diets (up to 42% in Australia)(5)(6) and have known adverse health (7) and environmental (8, 9) impacts. UPFs which contain NNS often display health claims and favourable front-of-pack labels (as non-sugar sweeteners are often not included in the nutrient profiling scores)(10) including 'low sugar' or 'healthy choice', and thus receive a 'health halo' and potentially displace nutritious whole foods from the diet. Finally, certain non-sugar sweeteners are considered environmental contaminants because they are not effectively removed from wastewater (11,12).

1. Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. *Public Health Nutrition*.:1-39.
2. Rios-Leyvraz M, Montez J, World Health Organization. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis.
3. Rios-Leyvraz M, Montez J, Organization WH. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. 2022.
4. Monteiro CA, Cannon G, Levy RB, Moubarac J-C, Louzada ML, Rauber F, et al. Ultra-processed foods: what they are and how to identify them. *Public health nutrition*. 2019;22(5):936-41.
5. Marchese L, Livingstone KM, Woods JL, Wingrove K, Machado P. Ultra-processed food consumption, socio-demographics and diet quality in Australian adults. *Public Health Nutrition*. 2022;25(1):94-104.
6. Marchese L, Livingstone KM, Woods JL, Wingrove K, Machado P. Ultra-processed food consumption, socio-demographics and diet quality in Australian adults. *Public health nutrition*. 2022 Jan;25(1):94-104.
7. Elizabeth L, Machado P, Zinöcker M, Baker P, Lawrence M. Ultra-processed foods and health outcomes: a narrative review. *Nutrients*. 2020;12(7):1955.
8. Leite FHM, Khandpur N, Andrade GC, Anastasiou K, Baker P, Lawrence M, et al. Ultra-processed foods should be central to global food systems dialogue and action on biodiversity. *BMJ Global Health*. 2022;7(3):e008269.
9. Anastasiou K, Baker P, Hadjikakou M, Hendrie GA, Lawrence M. A conceptual framework for understanding the environmental impacts of ultra-processed foods and implications for sustainable food systems. *Journal of Cleaner Production*. 2022 Jul 21:133155.
10. Dickie S, Woods J, Machado P, Lawrence M. Nutrition Classification Schemes for Informing Nutrition Policy in Australia: Nutrient-Based, Food-Based or Dietary-Based?. *Current Developments in Nutrition*. 2022 Jul 4.
11. Praveena SM, Cheema MS, Guo H-R. Non-nutritive artificial sweeteners as an emerging contaminant in environment: A global review and risks perspectives. *Ecotoxicology and environmental safety*. 2019;170:699-707.
12. Naik AQ, Zafar T, Shrivastava VK. Environmental Impact of the Presence, Distribution, and Use of Artificial Sweeteners as Emerging Sources of Pollution. *Journal of Environmental and Public Health*. 2021;2021:1-11.

Evidence to recommendations
<p>The attention and rigour undertaken in informing the WHO guideline for the use of non-sugar sweeteners is commendable. Healthy Food Systems Australia strongly supports the translation of the evidence to recommendations. We also appreciate the obvious consideration for the nuance within and between sweetener types, as described in the following: "The recommendation in this guideline was made based on evidence which suggests that there are health effects associated with NSS use irrespective of which NSS is being used, i.e. NSS as a class of compounds, despite individual NSS having different chemical structures, have an impact on health. It is recognized that NSS are not a homogenous class of compounds: each has a unique chemical structure and as a result, individual NSS have different sweetness intensities and organoleptic properties, and are processed differently by the body. Limited evidence suggests that individual NSS may also differ in their physiological effects in humans, however, evidence is currently insufficient to make recommendations for individual NSS." We hope that the inclusion of all sweeteners in this recommendation reduces the apparent 'health halo' that is given to foods that promote claims of 'low sugar' or the addition of a 'natural sweetener' (including stevia).</p>
Recommendations and supporting information
<p>Healthy Food Systems Australia strongly supports the recommendation included in the draft guideline. We strongly agree with the WHO draft position NOT to recommend non-sugar sweeteners to control weight OR to reduce the risk of non-communicable disease for the general population. In particular, the evidence provided demonstrates that not only do non-sugar sweeteners lack efficacy to reduce non-communicable disease rates, or to control weight; they in fact contribute to the development of these adverse health outcomes. As such, these additives are not a 'fit for purpose' solution to public health issues related to diet. As discussed previously, the sale of non-sugar sweeteners (and by proxy consumption) in both food and beverages is increasing globally and in most regions and country income categories (1). The promotion of these sweeteners as an alternative to added sugars to reduce the incidence of obesity and its related non-communicable diseases by the food industry, governments, and some public health organisations has only exacerbated their presence in the food supply. Given the links of non-sugar sweeteners outlined in the recently published WHO systematic review, this is an emerging and worrying trend.</p> <p>There is content in the draft regarding the need to promote minimally processed, nutritious, whole foods in the draft guideline, which we feel is imperative to sustainable public health improvements. We argue that this should be given stronger prominence in the guideline. "Efforts to reduce free sugars intake should be implemented in the context of achieving and maintaining a healthy diet. Because free sugars are often found in highly processed foods and beverages with undesirable nutritional profiles, simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected. Replacing free sugars in the diet with sources of naturally occurring sweetness, such as fruits, as well as 1 For prospective cohort studies it was generally not possible to determine the absolute highest intakes as the highest quantile was generally a specified amount or more (e.g. ≥ 2 servings per day), and though it is possible that some adults may have exceeded the ADI in some number of these studies, the number doing so would likely have been an extremely small percentage of the entire group. The likelihood that children exceed the ADI is greater given their lower body weight, however it is still expected to be a small percentage in most populations. Draft WHO Guideline: use of non-sugar sweeteners 11 minimally processed unsweetened foods and beverages, will help to improve dietary quality and should be the preferred alternatives to foods and beverages containing free sugars."</p> <p>1. Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. Public Health Nutrition.:1-39.</p>
Other comments
<p>With a growing focus on free sugars in public health and the media, and a number of policy actions to reduce their consumption, there has been an increasing reliance from manufacturers to add non-sugar sweeteners to their ultra-processed products. In Australia, and many other countries, there have been rapid and increasing approvals by Food Regulation Authorities to increase the type and amount of non-sugar sweeteners in a growing variety of food and drinks (1). We hope this recommendation will be useful for food regulators and governments when considering such policy actions and applications in the future.</p> <p>1. Russell, C, Baker, P, Grimes, C, Lindberg, R, & Lawrence, M. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. Public Health Nutrition. In Press</p>
Upload comments
<pre>[{"title":"","comment":"","size":"252.2353515625","name":"HFSA%20WHO%20NSS%20Consultation.pdf","filename":"fu_ntwuc22rh7azj9f","ext":"pdf" }]</pre>

Summary of Evidence:

Thank you for the opportunity to contribute to this important guideline draft. We note that on page 12 of the draft, it is stated “*Global trends on NSS use are unclear as NSS have yet to appreciably enter some markets and robust longitudinal intake data is not readily available for most countries outside North America, Europe and Australasia*”. However, since this draft was released, a study has been published (*Russell et al*) that assessed the global, regional, and country income category trends in added sugar and non-sugar sweetener sales globally (1). This study found that the sale of non-sugar sweeteners (and by proxy consumption) in both food and beverages is increasing globally and in most regions and country income categories. Of particular concern, the study found that the sweetness of the packaged food supply increased over time. Additionally, regions with more sugar-related policy actions had a significant increase in the volume of non-sugar sweetener from beverage sales ($r=0.68$, $p=0.04$).

Aside from this update to the evidence base, Healthy Food Systems Australia strongly supports the summary of evidence presented in the non-sugar sweetener draft guideline, underpinned by the recently published WHO systematic review and meta-analysis on the health effects of non-sugar sweeteners (2). From this review and supporting literature, there are clear links between non-sugar sweeteners and adverse health outcomes. Unfortunately, much of the literature, particularly around the impacts of habitual non-sugar sweetener intake on diet quality/energy consumption, are funded or affiliated with the food industry. As there is a clear bias for financial gain in this literature, we caution its inclusion in WHO’s decision making process.

There is also a growing body of literature that links non-sugar sweeteners to issues outside metabolic harms. First, habitual non-sugar sweetener consumption may contribute to shifting population taste preferences towards sweeter palates (3). Second, non-sugar sweeteners are used exclusively in ultra-processed foods (UPFs), defined as industrial formulations which contain processed food substances and cosmetic additives (4). These products are designed to be hyper-palatable, affordable, convenient and are often marketed intensively (4). UPFs are recognised by the Food and Agriculture Organization of the United Nations (FAO) as detrimental to health. UPFs are markers of poor diets and are increasingly comprising higher proportions in diets (up to 42% in Australia)(5)(6) and have known adverse health (7) and environmental (8, 9) impacts. UPFs which contain NNS often display health claims and favourable front-of-pack labels (as non-sugar sweeteners are often not included in the nutrient profiling scores)(10) including ‘low sugar’ or ‘healthy choice’, and thus receive a ‘health halo’ and potentially displace nutritious whole foods from the diet. Finally, certain non-sugar sweeteners are considered environmental contaminants because they are not effectively removed from wastewater (11,12).

1. Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. *Public Health Nutrition*.:1-39.
2. Rios-Leyvraz M, Montez J, World Health Organization. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis.
3. Rios-Leyvraz M, Montez J, Organization WH. Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. 2022.

4. Monteiro CA, Cannon G, Levy RB, Moubarac J-C, Louzada ML, Rauber P, et al. Ultra-processed foods: what they are and how to identify them. *Public health nutrition*. 2019;22(5):936-41.
5. Marchese L, Livingstone KM, Woods JL, Wingrove K, Machado P. Ultra-processed food consumption, socio-demographics and diet quality in Australian adults. *Public Health Nutrition*. 2022;25(1):94-104.
6. Marchese L, Livingstone KM, Woods JL, Wingrove K, Machado P. Ultra-processed food consumption, socio-demographics and diet quality in Australian adults. *Public health nutrition*. 2022 Jan;25(1):94-104.
7. Elizabeth L, Machado P, Zinöcker M, Baker P, Lawrence M. Ultra-processed foods and health outcomes: a narrative review. *Nutrients*. 2020;12(7):1955.
8. Leite FHM, Khandpur N, Andrade GC, Anastasiou K, Baker P, Lawrence M, et al. Ultra-processed foods should be central to global food systems dialogue and action on biodiversity. *BMJ Global Health*. 2022;7(3):e008269.
9. Anastasiou K, Baker P, Hadjikakou M, Hendrie GA, Lawrence M. A conceptual framework for understanding the environmental impacts of ultra-processed foods and implications for sustainable food systems. *Journal of Cleaner Production*. 2022 Jul 21:133155.
10. Dickie S, Woods J, Machado P, Lawrence M. Nutrition Classification Schemes for Informing Nutrition Policy in Australia: Nutrient-Based, Food-Based or Dietary-Based?. *Current Developments in Nutrition*. 2022 Jul 4.
11. Praveena SM, Cheema MS, Guo H-R. Non-nutritive artificial sweeteners as an emerging contaminant in environment: A global review and risks perspectives. *Ecotoxicology and environmental safety*. 2019;170:699-707.
12. Naik AQ, Zafar T, Shrivastava VK. Environmental Impact of the Presence, Distribution, and Use of Artificial Sweeteners as Emerging Sources of Pollution. *Journal of Environmental and Public Health*. 2021;2021:1-11.

Evidence to recommendations:

The attention and rigour undertaken in informing the WHO guideline for the use of non-sugar sweeteners is commendable. Healthy Food Systems Australia strongly supports the translation of the evidence to recommendations. We also appreciate the obvious consideration for the nuance within and between sweetener types, as described in the following: *“The recommendation in this guideline was made based on evidence which suggests that there are health effects associated with NSS use irrespective of which NSS is being used, i.e. NSS as a class of compounds, despite individual NSS having different chemical structures, have an impact on health. It is recognized that NSS are not a homogenous class of compounds: each has a unique chemical structure and as a result, individual NSS have different sweetness intensities and organoleptic properties, and are processed differently by the body. Limited evidence suggests that individual NSS may also differ in their physiological effects in humans, however, evidence is currently insufficient to make recommendations for individual NSS.”* We hope that the inclusion of all sweeteners in this recommendation reduces the apparent ‘health halo’ that is given to foods that promote claims of ‘low sugar’ or the addition of a ‘natural sweetener’ (including stevia).

Recommendations and supporting information:

Healthy Food Systems Australia strongly supports the recommendation included in the draft guideline. **We strongly agree with the WHO draft position NOT to recommend non-sugar sweeteners to control weight OR to reduce the risk of non-communicable disease for the general population.** In particular, the evidence provided demonstrates that not only do non-sugar sweeteners lack efficacy to reduce non-communicable disease rates, or to control weight; they in fact contribute to the development of these adverse health outcomes. As such, these additives are

not a ‘fit for purpose’ solution to public health issues related to diet. As discussed previously, the sale of non-sugar sweeteners (and by proxy consumption) in both food and beverages is increasing globally and in most regions and country income categories (1). The promotion of these sweeteners as an alternative to added sugars to reduce the incidence of obesity and its related non-communicable diseases by the food industry, governments, and some public health organisations has only exacerbated their presence in the food supply. Given the links of non-sugar sweeteners outlined in the recently published WHO systematic review, this is an emerging and worrying trend.

There is content in the draft regarding the need to promote minimally processed, nutritious, whole foods in the draft guideline, which we feel is imperative to sustainable public health improvements. We argue that this should be given stronger prominence in the guideline. *“Efforts to reduce free sugars intake should be implemented in the context of achieving and maintaining a healthy diet. Because free sugars are often found in highly processed foods and beverages with undesirable nutritional profiles, simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected. Replacing free sugars in the diet with sources of naturally occurring sweetness, such as fruits, as well as 1 For prospective cohort studies it was generally not possible to determine the absolute highest intakes as the highest quantile was generally a specified amount or more (e.g. ≥ 2 servings per day), and though it is possible that some adults may have exceeded the ADI in some number of these studies, the number doing so would likely have been an extremely small percentage of the entire group. The likelihood that children exceed the ADI is greater given their lower body weight, however it is still expected to be a small percentage in most populations. Draft WHO Guideline: use of non-sugar sweeteners 11 minimally processed unsweetened foods and beverages, will help to improve dietary quality and should be the preferred alternatives to foods and beverages containing free sugars.”*

1. Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. Public Health Nutrition.:1-39.

Other comments:

With a growing focus on free sugars in public health and the media, and a number of policy actions to reduce their consumption, there has been an increasing reliance from manufacturers to add non-sugar sweeteners to their ultra-processed products. In Australia, and many other countries, there have been rapid and increasing approvals by Food Regulation Authorities to increase the type and amount of non-sugar sweeteners in a growing variety of food and drinks (1). We hope this recommendation will be useful for food regulators and governments when considering such policy actions and applications in the future.

1. **Russell, C**, Baker, P, Grimes, C, Lindberg, R, & Lawrence, M. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. Public Health Nutrition. *In Press*

Survey response 37

General information

Family/last name
Khan
Given/first name
Tauseef
Organization/affiliation
University of Toronto
Sector
Academic/research
Sector [Other]
Country
Canada

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"WHO draft guideline on the use of non-sugar sweeteners: A short commentary","comment":"","size":"167.2685546875","name":"Khan%202022%20-%20WHO%20NSS%20draft%20guideline%20-%20a%20short%20commentary.pdf","filename":"fu_qj mp3uvswvjvcpj","ext":"pdf" }]

WHO draft guideline on the use of non-sugar sweeteners: A short commentary

Tauseef Khan^{1,2}, Sabrina Ayoub-Charente^{1,2}, Jennifer Lee¹, Jarvis Clyde Noronha^{2,3} and Laura Chiavaroli^{1,2}

¹ Department of Nutritional Sciences, Faculty of Medicine, University of Toronto ON, Canada

² Toronto 3D Knowledge Synthesis and Clinical Trials Unit, Clinical Nutrition and Risk Factor Modification Centre, St. Michael's Hospital, Toronto, Ontario, Canada

³ School of Medicine, Faculty of Medicine, The University of Queensland, Brisbane, QLD, Australia

Introduction

The Nutrition Guidance and Advisory Group of the World Health Organization (WHO) recently released the draft guideline for the use of non-sugar sweeteners (NSS) (1). Like the previous WHO guideline on sugar intake which were released in 2015 (2), this draft guidance is based upon evidence that was reviewed in a systematic manner and followed the WHO guideline development process.

The overall WHO recommendation for NSS states, **“NSS not to be used as a means of achieving weight control or reducing risk of non-communicable diseases (conditional recommendation).”**

The draft guideline declares that this recommendation is supported by the evidence base presented in the systematic review and meta-analysis (SRMA) published on the WHO website in April 2022 (3) and goes in length to provide a rationale behind the recommendation for not using NSS.

The draft guideline reports that NSS use in randomized controlled trials (RCTs) resulted in a reduction in body weight, BMI, and energy intake. Conversely, in prospective cohort studies, it reports that higher intake of NSS were associated with higher BMI, increased risk of incident obesity, type 2 diabetes, cardiovascular disease, and all-cause and cardiovascular mortality.

We have identified two major areas of concern in the WHO draft guideline which limits its usefulness and present a case to revisit of the overall recommendation.

Greater weight given to observational studies

The WHO draft recommendation ignored the hierarchy of evidence as followed by Grading of Recommendations Assessment, Development and Evaluation (GRADE) by disregarding evidence from the SRMA of RCTs and based their recommendations solely on the observational cohort studies. In the GRADE approach, evidence from RCTs start at high certainty due to the greatest protection against bias (4,5). The key advantage of using RCTs is that high quality RCTs (with protection of bias inherent in their design, e.g., randomization) have the ability to estimate causal relationship between an intervention (relative to a comparator) and the outcome. Prospective

cohort studies, with their lesser protection from bias and inability to estimate a causal relationship, start at low certainty of evidence. When evidence comes both from RCTs and cohort studies, one seeks consistency in results. If they are divergent, then the studies with most protection from bias, i.e., RCTs, are given precedence, especially since prospective studies are unable to estimate causality and risk of bias cannot be eliminated (6).

The draft guideline argues that the benefits seen with RCTs “does not represent a health benefit” and are short-term and, thus, do not provide evidence of long-term impact. This statement is unjustified as the meta-analysis for weight loss included two RCTs of 1 year duration (7,8) and three trials of 6 months duration (9–11) with no evidence of effect-modification by study duration. The draft guideline dismissed the evidence from RCTs, arguing that the discordant results between RCTs and prospective cohort studies mean that the weight loss in RCTs may not be relevant to long-term NSS use in the general population. This approach is methodologically flawed as it goes against conventional understanding and best practices in evidence synthesis by dismissing the causal RCT evidence (which included long-term studies) and focusing on the prospective cohort studies, which are prone to inherent bias and from which causality cannot be inferred. Furthermore, there is little biological reasoning to support that a consistent benefit on weight-related outcomes demonstrated in RCTs for up to 1-year would result in long-term harm. In fact, the RCT results in the WHO SRMA are consistent with the results of several other SRMAs of NSS trials which have shown similar benefits for weight loss and BMI (12–16) and demonstrate that the mechanism is through a reduction in net energy intake. This is supported by the WHO SRMA report of reduced sugar and energy intake when comparing NSS to a caloric comparator in RCTs (3).

Not using evidence from prospective cohort studies using methodologies that reduce bias

There is a consensus among NSS researchers (17–23) and dietary guidelines committees (24,25) that prospective cohort studies of NSS, which use prevalent exposure for association with cardiometabolic outcomes, are biased due to a high risk of behaviour clustering, residual confounding from incomplete adjustment of confounders, and reverse causality (i.e., being high risk for obesity, type 2 diabetes, and cardiovascular disease causes one to increase NSS intake as a risk reduction strategy). The presence of this bias (i.e., reverse causation and/or residual confounding) in prospective cohort studies of NSS was acknowledged and presented as a likely explanation of the adverse effects on cardiometabolic outcomes by the WHO SRMA (3) that informed the draft guideline. However, the draft guideline argued that these were bona-fide associations as the authors of the prospective cohort studies went to great lengths to adjust for confounders and reduce bias, notwithstanding that the authors of many of the included prospective cohort studies themselves have acknowledged the methodological limitations of their own work (26–30).

There are now new methodological strategies to address the issue of bias in prospective cohort studies of NSS, which include adjustment for adiposity in the primary analysis, sequential assessment to measure change in exposure, and a substitution analysis that specifically model

the intended replacement strategy (i.e., substitution of NSS for caloric sugars). These strategies are well described (18,20–23) and prospective cohort studies using these methodologies have been published in past years (27,31,32).

While the WHO draft guideline acknowledges the research gaps in evidence from the usual prospective cohort studies that inform the long-term effects of NSS, it does not attempt to address them. For example, it proposes improvements in cohort studies that include: i) robust exposure assessment including multiple, sequential assessment of exposure, and ii) efforts to address reverse causation. To this end, the draft guideline cite one study from the Harvard Pooling Project of Diet and Coronary Disease where replacement of sugar-sweetened beverages with NSS beverages was associated with a 12 percent reduction in coronary heart disease (33). However, this and similar prospective cohort evidence that explicitly modelled caloric substitution with NSS were not included in the SRMA, compared to evidence from other prospective studies which suggested harm, or considered as evidence for their overall recommendation. This approach contrasts with WHO's previous position when contrasting evidence is present from cohort studies that model replacement of nutrients. WHO in their commissioned SRMA on saturated and trans fat (34), interpreted their entire SRMA evidence of prospective cohort that employed prevalent exposure in light of a few observational studies that modelled replacement of saturated or trans fats. The authors in that study called that "dietary guidelines for saturated and trans fatty acids must carefully consider the effect of replacement of nutrients".

Recently, an SRMA of prospective cohort studies of NSS intake was published that included studies that employed i) change analysis of sequential assessments of intake, and ii) substitution analysis that modelled the intended replacement strategy of NSS (i.e., intended substitution of NSS beverages for sugar-sweetened beverages) and where investigators adjusted for initial adiposity (35). In this SRMA of 14 cohort studies with 416,830 participants, the authors demonstrated that an increase in NSS intake in studies with sequential assessments was associated with lower weight and borderline lower waist circumference without any adverse association with type 2 diabetes. Further, the substitution of NSS beverages for sugar-sweetened beverages was associated with lower weight and lower risk of incident obesity, coronary heart disease, cardiovascular mortality and total mortality, without any adverse association with any other cardiometabolic outcomes, including type 2 diabetes. The results from these prospective cohort studies, which use explicit analytical methodologies that minimize bias, are in complete agreement with the evidence from the SRMAs of RCTs where NSS intake reduced body weight and BMI (3,12–16). This is consistent with the mechanism that NSS lead to weight and cardiometabolic benefit insofar as they contribute to a reduction or displacement of calories in both types of studies.

Such prospective cohort studies which use analytical methods that reduce bias can provide more robust and biologically plausible associations that are consistent with the weight loss in RCTs. In GRADE, when there is a consistency of evidence from both RCTs and cohort studies, the overall recommendations can have higher certainty and are better suited to inform guidelines.

Implications for the draft guideline and conclusion

The WHO draft guideline based its overall recommendation solely on the evidence from long-term prospective cohort studies that used prevalent or baseline assessment of NSS. The analyses of such prospective cohort studies suffer from serious methodological limitations and recent evidence from prospective cohort studies with more rigorous analytical methods that involve change in intake of NSS and those that model replacement of calories with NSS show benefit for major cardiometabolic outcomes without any evidence of harm. The consistency of results between the RCTs and such analytically rigorous prospective cohort studies warrants that WHO should revisit their evidence base and recommendation.

In conclusion, dual evidence from RCTs and prospective cohort studies, which use methods to reduce bias, support the use of NSS as part of clinical and public health strategy to reduce caloric consumption and gain short- and long-term benefits for weight loss.

References

1. World Health Organization. WHO Draft guideline on use of non-sugar sweeteners [Internet]. 2022 [cited 2022 Aug 9]. Available from: <https://www.who.int/news-room/articles-detail/online-public-consultation-draft-guideline-on-use-of-non-sugar-sweeteners>
2. World Health Organization. WHO Guideline: sugars intake for adults and children [Internet]. World Health Organization; 2015. Available from: http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/
3. Rios-Leyvraz M, Montez J. World Health Organization: Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis [Internet]. World Health Organization; 2022 [cited 2022 Aug 9]. Available from: <https://www.who.int/publications/i/item/9789240046429>
4. Murad MH, Asi N, Alsawas M, Alahdab F. New evidence pyramid. *Evid Based Med* [Internet]. 2016 Aug;21(4):125–7. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27339128>
5. Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol* [Internet]. 2011 Apr [cited 2019 Jul 20];64(4):401–6. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S089543561000332X>
6. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. *Cochrane handbook for systematic reviews of interventions* 2nd Edition [Internet]. 2nd ed. Cochrane, Wiley-Blackwell; 2019. Available from: <https://training.cochrane.org/handbook>
7. Peters JC, Beck J, Cardel M, Wyatt HR, Foster GD, Pan Z, et al. The effects of water and non-nutritive sweetened beverages on weight loss and weight maintenance: A randomized clinical trial: Diet Beverages and Weight Loss. *Obesity* [Internet]. 2016 Feb [cited 2022 Aug 9];24(2):297–304. Available from: <https://onlinelibrary.wiley.com/doi/10.1002/oby.21327>
8. Ebbeling CB, Feldman HA, Steltz SK, Quinn NL, Robinson LM, Ludwig DS. Effects of Sugar-Sweetened, Artificially Sweetened, and Unsweetened Beverages on Cardiometabolic Risk Factors, Body Composition, and Sweet Taste Preference: A Randomized Controlled Trial. *J Am Heart Assoc* [Internet]. 2020 Aug 4 [cited 2022 Aug 9];9(15):e015668. Available from: <https://www.ahajournals.org/doi/full/10.1161/JAHA.119.015668>
9. Tate DF, Turner-McGrievy G, Lyons E, Stevens J, Erickson K, Polzien K, et al. Replacing caloric beverages with water or diet beverages for weight loss in adults: main results of the Choose Healthy Options Consciously Everyday (CHOICE) randomized clinical trial. *Am J Clin Nutr* [Internet]. 2012 Mar 1 [cited 2022 Aug 9];95(3):555–63. Available from: <https://academic.oup.com/ajcn/article/95/3/555/4578292>
10. Madjd A, Taylor MA, Delavari A, Malekzadeh R, Macdonald IA, Farshchi HR. Beneficial effects of replacing diet beverages with water on type 2 diabetic obese women following a hypo-energetic diet: A randomized, 24-week clinical trial: MADJD ET AL. *Diabetes Obes Metab* [Internet]. 2017 Jan [cited 2022 Aug 9];19(1):125–32. Available from: <https://onlinelibrary.wiley.com/doi/10.1111/dom.12793>
11. Engel S, Tholstrup T, Bruun JM, Astrup A, Richelsen B, Raben A. Effect of high milk and sugar-sweetened and non-caloric soft drink intake on insulin sensitivity after 6 months in overweight and obese adults: a randomized controlled trial. *Eur J Clin Nutr* [Internet]. 2018 Mar [cited 2022 Aug 9];72(3):358–66. Available from: <http://www.nature.com/articles/s41430-017-0006-9>
12. Miller PE, Perez V. Low-calorie sweeteners and body weight and composition: a meta-analysis of randomized controlled trials and prospective cohort studies. *Am J Clin Nutr* [Internet]. 2014 Sep 1 [cited 2021 Jun 21];100(3):765–77. Available from: <https://academic.oup.com/ajcn/article/100/3/765/4576435>
13. Rogers PJ, Hogenkamp PS, de Graaf C, Higgs S, Lluch A, Ness AR, et al. Does low-energy sweetener consumption affect energy intake and body weight? A systematic review, including meta-analyses,

- of the evidence from human and animal studies. *Int J Obes* [Internet]. 2016 Mar;40(3):381–94. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/26365102>
14. Laviada-Molina H, Molina-Segui F, Pérez-Gaxiola G, Cuello-García C, Arjona-Villicaña R, Espinosa-Marrón A, et al. Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts: Systematic review and meta-analysis. *Obes Rev* [Internet]. 2020 Jul [cited 2022 Aug 9];21(7). Available from: <https://onlinelibrary.wiley.com/doi/10.1111/obr.13020>
 15. Rogers PJ, Appleton KM. The effects of low-calorie sweeteners on energy intake and body weight: a systematic review and meta-analyses of sustained intervention studies. *Int J Obes* [Internet]. 2021 Mar [cited 2021 Jun 21];45(3):464–78. Available from: <http://www.nature.com/articles/s41366-020-00704-2>
 16. McGlynn N, Khan T, Wang L, Zhang R, Chiavaroli L, Au-Yeung F, et al. Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages With Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2022;e222092.
 17. Bright OJM, Wang DD, Shams-White M, Bleich SN, Foreyt J, Franz M, et al. Research Priorities for Studies Linking Intake of Low-Calorie Sweeteners and Potentially Related Health Outcomes: Research Methodology and Study Design. *Curr Dev Nutr* [Internet]. 2017 Jul 1 [cited 2022 Aug 9];1(7):e000547. Available from: <https://doi.org/10.3945/cdn.117.000547>
 18. Sievenpiper JL, Khan TA, Ha V, Vigiouliouk E, Auyeung R. The importance of study design in the assessment of nonnutritive sweeteners and cardiometabolic health. *CMAJ* [Internet]. 2017 Nov 20;189(46):E1424–5. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29158457>
 19. Khan TA, Malik VS, Sievenpiper JL. Letter by Khan et al Regarding Article, “Artificially Sweetened Beverages and Stroke, Coronary Heart Disease, and All-Cause Mortality in the Women’s Health Initiative.” *Stroke*. 2019 Jun;50(6):e167–8.
 20. Malik VS. Non-sugar sweeteners and health. *BMJ* [Internet]. 2019 Jan 3;364:k5005. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30606710>
 21. Ashwell M, Gibson S, Bellisle F, Buttriss J, Drewnowski A, Fantino M, et al. Expert consensus on low-calorie sweeteners: facts, research gaps and suggested actions. *Nutr Res Rev* [Internet]. 2020 Jun [cited 2022 Aug 9];33(1):145–54. Available from: https://www.cambridge.org/core/product/identifier/S0954422419000283/type/journal_article
 22. Khan TA, Sievenpiper JL. Low-energy sweeteners and cardiometabolic health: is there method in the madness? *Am J Clin Nutr* [Internet]. 2020 Oct 1 [cited 2022 Aug 9];112(4):917–9. Available from: <https://doi.org/10.1093/ajcn/nqaa260>
 23. Mela DJ, McLaughlin J, Rogers PJ. Perspective: Standards for Research and Reporting on Low-Energy (“Artificial”) Sweeteners. *Adv Nutr* [Internet]. 2020 May 1 [cited 2022 Aug 9];11(3):484–91. Available from: <https://doi.org/10.1093/advances/nmz137>
 24. Sievenpiper JL, Chan CB, Dworatzek PD, Freeze C, Williams SL. Nutrition Therapy. *Can J Diabetes* [Internet]. 2018 Apr [cited 2022 Aug 9];42:S64–79. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S1499267117308195>
 25. United States Department of Agriculture (USDA), United States Department of Health and Human Services (HHS). Dietary Guidelines for Americans 2020-2025 [Internet]. 2020 [cited 2022 Aug 9]. Available from: https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf
 26. Drouin-Chartier JP, Zheng Y, Li Y, Malik V, Pan A, Bhupathiraju SN, et al. Changes in Consumption of Sugary Beverages and Artificially Sweetened Beverages and Subsequent Risk of Type 2 Diabetes: Results From Three Large Prospective U.S. Cohorts of Women and Men. *Diabetes Care* [Internet]. 2019 Dec 1 [cited 2022 Aug 9];42(12):2181–9. Available from:

- <https://diabetesjournals.org/care/article/42/12/2181/36210/Changes-in-Consumption-of-Sugary-Beverages-and>
27. Malik VS, Li Y, Pan A, De Koning L, Schernhammer E, Willett WC, et al. Long-Term Consumption of Sugar-Sweetened and Artificially Sweetened Beverages and Risk of Mortality in US Adults. *Circulation* [Internet]. 2019 Apr 30 [cited 2022 Aug 9];139(18):2113–25. Available from: <https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.118.037401>
 28. Mossavar-Rahmani Y, Kamensky V, Manson JE, Silver B, Rapp SR, Haring B, et al. Artificially Sweetened Beverages and Stroke, Coronary Heart Disease, and All-Cause Mortality in the Women's Health Initiative. *Stroke* [Internet]. 2019 Mar [cited 2022 Aug 9];50(3):555–62. Available from: <https://www.ahajournals.org/doi/10.1161/STROKEAHA.118.023100>
 29. Anderson JJ, Gray SR, Welsh P, Mackay DF, Celis-Morales CA, Lyall DM, et al. The associations of sugar-sweetened, artificially sweetened and naturally sweet juices with all-cause mortality in 198,285 UK Biobank participants: a prospective cohort study. *BMC Med* [Internet]. 2020 Apr 24 [cited 2022 Aug 9];18(1):97. Available from: <https://doi.org/10.1186/s12916-020-01554-5>
 30. Farvid MS, Spence ND, Rosner BA, Chen WY, Eliassen AH, Willett WC, et al. Consumption of sugar-sweetened and artificially sweetened beverages and breast cancer survival. *Cancer* [Internet]. 2021 [cited 2022 Aug 9];127(15):2762–73. Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1002/cncr.33461>
 31. Pan A, Malik VS, Schulze MB, Manson JE, Willett WC, Hu FB. Plain-water intake and risk of type 2 diabetes in young and middle-aged women. *Am J Clin Nutr* [Internet]. 2012 Jun;95(6):1454–60. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/22552035>
 32. Smith JD, Hou T, Hu FB, Rimm EB, Spiegelman D, Willett WC, et al. A Comparison of Different Methods for Evaluating Diet, Physical Activity, and Long-Term Weight Gain in 3 Prospective Cohort Studies. *J Nutr* [Internet]. 2015 Nov;145(11):2527–34. Available from: [://WOS:000364264900013](https://wos.000364264900013)
 33. Keller A, O'Reilly EJ, Malik V, Buring JE, Andersen I, Steffen L, et al. Substitution of sugar-sweetened beverages for other beverages and the risk of developing coronary heart disease: Results from the Harvard Pooling Project of Diet and Coronary Disease. *Prev Med* [Internet]. 2020 Feb 1 [cited 2020 Jan 24];131:105970. Available from: <http://www.sciencedirect.com/science/article/pii/S0091743519304530>
 34. Souza RJ de, Mente A, Maroleanu A, Cozma AI, Ha V, Kishibe T, et al. Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. *BMJ* [Internet]. 2015 Aug 12 [cited 2022 Aug 13];351:h3978. Available from: <https://www.bmj.com/content/351/bmj.h3978>
 35. Lee JJ, Khan TA, McGlynn N, Malik VS, Hill JO, Leiter LA, et al. Relation of Change or Substitution of Low- and No-Calorie Sweetened Beverages With Cardiometabolic Outcomes: A Systematic Review and Meta-analysis of Prospective Cohort Studies. *Diabetes Care* [Internet]. 2022 Aug 1 [cited 2022 Aug 2];45(8):1917–30. Available from: <https://diabetesjournals.org/care/article/45/8/1917/147303/Relation-of-Change-or-Substitution-of-Low-and-No>

Survey response 38

General information

Family/last name
SINGH
Given/first name
ABHINAV
Organization/affiliation
FEDERATION OF INDIAN CHAMBERS OF COMMERCE & INDUSTRY (FICCI)
Sector
Other
Sector [Other]
Trade Association
Country
India

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"FICCI Representation on WHO Guidelines ","comment":"Comment Enclosed","size":"264.2392578125","name":"FICCI%20Representation%20on%20WHO%20Guidelines.docx","filename":"fu_c3knx2q4kyaftmr","ext":"docx" }]

To,

The Nutrition Guidance Expert Advisory Group,
World Health Organization (WHO),
WHO Headquarters,
Avenue Appia 20, 1211,
Geneva-27, Switzerland

Sub: FICCI Representation on World Health Organization (WHO) - Nutrition Guidance Expert Advisory Group (NUGAG): Sub-Group on Diet & Health - Draft Guidelines on Use of Non-Sugar Sweeteners

Dear Sir/Madam,

Federation of Indian Chamber of Commerce and Industry (FICCI), a non-government, not-for-profit organization, is the voice of India's business and industry. From influencing policy to encouraging debate, and engaging with policymakers and civil society, FICCI articulates the views and concerns of industry. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies. FICCI has a national network with 20 states.

Partnerships with 77 countries across the world carry forward our initiatives in inclusive development, which encompass health, education, livelihood, governance, skill development, etc. FICCI serves as the first port of call for Indian industry and the international business community. Our presence is in regions such as Africa, Arab, Israel, Pacific, East Asia, Europe, Latin America, North America, South Asia, etc. FICCI is also involved with Diaspora engagement, the forum of parliamentarians, Commonwealth of Independent States (CIS), multilateral, international policy, and strategy.

We take this opportunity to voice our concerns and comments on the “WHO draft guideline: use of non-sugar sweeteners” that was published on 15 July 2022 for public consultation. In the guideline, “WHO suggests that NSS not be used as a means of achieving weight control or reducing the risk of noncommunicable diseases” based on evidence of low certainty which, we strongly believe, is in contradiction to the other available scientific studies and the meta-analysis on NSS benefits.

While we at FICCI and our esteemed members fully support the intent of WHO in encouraging healthy and wholesome diets to global citizens, we would like to draw your kind attention toward the role of these Non-Sugar Sweeteners (NSS) are currently playing in offering a wide range of benefits to the consumers.

The use of NSS provides a handy resource for reformulation, renovation, and innovations in foods and beverages to replace, part or whole, of added sugars with a reasonable amount of NSS, as approved by the regulations, to reduce the calories without compromising much on the taste and sensorial attributes. Hence the use of such NSS is very critical and relevant to deliver on low sugar/low-calorie food products, especially in a country like India, where diabetes is one of the

serious non-communicable disease burdens on the nation, along with obesity and oral health. With the socio-economic shift, and the lifestyle of people undergoing rapid change, the rising incidences of non-communicable diseases, it is even more important to offer suitable dietary choices including NSS foods to consumers including children.

NSS is also important from the policy perspective in India as Govt. of India, very rightly, is pursuing a mission through the Food Safety Standards Authority of India, wherein besides other initiatives Food & Beverage (F&B) Industry is being motivated to reformulate their products to make them healthier such as with reduced sugar, salt, and fats. Some of the large Food & Beverage companies in India have also signed a pledge with Govt. to reformulate their products gradually to reduce Sugar, Salt, and Fat. NSS plays a major role in such reformulations when it comes to sugar reduction, along with food applications such as sugar-free chewing gum, mints, beverages, and candy.

We at FICCI strongly request that WHO reconsider overall priorities and return to science-based policy coherence when providing guidance to stakeholders in its efforts to achieve the UN Sustainable Development Goals by 2030. In 2015, when the UN first adopted the Global Goals, the call for action mandated an intensive global engagement in support of the implementation of all the Goals and targets, bringing together Governments, the private sector, civil societies, the United Nations system, and other actors and mobilizing all available resources. One of those resources specifically highlighted by the UN system was the food and beverage industry's ability to reformulate. You may please recollect that in 2018, the UN High-Level Meeting on NCDs called upon the industry to "strengthen its commitment" to make further efforts to reformulate foods and beverages with relatively reduced use of Sugar, Salt, and Fat. (Assembly, 2018)

In fact, Food Industry Asia in collaboration with IGD, a United Kingdom-based research agency, and China Food Information Centre (CFIC), an independent non-profit organization has been actively driving its reformulation commitments to reduce added sugar in products in Asian markets namely – India, Singapore, Malaysia, Thailand, Indonesia, Philippines, and China. As many as 82% of the samples studied in the survey have kickstarted their reformulation commitments in the last 4 years. (FIA, 2021; FIA & CFIC, 2021; FIA & IGD, 2021a, 2021b, 2021d, 2021c; Food Industry Asia & IGD, 2021)

It is indeed encouraging that Food & Beverage Industry across India is thriving to reformulate its products and offer choices to consumers with no or low sugar foods and beverages. It is equally promising that some of our members are making concerted efforts to change consumer behaviors by highlighting the benefits of the low sugar products to the consumers through their product commercials and other communications.

It is, therefore, critical that the messages going to consumers and policymakers from international agencies of repute like WHO are in sync with the scientific understanding that helps citizens get the right perspective about the use of NSS to achieve the larger goal of optimizing the sugar consumption by the consumers at large.

While FICCI fully supports the intent of WHO in encouraging healthy and wholesome diets to global citizens, we have the following submissions to be made in the context of the said draft guidelines:

A: Benefits of NSS in Diabetes:

The WHO draft guidelines conclude that the recommendations are not targeted at individuals with diabetes, which can create confusion amongst the consumers – whether or not they have diabetes. This also ignores the real-world implications of issuing guidelines to people around the world. For those who live with diabetes, NSS is an integral part of diabetes management.

As people with diabetes consist of 10% of the world's population (Statista, 2022), excluding them from the guidelines implies real-world repercussions when released globally. As we know, NSS is fundamental for diabetes management for people with diabetes, using vague recommendations such as “don't use non-sugar sweeteners for weight control” will sound confusing as in general people tend to focus on the headlines and not the subtext.

In a country like India, which has an enormous diabetic burden, this can be a counterproductive statement. The prevalence of diabetes in India has risen from 7.1% in 2009 to 8.9% in 2019. Currently, 25.2 million adults are estimated to have Impaired Glucose Tolerance, which is estimated to increase to 35.7 million in the year 2045. (Pradeepa & Mohan, 2021)

To explain further, the European Union allows a specific health claim related to NSS and glucose levels: “*Consumption of foods/drinks containing < name of sugar replacer > instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks*” (EFSA, 2017). There are other organizations like Diabetes UK, American Diabetes Association, US Academy of Nutrition and Diabetics, etc., who recognize that NSS can be safely used to replace added sugar in the nutritional management of diabetes. (Diabetes UK, 2018; Franz et al., 2017). Further, some studies also suggest that NSS such as stevia has medicinal properties in managing obesity and diabetes condition (YADAV & GULERIA, 2012).

NSS is a useful dietary tool for diabetic individuals who need to manage their carbohydrate and added sugar intake. Many researchers suggest that low- and no-calorie sweetened (LNCS) beverages/ Food can be a useful strategy in diabetes prevention and management by providing the option for low or no calories sweet tasting food products to satisfy the craving for sweet taste without any guilt and complication of glucose metabolism. Substituting sugars with low- and no-calorie sweetened (LNCS) beverages/foods provides patients with diabetes considerable flexibility in their health goals and personal dietary preferences. (GARDNER et al., 2012; Johnston et al., 2013; McGlynn et al., 2022)

WHO's recommendation to member states not to use NSS as a means for weight control could confuse people living with diabetes, especially when diabetes and nutrition-related organizations support the use of NSS for diabetes management hence it is very critical that the concluding statement kindly be reviewed.

B: Benefits of NSS in Weight Management:

As it is evident that WHO guidelines on sugar intake are considered a positive direction to manage weight besides other benefits. A review by Morenga et al. concludes that intake of free sugars or sugar-sweetened beverages was a determinant of body weight, with increased sugar intake leading to weight gain and inversely (Geneva: World Health Organization, 2015; Morenga et al., 2013).

Weight control and long-term weight loss management have been proven to be very challenging for individuals living with overweight and obesity. While the use of NSS alone in diets is not sufficient for weight loss, it can be a critical dietary tool in providing more options for sweet-tasting foods and beverages with fewer calories and added sugars, to help people living with obesity adhere to a better quality of living, while trying to manage their body weight. Academy of Nutrition and Dietetics in its position paper on Use of Nutritive and Non-nutritive Sweeteners states that “Consumers can safely enjoy a range of nutritive and non-nutritive sweeteners when consumed within an eating plan that is guided by current federal nutrition recommendations, such as the Dietary Guidelines for Americans and the Dietary Reference Intakes, as well as individual health goals and personal preference”. (Academy of Nutrition and Dietetics, 2012)

Therefore, the role of NSS, when replacing sugar should be obvious, and hence considering they all have been declared safe up to its ADI, their consumption by populations would invariably help in managing weight gain, by simply minimizing the sugar consumption.

Various scientific evidence, systematic reviews, and meta-analyses have confirmed and reaffirmed the important role of NSS to satisfy the consumer desire for sweet-tasting food without creating a calorie burden which results in an overall reduction of calorie consumption and thereby assisting in modest weight loss, especially in overweight or obesity person (Laviada-molina et al., 2020; McGlynn et al., 2022; Rios-leyvraz & Montez, 2022). Further, many studies have demonstrated that consumption of NNS-sweetened foods does not increase sweetness preference or energy intake (Wilk et al., 2022). A scientific statement from the American Heart Association (AHA) and American Diabetes Association (ADA) concluded that “when used judiciously, NNS could facilitate reductions in added sugars intake, thereby resulting in decreased total energy and weight loss/weight control, and promoting beneficial effects on related metabolic parameters”. (Current uses). (GARDNER et al., 2012).

C: Benefits of NSS in Oral Health:

There are 3.5 billion cases of dental caries causing periodontal (gum) disease leading to tooth loss globally. This makes oral diseases the most prevalent NCD globally, even though these oral conditions are almost entirely preventable, in part by the reduction in free sugar. To reduce these free sugars for health benefits as the WHO suggests, NSS is utilized in food and beverage reformulations. (World Health Organization, 2015; WHO, 2020)

FICCI respectfully requests in the final version of the WHO NUGAG NSS document to mention that NSS is an important tool in supporting oral/dental health management. It is a well-recognized

fact that excessive intake of sugar can contribute to dental caries as stated in the 2015 WHO report on sugars (WHO, 2020). Because NSS are non-fermentable by oral bacteria, they can contribute to good oral health when used in place of sugar. (FDI World Dental Federation, 2008)

European Food Safety Authority (EFSA) in 2011 itself has categorically concluded that sufficient scientific information exists, to support the claims that NSS, maintains tooth mineralization by decreasing tooth demineralization if consumed instead of added sugars (EFSA Panel on Dietetic Products, Nutrition, 2011)

USFDA has also specified that “Noncariogenic carbohydrate sweeteners, such as sugar alcohols, can be used to replace dietary sugars, such as sucrose and corn sweeteners, in foods such as chewing gums and certain confectioneries. These sweeteners are significantly less cariogenic than dietary sugars and other fermentable carbohydrates (U.S. Food and Drug Administration, 2022).

The conclusive statements in the Draft Guidelines, therefore, go against and are paradoxical to the recognized facts and consumer food habits that are established across the globe with scientifically proven results. Hence, it is critical that the said conclusive statement be reviewed appropriately as it is based on evidence of low certainty.

In light of the aforesaid, while we appreciate WHO’s efforts to provide guidance on NSS to policymakers and consumers at large, we unequivocally believe that any such guidelines be based on the scientifically established facts and proven benefits experienced by the consumers. Any decision based on low to very low certainty of the result without considering other scientifically well-established aspect of NSS usage as highlighted above may lead policymakers to legislate policies that may go against the established principles of public health.

We, therefore, earnestly request WHO to consider reviewing the limiting statements in the draft guidelines. We once again thank you for providing the opportunity to submit our comments on the draft guidelines.

Bibliography

1. Academy of Nutrition and Dietetics. (2012). Position of the Academy of Nutrition and Dietetics: Use of Nutritive and Nonnutritive Sweeteners. *Journal of the Academy of Nutrition and Dietetics*, 112, 739–758. <https://doi.org/10.1016/j.jand.2012.03.009>
2. Assembly, U. G. (2018). Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases. *International Organization*. <https://doi.org/10.1017/S0020818300012881>
3. Diabetes UK. (2018). *The use of low or no calorie sweeteners insights gathered: Position Statement*. December, 1–12.
4. EFSA. (2017). *COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012*. 1–55.
5. EFSA Panel on Dietetic Products, Nutrition, and A. (NDA). (2011). Scientific Opinion on the substantiation of health claims related to intense sweeteners and contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299), reduction of post-prandial glycaemic responses (ID 4298), maintenance. *EFSA Journal*, 9(6), 26. <https://doi.org/10.2903/j.efsa.2011.2229>

6. FDI World Dental Federation. (2008). *Sugar Substitutes and their Role in Caries prevention: Adopted by FDI General Assembly September, 2008 in Stockholm, Sweden Non-cariogenic*. <https://www.fdiworlddental.org/resources/policy-statements-and-resolutions/sugar-substitutes-and-their-role-in-caries-prevention>
7. FIA. (2021). *Healthier Product Reformulation in Philippines*.
8. FIA, & CFIC. (2021). *Healthier Product Reformulation in China*.
9. FIA, & IGD. (2021a). *Healthier Product Reformulation in India*. <https://retailanalysis.igd.com/Portals/1/Downloads/Healthier-Product-Reformulation-in-Indonesia.pdf>
10. FIA, & IGD. (2021b). *Healthier Product Reformulation in Indonesia*. <https://retailanalysis.igd.com/Portals/1/Downloads/Healthier-Product-Reformulation-in-Indonesia.pdf>
11. FIA, & IGD. (2021c). *Healthier Product Reformulation in Malaysia*. <https://retailanalysis.igd.com/Portals/1/Downloads/Healthier-Product-Reformulation-in-Indonesia.pdf>
12. FIA, & IGD. (2021d). *Healthier Product Reformulation in Thailand*. <https://retailanalysis.igd.com/Portals/1/Downloads/Healthier-Product-Reformulation-in-Indonesia.pdf>
13. Food Industry Asia, & IGD. (2021). *Healthier Product Reformulation in Singapore*.
14. Franz, M. J., MacLeod, J., Evert, A., Brown, C., Gradwell, E., Handu, D., Reppert, A., & Robinson, M. (2017). Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. *Journal of the Academy of Nutrition and Dietetics*, 117(10), 1659–1679. <https://doi.org/10.1016/j.jand.2017.03.022>
15. GARDNER, C., WYLIE-ROSETT, J., GIDDING, S. S., STEFFEN, L. M., JOHNSON, R. K., READER, D., & LICHTENSTEIN, A. H. (2012). Nonnutritive Sweeteners: Current Use and Health Perspectives. *DIABETES CARE*, 35(August), 1798–1808. <https://doi.org/10.2337/dc12-9002>
16. World Health Organization. (2015). *Guideline : Sugars intake for adults and children*.
17. Johnston, C. A., Stevens, B., & Foreyt, J. P. (2013). The Role of Low-calorie Sweeteners in Diabetes. *European Endocrinology*, 23 August, 96–98. <https://doi.org/10.17925/EE.2013.09.02.96>
18. Laviada-molina, H., Cuello-garcía, C., Molina-segui, F., Arjona-villicaña, R., Pérez-gaxiola, G., Espinosa-marrón, A., & Raigam Jafet Martinez-Portilla. (2020). Effects of nonnutritive sweeteners on body weight and BMI in diverse clinical contexts : Systematic review and meta-analysis. *ETIOLOGY AND PATHOPHYSIOLOGY*, 1–13. <https://doi.org/10.1111/obr.13020>
19. McGlynn, N. D., Khan, T. A., Wang, L., Zhang, R., Chiavaroli, L., & Au-yeung, F. (2022). Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages With Body Weight and Cardiometabolic Risk A Systematic Review and Meta-analysis. *Nutrition, Obesity, and Exercise*, 14 March, 1–19. <https://doi.org/10.1001/jamanetworkopen.2022.2092>
20. Morenga, L. Te, Mallard, S., & Mann, J. (2013). Dietary sugars and body weight : systematic review and meta-analyses of randomised controlled trials and cohort studies. *BMJ*, 7492(15 January), 1–25. <https://doi.org/10.1136/bmj.e7492>

21. Pradeepa, R., & Mohan, V. (2021). Epidemiology of type 2 diabetes in India. *Indian Journal of Ophthalmology*, 69(11), 2032–2938. <https://doi.org/10.4103/ijo.IJO>
22. Rios-leyvraz, M., & Montez, J. (2022). *Health effects of the use of non-sugar sweeteners: A systematic review and meta-analysis*. WHO.
23. Statista. (2022). *Diabetics prevalence worldwide 2021, 2030 and 2045*. 44(212), 2–3.
24. U.S. Food and Drug Administration. (2022). *CFR - Code of Federal Regulations Title 21*. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=170.3&SearchTerm=170.3>
25. WHO. (2020). Oral health: Achieving better oral health as part of the universal health coverage and noncommunicable disease agendas towards 2030. *EXECUTIVE BOARD 148th Session Provisional Agenda Item 6 EB148/8, 23 December*, 6.
26. Wilk, K., Wiktor Korytek, Pelczynska, M., Moszak, M., & Bogdanski, P. (2022). The Effect of Artificial Sweeteners Use on Sweet Taste Perception and Weight Loss Efficacy : A Review. *MDPI Nutrients*, 14(16 March), 15.
27. YADAV, S. K., & GULERIA, P. (2012). Steviol Glycosides from Stevia : Biosynthesis Pathway Review and their Application in Foods and Medicine Steviol Glycosides from Stevia : Biosynthesis Pathway Review and their Application in Foods. *Critical Reviews in Food Science and Nutrition*, 24 July, 988–998. <https://doi.org/10.1080/10408398.2010.519447>

Survey response 39

General information

Family/last name
Amaral Mais
Given/first name
Laís
Organization/affiliation
Brazilian Institute for Consumer Defense (Idec)
Sector
Non-governmental agency
Sector [Other]
Country
Brazil

Comments on the draft guideline

Summary of evidence

Evidence to recommendations

The extensive and robust body of evidence presented in the WHO NSS draft guideline shows the seriousness of WHO research to inform recommendations regarding the use of non-sugar sweeteners (NSS). Nonetheless, additional scientific evidence resulting in the inclusion of complementary information and more detailed recommendations, as suggested below, could enrich the guideline.

References:

- Carvalho TEM, Waisenberg A, Sato PM, Mais LA, Martins APB, Jaime PC, et al. Consumer perceptions of non-caloric sweeteners and the content of caloric and non-caloric sweeteners in ultra-processed products in Brazil. *Cien Saude Colet* 2022 May;27(5):1989-2000.
- Chazelas E, Deschasaux M, Srouf B, Kesse-Guyot E, Julia C, Alles B, et al. Food additives: distribution and co-occurrence in 126,000 food products of the French market, *Sci. Rep.*, 2020, 10, 3980.
- Davidou S, Christodoulou A, Frank K, Fardet A. A study of ultra-processing marker profiles in 22,028 packaged ultra-processed foods using the Siga classification. *Journal of Food Composition and Analysis* 99 (2021) 103848.
- Graham DJ, Heidrick C, Hodgins K. Nutrition Label Viewing during a Food-Selection Task: Front-of-Package Labels vs Nutrition Facts Labels. *J Acad Nutr Diet* 2015 Oct;115(10):1636-46.
- Kraemer MVS, Fernandes AC, Chaddad MCC, Uggioni PL, Rodrigues VM, Bernardo GL, et al. Aditivos alimentares na infância: uma revisão sobre consumo e consequências à saúde. *Rev Saúde Pública*. 2022;56:xx.
- Martuzzi M, Tickner JA, & World Health Organization. Regional Office for Europe. (2004). The precautionary principle: protecting public health, the environment and the future of our children. World Health Organization. Regional Office for Europe. <https://apps.who.int/iris/handle/10665/346211>.
- Ministry of Health. Argentina. Ley 27.642 de Promoción de la Alimentación Saludable. Noviembre 2021.
- Ministry of Health. Brazil. RDC nº 429, de 8 de outubro de 2020. Dispõe sobre a rotulagem nutricional dos alimentos embalados. *Diário Oficial da União*, 9 de outubro de 2020.
- Ministry of Health. Mexico. Modificación a la Norma Oficial Mexicana NOM-051-SCFI/SSA1-2010, Especificaciones generales de etiquetado para alimentos y bebidas no alcohólicas preenvasados-Información comercial y sanitaria, publicada el 5 de abril de 2010. *Diario oficial*, 13 de marzo de 2020.
- Montera VSP, Bortoletto APM, Borges CA, Canella DS. Distribution and patterns of use of food additives in foods and beverages available in Brazilian supermarkets. *Food Funct.*, 2021, 12, 7699.
- Rebolledo N, Reyes M, Popkin BM, Adair L, Avery CL, Corvalán C, et al. Changes in nonnutritive sweetener intake in a cohort of preschoolers after the implementation of Chile's Law of Food Labelling and Advertising. *Pediatr Obes* 2022 Jul;17(7):e12895.
- Reyes M, Garmendia ML, Olivares S, Aqueveque C, Zacarías I, Corvalán C. Development of the Chilean front-of-package food warning label. *BMC Public Health*. 2019 Jul 8;19(1):906.
- Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. *Public Health Nutr* 2022 Jul 28;1-39.
- Shangquan S, Afshin A, Shulkin M, Ma W, Marsden D, Smith J, et al. A Meta-Analysis of Food Labeling Effects on Consumer Diet Behaviors and Industry Practices. *Am J Prev Med*. 2019 Feb; 56(2): 300-314
- United Nations. A/RES/70/186 General Assembly. Consumer protection. Resolution adopted by the General Assembly on 22 December 2015. United Nations, 4 February 2016a.
- United Nations. United Nations Guidelines for Consumer Protection. United Nations Conference on Trade and Development. United Nations, New York and Geneva, 2016b.

Recommendations and supporting information

- Nutrition labelling:

Although the WHO NSS draft guideline recommends nutrition labelling (i.e. mandatory nutrient declaration), including front-of-pack (FoP) labelling system, as one of the strategies to reduce or prevent the use of NSS, the generalist approach of this recommendation may impair the achievement of the desirable results.

NSS declaration on foods and beverages can sometimes create confusion among consumers related to what they actually contain, especially when only listed on the list of ingredients. We suggest that WHO emphasizes the necessity of clearer description of the presence of NSS on product labels, providing more specific labelling recommendations.

Transparency and clear information to consumers regarding food content are an integral part of the United Nations (UN) consumer rights' principles (United Nations, 2016a and 2016b), which states that businesses should provide complete, accurate and not misleading information regarding the goods to enable consumers to take informed decisions, and ensure easy access to this information. UN also reinforces the need to combat substandard and falsely labelled products which pose threats to the health and safety of consumers and to the environment, and which also decrease consumer confidence in the marketplace. Hence, to conform with consumer rights' premises should be a priority.

Food labelling systems, in accordance with UN principles, represent one of the most important vehicles of disclosing product information to consumers, working as a determinant and protective factor in consumers' buying behavior (Shangguan et al., 2019).

In this regard, information about specific food components is easier visualized and perceived as important by the consumer when included in the FoP label through an explicit warning label or informative declaration (Graham et al., 2015; Reyes et al., 2019), e.g. "Contains non-sugar sweeteners". Furthermore, in order to enhance consumers' awareness of food content, a list of NSS on the label's list of ingredients, following the description of its technical function (i.e. "Non-sugar sweeteners:") —without which, each NSS name may not be perceived as a NSS by the consumer—, should be mandatory.

Since the information about the presence of specific compounds that may present health risks through a warning label or informative declaration and through a clear description of the referred compounds are complementary, the presence of either one of these labelling strategies alone tends not to inform consumers properly.

Chilean Food Labelling and Advertising Law that led to the local implementation of FoP warning labels on added sugars, sodium and saturated fat might be an example of this. Chilean innovative approach also subjects food products with FoP warning labels to child-directed marketing restrictions and banned them from sale or promotion in schools and nurseries. Chile didn't implement, however, a warning label for NSS. As a result of the Chilean labelling strategy, important and expected declines in sugar content of packaged foods occurred. However, in parallel, an increase in NSS use by the industry, particularly among products consumed by preschool children, was also identified. Product reformulation, through the use of NSS as a sugar substitute, as a strategy of the food industry to adapt to and to avoid negative results from FoP labelling law, may be the explanation for the increase of NSS in the food supply (Rebolledo et al., 2022)

Argentina and Mexico, on the other hand, not only followed Chilean FoP labelling model by implementing similar policies, as they included a warning label for NSS in order to help preventing NSS consumption by children, as follows: "CONTIENE EDULCORANTES - NO RECOMENDABLE EN NIÑOS" (e.g. CONTAINS NON-SUGAR SWEETENERS - NOT RECOMMENDED FOR CHILDREN) (Ministry of Health (Argentina), 2021; Ministry of Health (México), 2022). This strategy addresses government concerns about the potential health risks of these compounds, and reinforces the need for multiple labelling strategies combined. The results of Argentinean and Mexican labelling strategy is yet to be verified.

Attending public health demands, Brazil is another country about to implement a compulsory FoP nutrition labelling, which takes place from October 2022. Inspired by the Chilean initiative, it also contemplates warning labels on added sugars, sodium and saturated fat (Ministry of Health (Brasil), 2020). Warning labels specific for other nutrients are not included in the new Brazilian FoP labelling regulation.

In response to this new regulation, the Brazilian food industry, similarly to what happened in Chile, is already reformulating food products to lower total sugar and caloric content by substituting, partially or completely, sugar for NSS (Carvalho et al., 2022) —which may also lead to an increase in NSS Brazilian intake.

Considering that consumers are often not sure about the different types of sweeteners and their potential health risks, this scenario points out the urgent need of a more complete and integrated labelling strategy in order to present clearer additive and nutrition information to facilitate consumer comprehension and support healthy food choices worldwide (Carvalho et al., 2022). Besides that, as mentioned in the WHO draft, consumer education regarding not only NSS, but also in interpreting nutrient declarations, health claims, and other labelling attributes on foods and beverages is essential to the success of any policy measure to reduce or prevent the use of NSS, and should be contemplated as a main part of any labelling strategy implementation. An example is the word "edulcorante", the Brazilian term for NSS. As it is a technical term, Brazilians, in general, do not understand what "edulcorante" means, although it is present in the list of ingredients of a variety of food products. This situation reflects a frequent problem that concerns not only technical functions of food compounds, but other nomenclatures that consumers might find in food labels, and is one among many indicators that consumer education is fundamental to attend to UN consumer rights' principles.

In conclusion, given NSS potential health risks and the tendency of increased NSS consumption worldwide, we suggest the inclusion of a combined labelling strategy (warning label or informative declaration to indicate the presence of NSS plus NSS clear description) in the WHO document.

- Acceptable daily intakes (ADIs)

Regarding acceptable daily intakes (ADIs) of NSS, scientific studies are usually conducted considering the effects of specific NSS, without evaluating the impacts of medium- and long-term cumulative ingestion of one or more NSS, especially when combined with other compounds. Since NSS and other food additives are frequently co-occurring in food and beverage products,

the health impact of their cumulative ingestion due to the consumption of many food products daily, each possibly containing one or more NSS, as well as the consumption of NSS present in common clusters of food additives that may be associated to a variety of health risks (known as “cocktail effect”), need to be considered.

Recent studies conducted in France and Brazil analyzed food additive content of industrialized foods available in supermarkets in both countries, shedding light on the food additives cluster issue (Chazelas et al., 2020; Davidou et al., 2021; Montera et al., 2021). However, clusters of food additives may vary from country to country, and, more importantly, very few studies have analyzed the health risks associated with combinations of food additives (Chazelas et al., 2020), which leaves a void in terms of scientific evidence necessary to underpin the revision of safe levels of NSS intake.

Also, the impact of NSS and other food additives in children, who are more susceptible to their potential toxic effects due to their smaller body weight in comparison to adults’, is usually not taken into consideration when defining ADIs. Therefore, the current approach adopted to estimate ADIs disregards the precautionary principle, which is fundamental to protect public health, the environment and children’s future (Kraemer et al., 2022; Martuzzi et al., 2004)

In addition, the foresee gradual increase of NSS consumption worldwide, related to an increasing replacement of caloric sweetener for NSS in food and beverage products, may contribute to the formation of new food additive clusters, which health risks are still unknown. This trend has already been perceived in beverages, for example, with an estimated 36% increase of NSS volumes (g/per capita) sold in these products globally (Russell et al., 2022).

Thus, we suggest the inclusion of the above indicated remarks in the WHO document in order to encourage further research in this field, resulting in the revision of ADIs, so that they more accurately reflect safe consumption amounts of NSS, considering the current diet profile of the population.

Other comments

Upload comments

Survey response 40

General information

Family/last name
Orlan
Given/first name
Elizabeth
Organization/affiliation
Global Health Advocacy Incubator
Sector
Non-governmental agency
Sector [Other]
Country
United States of America

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"Global Health Advocacy Incubator comments on the WHO NSS Guideline","comment":"","size":"264.689453125","name":"GHAI%20comments%20on%20WHO%20NSS%20Guideline_August%202022.pdf","filename":"fu_9r22973i4nrzp6d","ext":"pdf"}]

About the Global Health Advocacy Incubator

The Global Health Advocacy Incubator (GHAI) works with civil society organizations across public health issues and political systems to provide strategic support to advocates that are working to enact and implement laws that save lives.

Our history is rooted in one of the most successful public health campaigns — tobacco control. Building on the successes and lessons learned in the global fight against tobacco deaths, the Campaign for Tobacco-Free Kids launched the GHAI in 2014 to strengthen advocacy capacity to improve public health around the globe.

Our experience designing successful campaigns and passing policies to save lives gave us an innovative and proven model for advocacy – one that is locally led and adaptable to culture, political context and issue area. Our expert multidisciplinary team has a broad range of experience planning, executing and evaluating high-impact policy advocacy campaigns. We provide capacity building and technical assistance across all components of effective policy advocacy, including political mapping, legal analysis and strategic planning to media advocacy, coalition building and grassroots mobilization.

Our Food Policy Program supports advocacy campaigns calling for healthy food policies at the national level in Brazil, Barbados, Colombia, Jamaica and South Africa. Through our Advocacy Fund and Legal Defense Fund, we help organizations and governments promote and defend their healthy food policy initiatives in Argentina, Ghana, India, Indonesia, Kazakhstan, Nigeria, Pakistan, St. Kitts & Nevis, Uruguay and Vietnam.

Overall clarity of the guideline

The evidence presented in the “WHO draft guideline: use of non-sugar sweeteners” (2022) states that studies have found that non-sugar sweeteners (NSS) are associated with greater risks of a range of health effects including obesity, increased risk of type 2 diabetes, cardiovascular diseases, bladder cancer, mortality and all-cause mortality (page 7, page 24-25). These studies should be enough evidence for the WHO and the Nutrition Guidance Expert Advisory Group (NUGAG) to discourage consumption of NSS and recommend the incorporation of mandatory NSS reduction strategies when developing healthy food policies.

The guideline states that any short-term beneficial impact that NSS may have would need to be “sustained over the long term to have a meaningful impact on health” (page 8), and “use of NSS is not the only way to achieve a reduction in free sugars intake” (page 8). Reformulation of ultra-processed products to include NSS in place of sugar is, according to this document, not providing a net gain to public health. Therefore, non-sugar sweeteners should be considered a constituent to limit when countries are developing Nutrient Profile Models (NPMs) and formulating food policies to encourage healthy food consumption.

In terms of articulating and communicating which foods and beverages should be limited in diets, using the categorization and terminology of “ultra-processed products” (UPP) and “processed products” as defined by the NOVA classification can help to clearly explain which products are harmful to health, and to encourage consumption of healthy, real foods on a population level (Monteiro et al., 2019). Ultra-processed products, or products ready to heat or eat that are made from ingredients not typically found in a kitchen, are harmful to health and contribute to non-communicable disease Askari et al., 2020; Pagliai et al., 2021; Duan et al. 2022; Neri 2022; Whatnall et al; 2022; Honicky et al., 2022). This product category consists of

hyper-palatable foods with an addictive nature. Consumption of these foods should be limited and replaced with healthier, minimally processed foods in the diet. The NOVA classification and the overall health harms related to consumption of UPPs should be highlighted more explicitly in the guideline so that the audience understands that products reformulated with NSS likely remain ultra-processed products.

The Pan American Health Organization (PAHO) NPM is the first regional NPM to explicitly focus on limiting consumption of ultra-processed products. In addition to setting thresholds for nutrients of concern (free sugars, sodium, saturated fat, etc.), the PAHO NPM encourages identification of products that contain any NSS (e.g., artificial or natural non-caloric sweeteners) as subject to regulation (PAHO, 2016). For example, policies that require warning labels on high-sugar drinks but do not consider that non-calorically sweetened drinks are also ultra-processed could have limited impact on reducing overall UPP intake, even while reducing sugar consumption.

Until now, reformulation (specifically replacing sugar with NSS) has been used as yet another marketing strategy for corporations to be able to make health claims. “Health halos” (or a false sense that food products are healthy and nutritious based on marketing or claims) stating that products are “sugar-free” (Stolze et al, 2021; Carvalho et al., 2022; McCann et al., 2022; Vignola et al., 2021) should not be allowed on NSS containing products.

We notice that the WHO Nutrition Guidance Expert Advisory Group (NUGAG) did not specifically look at individual policies or interventions related to NSS (as stated on page 32), but we urge the subgroup to investigate the impacts of both voluntary and mandatory policies on reformulation, and subsequently, increased consumption of NSS and other additives. Forthcoming dietary guidelines on these policy areas should include specific guidance on how to ensure that these policies are effective in reducing consumption of ultra-processed products.

Considerations and implications for adaptation and implementation of the guideline

- The guideline should stress that given NSS “should not be used as a means of achieving weight control or reducing risk of non-communicable disease,” (page 6) and therefore should be included within policies that reduce their consumption, like taxes on ultra-processed products (including beverages) and front of package warning labels.
- On page 9, the authors state *“Because of lack of certainty about the overall balance of desirable and undesirable effects associated with long-term effects of NSS use for reducing non communicable disease risk, including the possibility that reverse causation may have contributed to one or more of the associations observed between long-term NSS use and risk of disease in prospective observational studies, a conservative approach was taken, and the recommendation was considered to be conditional.”* In finalizing these guidelines, the authors should consider abiding by the precautionary principle, wherein from a legal perspective, harmful actions by industry “rests on the assurance of safety, and that when there are threats of serious damage, scientific uncertainty must be resolved in favor of prevention” (Goldstein, 2001). If there are unintended consequences of sweetener use, the WHO should recommend that use of sweeteners should not be encouraged, and instead, should be restricted to protect public health from uncertain consequences. (Sunstein, 2005; Goldstein, 2001)
- The use of the GRADE tool in this document and others should be revisited, as it understates the findings of research and may conflict with following the precautionary principle for public health, which should be followed when possible. Understating the evidence and providing low confidence

- classifications for these recommendations may have impacts on government’s decisions of whether to include NSS in policies that aim to restrict ultra-processed products.
- Case studies from Mexico and Chile, which have in place mandatory healthy food policies like front of package warnings, have shown cases of NSS being used as substitutes for sugar. We would encourage the NUGAG to investigate these real-world cases of Mexico and Chile, and include these examples as strong justification for incorporating all NSS in nutrient profile models and subsequent guidelines and regulations.
 - o Mexico’s FOPL, implemented in 2020, is based on a strong nutrient profile model, and requires products containing caffeine or artificial sweeteners to have mandatory warnings to avoid consumption by children. The policy is estimated to, within 5 years, reduce obesity prevalence in the country by 15% and save \$1.8 billion USD in direct and indirect costs (Basto-Abreu et al., 2020). However, now the food industry is reformulating products that formerly contained sugar with “natural” sweeteners, like allulose. Breakfast cereals marketed to children (complete with cartoons on their packaging) include NSS (Contreras-Manzano et al, 2022) and are advertised as being “sugar free.” We understand this is because including artificial sweeteners in a product would require including a warning seal but including “natural” sweeteners allow the product to continue to be marketed. If all non-sugar sweeteners are not also included in nutrient profile models or subsequent food policy restrictions, those products will continue to be advertised to children and the general public, which may have adverse consequences.
 - o A 2020 study of Chile’s mandatory Law of Food Labeling and Advertising found that there was a significant decrease in the proportion of products available on the market with high levels of sugars, and sodium in the first year of the policy (Reyes et al., 2020). After the implementation of the comprehensive Chilean food policy, purchases of beverages high in sugar fell by 23.7% by volume (-22.8 mL per person per day) (Taillie et al., 2020). In the first year of implementation of the law, there were significant declines in the purchases of calories, sugar and other nutrients of concern driven by reductions in purchases of products with front of package warning labeling (Taillie et al., 2021) Given the shift in the food supply to include more reformulated products., there is an increase of NSS purchase and consumption One study found that the volume of non-caloric sweetened beverages purchased increased by 6 mL per capita per day following the law’s implementation. (Rebolledo Fuentealba et al., 2020) While it is beneficial that sugar consumption is decreasing as a result of Chile’s package of healthy food policies, the substitution to NSS, particularly among children, could be a cause of concern. Therefore, future food policies should include warnings on NSS, and regulations to disincentivize reformulation from free sugars to NSS.
- On page 10, the authors state that this recommendation should be considered “*in the context of WHO recommendations to reduce free sugars intake and other guidance promoting healthy diets, including WHO guidance on dietary fat, carbohydrates, sodium and potassium.*” We would encourage the NUGAG and WHO at large to consider evaluating ultra-processed products as a category, given the strong evidence that demonstrates the increase of mortality and non-communicable diseases associated with the consumption of ultra-processed products (Askari et al., 2020; Pagliai et al., 2021; Duan et al. 2022; Neri 2022; Whatnall et al; 2022; Honicky et al., 2022) and providing recommendations based on that level of classification, in addition to nutrient-focused guidance.

- The section on health effects on children (page 25) states that the evidence is “much more limited” compared to the effects on adults, which is a frequent limitation as children are rightfully a protected population. However, we recommend that, based on the precautionary principle, NSS consumption should be restricted in the entire population, including children. A study among preschoolers in Chile using 24-hour dietary recalls, found that nonnutritive sweetener intake significantly increased among a sample of preschoolers between 2016 (before the Law on Food Labeling and Advertising was enacted) and 2017 (following enactment), showing even in countries where there are mandatory food policies restricting sugar and other nutrients of concern, there may likely be increases in consumption of products reformulated with non-sugar sweeteners (Rebolledo et al, 2022). The efforts to reduce child consumption of ultra-processed food in general, and NSS in particular, should be taken by governments, and this should be strongly encouraged through WHO guidelines.
- We believe the statement on page 34 is necessary to highlight and further focus on, wherein the guideline states *“It is further noted in the context of balance of desirable and undesirable effects, that NSS are not essential dietary components and provide no nutritional value themselves, the latter of which is also often the case with highly processed foods and beverages of which NSS are frequently a component. Therefore one of the implicit, possible undesirable effects of NSS use in the context of reducing free sugars intake is the inclusion of a greater number of highly processed foods and beverages in the diet than would be included if free sugars were reduced without NSS use.”* This statement underscores the need for the WHO and NUGAG to provide further guidance on how to regulate ultra-processed products to reduce their consumption and encourage consumption of foods without free sugars or NSS.
- We agree with the last paragraph of the Feasibility section (on page 36) that the level of NSS reduction will depend on policy. Consumer awareness can be increased through mandatory front of package warning labels that include warnings on NSS consumption, and also by restricting offer of these products in schools and marketing on foods that contain NSS, including banning health claims on these products and other ultra-processed products. These policies can help to encourage consumers to reduce their dietary intake of NSS containing products.
- On page 36 the authors mention that individual level acceptability of this recommendation “may be low.” We do not believe that this recommendation would be particularly impactful on an individual level, nor should it be. In public health, creating mandatory policies provides a population level impact and ultimately increases public acceptability of these measures. This justifies the need for stronger policies at the national level that encourage reduction of NSS as well as sugar, and ultimately create a food supply that will not depend on NSS. The onus should not be put on the consumer to make decisions about whether they are choosing products with NSS or not, particularly without interventions to communicate potential harms of NSS and consumption of ultra-processed products.
- We agree with the point on page 36 about public misperceptions on NSS based on “artificial” or “natural” language used in marketing, and therefore, the guideline should outright recommend that these claims should be banned to thwart these misperceptions.

Context and setting-specific issues that have not yet been captured

We applaud the mention of human rights frameworks and health equity on page 37 and would recommend elaborating on the point regarding mandatory policy impact on health equity. Mandatory fiscal policies like sweet beverage and ultra-processed product taxes can raise revenue for programs that impact those of low socioeconomic status. By taxing both NSS and sugar in beverages and other foods, governments can raise

revenue to provide broader access to potable water, and/or provide community health services, for example. (Powell et al. 2021)

Errors of fact or missing data

NSS have been associated with adverse health consequences, while the guide highlights that it is caveated by the “low confidence” certainty based on GRADE, which could discourage governments from taking actions to reduce NSS consumption. The following papers use robust study designs with large sample sizes and statically significant findings showing that NSS consumption is associated with increased risk of health harms such as cardiovascular disease, type 2 diabetes, stroke and all-cause mortality:

- Huang et al. (2017)’s meta-analysis showed that increased consumption of sugar-sweetened beverages and artificially sweetened beverages (ASBs) were positively associated with a greater risk of type 2 diabetes with Hazard Ratios (HR) ranging from 1.02-1.26 depending on daily number of servings consumed each week.
- Malik et al. (2019) examined associations between consumption of sugar sweetened beverages and artificially sweetened beverages with the risk of total and cause-specific mortality from two cohort studies of U.S health professionals. Analyses from the two cohorts showed a significant association between a high intake of artificially sweetened beverages and increased total cardiovascular disease mortality among women.
- Mossayar-Rahmani et al, (2019) conducted a longitudinal cohort study which examined the associations between self-reported consumption of artificially sweetened beverages and stroke, coronary heart disease and all-cause mortality in a cohort of postmenopausal women in the United States. The study found that a higher intake of ASBs among this cohort was associated with an increased risk of stroke within an average of 11 years follow-up. The study found that persons had a 23% (HR 1.23) and 31% (HR 1.31) increased risk of hemorrhagic stroke and ischemic stroke, respectively, due to high intake (over 2 servings) of ASBs per day.

Use of NSS has increased in the food supply globally, not only in high income countries (as stated through examples on page 12), but also in low- and middle-income countries where there are active efforts to reduce consumption of nutrients of concern on a population level through marketing restrictions, front of package warning labels and other healthy food policies.

We would recommend specifically looking at the literature which indicates that NSS are being consumed more in geographies with policies restricting sugar. We would also recommend looking specifically at so-called “natural” sweeteners, like allulose, and their long-term health impacts, as these types of natural sweeteners are becoming more commonly used.

Conclusion

Overall, NSS should not be used as a way for industry to circumvent healthy food policies, such as ultra-processed product marketing restrictions, front of package warning labels, school food policies and sweet beverage taxes. Products that contain NSS remain ultra-processed products, and the marketing of these products should not contain health claims nor any advertising elements that appeal to children. These products should not be allowed in schools. The WHO should advise that governments restrict consumption of nutrients of concern and include NSS as a restricted component of food and drink. Governments can and should use WHO regional nutrient profile models (NPMs) to guide their food policies, but should go a step further to include restriction of NSS, not only based on the available scientific evidence and the precautionary principle, but also based in the concrete experiences in countries where policies were implemented, and loopholes in the laws, created opportunities for industry to replace sugar with NSS and continue marketing their unhealthy products to children. The WHO may, in future iterations of the regional

NPMs, add NSS as a component to restrict, (i.e., if the product contains NSS, it should be restricted from marketing, and considered an ultra-processed product).

Citations

1. Duan, M.J., Vinke, P.C., Navis, G. *et al.* Ultra-processed food and incident type 2 diabetes: studying the underlying consumption patterns to unravel the health effects of this heterogeneous food category in the prospective Lifelines cohort. *BMC Med* **20**, 7 (2022). <https://doi.org/10.1186/s12916-021-02200-4>
2. Neri, D., Steele, E. M., Khandpur, N., Cediél, G., Zapata, M. E., Rauber, F., Marrón-Ponce, J. A., Machado, P., da Costa Louzada, M. L., Andrade, G. C., Batis, C., Babio, N., Salas-Salvadó, J., Millett, C., Monteiro, C. A., Levy, R. B., & NOVA Multi-Country Study Group on Ultra-Processed Foods, Diet Quality and Human Health (2022). Ultraprocessed food consumption and dietary nutrient profiles associated with obesity: A multicountry study of children and adolescents. *Obesity reviews : an official journal of the International Association for the Study of Obesity*, 23 Suppl 1, e13387. <https://doi.org/10.1111/obr.13387>
3. Askari, M., Heshmati, J., Shahinfar, H., Tripathi, N., & Daneshzad, E. (2020). Ultra-processed food and the risk of overweight and obesity: a systematic review and meta-analysis of observational studies. *International journal of obesity (2005)*, 44(10), 2080–2091. <https://doi.org/10.1038/s41366-020-00650-z>
4. Pagliai, G., Dinu, M., Madarena, M. P., Bonaccio, M., Iacoviello, L., & Sofi, F. (2021). Consumption of ultra-processed foods and health status: a systematic review and meta-analysis. *The British journal of nutrition*, 125(3), 308–318. <https://doi.org/10.1017/S0007114520002688>
5. Whatnall, M., Clarke, E., Collins, C. E., Pursey, K., & Burrows, T. (2022). Ultra-processed food intakes associated with 'food addiction' in young adults. *Appetite*, 178, 106260. Advance online publication. <https://doi.org/10.1016/j.appet.2022.106260>
6. Honicky, M., Cardoso, S., Kunradi Vieira, F., Hinnig, P., Back, I., & Moreno, Y. (2022). Ultra-processed food intake is associated with children and adolescents with congenital heart disease clustered by high cardiovascular risk factors. *British Journal of Nutrition*, 1-9. doi:10.1017/S0007114522002240
7. Pan American Health Organization. Nutrient Profile Model. In. Washington DC: Pan American Health Organization,; 2016:32.
8. Monteiro, C.A., Cannon, G., Lawrence, M., Costa Louzada, M.L. and Pereira Machado, P. 2019. Ultra-processed foods, diet quality, and health using the NOVA classification system. Rome, FAO
9. Mediano Stoltze, F., Busey, E., Taillie, L. S., & Dillman Carpentier, F. R. (2021). Impact of warning labels on reducing health halo effects of nutrient content claims on breakfast cereal packages: A mixed-measures experiment. *Appetite*, 163, 105229. <https://doi.org/10.1016/j.appet.2021.105229>
10. Carvalho, Terezinha E. M. de et al. Consumer perceptions of non-caloric sweeteners and the content of caloric and non-caloric sweeteners in ultra-processed products in Brazil. *Ciência & Saúde Coletiva* [online]. v. 27, n. 05 [Accessed 12 August 2022], pp. 1989-2000. Available from:

<<https://doi.org/10.1590/1413-81232022275.08452021>>.
<https://doi.org/10.1590/1413-81232022275.08452021>.

ISSN 1678-4561.

11. McCann, J., Woods, J., Mohebbi, M., & Russell, C. G. (2022). Regulated nutrition claims increase perceived healthiness of an ultra-processed, discretionary toddler snack food and ultra-processed toddler milks: A discrete choice experiment. *Appetite*, 174, 106044. <https://doi.org/10.1016/j.appet.2022.106044>
12. Vignola, E. F., Nazmi, A., & Freudenberg, N. (2021). What makes ultra-processed food appealing? A critical scan and conceptual model. *World Nutrition*, 12(4), 136–175. <https://doi.org/10.26596/wn.202112483-135>
13. Goldstein B. D. (2001). The precautionary principle also applies to public health actions. *American journal of public health*, 91(9), 1358–1361. <https://doi.org/10.2105/ajph.91.9.1358>
14. Sunstein, C. (2005). The Precautionary Principle as a Basis for Decision Making. *The Economists' Voice*, 2(2). <https://doi.org/10.2202/1553-3832.1079>
15. Basto-Abreu, A., Torres-Alvarez, R., Reyes-Sánchez, F., González-Morales, R., Canto-Osorio, F., Colchero, M. A., ... & Barrientos-Gutierrez, T. (2020). Predicting obesity reduction after implementing warning labels in Mexico: A modeling study. *PLoS medicine*, 17(7), e1003221. <https://doi.org/10.1371/journal.pmed.1003221>
16. Contreras-Manzano, A., Cruz-Casarrubias, C., Munguía, A., Jáuregui, A., Vargas-Meza, J., Nieto, C., ... & Barquera, S. (2022). Evaluation of the Mexican warning label nutrient profile on food products marketed in Mexico in 2016 and 2017: A cross-sectional analysis. *PLoS medicine*, 19(4), e1003968. <https://doi.org/10.1371/journal.pmed.1003968>
17. Reyes M, Smith Taillie L, Popkin B, Kanter R, Vandevijvere S, Corvalán C. Changes in the amount of nutrient of packaged foods and beverages after the initial implementation of the Chilean Law of Food Labelling and Advertising: A nonexperimental prospective study. *PLoS medicine* 2020;17(7):e1003220 <https://doi.org/10.1371/journal.pmed.1003220>
18. Taillie LS, Reyes M, Colchero MA, Popkin B, Corvalán C. An evaluation of Chile's Law of Food Labeling and Advertising on sugar-sweetened beverage purchases from 2015 to 2017: A before-and-after study. *PLOS Medicine* 2020;17(2):e1003015 doi: 10.1371/journal.pmed.1003015
19. Taillie LS, Bercholz M, Popkin B, Reyes M, Colchero MA, Corvalán C. Changes in food purchases after the Chilean policies on food labelling, marketing, and sales in schools: a before and after study. *The Lancet Planetary Health* 2021;5(8):e526-e33 DOI: 10.1016/S2542-5196(21)00172-8
20. Fuentealba, N. R., Reyes, M., Corvalan, C., Popkin, B., & Taillie, L. S. (2020). Do Sugary Drink Policies Increase Purchases of Non-Calorically Sweetened Beverages? Evidence from Chile. *Current Developments in Nutrition*, 4(Supplement_2), 1478-1478. https://doi.org/10.1093/cdn/nzaa061_106
21. Venegas Hargous, C., Reyes, M., Smith Taillie, L. *et al.* Consumption of non-nutritive sweeteners by pre-schoolers of the food and environment Chilean cohort (FECHIC) before the implementation

- of the Chilean food labelling and advertising law. *Nutr J* **19**, 69 (2020). <https://doi.org/10.1186/s12937-020-00583-3>
22. Baker-Smith, C. M., de Ferranti, S. D., Cochran, W. J., & COMMITTEE ON NUTRITION, SECTION ON GASTROENTEROLOGY, HEPATOLOGY, AND NUTRITION (2019). The Use of Nonnutritive Sweeteners in Children. *Pediatrics*, *144*(5), e20192765. <https://doi.org/10.1542/peds.2019-2765>
 23. Sylvestsky, A. C., Jin, Y., Clark, E. J., Welsh, J. A., Rother, K. I., & Talegawkar, S. A. (2017). Consumption of Low-Calorie Sweeteners among Children and Adults in the United States. *Journal of the Academy of Nutrition and Dietetics*, *117*(3), 441–448.e2. <https://doi.org/10.1016/j.jand.2016.11.004>
 24. Rebolledo, N., Reyes, M., Popkin, B. M., Adair, L., Avery, C. L., Corvalán, C., Ng, S. W., & Taillie, L. S. (2022). Changes in nonnutritive sweetener intake in a cohort of preschoolers after the implementation of Chile's Law of Food Labelling and Advertising. *Pediatric obesity*, *17*(7), e12895. <https://doi.org/10.1111/ijpo.12895>
 25. Powell, L. M., & Leider, J. (2021). Impact of a sugar-sweetened beverage tax two-year post-tax implementation in Seattle, Washington, United States. *Journal of public health policy*, *42*(4), 574–588. <https://doi.org/10.1057/s41271-021-00308-8>
 26. Mengna Huang, Abdullah Quddus, Lynda Stinson, James M Shikany, Barbara V Howard, Randa M Kutob, Bing Lu, JoAnn E Manson, Charles B Eaton, Artificially sweetened beverages, sugar-sweetened beverages, plain water, and incident diabetes mellitus in postmenopausal women: the prospective Women's Health Initiative observational study, *The American Journal of Clinical Nutrition*, Volume 106, Issue 2, August 2017, Pages 614–622, <https://doi.org/10.3945/ajcn.116.145391>
 27. Malik, V. S., Li, Y., Pan, A., De Koning, L., Schernhammer, E., Willett, W. C., & Hu, F. B. (2019). Long-Term Consumption of Sugar-Sweetened and Artificially Sweetened Beverages and Risk of Mortality in US Adults. *Circulation*, *139*(18), 2113–2125. <https://doi.org/10.1161/CIRCULATIONAHA.118.037401>
 28. Mossavar-Rahmani, Y., Kamensky, V., Manson, J. E., Silver, B., Rapp, S. R., Haring, B., Beresford, S., Snetselaar, L., & Wassertheil-Smoller, S. (2019). Artificially Sweetened Beverages and Stroke, Coronary Heart Disease, and All-Cause Mortality in the Women's Health Initiative. *Stroke*, *50*(3), 555–562. <https://doi.org/10.1161/STROKEAHA.118.023100>

Survey response 41

General information

Family/last name
Renaldi
Given/first name
Rocco
Organization/affiliation
International Food & Beverage Alliance
Sector
Private sector
Sector [Other]
Country
Belgium

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[{"title":"","comment":"","size":"200.9375","name":"IFBA%20comments%20WHO%20NSS%20guideline.pdf","filename":"fu_sn6nbwtfz4pe6p5","ext":"pdf" }]

Online public consultation on the “Draft WHO guideline on use of non-sugar sweeteners”

Comments by the International Food and Beverage Alliance

Introduction

The International Food and Beverage Alliance (IFBA) welcomes the opportunity to provide comments on the “Draft WHO guideline on use of non-sugar sweeteners”.

IFBA is a group of eleven international food and non-alcoholic beverage companies – The Coca-Cola Company, Danone, Ferrero, General Mills, Grupo Bimbo, Kellogg’s, Mars, Mondelēz International, Nestlé, PepsiCo and Unilever – who share a common goal of helping people around the world achieve balanced diets and healthy, active lifestyles. IFBA is a non-commercial, non-profit making organization, in special consultative status with ECOSOC.

Since its establishment in 2008, IFBA has been championing voluntary food industry action to improve nutrition and health outcomes, in support of the World Health Organisation’s (WHO) actions to tackle Non-Communicable Diseases (NCDs). In line with calls by the United Nations and the WHO, IFBA members are continuously working to help consumers improve their dietary quality and manage their caloric and sugar intake. We contribute to lowering sugar and caloric intake by formulating products with less or no sugar, including by using low- and no-calorie sweeteners and other ingredients as alternatives to sugars, by offering smaller portion sizes and providing portion guidance.

A range of commitments have been made by IFBA members to remove sugar from the food supply. These include reformulating products, developing new products with low- or no-sugar, and providing smaller portions. These commitments are published on IFBA’s website.¹

The WHO draft guideline

The draft guideline suggests that non-sugar sweeteners (NSS) should not be used as a means of achieving weight control or reducing risk of non-communicable diseases (*conditional recommendation).

This recommendation is based on evidence of overall *low* certainty, and in the absence of any credible research challenging the safety of NSS. Indeed, NSS are widely recognized as safe by competent authorities from around the world. This guideline, therefore, risks adversely impacting policy making, by hindering the use of NSS as a means of lowering sugar/caloric intake, which may ultimately undermine public health outcomes.

In addition, the title of the draft recommendation: “WHO draft guideline: use of non-sugar sweeteners” could be misleading as the WHO guidance covers only one area of NSS usage, namely weight control & reduction. Therefore, since there was not adequate evidence to review the effect of NSS on oral health in the 2022 systematic review, the existing wording is not founded on scientific evidence and will lead to misunderstanding. Accordingly, it is recommended to re-word the final WHO NUGAG declaration in order to confirm the greatest understanding, message and interpretation of the final recommendation and only reference the precise results from the systematic review and meta-analysis and not generalize to all NCDs.

NSS can be used for a number of other purposes, including the production of energy-reduced food (food with reduced energy by at least 30%), non-cariogenic food or food with no added sugar, dietary foods intended for low-caloric diets as it is included in Food Regulations at local or regional level.

¹ <https://ifballiance.org/commitments/product-formulation/reducing-sugar-and-calories/>

1. Scientific evidence underpinning the WHO guideline should be strong

IFBA supports science- and evidence-based policy recommendations that effectively help deliver positive public health outcomes. In this instance, we do not believe that it is appropriate to make a recommendation not to use NSS for weight control and reducing the risk of NCDs when the evidence underpinning the recommendation is of low quality and the recommendation is classified as “conditional”.

Member States and other stakeholders – including non-state actors – look to WHO to make science-based recommendations to inform the development of their policy responses and therefore expect such recommendations to be supported by strong scientific consensus and based on evidence directly related to the object of the guideline.

The draft guideline does not challenge the safety of NSS, but it suggests, on the basis of low-quality evidence, that NSS should not be used for weight management or NCD risk-reduction based on long-term population studies. The draft guideline does not address directly the well-evidenced short-term benefits of NSS for multiple vulnerable demographics.

The guideline reaches beyond the matter of the safety and recommended intake of NSS by making assumptions on their ultimate role in the diet. The overall draft recommendation is based, among other things, on the suggestion that NSS could – in addition to being a safe, sugar free alternative to high-caloric sugar – ultimately shape the overall diet of consumers:

“Because free sugars are often found in highly processed foods and beverages with undesirable nutritional profiles, simply replacing free sugars with NSS results in a food or beverage in which any other unhealthy elements are mostly retained, and as a result, the overall quality of the diet remains largely unaffected.”²

This overreach of the guideline’s scope is in conflict with actions taken worldwide by public health authorities and private sector organisations to reduce sugar intake. The statement is furthermore not supported by science and discounts the many nutritious and affordable products that positively contribute to overall diet quality by delivering under-consumed food groups like whole grain, dairy and fruits, as well as important nutrients like fiber, protein, and vitamins/minerals.

It is regrettable that the draft guidelines are based on low-quality evidence, chiefly relying on observational studies, which cannot establish a causal relationship. It is concerning that the draft guideline seems to uphold the conclusions from the prospective cohort studies and weight them more heavily than the results of Randomized Control Trials (RCTs), despite the findings from RCTs that suggest that NSS may be effective for short term weight loss (decrease in BMI and body weight) and helping people reduce energy intake as well as total sugar intake. The WHO-commissioned meta-analysis of RCTs reinforced the findings of an earlier, 2019 WHO-commissioned review,³ and acknowledges the moderate-to-high certainty clinical trial evidence showing either beneficial effects or an absence of detrimental effects from non-sugar sweetener consumption on body fatness and waist circumference, body weight, BMI, fasting glucose, glycated hemoglobin, systolic blood pressure, diastolic blood pressure, HDL cholesterol.⁴ This stronger evidence was seemingly dismissed in favor of the very-low-to-low-certainty observational evidence (known to suffer from residual confounding and reverse causality). Evidence selected for this guideline should adhere to the GRADE systematic review guidelines.

2. The available scientific evidence does not challenge the safety of NSS

² WHO draft guideline, p. 45.

³ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis. <https://apps.who.int/iris/handle/10665/353064>.

⁴ See Annex 6 ‘GRADE Evidence Profiles’ in the Draft Guidelines (see p.57)

The benefits of low- and no-calorie sweeteners when used in place of sugars are supported by a wealth of well-conducted, acute, short- and longer-term randomized controlled trials in humans, which provide high quality evidence. Failing to consider the collective evidence on the health effects of non-sugar sweeteners and to accurately translate the totality of available evidence into a recommendation in view of the hierarchy of scientific evidence, may hinder public health efforts to reduce sugars and calorie intake, provide lower and no added sugar options for those with diabetes, and impact oral health.

There is an extensive body of evidence from both animal models and human studies that support the safety of NSS for the general population including the elderly, children, pregnant and lactating women, within Acceptable Daily Intake (ADI) limits.

All NSS undergo extensive safety evaluation processes by international and national regulatory food safety bodies both before and after their approval for use in the market. The FAO/ WHO Joint Expert Committee on Food Additives (JECFA)², the US Food and Drug Administration (FDA)³ and EFSA⁴, have confirmed the safety of all approved NSS as food additives.

In addition, results from meta-analyses of RCTs confirm that NSS have no adverse impact on cardiometabolic risk factors, including glucose and insulin levels, blood lipids and blood pressure. In the presence of higher-quality evidence from RCTs, low certainty evidence from observational studies should be interpreted with caution. As it is indicated in the WHO draft document, global data on NSS usage and intake are unclear as robust longitudinal statics is not readily available for most countries outside North America, Europe and Australasia.

3. NSS are a critical tool for product formulation and to meet public health goals

NSS are used to replace sugars in food and beverage products, resulting in lower-sugar foods and beverages that can contribute to positive dietary outcomes in several ways: to lower calorie intake when there is excess sugar intake; for diabetes meal planning; and for nutritional strategies for dental health. All these objectives are aligned with the priorities adopted by the UN and the WHO on NCDs, and NSS are one of many tools to respond to these specific challenges. This includes responding to the WHO's recommendation on the intake of free/added sugars, adopted in 2015⁵, and which was classified as a "strong" recommendation.

In 2018, the Political Declaration of the UN High Level Meeting on NCDs called upon the private sector to "*strengthen its commitment*" to make further efforts to reformulate foods and beverages to reduce the excessive use of salts, sugars and fats.⁶ The industry has responded to this challenge by stepping up efforts to reformulate products. NSS are a critical part of this response.

During the 75th World Health Assembly, Member States endorsed a global strategy on oral health, with one of the overarching goals being to reduce oral disease.⁷ Because low- and no-calorie sweeteners are non-fermentable by oral bacteria, they can contribute to good oral health when used as a replacement for sugar.⁸ The European Food Safety Authority argues that "*there is sufficient scientific information to support the claims that intense sweeteners, as all sugar replacers, maintain tooth mineralization by decreasing tooth demineralization if consumed instead of sugars*"⁹. These benefits are also widely recognized by health authorities in Canada, Australia and Germany and the

⁵ Guideline: sugars intake for adults and children, World Health Organisation, 2015.

⁶ See 2018 UN High Level Meeting on NCDs Political Declaration, A-73-L-2-EN at OP 44, available at <https://digitallibrary.un.org/record/1645265?ln=en>.

⁷ See <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

⁸ FDI Policy Statement: Sugar substitutes and their role in caries prevention. Adopted by the FDI General Assembly, 26th September 2008, Stockholm, Sweden

⁹ EFSA, Scientific opinion on the substantiation of health claims related to intense sweeteners. EFSA Journal 2011;9(6):2229. Available online: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

FDI World Dental Federation. The global economic burden of dental caries treatment is already significant, with combined direct and indirect costs estimated at as much as US\$245 billion, and failing to acknowledge the well-established benefits of NSS use in dental health is a risk to public health efforts to address caries and related conditions such as gum disease and tooth loss.

Similarly, during the same World Health Assembly, Member States supported the creation of the first-ever global targets for diabetes, as part of WHO's Global Diabetes Compact.¹⁰ The draft guideline excludes people with diabetes (10% of the global population, according to International Diabetes Federation) from the scope of their conditional recommendation. This is a missed opportunity to reinforce action around diabetes management, including with low- and no- calorie sweeteners.

Indeed, health organizations around the world recognize that low- and no- calorie sweeteners can be safely used to replace sugar in the nutritional management of diabetes. Diabetes UK produced a Position Statement on low- and no-calorie sweeteners which concludes that: "LNCS are shown to be safe and they can be used as part of a strategy for adults and children in the management of weight and diabetes".¹¹ Both the American Diabetes Association (ADA)¹² and the US Academy of Nutrition and Dietetics (AND)¹³, in their nutrition recommendations for type 1 and type 2 diabetes, conclude that the use of low- and no-calorie sweeteners have the potential to reduce overall calorie and carbohydrate intake. Finally, the EU authority recognizes that *"the consumption of foods containing intense sweeteners instead of sugar induces a lower blood glucose rise after their consumption compared to sugar-containing foods."*¹⁴

NSS usage can help maintain weight as a part of balanced diet (especially energy-reduced food, low caloric food). Healthy diet, regular physical activities, people education to encourage healthy eating habits – weight loss requires a holistic approach. NSS can significantly reduce daily energy intake (-569 kJ) and daily sugar intake (-38,4 g) as is indicated in the WHO draft.

Conclusion

We call on the WHO to revisit the scope and the conclusions of the draft guideline to take into consideration the priorities identified by the United Nations 2018 Political Declaration on NCDs, as well as subsequent WHO Strategies on diabetes and on oral health, including Resolution WHA74.5 on oral health adopted in May 2021.

NSS play a critical role in the management of and response to these challenges, and their safe use is recognized and encouraged by competent authorities around the world. It is regrettable that a conditional recommendation based on weak evidence does not recognize that role, given the risks that it may negatively impact the ability of food manufacturers to use NSS to reduce sugar consumption and have long-term unintended consequences. There is concern that the recommendation could reinforce consumer skepticism around the safety of NSS, and may ultimately lead to a net increase in sugar consumption, which is surely not in the public health interest. Rather

¹⁰ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

¹¹ Diabetes UK. The use of low or no calorie sweeteners. Position Statement (Updated December 2018). Available at: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>.

¹² Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019 May;42(5):731-754;

¹³ Franz M. J. et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹⁴ Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

than advising against the use of NSS on the basis of weak evidence and in a “conditional” manner, it would be advisable for WHO to recommend further research to build the evidence base.

Survey response 42

General information

Family/last name
Duran
Given/first name
Ana Clara
Organization/affiliation
University of Campinas
Sector
Academic/research
Sector [Other]
Country
Brazil

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
[[{"title":"Comments for Recommendation and supporting information","comment":"","size":"21.6318359375","name":"Comment_NSS_WHO_tabela.docx","filename":"fu_z9izrb5iamfe23n","ext":"docx"}]]

Ana Clara Duran. Center for Food Studies and Research, University of Campinas - Albert Einstein Av., 291, Cidade Universitária, Campinas, Brazil 13083-852; Graduate Program in Collective Health, School of Medical Sciences, University of Campinas, Campinas, Brazil; Center for Epidemiological Studies in Nutrition and Health, University of São Paulo, São Paulo, Brazil. E-mail: anaduran@unicamp.br. ORCID: <https://orcid.org/0000-0001-7317-5790>.

Mariana Fagundes Grilo. Center for Food Studies and Research, University of Campinas - Albert Einstein Av., 291, Cidade Universitária, Campinas, Brazil 13083-852. E-mail: marianafgrilo@gmail.com, ORCID: 0000-0002-0864-2169

Online public consultation: draft guideline on use of non-sugar sweeteners

Recommendation and supporting information

Aligned with WHO suggestion that non-sugar sweeteners (NSS) should not be used as a means of achieving weight control or reducing risk of noncommunicable diseases (*conditional recommendation*), besides the great evidence presented in the document, we recommend to include the following evidences that show that, despite a growing body of evidence shows little or no beneficial effects of NSS on weight loss or glucose control, some NSS have been associated with health outcomes. We hope these evidences help elucidate some of the research gaps highlighted in the document related to how exposure to NSS in children might impact sweet preference and other neural and behavioral response to sweetness later in life, the potential long-term effects of NSS use on health outcomes, and differences in NSS use by age, ethnicity, socioeconomic status.

References	Main results
1. Ruiz-Ojeda FJ, Plaza-Díaz J, Sáez-Lara MJ <i>et al.</i> (2019) Effects of Sweeteners on the Gut Microbiota: A Review of Experimental Studies and Clinical Trials. <i>Advances in Nutrition</i> 10 , S31-S48. DOI: 10.1093/advances/nmy037	Saccharin and aspartame appear to be associated with increased gut production of bacteria (1) associated with weight gain, and sucralose and saccharin may lead to inflammation and compromise the insulin response to sugar intake (2). Similarly, beverages sweetened with NSS are not necessarily healthier alternatives to sugary drinks for the prevention of type 2 diabetes (3) or gestational diabetes (4).
2. Cabral T, Pereira M, Falchione A <i>et al.</i> (2018) Artificial Sweeteners as a Cause of Obesity: Weight Gain Mechanisms and Current Evidence. <i>Health</i> 10 , 700-717. DOI: 10.4236/health.2018.105054	
3. Imamura F, O'Connor L, Ye Z <i>et al.</i> (2015) Consumption of sugar sweetened beverages, artificially sweetened beverages, and fruit juice and incidence of type 2 diabetes: systematic review, meta-	

<p>analysis, and estimation of population attributable fraction. <i>Bmj</i> 351, h3576. DOI: 10.1136/bmj.h3576.</p> <p>16, 6. DOI: 10.1016/j.dsx.2022.102500.</p> <p>4. Hinkle SN, Rawal S, Bjerregaard AA <i>et al.</i> (2019) A prospective study of artificially sweetened beverage intake and cardiometabolic health among women at high risk. <i>Am J Clin Nutr.</i> DOI: 10.1093/ajcn/nqz094</p>	
<p>5. Debras C, Chazelas E, Srouf B <i>et al.</i> (2022) Artificial sweeteners and cancer risk: Results from the NutriNet-Santé population-based cohort study. <i>PLOS Medicine</i> 19, e1003950. DOI: 10.1371/journal.pmed.1003950</p> <p>6. Azad MB, Abou-Setta AM, Chauhan BF <i>et al.</i> (2017) Nonnutritive sweeteners and cardiometabolic health: a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies. <i>Cmaj</i> 189, E929-e939. DOI: 10.1503/cmaj.161390.</p>	<p>A population-based cohort in France showed that aspartame and acesulfame can be associated with increased cancer risk (5). Besides that, evidences suggests that regular consumption of foods and beverages with NSS may be associated with cardiometabolic risk (6).</p>
<p>7. Sylvetsky AC, Chandran A, Talegawkar SA <i>et al.</i> (2020) Consumption of Beverages Containing Low-Calorie Sweeteners, Diet, and Cardiometabolic Health in Youth With Type 2 Diabetes. <i>Journal of the Academy of Nutrition and Dietetics</i> 120, 1348-1358.e1346. DOI: 10.1016/j.jand.2020.04.005</p> <p>8. Karalexi MA, Mitrogiorgou M, Georgantzi GG <i>et al.</i> (2018) Non-Nutritive Sweeteners and Metabolic Health Outcomes in Children: A Systematic Review and Meta-Analysis. <i>J Pediatr</i> 197, 128-133.e122. DOI: 10.1016/j.jpeds.2018.01.081</p>	<p>Among children and adolescents, the consumption of foods and beverages with NSS has been associated with higher energy intake (7) and increased body-mass index (8).</p>
<p>9. Ambrosini GL (2014) Childhood dietary patterns and later obesity: a review of the evidence. <i>Proc Nutr Soc</i> 73, 137-146. DOI: 10.1017/S0029665113003765.</p> <p>10. Young J, Conway EM, Rother KI <i>et al.</i> (2019) Low-calorie sweetener use, weight, and metabolic health among children: A mini-review. <i>Pediatr Obes</i> 14, e12521. DOI: 10.1111/ijpo.12521</p>	<p>Children and adolescents, in fact, constitute a risk group because they have a higher intake of foods and beverages per kilogram of their body weight, because the consumption of products sweetened with NSS during childhood can modulate dietary preferences throughout life and contribute to overweight and obesity (9), and because of the unclear knowledge of the long-term effects of NSS consumption. In addition, children consuming beverages with NSS can even</p>

	compensate for the diluted energy content by eating more solid food calories (10).
11. Azad MB, Archibald A, Tomczyk MM <i>et al.</i> (2020) Nonnutritive sweetener consumption during pregnancy, adiposity, and adipocyte differentiation in offspring: Evidence from humans, mice, and cells. <i>Int. J. Obes</i> , 44, 2137–2148.	Yet, by triangulating evidence from humans, mice, and cultured adipocytes, this study showed that maternal NSS consumption during pregnancy may program obesity risk in offspring through effects on adiposity and adipocyte differentiation (11).
12. O BY, Coyle DH, Dunford EK <i>et al.</i> (2021) The Use of Non-Nutritive and Low-Calorie Sweeteners in 19,915 Local and Imported Pre-Packaged Foods in Hong Kong. <i>Nutrients</i> 13 . DOI: 10.3390/nu13061861 13. Ng SW, Slining MM, Popkin BM (2012) Use of caloric and noncaloric sweeteners in US consumer packaged foods, 2005-2009. <i>J Acad Nutr Diet</i> 112 , 1828-1834.e1821-1826. DOI: 10.1016/j.jand.2012.07.009 14. Grilo MF, Taillie LS, Ricardo CZ <i>et al.</i> (2021) Prevalence of low-calorie sweeteners and related front-of-package claims in the Brazilian packaged food supply. <i>J Acad Nutr Diet</i> . DOI: 0.1016/j.jand.2021.12.009 15. Grilo MF, Duarte LM, Crispim SP <i>et al.</i> (2022). Consumption of low-calorie sweeteners: findings from the Campinas Nutrition and Health Survey. <i>Brith J Nutr. Accepted for publication.</i>	Besides the current adverse effects associated with frequent consumption of NSS, they are being found in a wide range of foods and beverages, comprising a sizeable share of the market of sweetened beverages, yogurts, flavored waters, breakfast cereal and granola bars (12, 13, 14), with advertising directed to children (14), and consumed by the entire population (15). In a study in Brazil, it was found that the consumption of foods and beverages with NSS among adolescents, adults and the elderly, was not different across most age, gender, race/color, and socioeconomic strata (near 40% of the population consumed at least one food or beverage with NSS). Nor was the prevalence of consumption of foods and beverages with NSS among adults and elders with obesity or a self-reported diagnosis of diabetes when compared with folks without these health conditions (15).
16. Zancheta Ricardo C, Corvalán C, Smith Taillie L <i>et al.</i> (2021) Changes in the Use of Non-nutritive Sweeteners in the Chilean Food and Beverage Supply After the Implementation of the Food Labeling and Advertising Law. <i>Frontiers in Nutrition</i> 8 , 906. DOI: 10.3389/fnut.2021.773450 17. Scarborough P, Adhikari V, Harrington RA <i>et al.</i> (2020) Impact of the announcement and implementation of the UK Soft Drinks Industry Levy on sugar content, price, product size and number of available soft drinks in the UK, 2015-19: A controlled interrupted time series analysis. <i>PLoS Med</i> 17 , e1003025. DOI: 10.1371/journal.pmed.1003025	Recent regulatory measures aimed at contributing to healthier food choices, such as front-of-package warning labels and taxation, may lead to an unwanted increased prevalence of foods and beverages with NSS as a response of the food industry to replace sugar with NSS (16, 17). In Chile, adopted regulatory policies to target foods with a high content of total sugars or sugar-sweetened beverages led to an increase in NSS use from 37.9 to 43.6% after the initial implementation of the labeling law (16).

<p>18. Nichol AD, Holle MJ, An R (2018) Glycemic impact of non-nutritive sweeteners: a systematic review and meta-analysis of randomized controlled trials. <i>European Journal of Clinical Nutrition</i> 72, 796-804. DOI: 10.1038/s41430-018-0170-6</p> <p>19. Chazelas E, Druesne-Pecollo N, Esseddik Y et al. (2021) Exposure to food additive mixtures in 106,000 French adults from the NutriNet-Santé cohort. <i>Scientific Reports</i> 11, 19680. DOI: 10.1038/s41598-021-98496-6</p> <p>20. Montera VdSP, Martins APB, Borges CA et al. (2021) Distribution and patterns of use of food additives in foods and beverages available in Brazilian supermarkets. <i>Food & Function</i> 12, 7699-7708. DOI: 10.1039/D1FO00429H</p>	<p>Finally, recent epidemiological studies indicate concerns regarding the consumption of food additives – having NSS been the subject of recent systematic reviews and meta-analyses – and reinforce that further research is warranted to better understand the long-term risks of NSS (6, 8, 18). Despite being often used in combination with other NSS and food additives (14, 19, 20), toxicity tests on additives do not take into account synergies with other additives and dietary components.</p>
<p>21. Goldstein BD. The precautionary principle also applies to public health actions. (2001) <i>Am J Pub Health</i>, 91:1358-61.</p>	<p>Technological advances in the development of new NSS types and the ability to combine different NSS without exceeding the individual ADI levels, population exposure to high levels of NSS can increase. In the case of substances with contradictory evidence, such as NSS, the suggestion for public health purposes is to limit population exposure to that substance (21). Meanwhile, to guarantee that the population is not exposed to high levels of NSS, a more standardized approach to monitor changes in dietary exposure in combination with monitoring NSS levels in foods and beverages, NSS toxicity and NSS health effects is key, especially in the presence of sugar reduction strategies.</p>

Survey response 43

General information

Family/last name
Johns
Given/first name
Paula
Organization/affiliation
ACT Promoção da Saúde
Sector
Non-governmental agency
Sector [Other]
Country
Brazil

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
See following

Online public consultation: draft guideline on use of non-sugar sweeteners

The NUGAG group presented a robust systematic review to inform recommendations regarding the use of non-sugar sweeteners (NSS). Nonetheless, additional scientific evidence resulting in the inclusion of complementary information and more detailed recommendations could enrich the guideline.

Summary of evidence

- It is worth clarifying when you mention assertive sentences about studies but then use the "low certainty of evidence" as some statements seem to lose relevance. Perhaps at the beginning of the text, ponder what the given statements associated with these parentheses mean. This appears clear in the middle of the draft, however sentences as "In prospective observational studies with up to 10 years of follow-up, higher intakes of NSS were associated with higher BMI and increased risk of incident obesity, but not other measures of body fatness, (very low to low certainty evidence)" in page 7, seem confused.
- It seems the sentence in page 8 lacks clearance "There were no identified undesirable effects or other mitigating factors that would argue against not using NSS". If evidence is lacking, it cannot be stated there are no undesirable effects, only that they were not observed in studies

Evidence to recommendations

- Despite WHO systematic review mention on twenty of fifty randomized control trials either partially or totally funded by the industry, and the sensitivity analysis of NSS use excluding these studies attenuated the reduction in body weight, which was no longer statistically significant (MD -0.33 kg; 95% CI -0.80, 0.13; 18 studies with 1277 participants; I² 74%), the guideline should be clear on how the recommendation should consider preventing industry influence and the corporate capture of policy-making spaces and manage scientific literature financed by these actors. Specific recommendations on how to expose and manage the studies with conflict of interests should be included in the guideline.

- About missing research: studies that show the increase in consumption and massive migration of consumption of ultra-processed products and foods in still undisclosed amounts of sweeteners need to be detailed.

Recommendations and supporting information

- The WHO “conditional recommendations” establishment is a relevant statement that implies “further debate and involvement of various stakeholders” on policy making and, therefore, should be highlighted and explained more explicitly in the final guideline version.
- The exclusion criteria recommendation for the individuals with pre-existing diabetes is constantly repeated in the guideline. This mention should only be included in the explanation of exclusion criteria, because if people who are healthy and at risk of developing the outcome the use of NSS is not recommended, as prospective cohorts show the risks of developing type 2 diabetes, cardiovascular problems and increased mortality, for people with diabetes the prognosis of the disease may have a potential worse outcome, so the recommendation should also include them. Also, the guide should explicitly recommend further studies to evaluate mortality and disease severity of diabetic population due to the use of NSS and emphasize recommendation for people with diabetes, a well known vulnerable population.
- Although the WHO NSS draft guideline recommends fiscal policies and nutrition labelling (including front-of-pack (FoP) labelling system) as some of the strategies that may prevent the use of NSS, we suggest WHO emphasizes clear recommendations on these policies, considering the subsequent aspects:
 - ◆ NSS declaration on foods and beverages can sometimes create confusion among consumers related to what they actually contain, especially when only listed on the list of ingredients. Chilean innovative approach of FoP warning labels on added sugars, sodium and saturated fat; however, Chile did not implement a warning label for NSS. As a result, important declines in sugar content of packaged foods occurred, but an increase in NSS use by the industry, particularly among products consumed by preschool children, probably through the use of NSS as a sugar substitute (Rebolledo *et al.*, 2022). Inspired by Chile, Brazil is about to implement a compulsory FoP nutrition labelling on saturated fat, sugar and sodium, which takes place from October 2022 (Ministry of Health (Brasil), 2020). In response to this new regulation, the Brazilian food industry, is already reformulating food products to lower total sugar and caloric content by substituting, partially or completely, sugar for NSS (Carvalho *et al.*, 2022), which may also lead to an increase in NSS Brazilian intake.
 - ◆ Consumers are often not sure about the different types of sweeteners and their potential health risks, this scenario points out the urgent need of a more complete and integrated labelling strategy in order to present clearer additive and nutrition information to facilitate consumer comprehension and support healthy food choices worldwide (Carvalho *et al.*, 2022).
 - ◆ The taxation of sugary drinks has also seen an effect on the reformulation of products with greater availability of products with sweeteners on the market.

The United Kingdom is one example. In 2018, a sugar tax took place in the country tiered-sugar content for industrially pre-packaged drinks (beverages with sugar content above 5 g/100 ml). A positive impact was a 50% sales reduction of taxed beverages, but a 40% increase in sales of beverages with low or no sugar content was observed, most due to reformulation rather than changes in purchasing behavior (Bandy et al., 2020). Other analysis of the impact on purchases after the tax was announced - and prior to the implementation of the measure - revealed reductions in the volume and quantity of sugar of beverages included in the lowest taxable category (sugar content between 5-8 g/100 ml) and researchers suggested a potential reformulation of beverage sugar content from the lowest taxable category to fit the non-taxable category, with partial but not total removal of sugar (Pell et al., 2020).

- ◆ On the other hand, the taxation of NSS beverages was experienced in several countries, with positive effects observed after a few years of implementation, such as the reduction of demand of taxed NSS beverages (ESCIP, 2014; Zhong et al., 2018; Roberto et al., 2019).
- ◆ Given NSS potential health risks and the tendency of increased NSS consumption worldwide, we suggest the inclusion of a detailed combined labelling and fiscal policies strategies in the WHO document.

References on this topic:

- Bandy LK, Scarborough P, Harrington RA, et al. Reductions in sugar sales from soft drinks in the UK from 2015 to 2018. *BMC Med.* 2020;18(20).
- European Competitiveness and Sustainable Industrial Policy Consortium (ECSIP). Food taxes and their impact on competitiveness in the agri-food sector. Final Report. Rotterdam: ECORYS Consortium; 2014. 78 p.
- Ministry of Health. Brazil. *RDC nº 429, de 8 de outubro de 2020*. Dispõe sobre a rotulagem nutricional dos alimentos embalados. Diário Oficial da União, 9 de outubro de 2020.
- Pell D, Penney TL, Mytton O, et al. Anticipatory changes in British household purchases of soft drinks associated with the announcement of the Soft Drinks Industry Levy: A controlled interrupted time series analysis. *PLoS Med.* 2020;17(11):e1003269.
- Rebolledo N, Reyes M, Popkin BM, Adair L, Avery CL, Corvalán C, et al. Changes in nonnutritive sweetener intake in a cohort of preschoolers after the implementation of Chile's Law of Food Labelling and Advertising. *Pediatr Obes* 2022 Jul;17(7):e12895.
- Roberto CA, Lawman HG, LeVasseur MT, et al. Association of a Beverage Tax on Sugar-Sweetened and Artificially Sweetened Beverages With Changes in Beverage Prices and Sales at Chain Retailers in a Large Urban Setting. *JAMA.* 2019;321(18):1799-810.
- Zhong Y, Auchincloss AH, Lee BK, et al. The Short-Term Impacts of the Philadelphia Beverage Tax on Beverage Consumption. *Am J Prev Med.* 2018;55(1):26-34

Other comments

- The guideline should clearly highlight the industry as a target audience that can not participate in policy formulation on which they have conflict of interests.
- Regarding acceptable daily intakes (ADIs) of NSS, scientific studies are usually conducted considering the effects of specific NSS with no evaluation on the impacts of medium- and long-term cumulative ingestion of one or more NSS, especially when combined with other compounds. Since NSS and other food additives are frequently co-occurring in food and beverage products, the health impact of their cumulative consumption in many food products daily, each possibly containing one or more NSS, as well as the consumption of NSS present in common clusters of food additives that may be associated to a variety of health risks (known as “cocktail effect”), need to be considered.
- Recent studies conducted in France and Brazil analyzed food additive content of industrialized foods available in supermarkets in both countries, shedding light on the food additives cluster issue (Chazelas *et al.*, 2020; Davidou *et al.*, 2021; Montera *et al.*, 2021). However, clusters of food additives may vary from country to country, and, more importantly, very few studies have analyzed the health risks associated with combinations of food additives (Chazelas *et al.*, 2020), which leaves a void in terms of scientific evidence necessary to underpin the revision of safe levels of NSS intake.
- Children: the impact of NSS and other food additives in children, more susceptible to their potential toxic effects due to their smaller body weight in comparison to adults’, is usually not taken into consideration when defining ADIs. Therefore, the current approach adopted to estimate ADIs disregards the precautionary principle, which is fundamental to protect public health, the environment and children’s future (Kraemer *et al.*, 2022; Martuzzi *et al.*, 2004)
- The foresee gradual increase of NSS consumption worldwide, related to an increasing replacement of caloric sweetener for NSS in food and beverage products, may contribute to the formation of new food additive clusters, which health risks are still unknown. This trend has already been perceived in beverages, for example, with an estimated 36% increase of NSS volumes (g/per capita) sold in these products globally (Russell *et al.*, 2022).
- Thus, we suggest the inclusion of the above indicated remarks in the WHO document in order to encourage further research in this field, resulting in the revision of ADIs, so that they more accurately reflect safe consumption amounts of NSS, considering the current diet profile of the population.

References on this topic:

- Chazelas E, Deschasaux M, Srouf B, Kesse-Guyot E, Julia C, Alles B, et al. Food additives: distribution and co-occurrence in 126,000 food products of the French market, *Sci. Rep.*, 2020, 10, 3980.
- Davidou S, Christodoulou A, Frank K, Fardet A. A study of ultra-processing marker profiles in 22,028 packaged ultra-processed foods using the Siga classification. *Journal of Food Composition and Analysis* 99 (2021) 103848.
- Martuzzi M, Tickner JA, & World Health Organization. Regional Office for Europe. (2004). *The precautionary principle: protecting public health, the environment and the future of our children*. World Health Organization. Regional Office for Europe. <https://apps.who.int/iris/handle/10665/346211>.

- Kraemer MVS, Fernandes AC, Chaddad MCC, Uggioni PL, Rodrigues VM, Bernardo GL, et al. Aditivos alimentares na infância: uma revisão sobre consumo e consequências à saúde. *Rev Saúde Pública*. 2022;56:xx
- Montera VSP, Bortoletto APM, Borges CA, Canella DS. Distribution and patterns of use of food additives in foods and beverages available in Brazilian supermarkets. *Food Funct.*, 2021, 12, 7699.
- Russell C, Baker P, Grimes C, Lindberg R, Lawrence MA. Global trends in added sugars and non-nutritive sweetener use in the packaged food supply: drivers and implications for public health. *Public Health Nutr* 2022 Jul 28;1-39.

Survey response 45

General information

Family/last name
Given/first name
Organization/affiliation
Cámara Argentina de la Industria de Bebidas sin Alcohol (CADIBSA)
Sector
Sector [Other]
Trade Association
Country
Argentina

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
See following

Ciudad de Buenos Aires, 26 de agosto de 2022

**Ref: BORRADOR de las pautas de la OMS: Uso
de edulcorantes sin azúcar**

Estimado señor/a:

La Cámara Argentina de la Industria de Bebidas sin Alcohol (CADIBSA), es la organización que nuclea y representa en el país, a las empresas productoras de gaseosas, aguas con y sin gas, aguas saborizadas, jugos, isotónicos y energizantes. Su objetivo central es representar a la industria de las bebidas sin alcohol, contribuir a su desarrollo en la Argentina, y complementariamente, colaborar con el crecimiento de la economía nacional desde la actividad empresarial. La cadena de valor de la industria de bebidas sin alcohol tiene como primer eslabón a los productores agropecuarios de 12 provincias, e incluye además de los proveedores de insumos a los canales de venta como supermercados, almacenes, autoservicios y kioscos. El sector genera cerca de 30.000 empleos directos y más de 100.000 empleos indirectos.

En 2015, cuando la ONU adoptó por primera vez los Objetivos Globales, el llamado a la acción exigió un compromiso global intensivo en apoyo de la implementación de todos los Objetivos y metas, reuniendo a los Gobiernos, *el sector privado*, la sociedad civil, el sistema de las Naciones Unidas y otros actores y *movilizando todos los recursos disponibles*.¹ De particular interés, uno de esos recursos específicamente destacados por el sistema de la ONU es la capacidad de reformulación de la industria de alimentos y bebidas. En 2018, la Declaración Política de la Reunión de Alto Nivel de la ONU sobre las ENT pidió al sector privado que “fortalezca su compromiso” de hacer más esfuerzos por reformular los alimentos y las bebidas para reducir el uso excesivo de sales, azúcares y grasas.² Como se analizó en el Anexo adjunto, nuestra industria ha atendido este llamado de la ONU, y durante los últimos años ha intensificado significativamente los esfuerzos por reformular las bebidas para reducir los azúcares agregados, confiando en una herramienta clave de reformulación, los edulcorantes bajos en calorías, para lograrlo.

Y, si bien estamos haciendo este esfuerzo completo y sólido, la OMS está emitiendo simultáneamente pautas preliminares que buscan suprimir esta importante herramienta de reformulación de nuestras herramientas, todo mientras reconocemos que estas pautas preliminares son 1) basadas en evidencia de baja certeza y 2) no basadas en inquietudes de seguridad. Estamos, francamente, preocupados por

¹ “Transformación de nuestro mundo: la Agenda para el Desarrollo Sostenible 2030”, Resolución adoptada por la Asamblea General el 25 de septiembre de 2015, A/RES/70/1 en los párrafos 39 y 60. (énfasis añadido)

² Consulte la Reunión de Alto Nivel de la ONU 2018 sobre la Declaración Política sobre ENT, A-73-L-2-EN en OP 44, disponible en <https://digitallibrary.un.org/record/1645265?ln=en>.

este aparente giro en U de la política. Como declaró el Secretario General de la ONU, Antonio Guterres, en el Foro Político de Alto Nivel de la ONU 2022 de este año, “el mundo está en serios problemas, al igual que los Objetivos de Desarrollo Sostenible”. De particular interés para los objetivos de la OMS, la misma OMS reconoció que el mundo no está “encaminado para alcanzar los Objetivos de Desarrollo Sostenible 3,4 (SDG target 3.4), para reducir las muertes prematuras por ENT, y ningún país está logrando los nueve objetivos voluntarios establecidos en el Plan de Acción Global para la Prevención y el Control de las ENT 2013-2030”.³

¿Por qué entonces la OMS emitiría pautas preliminares con asesoramiento para la población general basado en evidencia de “baja certeza general”? **Solicitamos que la OMS revise este Borrador de las pautas en el contexto de las hojas de ruta recientes de la ONU de nivel superior** (que en particular, han dejado de citar en su borrador, haciendo referencia solo a las Reuniones de Alto Nivel de la ONU de 2011 y 2014 sobre las ENT, omitiendo completamente la Reunión de Alto Nivel de la ONU de 2018 sobre las ENT). Creemos en el valor de estas hojas de ruta de la ONU: estas son las prioridades establecidas con los aportes de los Estados miembros para ayudar a establecer el camino hacia los Objetivos globales, a diferencia de las recomendaciones recientes del comité de la OMS. Si las pautas preliminares que emanan de los comités dentro de las agencias son incoherentes (y se basan en evidencia de baja calidad) y no son consistentes con las directivas generales de la política establecidas por los Estados miembros de la ONU, entonces recomendamos encarecidamente a los líderes de la OMS que revisen las pautas por sí mismos.

I. Las recomendaciones de la OMS corren el riesgo de socavar las prioridades clave de la OMS establecidas por los estados miembros relacionadas con la diabetes y la salud dental

El pasado mes de mayo, en la 75.^a Asamblea Mundial de la Salud, los Estados Miembros respaldaron una **estrategia mundial histórica sobre la salud bucal**, y uno de sus objetivos generales era reducir las enfermedades bucales.⁴ De manera similar, en esta misma Asamblea Mundial de la Salud, los Estados Miembros apoyaron la creación de los **primeros objetivos globales para la diabetes**, como parte del Pacto Mundial contra la Diabetes de la OMS.⁵ En ambos casos, estos son objetivos de prioridades de alto nivel para la OMS avalados por los Estados miembros.

Los edulcorantes bajos en calorías y sin calorías son una herramienta importante para apoyar la salud bucal y el control de la diabetes. Con respecto a la salud bucal, se reconoce bien que la ingesta excesiva de azúcar puede contribuir a la caries dental. Debido a que los edulcorantes bajos en calorías y sin calorías no son fermentables por las bacterias bucales, pueden contribuir a una buena salud bucal

³ [https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-\(ncds\)](https://www.who.int/news-room/feature-stories/detail/world-health-assembly-approves-a-global-implementation-roadmap-to-accelerate-action-on-noncommunicable-diseases-(ncds)).

⁴ Consulte <https://www.who.int/news-room/feature-stories/detail/landmark-global-strategy-on-oral-health-adopted-at-world-health-assembly-75>

⁵ <https://www.who.int/news-room/feature-stories/detail/first-ever-global-coverage-targets-for-diabetes-adopted-at-the-75-th-world-health-assembly>

cuando se usan en lugar del azúcar.⁶ Como indicó la Autoridad Europea de Seguridad Alimentaria, “hay suficiente información científica para respaldar las afirmaciones de que los edulcorantes intensos, como todos los sustitutos del azúcar, mantienen la mineralización dental al disminuir la desmineralización si se consumen en lugar de azúcares”.⁷

Aunque la OMS simplemente dice que las personas con diabetes están excluidas de estas pautas, esta declaración sin tratamiento previo ignora las implicaciones del mundo real de emitir pautas para las personas de todo el mundo. Cuando la OMS emite recomendaciones generales como “no use edulcorantes sin azúcar para controlar el peso”, eso confundirá a las personas, ya sea que tengan o no diabetes. En el mundo real, las personas adoptan los titulares, no la letra pequeña. Y para aquellos que viven con diabetes, los edulcorantes bajos en calorías y sin calorías son una parte integral del control de la diabetes.

Por ejemplo, la UE permite una declaración de salud específica relacionada con edulcorantes bajos en calorías y sin calorías y niveles de glucosa: “*El consumo de alimentos que contienen edulcorantes intensos en lugar de azúcar induce un menor aumento de la glucosa en sangre después de su consumo en comparación con los alimentos que contienen azúcar*”.⁸ **Las organizaciones de salud a nivel mundial reconocen que los edulcorantes bajos en calorías y sin calorías pueden utilizarse de manera segura para reemplazar el azúcar en el manejo nutricional de la diabetes.**⁹ Por ejemplo, tanto la Asociación Americana de Diabetes (American Diabetes Association, ADA)¹⁰ como la Academia de Nutrición y Dietética (Academy of Nutrition and Dietetics, AND)¹¹ de los EE. UU., en sus recomendaciones nutricionales para la diabetes tipo 1 y tipo 2, concluyen que el uso de edulcorantes bajos en calorías y sin calorías tiene el potencial de reducir la ingesta general de calorías y carbohidratos

⁶ Declaración de la política de FDI: Sustitutos del azúcar y su función en la prevención de caries. Adoptado por la Asamblea General del FDI, 26 de septiembre de 2008, Estocolmo, Suecia

⁷ EFSA, Opinión científica sobre la justificación de afirmaciones de salud relacionadas con edulcorantes intensos. EFSA Journal 2011;9(6):2229. Disponible en línea: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

⁸ Regulación de la Comisión (UE) n.º 432/2012 del 16 de mayo de 2012 que establece una lista de reclamaciones de salud permitidas hechas sobre alimentos, que no sean aquellas que se refieren a la reducción del riesgo de enfermedad y al desarrollo y la salud de los niños

⁹ Diabetes UK. El uso de edulcorantes bajos en calorías o sin calorías. Declaración de posición (actualizada en diciembre de 2018). Disponible en: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

¹⁰ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelman A, Urbanski PB, Yancy Jr. WS. “Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report”. Diabetes Care. mayo de 2019;42(5):731-754;

¹¹ Franz M. J. et al. “Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process”. Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

si se sustituyen por edulcorantes calóricos y sin compensación por la ingesta de calorías adicionales de otras fuentes de alimentos. Además, la última declaración de posición de Diabetes UK sobre edulcorantes bajos en calorías y sin calorías concluye que: “*Se ha demostrado que los edulcorantes bajos en calorías o sin calorías son seguros y pueden usarse como parte de una estrategia para adultos y niños en el control del peso y la diabetes*”.¹⁰

Además, es interesante destacar que el Comité Asesor de Pautas Alimentarias (DGAC) de los EE. UU. de 2020 reconoce que las bebidas endulzadas bajas en calorías y sin calorías son “una ayuda útil en el control del peso en adultos”, y señala que las ingestas de azúcares agregados podrían reducirse en gran medida al consumir versiones reformuladas endulzadas bajas en calorías y sin calorías de alimentos y bebidas”.¹²

Nuevamente, observamos que la recomendación de la OMS sobre el uso de edulcorantes sin azúcar en estas pautas preliminares es una recomendación “condicional” o débil, lo que significa que se basa en evidencia de baja certeza. Solicitamos que los estados miembros revisen la necesidad de una recomendación tan débil a la luz de las prioridades existentes de la OMS establecidas por los estados miembros, como las relacionadas con el Pacto de la Diabetes y la Estrategia global sobre salud bucal.

II. Los estados miembros deben esperar que las pautas de la OMS se basen en la ciencia más sólida, no en ciencia de “baja certeza”

Como se indicó anteriormente, la recomendación de la OMS en este Borrador de las pautas es “condicional” o débil, porque se basa en evidencia de certeza general baja. Nos preocupan las implicaciones generales de que la OMS, en la que los países de todo el mundo confían como la “regla de oro” para el asesoramiento científico, desarrolle pautas de políticas basadas en evidencia de baja calidad. Observamos que estas pautas preliminares tienen implicaciones en el mundo real: debido a la dependencia de esta “evidencia de baja certeza”, podemos ver a los Estados miembros desarrollar una legislación que realmente no cumpla con los objetivos de salud pública para reducir los azúcares agregados en la dieta. Recomendamos encarecidamente a la OMS que vuelva al uso de las mejores prácticas en el desarrollo de pautas; con una ciencia sólida como base, las pautas serán más que “informadas por evidencia”.

Observamos con preocupación que la OMS no confió en la ciencia más sólida disponible para desarrollar estas pautas. La OMS se ha basado en gran medida en estudios observacionales, que no pueden establecer una relación de causa y efecto, y, como concluyó la OMS en última instancia, proporcionan evidencia de una baja calidad.

Nos sorprende que la OMS haya marginado su propio metaanálisis de ensayos controlados aleatorizados (ECA), que son la “regla de oro” en nutrición e investigación clínica, al desarrollar estas

¹²2020 U.S. Dietary Guidelines Advisory Committee Report (https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf). págs. 633, 636, 180, 691 del documento pdf de 835 páginas. Consultado el 21 de julio de 2022. (El Comité de Pautas Alimentarias de los EE. UU. declaró además: “Se ha recomendado que el agua común desplace otras bebidas que producen energía en la dieta para diluir la densidad de energía de la dieta, reducir la ingesta total de energía y ayudar a controlar el peso. El éxito de esta estrategia no se ha establecido y justifica un estudio adicional.”)

pautas. A principios de este año, la OMS publicó un metaanálisis de los ECA que demostró un beneficio modesto pero significativo para la pérdida de peso (entre otros beneficios) en adultos, lo que refuerza los hallazgos de una revisión basada en evidencia realizada a principios de 2019 por la OMS.¹³ Estamos desconcertados porque la propia evaluación de la OMS que reconoce la evidencia de ensayos clínicos de certeza moderada a alta que muestran efectos beneficiosos o una ausencia de efectos perjudiciales por el consumo de endulzantes sin azúcar (en la grasa corporal y la circunferencia de la cintura, peso corporal, IMC, glucosa en ayunas, hemoglobina glicosilada, presión arterial sistólica, presión arterial diastólica, colesterol HDL),¹⁴ fue desestimada a favor de la evidencia observacional de certeza muy baja a baja (conocida por sufrir de confusión residual y causalidad inversa) que finalmente sirvió como base para las Recomendaciones condicionales en este Borrador de la pautas.

Los beneficios de los edulcorantes bajos en calorías y sin calorías cuando se usan en lugar de azúcares están respaldados por una gran cantidad de ensayos controlados aleatorizados a corto y largo plazo en seres humanos, bien realizados y que proporcionan evidencia de alta calidad. No considerar la evidencia colectiva sobre los efectos en la salud de los edulcorantes sin azúcar ni traducir con precisión la totalidad de la evidencia disponible en una recomendación en vista de la jerarquía de la evidencia científica, puede obstaculizar los esfuerzos de salud pública para reducir el consumo excesivo de azúcar y abordar la obesidad.

III. Conclusión

En conclusión, apreciamos el esfuerzo de la OMS por brindar orientación a los responsables de formular políticas sobre edulcorantes sin azúcar. Sin embargo, creemos que cualquier orientación debe estar fundamentada en los principios de la política basada en la ciencia, exhibir coherencia en la política y seguir la hoja de ruta de las prioridades de salud recientes establecidas por los Estados miembros. Nos preocupa que la decisión de basar las pautas en evidencia de baja calidad pueda, en última instancia, llevar a los Estados miembros a promulgar una legislación que potencialmente ponga en peligro los resultados positivos de la salud pública. Le agradecemos la oportunidad de enviar estos comentarios. Háganos saber si tiene alguna pregunta o necesita información adicional.

Cordialmente,



Florencia Canzonieri
Directora Ejecutiva

¹³ World Health Organization, Rios-Leyvraz, Magali & Montez, Jason. (2022). *Health effects of the use of non-sugar sweeteners: a systematic review and meta-analysis*. World Health Organization. <https://apps.who.int/iris/handle/10665/353064>. Licencia: CC BY-NC-SA 3.0 IGO; “Toews I, Lohner S, K Ållenberg de Gaudry D, Sommer H, Meerpohl J. “Association between intake of non-sugar sweeteners and health outcomes: systematic review and meta-analyses of randomised and non-randomised controlled trials and observational studies” BMJ 2019; 364 :k4718 doi:10.1136/bmj.k4718)

¹⁴ Consulte el Anexo 6 “Perfiles de evidencia de GRADO” en el Borrador de la pautas (consulte la pág. 57).

Anexo

Compromisos de reducción de azúcar de la industria mundial de bebidas

El ICBA y sus miembros han apoyado durante mucho tiempo los esfuerzos significativos y basados en la ciencia para ayudar a los consumidores a tomar decisiones informadas sobre alimentos y bebidas para dietas saludables, y tenemos una sólida trayectoria de apoyar iniciativas de liderazgo sólidas. Por ejemplo, nuestra industria ha asumido compromisos voluntarios con respecto al marketing responsable, el marketing para niños y las bebidas que se ofrecen en las escuelas. Además, los miembros del ICBA apoyan el etiquetado interpretativo de nutrición en el frente del envase basado en la ciencia, ya que estamos de acuerdo en que se ejecutó bien, es una herramienta útil para ayudar a las personas a tomar decisiones alimentarias informadas, así como para incentivar a las empresas a innovar y reformular.¹⁵ La industria de las bebidas ha estado trabajando arduamente para reformular las bebidas con el fin de reducir el azúcar, ofrecer más opciones bajas en calorías y sin calorías, e intentar que haya una disponibilidad más amplia de los recipientes más pequeños. En todo el mundo, nuestra industria está implementando e informando públicamente sobre los compromisos de reducción de azúcar, a través de una variedad de asociaciones público-privadas. **Es importante destacar que los edulcorantes sin azúcar son una herramienta clave para el éxito de estos compromisos de reducción de azúcar.** Ofrecemos solo algunos ejemplos:

- En junio de 2018, el **Consejo Australiano de Bebidas** se comprometió a una reducción del 20 por ciento en el azúcar en toda la cartera de la industria de bebidas para 2025. A partir de 2021, el tercer informe de progreso demostró que se había logrado una reducción del 16 % en el azúcar, lo que demuestra que la industria estaba bien encaminada para alcanzar su objetivo general.¹⁶
- En noviembre de 2018, el **Ministerio de Salud de Brasil y las asociaciones brasileñas de alimentos y bebidas** firmaron un Memorando de Entendimiento para establecer objetivos nacionales para la reducción del azúcar. El acuerdo describe una serie de compromisos que debe asumir el sector de alimentos y bebidas para ayudar a reducir la ingesta de azúcar de los brasileños a menos del 10 % de las calorías diarias totales consumidas, incluida la reducción del azúcar en categorías clave como bebidas azucaradas, golosinas y otros alimentos.
- Junto con la **Junta de Conferencias de Canadá**, la Asociación Canadiense de Bebidas y sus miembros se han comprometido a reducir las calorías de bebidas consumidas por persona en un 20 por ciento para 2025. Un informe preparado por la Junta de Conferencias de Canadá muestra que, a través de innovaciones en productos y envases, las calorías de las bebidas

¹⁵ ICBA, “The Global Non-Alcoholic Beverage Industry Supports Science-Based Front-of-Package Interpretative Labeling to Support Consumer Health” (23 de junio de 2021), disponible en <https://icba-bigtrees3.amazonaws.com/files/resources/icbainterpretativelabelingpositionfinal.pdf>.

¹⁶ Consulte la declaración del Consejo Australiano de Bebidas disponible en <https://www.australianbeverages.org/non-alcoholic-beverages-industry-sugar-reduction-report-exceeds-target/>

consumidas por los canadienses han disminuido un 16 % entre 2014 y 2020, y la industria está en camino de cumplir con el objetivo de reducción del 20 % para 2025. Eso significa que desde 2004 ha habido una reducción de casi el 30 por ciento en calorías.¹⁷

- En 2020 en **México, los miembros de ANPRAC**, la asociación nacional de bebidas, se comprometieron a reducir las calorías en sus productos un 20 % adicional para 2024 mediante la reformulación de más de 50 productos y el aumento de su cartera de productos bajos en calorías o no calóricos al 70 %.
- En 2014, en asociación con Alliance for a Healthier Generation, las principales compañías de bebidas de los Estados Unidos unieron fuerzas en un acuerdo histórico para reducir las calorías de las bebidas en la dieta estadounidense en un 20 por ciento por persona para 2025. Keybridge, un evaluador independiente, ha monitoreado y medido el progreso anualmente. De 2014 a 2020, las calorías promedio de las bebidas por persona disminuyeron un 10,0 %, la mitad del objetivo de reducción de calorías del 20 % que se estableció para 2025. La disminución anual se ha acelerado cada año desde 2016, y la mayor disminución de un solo año (-5,0 %) se produjo en 2020. Las tendencias más importantes en términos de impacto en las calorías han sido el cambio hacia bebidas bajas en calorías y sin calorías, incluidas el agua y las aguas gasificadas. Esta tendencia se ha acelerado cada año desde 2016, ya que los consumidores seleccionan cada vez más las versiones bajas en calorías de todos los tipos de bebidas.
- A principios de este mes, **la Federación Europea de Bebidas Refrescantes, UNESDA**, emitió un comunicado de prensa en el que comunicaba que la industria de los refrescos ha reducido el azúcar en un 17,7 % desde 2015 y también el progreso del sector frente a su nuevo compromiso de reducir los azúcares agregados en otro 10 % para 2025 como parte del compromiso presentado el año pasado en virtud del Código de conducta de la UE sobre prácticas comerciales y de marketing responsables de alimentos de Farm to Fork Strategy. Esta nueva promesa llevará la reducción de azúcar agregada promedio total de nuestro sector en Europa al 33 % para 2025 (inicio 2000).
- Inspirados en la serie de tres compromisos consecutivos de reducción de azúcar de la UNESDA a nivel de la UE, 14 de sus miembros nacionales en toda Europa han asumido compromisos nacionales de reducción de azúcar/calorías, y muchos ya han informado logros notables, por ejemplo:
 - el sector **austriaco** de refrescos está trabajando para reducir el promedio de azúcares agregados en sus bebidas en un 15 % para 2025 (inicio 2019);

¹⁷ La Junta de Conferencias de Canadá, “Counting the Calories, Canadian’s Consumption of High-Calorie Beverages Continues to Decline” (agosto de 2018), *disponible en* <https://www.conferenceboard.ca/press/newsrelease/2018/08/09/counting-the-calories-canadians-consumption-of-high-calorie-beverages-continues-to-decline?AspxAutoDetectCookieSupport=1> (último acceso el 29 de mayo de 2019).

- la industria **belga** de refrescos logró en 2020 una reducción del 20 % en el azúcar (inicio 2012);
- la industria **holandesa** de refrescos logró en 2020 una reducción del 26,7 % en las calorías (inicio 2012);
- el sector **francés** de refrescos ha logrado una reducción del 9,8 % en azúcares entre 2010 y 2018, aprovechando su compromiso de una reducción del 5 % entre 2010 y 2015;
- el sector **alemán** de refrescos se ha comprometido a hacer una reducción del 15 % para 2025 en calorías de las bebidas que pone en el mercado (inicio 2015);
- el sector **italiano** de refrescos ya ha logrado una reducción del 20 % en azúcar y calorías entre 2009 y 2016 y se ha comprometido a una reducción adicional del 10 % en azúcar para 2022 (inicio 2020), cabe destacar que el sector italiano de refrescos redujo el azúcar en un 27 % entre 2009 y 2019;
- en **Letonia**, el sector de refrescos tiene como objetivo reducir el promedio de azúcares agregados en sus bebidas en un 20 % para 2030 (inicio 2015);
- la industria **portuguesa** de refrescos logró en 2020 una reducción del 30,5 % en calorías (inicio 2013) y en 2019 anunció una reducción adicional del 10 % para 2022 (inicio 2019);
- en **España**, la industria de refrescos ha reducido los azúcares agregados en un 43 % y en mayo de este año anunció un nuevo compromiso de reducción del 10 % que llevará la reducción total de azúcar al 53 % para 2025 (inicio 2005); y
- el sector **sueco** de refrescos se compromete a ofrecer una reducción adicional del 15 % en el promedio de azúcares agregados para 2025 (inicio 2019).

Survey response 44

General information

Family/last name
Palacios García
Given/first name
Guillermo
Organization/affiliation
Asociación de la Industria de Bebidas y Refrescos sin Alcohol del Perú
Sector
Sector [Other]
Trade Association
Country
Perú

Comments on the draft guideline

Summary of evidence
Evidence to recommendations
Recommendations and supporting information
Other comments
Upload comments
See following

Lima, 12 de Agosto de 2022

Ref: BORRADOR de las pautas de la OMS: Uso de edulcorantes sin azúcar

Por correo electrónico (NFS@WHO.int)

Estimado señor/a:

La Asociación de Bebidas y Refrescos Sin Alcohol del Perú (ABRESA) es el gremio de las empresas más importantes de la industria de bebidas sin alcohol del país y, en los últimos años y hasta la actualidad, seguimos aportado de forma importante a la economía peruana y al desarrollo de la nación desde diferentes ejes.

En línea con ese propósito, promovemos el desarrollo de todas y todos los peruanos generando puestos de empleo, aportando al PBI del país, desarrollando iniciativas sociales que ayuden a mejorar las problemáticas más complejas y, en general, a buscar el bienestar común. Bajo ese mismo objetivo, tenemos un compromiso genuino por seguir trabajando en favor de los miles de familias que dependen de esta actividad, que impacta directamente en la generación bienestar y desarrollo; consumo; dinamismo económico y, por ende, mayor recaudación. Por esta razón, vemos necesario presentar nuestros comentarios sobre el **borrador de las pautas de la OMS sobre el uso de edulcorantes sin azúcar**.

Es importante precisar que formamos parte de la industria de bebidas que promueve y apoya los esfuerzos de la OMS sobre dietas saludables, lo que se demuestra con la innovación y reformulación constante de nuestro portafolio de productos reducidos en azúcar, y para lograr ese objetivo se utilizan edulcorantes de bajos o sin calorías.

No obstante, la actual recomendación condicional por parte de la OMS, organismo que reconoce en su borrador de pautas que los estudios están fundamentados en “evidencia de baja certeza” respecto del consumo de edulcorantes, condiciona de manera riesgosa y debilita estrategias de salud, como la concerniente a la salud bucal y a la diabetes, solo por mencionar algunos ejemplos, pues los edulcorantes son herramientas importantes para poner en marcha estas prioridades. Existen diversas investigaciones y organizaciones, ajenas a la industria y expertas en la materia, que, con rigor científico y técnico, demuestran y avalan que los edulcorantes bajos en calorías y sin calorías pueden tener efectos positivos en la salud bucal, el control del peso y la diabetes cuando se les reemplaza por el azúcar. Asimismo, dichas entidades e investigaciones respaldan que las ingestas de azúcares agregados “podrían reducirse en gran medida al consumir

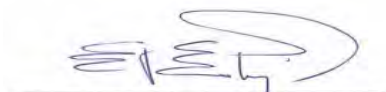
Lima, 12 de Agosto de 2022

versiones reformuladas endulzadas bajas en calorías y sin calorías de alimentos y bebidas. ^{1 2 3 4 5 6}

Nuestra posición responsable nos hace exponer estos riesgos, que pueden traducirse en legislaciones incoherentes de los países miembros que desorienten o direccionen de mala manera las políticas públicas sobre guías o pautas condicionales basada en evidencia de baja certeza.

Para finalizar, valoramos el trabajo de la OMS por brindar orientación a los responsables de formular políticas públicas. Sin embargo, consideramos que las pautas presentadas sobre el uso de edulcorantes sin azúcar deben ser reevaluadas bajo la información brindada para evitar legislaciones que perjudiquen la salud.

Atentamente,



María Luisa Málaga Silva
Directora Ejecutiva

¹ EFSA, Opinión científica sobre la justificación de afirmaciones de salud relacionadas con edulcorantes intensos. EFSA Journal 2011;9(6):2229. Disponible en línea: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2229/epdf>

² Regulación de la Comisión (UE) n.º 432/2012 del 16 de mayo de 2012 que establece una lista de reclamaciones de salud permitidas hechas sobre alimentos, que no sean aquellas que se refieren a la reducción del riesgo de enfermedad y al desarrollo y la salud de los niños

³ Diabetes UK. El uso de edulcorantes bajos en calorías o sin calorías. Declaración de posición (actualizada en diciembre de 2018). Disponible en: <https://www.diabetes.org.uk/professionals/position-statements-reports/food-nutrition-lifestyle/use-of-low-or-no-calorie-sweeteners>; Franz M. J. et al. "Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process". Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

⁴ Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, Mitri J, Pereira RF, Rawlings K, Robinson S, Saslow L, Uelmen A, Urbanski PB, Yancy Jr. WS. "Nutrition Therapy for Adults with Diabetes or Prediabetes: A Consensus Report". Diabetes Care. mayo de 2019;42(5):731-754;

⁵ Franz M. J. et al. "Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process". Journal of the Academy of Nutrition and Dietetics 2017;117(10):1659-79

⁶ 2020 U.S. Dietary Guidelines Advisory Committee Report (https://www.dietaryguidelines.gov/sites/default/files/2020-07/ScientificReport_of_the_2020DietaryGuidelinesAdvisoryCommittee_first-print.pdf). págs. 633, 636, 180, 691 del documento pdf de 835 páginas. Consultado el 21 de julio de 2022. (El Comité de Pautas Alimentarias de los EE. UU. declaró además: "Se ha recomendado que el agua común desplace otras bebidas que producen energía en la dieta para diluir la densidad de energía de la dieta, reducir la ingesta total de energía y ayudar a controlar el peso. El éxito de esta estrategia no se ha establecido y justifica un estudio adicional.")