WHO Discussion Paper (version dated 11September 2017)

<u>Safeguarding against possible conflicts of interest in nutrition</u> programmes:

Draft approach for the prevention and management of conflicts of interest in the policy development and implementation of nutrition programmes at country level

BACKG ROUND

- 1. The Comprehensive implementation plan on maternal, infant and young child nutrition, endorsed at the Sixty-fifth World Health Assembly (WHA) in 20121, recommends the creation of "a supportive environment for the implementation of comprehensive food and nutrition policies" and calls on Member States to "establish a dialogue with relevant national and international parties and form alliances and partnerships to expand nutrition actions with the establishment of adequate mechanisms to safeguard against potential conflicts of interest".
- 2 Resolution WHA65.62 requested the Director-General to "develop risk assessment, disclosure and management tools to safeguard against possible conflicts of interest in policy development and implementation of nutrition programmes consistent with WHO's overall policy and practice".
- **3** Furthermore, decision WHA67(9) requested the Director-General to "convene informal consultations with Member States to complete the work, before the end of 2015, on risk assessment and management tools for conflicts of interest in nutrition, for consideration by Member States at the Sixty-ninth World Health Assembly".
- A In response to this request, the Secretariat convened a technical consultation on "Addressing and managing conflicts of interest in the planning and delivery of nutrition programmes at country level" in Geneva between 8 and 9 October 2015. The technical consultation brought together experts from different fields such as nutrition, health systems, NCDs, legal, economic and social sciences. In addition, a diversity of stakeholders, including public officials from the six World Health Organization (WHO) regions, experts from non-governmental organizations (NGOs) and from multi-stakeholder initiatives, academic researchers, lawyers and experts from other United Nations (UN) agencies working on the area of "Partnerships," participated. Member States were invited as observers to overview the process.

_

Resolution WHA65.61

- 5 Following up on the outcomes of the technical consultation, the Secretariat developed a draft "Approach on the prevention and management of conflicts of interest in the policy development and implementation of nutrition programmes at country level". The approach proposes a methodology that Member States may consider following in their engagement with non-State individuals and institutions ("external actors") for the prevention and management of conflicts of interest in the area of nutrition. The approach targets government's officials involved in the development, design, and implementation of public health nutrition policies and programmes.
- To develop the proposed approach, WHO has considered different procedures and practices on prevention and management of conflicts of interest including those adopted by UN agencies, governmental bodies, NGOs, and health professional organizations. WHO has also reviewed the scientific literature on conflicts of interest in policy development for NCDs; categories of conflicts of interest, non-state institutions and individuals, purpose and forms of engagement; comparison of corporate tactics between the tobacco and food and beverage industries.
- **7.** The proposed approach is developed consistent and in line with WHO's overall policies and practices including, inter alia, the WHO Framework of Engagement with non- State Actors (FENSA)³. The approach also acknowledges the differences and specificities in addressing conflict of interest in the area of nutrition at country level.
- 8 This discussion paper includes: (a) a summary of general principles that have been considered in the development of the tool and presented in the introductory paper 4 ; (b) a summary of the main steps included in the tool 5 .

GENERAL PRINCIPLES OF THE APPROACH

- A conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of Member States' work in the area of nutrition) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (related to Member States' work). The existence of conflict of interest in all its forms does not as such mean that improper action has occurred, but rather the risk of such improper action occurring. Conflict of interest is not only financial, but can take other forms as well.
- 10. **Institutional conflicts of interest** is a situation where the Member State's primary interest, as reflected in its institutional mandate to protect and promote public health, may be unduly influenced by the conflicting interest of a non-State institution in a way that

Note that the WHO Framework of engagement for non-State actors (FENSA) refers to "actors" for "institutions". Since individuals are also addressed in this document, the term "institutions" is explicitly used forclarity purposes.

Comment [AF1]: Request WHO to add in a new section providing advice or guidance to Member States in the development and implementation of industry led or so-called "self regulatory" regimes, as are sometimes used instead of legislative approaches.

http://www.who.int/about/collaborations/non-state-actors/ en/

 $^{^4}$ An expanded version of the review of literature and practices is provided in URLl- "Introductory paper"

⁵ The draft to ol is available in ... URL2- "Tool"

affects, or may reasonably be perceived to affect, the independence and objectivity of Member States's work.

- 11. Individual conflicts of interest can involve public officials or non-State individuals. Individual people engaged to work on the development of nutrition policies, or on the implementation of nutrition programmes may be conflicted if a private interest (financial, personal, or other non-government interest or commitment) interferes-or appears to interfere-with their ability to act impartially, to discharge their functions and to regulate their conduct with the interests of public health nutrition only in view. A conflict of interest does not necessarily mean that the individual involved is actually conflicted: tThe perception of a conflict of interest alone may also create a negative image.
- 12 Conflicts of interest can arise when interacting with external actors of two distinct natures: "non-State institutions"; and "non-State individuals" who may provide advice, expertise, or be otherwise associated with the development of policies or the implementation of nutrition programmes.
 - (a) **Non-State institutions** are: 1) nongovernmental organizations (NGOs); 2) private sector entities; 3) philanthropic foundations; 4) academic institutions.
 - (b) **Non-State individuals** are considered to be either individuals representing the interests of any of the above-mentioned institutions or individuals acting in their individual capacity.
- 13 An entity is considered "at arm's length" from another entity if it is independent from the other entity, does not take instructions and is clearly not influenced or clearly not reasonably perceived to be influenced in its decisions and work by the other entity. Although the term "at arm's length" does not cover individuals, for the purpose of this document, the same concept is applied to them.
- **14 Engagement** refers to any formalized interaction with the non-State individual or institution, ranging from a donation to a partnership.
- **15 Contributions** refer to the resources (financial or in-kind) that the external actor may provide for the engagement, such as delivery of goods and services, technical expertise.
- **16 Purpose of engagement** refers to the impact -of the activity performed by the non-State individual or institution will have at different phases of the policy cycle (policy development, implementation or monitoring).
- 17. Forms of engagement are means or channels to shape the purpose of engagement. The same purpose of engagement can be established through different forms, described as follows:

 1) charitable (such as donations);

 2) transactional (such as sponsorships); and

 3) transformational (such as multi-stakeholder platforms).
- 18 By applying the following overarching principles of engagement, Member States' engagement with non-State institutions and individuals may be successful if it:

- conforms with the Member State's agenda and demonstrate a clear benefit to public health and nutrition;
- 2 respects the Member State's decision-making authority and leadership over the engagement in all settings;
- **3** does not compromise the Member State's integrity, independence, and reputation;
- **4** is aligned and coherent with other Member State's policies and objectives such as those related to NCDs and the Sustainable Development Goals (SDGs);
- 5 conforms with internationally recognized human rights standards international obligations the Member State are is a State Party to;
- **6** is conducted on the basis of evidence as well as transparency, independent monitoring and accountability.
- 19. An effective prevention and management of conflicts of interest in the area of nutrition would call for Member States to adopt clear policies and procedures, as appropriate. Member States may, at their discretion, should ideally have an internal conflicts of interest management system in place for public officials.

MAIN STEPS INCLUDED IN THE TOOL

20 The tool is a step-by-step decision-making process that will assist Member States in the process related to conflict of interest in the area of nutrition. The process consists of six steps, each followed by an assessment by the national authority of whether the engagement should continue or stop.

STEP 1: Rationale for engagement

Objective:

Clarify the public health nutrition issue or goal

21. The purpose of an engagement in the area of nutrition should support implementation of the Member State's policies and recommendations, as well as the application of the technical norms and standards. In this first step, clarification of the public health nutrition goal is key before interacting with the external actor.

STEP 2: Profiling and performing due diligence and risk assessment Objective:

Have a clear understanding the risk's profile of the external actor and the engagement

Due diligence refers to the actions taken by the national authority to gather and verify relevant information on an external actor and to reach a clear understanding of its profile. It combines, for instance, a review of the information provided by the external actor and an in-depth search and analysis of information about the non-State institution or individual concerned. A conflict of interest risk assessment of the external actor and of the proposed engagement is conducted in addition to the due diligence. The outcome of the risk assess ment can lead to three different paths: i) if risks of engagement are too high, the national authority should consider avoiding the engagement; ii) if risks of engagement are mixed, the national authority should balance risks against benefits (step three); iii) if the risks of engagement are low, the national authority may go directly to step four, risk management of the conflicts of interest identified.

Comment [JR(2]: There may not always be a goal as such but the engagement could be over emerging nutrition issues as well.

WHO Discussion Paper - Not to be cited or disseminated

The risk assessment should also consider the risks associated with not engaging.

STEP 3: Balancing risks and benefits

Objective:

Analyze the risks and benefits of the proposed engagement based on impacts

In principle, the identification of the conflict of interest with its related risks may be balanced against the expected benefits. The national authority may consider the impact of the engagement on the Member States' reputation, integrity and independence ("ethical impacts"), but also on the nutrition interventions and on policy coherence with other government policies and objectives ("technical impacts"). If benefits are equal or less than the risks, the relevant national authority may not proceed with engagement, as it may not be worth the effort for the Member States. On the other hand, if the benefits outweigh the risks, the national authority may proceed with engagement and go to step four.

STEP 4: Risk management

Objective:

Manage the risks based on mitigation measures and develop a formal engagement agreement

24. Risk management relates to the process leading to a management decision whereby the national authority decides explicitly and justifiably to enter into engagement, continue engagement, engage with measures to mitigate conflict of interest related risks, or disengage from an existing engagement. A risk-management approach to an engagement may be considered when the benefits interms of direct or indirect contributions to public health nutrition and the fulfilment of the Member State's mandate, outweigh any residual conflict of interest related risk, as well as the time and expense involved in establishing and maintaining the engagement.

STEP 5: Monitoring and evaluation and accountability

Objective:

Ensure that the engagement has $\underline{\text{contributed to or}}$ achieved the public health nutrition $\underline{\text{goal}}$ and decide to

25. Step five is aimed at ensuring that the engagement has achieved <u>its purpose and contributed</u> to or <u>helped</u> inform

the nutrition and public health <u>issues or goals</u>. This should be done through a systematic process of evaluation that includes assessment of the engagement, communication of the relevant results to all participants, enforcement <u>if appropriate</u>, and a system that enables the Member State to respond to observed weaknesses. In this regard, step five is closely related to step four, because if the outcome of monitoring and evaluation suggests that there are weaknesses in the mitigation measures, the national authorities may reconsider their approach related to risk assessment and mitigation as well as whether to continue the engagement or disengage.

STEP 6: Transparency and communication

Objective:

Communicate the engagement activities and outcomes to relevant audiences

WHO Discussion Paper - Not to be cited or disseminated
The Member States should communicate to the relevant audience the information 26 about engagement and related conflict of interest in an open, transparent and timely manner.

NEXT STEPS

- **27.** Member States are invited to provide comments on this discussion paper and on the accompanying draft introductory paper and tool.
- **28** In particular, Member States are invited to comment on whether the approach presented in this discussion paper, including the general principles as well as the main steps included in the tool, meet their expectations and are sufficiently clear and of practical value to assess, disclose and manage and safeguard against possible conflicts of interest in the policy development and implementation of nutrition programmes.
- 29. Member States may provide feedback in response to this discussion paper during the web-based consultation (details on website).
- 30 Following this consultation, the Secretariat will finalize the report containing the "Approach for the prevention and management of conflicts of interest in the policy development and implementation of nutrition programmes at country level" (similar in scope and purpose to this discussion paper) to be presented to the Executive Board at its 142nd session in January 2018. The Secretariat will also update the introductory paper and the tool and invite the Executive Board to note the approach and the tool.

DISCLAIMER

All rights reserved.

This WHO Discussion Paper does not represent an official position of the World Health Organization. It is a tool to explore the views of interested parties on the subject matter. References to international partners are suggestions only and do not constitute or imply any endorsement whatsoever of this discussion paper.

The World Health Organization does not warrant that the information contained in this discussion paper is complete and correct and shall not be liable for any damages incurred as a result of its use.

The information contained in this discussion paper may be freely used and copied for educational and other non-commercial and non-promotional purposes, provided that any reproduction of the information be accompanied by an acknowledgement of the World Health Organization as the source. Any other use of the information requires the permission from the World Health Organization, and requests should be directed to World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland.

The designations employed and the presentation of the material in this discussion paper do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this discussion paper. However, this discussion paper is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the presentation lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

© World Health Organization, 2017. All rights reserved.

The following copy right notice applies: www.who.int/about/copyright