Informal Technical Member State Consultation

Risk assessment and management tools for safeguarding against potential conflicts of interest in nutrition

4 February 2019, WHO Headquarters, Geneva, Switzerland

When, in 2012, the World Health Assembly endorsed the Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition, the Assembly also 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.”

Two years later, the Director-General was requested “[...] to convene informal consultations with Member States to complete the work, before the end of 2015, on risk assessment and management tools for conflict of interest in nutrition, for consideration by Member States at the Sixty-Ninth World Health Assembly”. In response, a technical consultation was convened on 8-9 October 2015 and the Secretariat subsequently devised a draft approach on preventing and managing conflicts of interest in policy development and implementation of nutrition programmes at country level. The approach proposed a risk assessment tool comprising a six-step methodology for Member States to consider in their engagement with individuals and non-State actors for preventing and managing conflict of interest in the area of nutrition. Following consultation on the draft approach, an amended version was submitted to the WHO Executive Board in January 2018 and later to the World Health Assembly in May 2018. The approach being considered “a living document to be revised according to Member States’ needs and the evolution of engagement with external actors”, the Secretariat continues to consult with Member States about their experience on the matter.

Therefore, a further informal technical Member State consultation on this issue was held at WHO headquarters in Geneva on 4 February 2019.

The consultation aimed:
- to share Member States’ experiences on engaging with non-State actors;
- to share current approaches on risk assessment and management of conflicts of interest;
- to learn about country experience on the WHO risk assessment tool and identify next steps in this area.

Twenty Member States and the European Union participated in the consultation.

Country experience of assessing and managing conflicts of interest

Ten Member States related their experiences in identifying and managing conflicts of interest in relation to nutrition, and outlined the challenges and opportunities associated with engagement with non-State actors.

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1 WHA Resolution 65.6.
2 In decision WHA67/65 of the Sixty-Seventh WHA held in 2014,
3 See Annex 1 for the consultation concept note and Annex 2 for the agenda.
4 See Annex 3 for a list of participating countries.
5 For more detail see the Member States presentations available online at https://www.who.int/nutrition/events/2019-memberstates-consultation-COI-4Feb/en/.
There was widespread acknowledgement that engagement with a broad range of non-State actors, including the private sector, is important for Member States in their efforts to improve nutrition. It is clear that not all such engagements are equal – they differ according to various factors, such as, the type of policy lever under consideration, the stage in the policy or programme implementation process, and the different stakeholders involved. Safeguarding against potential conflicts of interest is crucial to ensure that the government’s integrity, independence and reputation are not compromised and to maintain public trust and confidence in the policy-making process and in emergent policies, guidance and programmes. It is helpful, therefore, to establish criteria and clear processes to analyze the potential engagements and decide on their public health value, as well as to enable Member States to assess and manage conflicts of interest.

Different country approaches to stakeholder engagement and to assessing and managing potential conflicts of interest were described. A number of approaches to safeguarding against conflicts of interest in the development of dietary guidelines, for example, were outlined. One country reported measures to ensure that officials had no direct interactions with private sector actors during a period of developing new healthy eating guidelines, while another country permitted officials to have contact with private sector actors, but protected committee members from any direct contact. Other countries reported having excluded representatives of the food industry from the guideline development process.

Several countries reported processes requiring declaration of interests by scientists and other experts involved in guideline or policy development. One country has created a single open access online register of interests to ease the administrative burden on experts. In another country, financial declarations of experts are reviewed on appointment and then on an annual basis. In another example, harmonized guidelines for identifying and managing conflicts of interest across several decentralized agencies have been developed. There was discussion of whether requiring experts to disclose their interests could discourage their participation and there has been some experience of experts having expressed concern about the level of disclosure required, while other Member States indicated that, to date, there have always been enough experts willing to participate in the review process.

Processes to separate out provision of scientific advice from advice on policy implementation were applied in some cases. For the implementation of policy, several countries reported examples of engagement with the private sector, in relation to:

- food fortification,
- reformulation,
- restrictions on marketing to children, and
- front-of-pack nutrition labelling.

These engagements range from consensus-building workshops to multisector collaboration, formalized partnerships, or signing of a Memorandum of Understanding with food producer alliances.

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6 The WHO tool defines engagement as “any formalized interaction with the individual or non-State actor” and describes different forms of engagement including charitable (such as donations), transactional (such as sponsorships or public-private partnerships) and transformational (such as multi-stakeholder platforms). Transformational engagements involve the highest level of interaction and resources.
Several Member States reported ongoing challenges with managing conflicts of interest. One challenging area, for example, relates to the engagement of other ministries, local government or other public sector bodies with the private sector. In these other public bodies – such as the government departments responsible for trade, industry, agriculture, education, food aid or sport and local authorities – officials may not consider public health-related conflicts of interest when faced with funding opportunities. This has resulted in, for example, schools involved in partnerships with soft drinks companies, sponsorship of higher education courses by breast-milk substitute manufacturers or acceptance of donated infant formula. Another area which remains challenging relates to the activities of breast-milk substitute manufacturers and distributors. Given the many examples of continued violations of the International Code of Marketing of Breast-Milk Substitutes and the conflicts of interest these create, some Member States highlighted that engagement with any companies that violate the Code is highly problematic, even if that engagement relates to other products in their portfolio.

Member States underlined the importance of public consultation and ensuring that all voices are heard, while enabling policymakers to take decisions without undue influence. It needs to be recognised, however, that the process of public consultation requires resources and can be highly challenging, given the high volume of responses that may be received. One option, for example, could be to engage an external company to compile, analyze and summarize responses, while another suggestion was to only invite representatives or elected bodies to respond to consultations.

Additionally, Member States underlined the importance of reliance on consultation, openness and transparency to ensure accountability in the policy-making and implementation process and identified key elements for successful collaboration with the private sector (see Conclusions, below). It is also important to ensure that any engagement with non-State actors is coherent with relevant laws (e.g. on competition) and trade rules.

Risk mitigation strategies include clear government leadership, openness and transparency of engagement, creating firewalls between officers deciding on policies and interested stakeholders, clear rules for any engagement, and external evaluation of engagement.

**Country feedback on the WHO draft decision-making process and tools**

Several Member States underlined the ongoing need for more guidance and tools from the Secretariat, in order to be able to safeguard against potential conflicts of interest while having appropriate engagement with all stakeholders. Moreover, several countries explicitly thanked WHO for its work on this process and for the development of the tool, which was welcomed as necessary, flexible and useful for helping understand stakeholders and their potential interactions and for guiding and justifying decision-making.

There was some discussion on the need for greater clarity on the definition of engagement and its various forms, particularly the concept of partnership and terminology such as ‘cooperation’ and ‘collaboration’. There is recognition that partnership is the most complex form of engagement, and an area where further guidance may be needed. There was also clarification
that the WHO tool is accompanied by an introductory paper that provides definitions and addresses some of these issues.7

There was some discussion of whether use of the tool could risk limiting any engagement with the private sector. There was clarification that this is not the intention of the tool, which is designed to ensure safe engagement with all stakeholders. Several Member States stressed that use of the tool (or similar national arrangements) should not impede fruitful engagement but – by enabling governments to take clear, objective decisions and to manage potential conflicts of interest – could actually open up possibilities for effective engagement. A rigorous process may sometimes create opportunities for engagement, while at other times it will limit certain types of engagement. Well-defined processes to safeguard against conflicts of interest provide clarity for all stakeholders.

During the discussion, the WHO Secretariat has clarified that the current process should be considered separately from the process that WHO is applying for its engagement with non-State actors through, inter alia, the WHO’s Framework for Engagement with non-State Actors (FENSA). It was confirmed that the risk assessment and management tool for safeguarding against potential conflicts of interest in nutrition, in contrast, is developed to guide Member States in the development and implementation of policy at the national level.

One Member State provided feedback on its experience with piloting the draft tool. A national workshop was organized to review the WHO draft tool, at which it was proposed that a simpler, shorter version could be more appropriate in some situations. A shorter version of the WHO tool was therefore piloted, with the support of the Pan-American Health Organization, across five teams involved in nutrition issues in the country. This shorter version was easier and quicker to use and was able to identify and exclude simple and obvious conflicted cases. It could, therefore, be used as a first screening tool, while application of the full-length version of the WHO tool would still be necessary in more complex cases. The simplified version will be made available for other Member States consideration.

Several suggestions for potential amendments to the WHO risk assessment tool emerged:

- Inclusion of more practical examples and country case studies to illustrate how to assess and manage conflicts of interest.
- Possible integration of a scoring system (with different weights for different questions) to indicate the risk of conflicts of interest and whether or not engagement is recommended.
- Inclusion of more guidance on the meaning of exclusionary criteria, and inclusion of examples of inappropriate partnerships and potential conflicts of interest. This could be informed, it was suggested, by an analysis documenting the various lobbying strategies used by non-State actors.
- Simplification of the tool, possibly through the use of questionnaires, an online form and links to examples.
- Inclusion of a check-list or decision tree, with different levels of complexity depending on the context.
- More detailed explanation of the different types of engagement and particularly more specific guidance relating to development of partnerships.
- More in-depth guidance on how to conduct public consultations and handle responses received.

7 https://www.who.int/nutrition/consultation-doi/nutrition-introductory-paper.pdf?ua=1
It was pointed out that widespread dissemination of the revised tools will be very important, as will technical assistance to build the capacities of government officers on understanding and managing conflicts of interest and appropriate application of the tools to ensure sustained implementation and monitoring. There was also the suggestion that WHO should provide technical support to governments of under-resourced countries to facilitate decision-making.

Conclusions and next steps

Engagement with non-State actors, including the private sector, is clearly important for Member States in their efforts to improve health and nutrition. It is also clear that safeguarding against potential conflicts of interest is crucial to protect the integrity, independence, and reputation of governments, to maintain public trust and confidence in institutions, processes and policies and to ensure that public health and nutrition are safeguarded.

Key elements for successful engagement

The key elements of success in any engagement that were highlighted include:

- strong government leadership and oversight;
- full commitment to openness and transparency (e.g., publication of all documents – including agreements, all correspondence and communications, meeting agenda and notes, reports of feedback received and evaluation reports);
- careful definition of objectives for any engagement;
- clear allocation of roles and responsibilities;
- regular communication and sustained coordination;
- establishment of codes of conduct for government officials; and
- development of mutual understanding and trust.

There continues to be demand from Member States for guidance and tools to support their efforts to assess and manage potential conflicts of interest. The Secretariat undertook to do further work on an approach for risk assessment and management for safeguarding against potential conflicts of interest in nutrition to assist Member States with implementation of their programmes at country level. The proposed approach is a living document to be revised according to Member States’ needs and further piloting and testing of the revised tool would be very helpful to inform its development and clarify how it can potentially be improved to ensure that it facilitates safe and effective engagement.

There was broad agreement that the exchange of experience had been very valuable – for Member States and for the Secretariat – and there was interest in further dialogue and exchange on the ongoing development and use of the WHO tool and guidance. It was suggested that strengthening capacities in Member States on conflicts of interest should be a test case for WHO’s new emphasis – from the Thirteenth General Programme of Work 2019-2023⁸ – on enhancing impact at country level. The Secretariat undertook to keep Member States informed and to explore options for ongoing dialogue on this issue.

⁸ http://origin.who.int/about/what-we-do/gpw-thirteen-consultation/en/
Annex 1

Informal Member State Consultation on Conflicts of Interest

Concept Note

Informal Technical Member State consultation

Risk assessment and management tools for safeguarding against potential conflicts of interest in nutrition

WHO Headquarters, Salle C, 4 February 2019

Context:
SDG17 calls for strengthening the means of implementation and revitalization of the global partnership for sustainable development, through finance, technology, capacity building, trade and systematic issues. More specifically, target 17.17 calls to “Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships”. At the same time, the World Health Assembly (resolution 65.6) has called upon Member States to establish adequate mechanisms to safeguard against potential conflict of interest when forming alliances and partnerships. A conflict of interest arises in circumstances where there is potential for a secondary interest to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectively of professional judgement or actions regarding a primary interest.

Background:
In 2012, the Sixty-Fifth World Health Assembly (WHA) adopted resolution WHA65.6 and endorsed the comprehensive implementation plan on maternal, infant and young child nutrition. The resolution 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.” In decision WHA67(9) of the Sixty-Seventh WHA held in 2014, the Director-General was requested “[…] to convene informal consultations with Member States to complete the work, before the end of 2015, on risk assessment and management tools for conflict of interest in nutrition, for consideration by Member States at the Sixty-Ninth World Health Assembly”.

In response to this request, a technical consultation was convened on 8-9 October 2015 with the aim of supporting efforts to address governance gaps on conflict of interest in order to safeguard nutrition policy development and implementation at country level. The technical consultation brought together experts from different constituencies and fields, such as, nutrition, health systems, noncommunicable diseases, law, economic and social science, as well as representatives of the six WHO regions.

Following up on the outcomes of the technical consultation, the Secretariat devised a draft approach on preventing and managing conflict of interest in policy development and implementation of nutrition programmes at country level. The approach proposed a six-step
methodology for Member States to consider in their engagement with individuals and non-State actors for preventing and managing conflict of interest in the area of nutrition. A public consultation on the draft approach was held between 11 and 29 September 2017. Member States, United Nations representatives and non-State actors provided comments on the draft tools, which are publicly available. Feedback was received from Member States and other stakeholders. The Secretariat developed an amended version of the tools and submitted a report to the Executive Board at its 142nd session in January 2018, which was noted by the Board.

At the WHA71 in May 2018, the Member States discussed report A71/23 and the report was noted. In addition, 21 Member States, in their formal statements, commented or referred to the work of conflict of interest in Committee A on 25 May 2018. Several countries suggested to further discuss the approach and collect expectations on country needs and country experiences. Six Member States volunteered to test the applicability and practical value of the tools in their context.

Objective:
The Secretariat is organizing an informal technical consultation on 04 February 2019 for Member States to further share their experience on engaging with non-State actors in the area of nutrition. This consultation provides an opportunity for discussion among Member States’ representatives to share experiences and discuss the practicality and utility of the proposed tools.

Objectives of the consultation are:
1. to share Member States’ experiences on engaging with NSAs;
2. to share current approaches on risk assessment and management of conflict of interest;
3. to learn about country experience on the WHO tools and identify next steps in this area.

About the consultation:
This consultation will include Member States’ representatives only. The meeting will take place at WHO HQ, Geneva 04 February 2019. Interpretation services will be provided in the six UN languages. The consultation will be live cast via WebEx (via a protected link) and will be recorded for reporting purposes. A meeting report will be developed.

Proposed agenda:
09:00-10:30: Session on country experiences of engaging with NSAs

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9 For the purpose of the WHO Framework of Engagement with Non-State Actors, non-State actors are nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions (see document WHA69/2016/REC/1, Annex 5)
11 See document EB142/23 and the summary records of the Executive Board at its 142nd session, tenth meeting, section 3
10:30-11:00: Coffee/tea Break
11:00-12:30: Session on the opportunities and challenges of engaging with NSA
12:30-14:00: Lunch
14:00-15:30: Risk assessment and management tools: the way forward
15:30-16:00: Coffee/tea Break
16:00-17:00: Next steps and closure
Annex 2

Informal Technical Member State Consultation
Risk assessment and management tools for safeguarding against potential conflict of interest in nutrition
WHO Headquarters, Geneva, Switzerland
4 February 2019, Salle C
09:00 to 17:00
AGENDA

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<tr>
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<th>Time</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>09:00 – 09:05</td>
<td>Welcome, rules of procedure, and opening remarks by WHO ADG NMH Dr Svetlana Axelrod</td>
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**Session 1: Country experience of engaging with non-State actors**
Chair: Zambia

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<tr>
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<th>Time</th>
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<tbody>
<tr>
<td>2</td>
<td>09:05 – 09:15</td>
<td>Canada</td>
<td>• Canada’s Healthy Eating Strategy Initiatives (Canada’s Food Guide, marketing to children, front-of-package labelling); • Engagement with NSAs: process and outcomes</td>
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<td>09:15 – 09:20</td>
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<td>Opportunity for short Q&amp;A on the country presentation</td>
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<td>3</td>
<td>09:20 – 09:30</td>
<td>Nigeria</td>
<td>• Food fortification and Code of marketing Breastmilk Substitutes; • Engagement with NSAs: process and outcomes</td>
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<td>09:30 – 09:35</td>
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<td>Opportunity for short Q&amp;A on the country presentation</td>
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<td>4</td>
<td>09:35 – 09:45</td>
<td>Norway</td>
<td>• Marketing foods to children, labelling and reformulation; partnership for a healthier diet • Engagement with NSAs: process and outcomes</td>
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<td>09:45 – 09:50</td>
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<td>Opportunity for short Q&amp;A on the country presentation</td>
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<td>5</td>
<td>09:50 – 10:00</td>
<td>United States of America</td>
<td>• Promoting healthy diet in the US • Engagement with NSAs: process and outcomes</td>
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<td>Opportunity for short Q&amp;A on the country presentation</td>
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<td>10:05 - 10:30</td>
<td>Plenary discussion on country experiences of engaging with non-State actors: statements, questions and comments from other Member States</td>
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<td>10:30 - 10:45</td>
<td>COFFEE/TEA BREAK</td>
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<td>10:45 – 10:55</td>
<td>Session 2: The opportunities and challenges of engaging with non-State actors</td>
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<td>10:55 – 11:00</td>
<td>Opportunity for short Q&amp;A on the country presentation</td>
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<td>11:00 – 11:10</td>
<td>Namibia (via WebEx)</td>
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<td>Opportunity for short Q&amp;A on the country presentation</td>
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| 12| 11:45 – 11:55 | Uruguay       | - Illustrative examples of challenges with non-state actors in the development of public policies related to nutrition guidelines and regulation on front of packaging labelling;  
- How conflict of interest was managed within a new institutional framework created to advance public policies to address overweight and obesity;  
- Are the WHO tools responding to country’s needs? |
|   | 11:55 – 12:00 |               | Opportunity for short Q&A on the country presentation                        |
| 14| 12:00 – 14:00 | LUNCH         |                                                                              |
|   |               |               |                                                                              |
|   |               |               | **Session 3: Risk assessment and management tools: the way forward**          |
|   |               |               | **Chair: Finland**                                                          |
| 15| 14:00 – 14:30 | Plenary       | Plenary discussion on existing practices of risk assessment and management of the conflict of interest: statements, questions and comments from other Member States, questions and comments from the Member States on the six-step tool developed by the Secretariat. |
| 16| 14:30 – 14:40 | Brazil        | Testing the use of WHO tool in Brazil                                       |
|   | 14:40 – 14:45 |               | Opportunity for short Q&A on the country presentation                        |
| 17| 14:45 – 14:55 | France        | - Experience on risk assessment and management of Conflict of Interest;  
- Comments on the WHO tools |
<p>|   | 14:55 – 15:00 |               | Opportunity for short Q&amp;A on the country presentation                        |
| 18| 15:00 – 15:30 | Plenary       | Plenary discussion, sharing more examples from Member States on adaptation of the tools to a national context, further questions and comments from the Member States |
| 19| 15:30 – 16:00 | COFFEE/TEA BREAK |                                                                              |</p>
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| 20:00 | 16:00 – 16:45 | - What is needed to protect public interest in the engagement with NSAs in nutrition?  
- What actions Member States would like to take?  
- How to improve the WHO tools?  
- How will Member States be kept informed about progress?  
- Are resources available to finish the work? |
| 21:00 | 16:45 – 17:00 | Conclusions and closing remarks by WHO ADG NMH Dr Svetlana Axelrod                 |
Annex 3

Member State Participation in the Technical Consultation

Australia
Austria
Brazil
Canada
Ecuador
European Union
Finland
France
Germany
Italy
Kenya*
Mexico
Namibia*
New Zealand
Nigeria
Norway
Philippines*
Ukraine
Uruguay
USA
Zambia

* Participated via online connection