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JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

One hundred and second meeting (Safety evaluation of certain food additives and contaminants)
9–18 June 2026

SUMMARY AND CONCLUSIONS

Issued on 7 July 2026

The one hundred and second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Nanjing from 9 to 18 June 2026. The meeting was made possible through the generous support of the Government of China, in particular the China National Center for Food Safety Risk Assessment and Nanjing Medical University. The tasks before the Committee were to (i) undertake safety evaluations of certain food additives; (ii) review and prepare specifications for certain food additives; (iii) review and prepare specifications for certain processing aids; and (iv) undertake safety evaluations of certain previous cargoes.

Dr D. Benford served as Chairperson and Dr R. Cantrill served as Vice-chairperson. Ms A. Vlachou and Mr K. Petersen served as joint secretaries for FAO and WHO, respectively.

The Committee evaluated the safety of seven food additives and one substance as a previous cargo, revised the specifications for three food additives, established specifications for one food additive and revised the specifications for lead for three processing aids.

The report of the meeting will be published as WHO Technical Report Series No. 1062. The report will summarize the main conclusions of the Committee in terms of acceptable daily intakes (ADIs) and other toxicological, dietary exposure and safety recommendations. Information on deliberations and conclusions with regards to the specifications for the identity and purity of certain food additives and processing aids examined by the Committee will also be included.

The participants are listed in Annex 1. Information of a general nature that the Committee wishes to disseminate quickly is provided in Annex 2. Recommendations arising from the report of the one hundred and second meeting are summarized in Annex 3. Finally, Annex 4 includes requests for corrections that were reported to the JECFA Secretariat, evaluated by the Committee and found to be necessary (note that these corrections will only be made in the electronic versions available in the online database).

Toxicological monographs summarizing the data that were considered by the Committee in establishing ADIs will be published as WHO Food Additives Series No. 93. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs No. 36.

More information on the work of JECFA is available at: <http://www.fao.org/food-safety/scientific-advice/jecfa/en/> and <https://www.who.int/foodsafety/en/>.

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Toxicological and dietary exposure information and conclusions

Food additives evaluated toxicologically, assessed for dietary exposure and/or specifications revised

Food additive	Specifications	ADIs and/or other conclusions on toxicology and dietary exposure
β -Carotenes and β -apo-8'-carotenal	No	<p>The estimates of dietary exposure to β-carotenes (INS No. 160a(i-iv)) based on typical use levels and food consumption data from individuals were higher at the upper end of the range of dietary exposures considered at the current meeting than those considered at the eighty-seventh meeting. In the absence of an ADI for β-carotenes, the toxicological relevance of this finding of the higher estimates of dietary exposure cannot be characterized.</p> <p>Dietary exposures to β-apo-8'-carotenal (INS No. 160e) reviewed at the current meeting were up to 0.45 mg/kg bw per day for high exposures for toddlers in the EU based on typical use levels, similar to those considered at the eighty-seventh meeting based on maximum use levels. The Committee noted that the ADI of 0.3 mg/kg bw established by the eighty-seventh Committee is exceeded by the high estimate of dietary exposure.</p>
Monk fruit extract	N, T ^a	<p>The Committee established a temporary ADI of 0–10 mg/kg bw per day, expressed as mogroside V, based on a NOAEL of 2144 mg/kg bw per day for mogroside V, the highest dose tested in a 52-week rat study and the application of a 200-fold uncertainty factor.</p> <p>The Committee considered that the conservative estimate of the highest dietary exposure to monk fruit extract (expressed as mogroside V) of 38 mg/kg bw per day for children was appropriate for the safety evaluation. However, it was noted that this estimate is based on proposed GSFA food categories and maximum levels.</p> <p>The Committee concluded that the current estimated dietary exposure to monk fruit extract (expressed as mogroside V) exceeds the temporary ADI by approximately four-fold, which would pose a potential safety concern under the proposed uses and proposed maximum levels.</p>
Neohesperidin dihydrochalcone (NHDC)	N, T	<p>The Committee established a temporary ADI (pending the submission of a reproductive toxicity study that assesses the reproductive capacity of the F1 generation) of 0–3.8 mg/kg bw per day for NHDC by applying a 200-fold uncertainty factor to the NOAEL of 760 mg/kg bw per day from a 90-day oral toxicity study in rats.</p> <p>The Committee considered the dietary exposure estimate of 1.8 mg/kg bw per day, the upper end of the range of high exposures in children, appropriate for the safety evaluation of NHDC.</p> <p>The dietary exposure for NHDC of 1.8 mg/kg bw per day is below the temporary ADI and does not represent a safety concern for the proposed uses and the proposed maximum levels.</p>
Phosphates ^b	No	<p>The Committee concluded that a group MTDI for phosphoric acid and phosphate salts, based on the end-point of nephrocalcinosis and nephropathy in rats, remained appropriate. The Committee considered the CSAF approach taken by EFSA to be appropriate to refine the uncertainty factor to be used for establishing an MTDI. Applying the CSAF of 4 for interspecies and intraspecies variation, together with an additional uncertainty factor of 3 for use of a LOAEL instead of a NOAEL (total factor of 12) to the LOAEL of 910 mg/kg bw per day, resulted in an MTDI value of 76 mg/kg bw per day. This assessment supports maintaining the current MTDI of 70 mg/kg bw per day.</p> <p>This value is also supported by the UL for adults for phosphorus intake established by NHMRC/MOH, Health Canada and NIH of 4000 mg/day, equal to 67 mg/kg bw per day based on a 60 kg body weight.</p> <p>The Committee also noted that the MTDI is consistent with DRVs for phosphorus intake by infants. At the lower end of the body weight range for infants aged 0–6 and 7–12 months, the DRV of 100 and 275 mg/day equates to 50 and 55 mg/kg bw per day, respectively, lower than the MTDI. The Committee therefore concluded that the MTDI of 70 mg/kg bw established by the previous Committee should be retained.</p> <p>Dietary exposure to phosphorus from phosphates for infants younger than 12 weeks ranged over 27–117 mg/kg bw per day. The Committee noted that phosphorus is an essential nutrient for infant development, and total phosphorus levels in infant formula, including from additive use, should be within the minimum and guidance upper levels (170 and 670 mg/L, respectively). Based on this consideration, the Committee concluded that the estimated dietary exposures for infants younger than 12 weeks are not a safety concern.</p>
Polysorbates	No ^a	<p>The Committee considered that the toxicological data reviewed support the previously identified NOAEL of 2500 mg/kg bw per day, the highest dose tested in two long-term toxicity studies in rats, used to establish the group ADI of 0–25 mg/kg bw for the polysorbates. The Committee therefore confirmed the group ADI of 0–25 mg/kg bw for the polyoxyethylene (20) sorbitan monoesters of lauric, oleic, palmitic and stearic acid and the triester of stearic acid.</p> <p>The highest estimate of dietary exposure was 24.5 mg/kg bw per day, for children aged 1–17 years in Europe. This estimate is within the upper bound of the group ADI. The Committee concluded that the use of polysorbates in accordance with the current uses and maximum levels in the GSFA does not pose a safety concern.</p>
Sorbitan esters	T ^a	<p>The previous Committee derived a group ADI of 0–25 mg/kg bw for the sum of sorbitan fatty acid esters (INS No. 491–495), based on the NOAEL of 2500 mg/kg bw per day and applying an uncertainty factor of 100. However, the genotoxicity studies available to the current Committee provided an indication of the clastogenic effects of sorbitan monostearate, requiring further investigation. In the absence of the additional data that were available to EFSA, the Committee was not able to conclude on the potential for genotoxicity and withdrew the group ADI of 0–25 mg/kg bw, establishing a temporary group ADI of 0–25 mg/kg bw.</p> <p>The highest dietary exposure estimate of 24 mg/kg bw per day for the sum of sorbitan esters of fatty acids using reported use levels is below the temporary group ADI of 0–25 mg/kg bw. However, use levels</p>

Steviol glycosides	N	<p>for the sum of the five individual sorbitan esters of fatty acids were not considered for important food categories such as water-based flavoured drinks (carbonated, non-carbonated and concentrates), soybean-based beverages, dry and precooked pasta, or eggs and egg-based desserts because they were not available to the Committee. The Committee therefore concluded that the highest exposure estimates, which are based on data from the EU, could be underestimated relative to exposure based on GSFA permissions.</p> <p>No new information was identified in the literature that would indicate a need to revise the current ADI for steviol glycosides. The current ADI of 0–4 mg/kg bw, expressed as steviol, was confirmed. The Committee concluded that the evaluated enzymes and protein present in the production strains are unlikely to be toxins and have not been detected in the purified rebaudioside M preparations produced by two separate methods.</p> <p>In the absence of dietary exposure to proteins from the rebaudioside M production organisms for either production method, the purified rebaudioside M preparations are not anticipated to pose a risk for allergenicity.</p> <p>The dietary exposure to steviol glycosides of up to 4.8 mg/kg bw per day (expressed as steviol equivalents) for children from the EU who were high consumers exceeded the upper bound of the ADI, but the ADI was not exceeded for other age groups. Considering the conservative nature of the dietary exposure estimate, based on maximum permitted levels applied to all food consumed from categories with permissions for use in the EU, the Committee concluded that the estimated dietary exposures are not likely to present a health concern for any age group.</p>
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ADI: acceptable daily intake; bw: body weight; CSAF: chemical-specific adjustment factor; DRV: dietary reference value; EFSA: European Food Safety Authority; EU: European Union; GSFA: Codex General Standard for Food Additives; INS: International Numbering System for Food Additives; LOAEL: lowest-observed-adverse-effect limit; MTDI: maximum tolerable daily intake; N: new specifications; NHDC: neohesperidin dihydrochalcone; NOAEL: no-observed-adverse-effect limit; R: revised specifications; T: tentative specifications; UL: tolerable upper intake level.

^a Information is required to complete the specifications.

^b Sodium dihydrogen phosphate (INS No. 339(i)), disodium hydrogen phosphate (INS No. 339(ii)), trisodium phosphate (INS No. 339(iii)), potassium dihydrogen phosphate (INS No. 340(i)), dipotassium hydrogen phosphate (INS No. 340(ii)) and tripotassium phosphate (INS No. 340(iii)).

Food additives and processing aids considered for specifications only

Food additive or processing aid	Specifications	Details
Glycolipids	R, N	Based on additional data submitted by the sponsor, the specifications for Pb, As, cadmium and mercury were revised, and a new specification for nickel was added.
Lead levels in activated carbon (activated charcoal), bentonite and diatomaceous earth	R	The Committee revised the specifications monograph of activated carbon and lowered the specification limit for Pb from 5 to 3 mg/kg; revised the specifications monograph of diatomaceous earth and lowered the specification limit for Pb from 10 to 2.5 mg/kg; and proposed that the level of Pb in bentonite used as a processing aid does not exceed 10 mg/kg.
Potassium hydrogen sulfite (aqueous)	N	A new specifications monograph for potassium hydrogen sulfite (aqueous) was prepared.
Thaumatococcus	R	The Committee reconsidered the specifications to address the calculation for the concentration of thaumatococcus and the placement and identification of the representative chromatograms. The specifications monograph for thaumatococcus was revised accordingly.
Tricalcium phosphate	R	The Committee received data allowing new limits for Pb and As specifically for use in infant formula and FSMPs for infants to be introduced into the specifications.

As: arsenic; FSMP: formula for special medical purposes; INS: International Numbering System for Food Additives; N: new specifications; Pb: lead; R: revised specifications.

Previous cargo evaluated toxicologically and assessed for dietary exposure

Previous cargo	Conclusions on toxicology and dietary exposure
Calcium lignosulfonate (CLS) liquid	The Committee considered the NOAEL of 2000 mg/kg bw per day, the highest dose tested, from a 90-day oral toxicity study of CLS (40-65) to be a suitable point of departure for the estimation of an MOE for dietary exposure to the non-food-grade CLS. The Committee used the generic worst-case estimate of dietary exposure of 0.3 mg/kg bw per day that was calculated at its ninetieth meeting, yielding an MOE of more than 6000. There are no data on allergenicity upon oral exposure to CLS that indicate that it is, or contains, a known food allergen. It is also not expected to react with edible fats and oils to form any reaction products. The Committee concluded that CLS liquid meets the criteria for acceptability as a previous cargo for edible fats and oils.

CLS: calcium lignosulfonate; MOE: margin of exposure; NOAEL: no-observed-adverse-effect limit.

Annex 1. List of participants

Members

- Dr S. Barlow, Brighton, East Sussex, United Kingdom of Great Britain and Northern Ireland (*invited by WHO*)
- Dr D. Benford, Cheddington, Buckinghamshire, United Kingdom (*Chairperson*) (*invited by WHO*)
- Dr R. Cantrill, Bedford, Nova Scotia, Canada (*Vice-Chairperson*) (*invited by FAO*)
- Mr P. Cressey, New Zealand Institute for Public Health and Forensic Science, Christchurch, New Zealand (*invited by FAO*)
- Dr E. Dessipri, General Chemical State Laboratory, Athens, Greece (*invited by FAO*)
- Dr N. Fletcher, Food Standards Australia New Zealand, Kingston, Australia (*invited by WHO*)
- Dr M.J. Frutos-Fernández, Agro-Food Technology Department, Miguel Hernández University, Orihuela, Spain (*invited by FAO*)
- Dr S.M.F. Jeurissen, Department for Chemical Food Safety, Centre for Prevention, Lifestyle and Health, National Institute for Public Health and the Environment, Bilthoven, the Kingdom of the Netherlands (*invited by WHO*)
- Dr J.-C. Leblanc, Laboratory for Food Safety, French Agency for Food, Environmental and Occupational Health and Safety, Maisons-Alfort, France (*invited by WHO*)
- Dr U. Mueller, Perth, Western Australia, Australia (*Joint Rapporteur*) (*invited by WHO*)
- Dr J.R. Srinivasan, Division of Cosmetics, Office of Cosmetics and Colors, United States Food and Drug Administration, College Park (MD), USA (*invited by FAO*)

Additional experts invited by FAO and WHO

- Dr P.E. Boon, Department for Chemical Food Safety, Centre for Prevention, Lifestyle and Health, National Institute for Public Health and the Environment, Bilthoven, the Kingdom of the Netherlands (*invited by WHO*)
- Dr R.P. Brinas, Division of Food Contact Substances, Office of Pre-Market Additive Safety, Human Foods Program, United States Food and Drug Administration, College Park (MD), USA (*invited by FAO*)
- Dr S. Creton, Food Standards Australia New Zealand, Wellington, New Zealand (*invited by WHO*)
- Dr R. Dalefield, Food Standards Australia New Zealand, Wellington, New Zealand (*invited by WHO*)
- Dr A. Edwards, Division of Food Ingredients, Office of Pre-market Additives Safety, Human Foods Program, United States Food and Drug Administration, College Park (MD), USA (*invited by FAO*)
- Dr D.E. Folmer, Division of Additives and Ingredients, Office of Post-market Assessment, Human Foods Program, United States Food and Drug Administration, College Park (MD), USA (*Joint Rapporteur*) (*invited by FAO*)
- Ms T. Hambridge, Food Standards Australia New Zealand, Kingston, Australia (*invited by WHO*)
- Dr S.V. Kabadi, Division of Food Contact Substances, Office of Pre-market Additives Safety, Human Foods Program,, United States Food and Drug Administration, College Park (MD), USA (*invited by WHO*)
- Dr G. Kass, University of Galway, Galway, Ireland (*invited by WHO*)
- Dr D. Rawn, Food Research Division, Health Canada, Ottawa, Canada (*invited by FAO*)
- Dr C.A. Smith, Food Contaminant Toxicology Assessment Section, Bureau of Chemical Safety, Health Products & Food Branch, Health Canada, Canada (*invited by WHO*)
- Dr A. Tada, Division of Food Additives, National Institute of Health Science, Japan (*invited by FAO*)
- Dr Y. Xiao, Faculty of Medicine, Macau University of Science and Technology, Macao, Special Administrative Region (China) (*invited by FAO*)

Dr H.-J. Yoon, Department of Food Safety and Regulatory Science, Chung-Ang University, Republic of Korea
(*invited by FAO*)

Secretariat

Dr Y.X. Fan, Codex Committee on Food Additives, Beijing, China (*invited by FAO and WHO*)

Ms N.Y. Ho, Department of Nutrition and Food Safety, World Health Organization, Geneva, Switzerland
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Annex 2. General considerations

A2.1 Screening methods for dietary exposure assessment within the JECFA safety evaluation of food additives

Dietary exposure assessment is an essential component of the four-step risk assessment process considered by scientific bodies such as JECFA, within the risk analysis framework established by the Codex Alimentarius Commission (1).

During the initial integration of dietary exposure assessment into the JECFA safety evaluation of food additives, particularly during the 1990s and early 2000s, screening methods, such as the budget method and the sugar substitution model, were regularly used (2). In many cases, these screening methods, which only require modest resources, were used within a tiered approach as a first step to distinguish substances unlikely to raise safety concerns from those requiring more refined assessments. Such screening methods have historically formed part of the dietary exposure information expected from sponsors when submitting a dossier for the safety evaluation of food additives by JECFA.

Since that time, the principles and methods used to estimate dietary exposure to food additives have evolved considerably to more refined dietary exposure models that rely on more specific food consumption and concentration data, and improved mapping of these two datasets. The increased use of refined dietary exposure estimates in JECFA safety evaluations has helped to reduce the uncertainty and conservativeness of the safety evaluation of food additives.

An important contribution to the calculation of refined dietary exposure estimates is the availability of the food consumption data from the FAO/WHO Chronic individual food consumption database – summary statistics (CIFOCOs). CIFOCOs is a database hosted by WHO that contains summary statistics based on food consumption data from individuals acquired from national dietary surveys covering all WHO regions (87 surveys covering all age classes from 46 countries to date, see annex 4 in the full report). It was developed to collate available data on food consumption from different countries in a harmonized format using the FoodEx2 classification system (3) for use by FAO and WHO scientific committees to assess chronic dietary exposure. The Codex Committee on Food Additives (CCFA) has mapped FoodEx2 codes to Codex General Standard for Food Additives (GSFA) food categories to enable concentrations of food additives to be combined with food consumption data for the purpose of dietary exposure assessment, and has published this as an Excel (Microsoft, Redmond, USA) file linked to the agenda item 12 paper of its fifty-sixth session (4).

Because refined dietary exposure estimates are frequently available from the literature, or can be derived using CIFOCOs in combination with GSFA permissions and/or reported use levels submitted by sponsors, the Committee considers that conservative dietary exposure estimates using screening methods should no longer be used in JECFA safety evaluations of food additives.

The Committee recommends that CCFA continues to encourage Member States, food industry and sponsors to collect and provide data on use levels for food additives under evaluation. Such data are essential to support JECFA in evaluating refined and reliable worldwide dietary exposure estimates in its safety evaluation of food additives.

A2.2 Data submission for consideration of the acceptability of previous cargoes

At its ninetieth (5), ninety-first (6) and current meeting, the Committee considered the safety of substances present as previous cargoes in the shipment of edible fats and oils following a request for scientific advice by the Codex Committee for Fats and Oils (7). The assessments were conducted against the following criteria for previous cargoes adopted by CCFO at its twenty-second session (8) and revised at the ninetieth meeting of the Committee (5).

- (i) The substance is transported/stored in an appropriately designed system with adequate cleaning routines, including the verification of the efficacy of cleaning between cargoes, followed by effective inspection and recording procedures.
- (ii) Based on the consumption of fats and oils by infants and young children, there is no health concern for the general population from dietary exposure to previous cargo chemical substances if the ADI or TDI is sufficiently protective, for example, the ADI or TDI is greater than or equal to 0.3 mg/kg bw per

day. Substances for which there is no numerical ADI or TDI should be evaluated on a case-by-case basis (e.g. margin of exposure [MOE] approach). Where there are additional sources of dietary exposure to the previous cargo chemical substances, they should be considered in the exposure assessment.

- (iii) The substance should not be or contain a known food allergen, unless the identified food allergen can be adequately removed by subsequent processing of the fat or oil for its intended use.
- (iv) Most substances do not react with edible fats and oils under normal shipping and storage conditions. However, if the substance does react with edible fats and oils, any known reaction products must comply with criteria (ii) and (iii).

Twenty-three substances for consideration at these Committee meetings had not previously been reviewed as either food additives or flavouring agents. Three evaluations could not be completed as a result of deficiencies in the data submitted. In order to avoid incomplete evaluations in the future, the present Committee has provided a list of information (Table A2.1) that should be made available for any future review.

Table A2.1
Information required to be included in data for a JECFA previous cargo assessment

Information	Relevant notes
Chemical information	
1. Name	Chemical name and common name
2. CAS No.	–
3. Chemical details; appearance; structure; molar mass; melting point; solubility	Provide appropriate information
4. Route(s) of synthesis	Detail main synthetic processes with details of feedstocks, catalysts and intermediates
5. Composition	Give details of composition including residues, intermediates, impurities and breakdown products present in grades of substance transported
6. Uses	Outline major uses of the substance
7. Analytical methods	Provide brief details and references for relevant methods of analysis; give values for LOD and LOQ
8. Potential reaction(s) with a subsequent cargo of fats or oils	Give details of possible reactions with fats and oils
Biochemical and toxicological studies on the substance	
1. Biochemical aspects	Any information on absorption, distribution, metabolism and excretion
2. Acute oral toxicity	Any information on oral LD ₅₀ values in rodent species
3. Short-term oral toxicity	Reports from any experimental animal studies using repeated dosing (e.g. 28- or 90-day rodent studies)
4. Long-term oral toxicity	Reports from any experimental animal studies using repeated dosing (e.g. 1- or 2-year rodent studies)
5. Reproductive and developmental toxicity	Reports from any experimental animal studies addressing reproduction and/or embryo-fetal development
6. Genotoxicity studies	Reports from any in vitro or in vivo studies addressing the end-points of gene mutation, structural chromosome aberrations and numerical chromosome aberrations (aneuploidy) (e.g. bacterial reverse mutation assay, in vitro mammalian cell micronucleus test)
Allergenicity considerations	
1. Allergenicity of the substance itself	Any human reports of allergenicity upon oral exposure
2. Known food allergens	Any information on whether the substance contains any known food allergens
Exposure assessment	
Human dietary exposure estimates	From sources other than previous cargoes (e.g. from contamination of drinking water or from food additive use)

CAS: Chemical Abstracts Service; LD₅₀: lethal dose; LOD: limit of detection; LOQ: limit of quantification.

A2.3 Lead and arsenic levels in phosphate additives used in infant formula and in FSMPs for infants

The Committee considered six phosphates (sodium dihydrogen phosphate (INS No. 339(i)), disodium hydrogen phosphate (INS No. 339(ii)), trisodium phosphate (INS No. 339(iii)), potassium dihydrogen phosphate (INS No. 340(i)), dipotassium hydrogen phosphate (INS No. 340(ii)) and tripotassium phosphate (INS No. 340(iii))) for their use as acidity regulators in infant formula and formula for special medical purposes (FSMPs) for infants.

The Committee noted that the specifications limits for lead (Pb) and arsenic (As) were revised at the fifty-ninth meeting (9) to 4 and 3 mg/kg, respectively, for all the phosphates under consideration. Limited data were provided at the present meeting to support lowering the limits for Pb and As.

The Committee noted that the Codex Committee on Contaminants in Foods at its eighth session (10) set a maximum level of 0.01 mg/kg for Pb in infant formula (as consumed). The Committee also noted that the use of some of the hydrated forms of the phosphate additives under consideration, at the current GSFA maximum level of 450 mg/L, expressed as phosphorus, in infant formula and FSMPs for infants could result in an exceedance (up to 0.022 mg/L as consumed) of the maximum level for Pb in infant formula, if Pb were present at the specified limit of 4 mg/kg. This was calculated without considering the contribution of other ingredients to the overall Pb level in infant formula. The Committee noted that lower Pb limits in the specifications (e.g. 0.5 mg/kg) were supported by limited data provided by the infant formula manufacturers for dipotassium hydrogen phosphate (INS No. 340(ii)).

The Committee reaffirmed that the responsibility for ensuring that the final infant formula (as consumed) comply with the maximum level for Pb remains with infant formula producers.

Furthermore, the Committee has previously noted that infants and children are the subgroups that are the most sensitive to Pb and that a dietary exposure level of 1.9 µg/kg bw per day is associated with a population decrease of 3 IQ points (11). The current Committee noted that this exposure is equalled or exceeded by the estimated range of dietary exposures from infant formula (2.1–5.7 µg/kg bw per day, depending on the phosphate) if Pb were present at the specified limit (i.e. 4 mg/kg) and based on high daily consumption value of 260 mL of infant formula/kg bw, supporting a need for measures to reduce exposure.

In addition, Jakobsen et al. (12) reported an update of the WHO Global Burden of Disease Study. Inorganic arsenic (iAs) and Pb were identified as the major foodborne chemical causes of deaths and loss of healthy life-years. The Committee considered that this finding supports the need for an “as low as reasonably achievable” approach for these contaminants.

At its one hundred and first meeting, the Committee highlighted that mean dietary exposures to iAs in many areas exceed the point of departure (POD) (0.3 µg/kg bw per day) associated with a 0.5% increase in incidence of ischaemic heart disease above background levels, and recommended that national and regional authorities should consider appropriate risk management action (13). The Committee at the present meeting noted that the use of the six phosphate additives under consideration at the current GSFA maximum level of 450 mg/L, expressed as phosphorus, in infant formula and FSMPs for infants, will result in dietary exposure to iAs (1.5–4.3 µg/kg bw per day, depending on the phosphate) exceeding the POD for iAs (0.3 µg/kg bw per day), if As were present at the specified limit (i.e. 3 mg/kg) and based on a high daily consumption value of 260 mL of infant formula/kg bw. This was calculated without considering the contribution of other ingredients to the overall As level in infant formula. CCCF has not set a maximum level for As in infant formula. The Committee noted that lower As limits in the specifications (e.g. 1 mg/kg) were supported by limited data provided from the infant formula manufacturers for dipotassium hydrogen phosphate (INS No. 340(ii)).

The specifications for the phosphates for use in infant formulae that were considered for safety review at this meeting are also used in the manufacture of other foods. The Committee therefore agreed that it would be necessary to confirm with manufacturers whether lower Pb and As limits would be achievable for the intended use of these food additives in products other than infant formula.

The Committee reiterated that food additive manufacturers should comply with Good Manufacturing Practice with an emphasis on further minimizing Pb and As impurities. The Committee further recommended that data are submitted to the Committee so that specifications reflect currently achievable levels of Pb and As. Furthermore, the Committee recommended that food manufacturers consider levels of Pb and As impurities in their selection of ingredients for use in formula and FSMPs for infants.

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Annex 3. Recommendations

Table A3.1

Information required by the Committee to complete the safety evaluation and/or revise the specifications

Food additive	Recommendations
β-Carotenes and β-apo-8'-carotenal	The Committee reiterated its recommendation from the eighty-seventh meeting that the provisions for β-carotenes and β-apo-8'-carotenal in the GSFA be reviewed. The review should focus on the foods that contribute the most to dietary exposure, particularly water-based flavoured drinks and fine bakery wares.
Monk fruit extract	<p>The following information on monk fruit extract is required by the end of 2029 to complete the safety evaluation: a study on reproductive toxicity that evaluates the reproductive capacity of the F1 generation; and revised proposed uses in GSFA and maximum levels to refine the assessment of dietary exposure.</p> <p>Further information is required to remove the tentative status of the specifications. For monk fruit extract (45–55% mogroside V content), the following information is required: detailed information on the manufacturing process for monk fruit extract; detailed characterization of protein content from five batches of the commercial product and an explanation for the presence of relatively high reported protein levels, despite multiple purification steps; a suitable validated analytical method for the determination of proteins in monk fruit extract, including justification of nitrogen conversion factor applied; microbiological purity criteria applicable to monk fruit extract; identification of the chemical components referred to as “other saponins” in the monk fruit extract; a validated analytical method for quantifying the “other saponins”; and a comprehensive compositional profile that accounts for 100% of the monk fruit extract, including data from five batches of the commercial product. For monk fruit extract (mogroside V > 20%), the following information is required: detailed compositional information accounting for the remaining components (~ 80%) of this monk fruit extract, beyond the mogroside V content; detailed description of the manufacturing process for the monk fruit extract with mogroside V content of more than 20%; and confirmation of whether dried monk fruits are used for the manufacturing of monk fruit extract.</p>
Neohesperidin dihydrochalcone (NHDC)	A study on reproductive toxicity that evaluates the reproductive capacity of the F1 generation is required by the end of 2029 to complete the safety evaluation.
Polysorbates	In order to revise the specifications, the Committee requests the following information: a detailed description of the current manufacturing process for the five polysorbates; composition of all starting materials; validated methods for the determination of potential processing impurities, namely ethylene oxide, ethylene glycols (mono- and di-) and 1,4-dioxane and associated validation data; quantitative data from at least five non-consecutive batches of each of the five articles of commerce showing the levels of the potential processing impurities, namely ethylene oxide, ethylene glycols (mono- and di-) and 1,4-dioxane; and levels of toxic element impurities (arsenic, lead, mercury and cadmium) for a minimum of five non-consecutive batches of the five articles of commerce, obtained using validated analytical methods.
Sorbitan esters	<p>The following information is required by the end of 2027 to complete the safety assessment for the sorbitan fatty acid esters: studies on the genotoxicity (mutagenicity and micronuclei and/or chromosomal aberrations) of sorbitan fatty acid esters; and uses and use levels for the five sorbitan esters of fatty acids for food categories in the GSFA, to allow for a refined dietary exposure using the CIFOCS database.</p> <p>In order to remove the tentative status of the specifications, the following information is required by the end of 2027: detailed description of the current manufacturing process; composition of the starting materials (e.g. fatty acid component specifications, minimum and maximum contents); composition of the process intermediates (i.e. sorbitol, 1,4-sorbitan, 1,5-sorbitan, 2,5-sorbitan, isosorbide and other reaction intermediates); sulfated ash values from five non-consecutive batches of the article of commerce; iodine values and fatty acid composition data by gas chromatography from five non-consecutive batches of the article of commerce; levels of metallic impurities (lead, arsenic, mercury and cadmium) from five non-consecutive batches of the article of commerce; and an example of a representative IR spectrum.</p>

CIFOCSs: FAO/WHO chronic individual food consumption database – summary statistics; GSFA: General Standard for food Additives; IR: infrared.

Annex 4. Errata

Table A4.1

Requests for corrections reported to the JECFA Secretariat that were evaluated by the Committee and found to be necessary (corrections will be made only in the online database for specifications)

Substance	Original text	Revised text	Additional information
Gardenia (Genipin) blue	Genipin: not more than 5 mg/kg at a colour value of 300; see description under PURITY TESTS	Genipin (unreacted): not more than 5 mg/kg at a colour value of 300; see description under PURITY TESTS	
Green S	CAS No. 860-22-0	CAS No. 3087-16-9	
Ponceau 4R	<p><u>Calculation</u> Calculate the percentage of subsidiary colouring matters from:</p> $\text{Subsidiary colouring matters (\%)} = \left(\frac{A_{\text{total}} - A_{\text{main}}}{A_{\text{total}}} \right) \times D \times 100$ <p>where D is the total colouring matters content of sample (%); A_{total} is the sum of the area of all the peaks in the chromatogram between 2 and 40 min; and A_{main} is the area of main peak.</p>	D is the total colouring matters content of sample	D should be expressed as a decimal and not a percentage
Sodium copper chlorophyllin	According to the procedure, approximately 1 g of the sample is dissolved in 20 mL of phosphate buffer solution (pH 7.5) and diluted to 1000 mL with distilled water. Then, 10 mL of this solution is further diluted to 100 mL with phosphate buffer, and the absorbance is measured in a spectrophotometer (0.001% w/v expected final concentration).	According to the procedure, approximately 1 g of the sample is dissolved in 20 mL of phosphate buffer solution (pH 7.5) and diluted to 1000 mL with distilled water. Then, 1.0 mL of this solution is further diluted to 100 mL with phosphate buffer, and the absorbance is measured in a spectrophotometer (0.001% w/v expected final concentration).	Typographical error
Sodium saccharin	CAS No. 128-44-9	CAS No. 6155-57-3 (dihydrate), (128-44-9 (anhydrous)	

CAS: Chemical Abstracts Service.