

Ad hoc open-ended working group on a science-policy panel to contribute further to the sound management of chemicals and waste and to prevent pollution

Third session - Geneva, 17-21 June 2024 (OEWG 3)

WHO comments on proposed "Conflicts of Interest" arrangements OEWG3 Pre-session Documents

As noted in the draft Conflict of Interest policy set out in Annex 5 to the Compilation of proposals for establishing a science-policy panel:

'The operating principles of the Panel provide that, in carrying out its work, the Panel and the supporting subsidiary bodies must be scientifically independent and ensure credibility, relevance and legitimacy through its work and transparency in its decision-making processes and use clear, transparent and scientifically credible processes for the exchange, sharing and use of data, information and technologies from all relevant sources, including peer-reviewed and non-peer-reviewed literature, as appropriate, [alongside other reliable sources, to ensure a comprehensive, and robust assessment process](del). ... The role of the Panel requires that it pays special attention to issues of independence and bias in order to maintain the integrity of, and public confidence in, its outputs and processes. It is essential that the work of the Panel is not compromised by any conflict of interest for those who execute it.'

WHO considers declaration and management of conflicts of interest essential to the development of unbiased and credible recommendations and guidance. We welcome the recognition in the Panel's operating principles of the need for scientific independence, credibility, transparency in decision-making and transparent and scientifically credible processes, as well as to maintain integrity and public confidence in Panel work and outputs and to ensure that the work of the Panel is not compromised by conflicts of interest.

WHO is a science- and evidence-based organization focused on public health. Guidelines and delivery of evidence-based technical recommendations and guidance are fundamental means through which WHO fulfils its mandate of providing technical leadership in health. Accordingly, we offer the following comments as insights from the WHO experience and to suggest ways in which the SPP conflicts of interest (COI) policy and declaration of interests form could be strengthened and better align with WHO processes and requirements.

Compilation of proposals for establishing a science-policy panel UNEP/SPP-CWP/OEWG.3/2

Annex 5. Conflict-of-Interest policy

A. Purpose and B. Scope

- '1. ... According to the operating principles of the Panel, in carrying out its work, the Panel and the supporting subsidiary bodies must be <u>scientifically independent</u> and <u>ensure credibility</u>, relevance and <u>legitimacy</u> through its work and <u>transparency in its decision-making processes</u> and use <u>clear</u>, <u>transparent and scientifically credible processes for the exchange</u>, <u>sharing and use of data</u>, <u>information and technologies</u> from all relevant sources, including peer-reviewed and non-peer-reviewed literature, as appropriate, [alongside other reliable sources, to ensure a comprehensive, and robust assessment process](del).'
- Chapter 6 of the WHO Guideline Development Handbook (2nd Ed.) https://www.who.int/publications/i/item/9789241548960 notes that the declaration and management of conflicts of interest is essential to the development of unbiased and credible recommendations and guidelines. The chapter defines the basic concepts, describes the principles involved, and outlines how WHO staff who develop guidelines can collect declarations of interest and assess and manage any conflicts. This Handbook can provide guidance from the experience of WHO, as the peak global technical body on health and a trusted adviser to governments, including through publication and dissemination of policy guidance based on best available science.
- The Panel and subsidiary bodies must be scientifically independent according to the operating principles of the Panel. As setting the scientific agenda can influence outcomes, all those involved at the Panel or subsidiary bodies in setting the scope and parameters of scientific inquiries and deliverables should be subject to the COI policy, not just those directly involved in preparing reports and deliverables (para 3 and 7 scope).
- In establishing independence, it would be beneficial to include in the COI policy a strong statement/reminder that panel members are appointed to act independently and not represent the Member, organization or institution appointing them.

C. Conflict of Interest

- See comments below on the SPP COI form regarding the limitations to the definition of conflict of interest used in this Annex, as detailed in paragraphs 12, 13, 15, 16 and 17.
- Paragraph 13 Noting the need to balance bias and differing viewpoints in Panel author teams, the existing or previous and ongoing relationships, and a history of engagements and publications must be disclosed in order to allow a determination of potential biases and different viewpoints, as well as potential conflicts of interests. For this purpose, the WHO DOI form requires disclosure of interests in the previous 4 years and the WHO Handbook for Guideline Development requires experts applying to work on guidelines to provide their professional CV.
- Paragraph 17 If it is intended that only 'significant and relevant' financial interests are disclosed, a clear number should be provided which is regarded as significant. The WHO DOI form sets these figures low, at 'any remuneration' for employment, consulting or financial research support, \$1,000 for non-monetary research support and \$5,000 for investments. As clearly stated in the form, declaring an interest does not automatically disqualify and applicant or limit participation, but allows the Secretariat to assess potential conflicts of interest based on all relevant information.

Appendix A

 Paragraph 3 – Noted that the requirement to submit a COI form is square bracketed for the Interdisciplinary expert Committee of the Panel. It is critical to meet the objectives of the panel in ensuring independence, transparency, credibility and in building trust in the work of the Panel and its outputs that all experts involved in setting the scientific agenda

- or determining the approach and scope of products, as well as experts engaged in developing products, to submit declarations of potential conflicts of interest.
- In the process prior to appointment, we recommend a public comment period, during
 which the names of potential panel members are published for two weeks/one month to
 allow for the public to submit comments, as in some cases public comments can inform
 of additional conflicts than those disclosed. The WHO guidelines/expert process includes
 this step.
- WHO processes make clear that further information will be sought from an expert if necessary as part of the review and engagement process. We recommend that this is also explicitly stated in this policy and on the DOI form.
- Paragraph 7 Periodic updates to Dol should apply to all groups including Panel members to ensure that they retain currency and meet the objectives of the policy. While all should routinely notify changes, a stronger process would require a new form from every person within the scope of the policy at a fixed time (e.g. annually).
- Paragraph 7bis It is strongly suggested that (c) (the ability to assign future intellectual property rights) and (d) (confidentiality of commercial, government or industrial information) are deleted from the exemptions to disclosure. Both categories are potentially extremely broad and can be subjectively interpreted. Accordingly, neither should exempt disclosure for the purpose of determining conflicts of interest. If it is determined that disclosure beyond the COI committee or Panel would adversely and materially impact such interests, the information can be managed in accordance with confidentiality procedures.
- Paragraph 10 It is strongly suggested that the final sentence in square brackets is not deleted and should in fact be strengthened by giving the COI Committee (which must be independent of the Panel) decision-making authority. In cases where a COI cannot be resolved, it is critical to protect the integrity and work of the Panel that the COI Committee retains the capacity to exclude an individual from Panel work, for specific activities or in general.
- Paragraph 13 Whilst taking all legally required steps to protect personal information, in
 the interests of meeting the principles detailed in the Panel's operating procedures, in
 WHO Guidelines and related products, the existence of any conflicts of interest, and the
 way in which they have been managed, is published in the final product.
- There is value (for example to help build credibility and trust) in routinely publishing information about interests declared (but not the COI form itself) by all experts on a continuous basis. WHO states that it retains the right to publish further information about an expert from their DoI form (not necessarily the form itself) if it becomes necessary due to questions raised. Other technical organizations also take this approach for example IARC does this routinely, without disclosing too much personal information.
- Paragraph 14 19: If a COI Committee is considered necessary by Member States, a smaller committee might be considered to expedite its operations. A COI Committee should be established to operate and consider potential conflicts independently of the Panel.
- In addition, noting the operating principle for the Panel to have <u>clear, transparent and scientifically credible processes for the exchange, sharing and use of data, information and technologies from all relevant sources, it is suggested that as in WHO guidelines and guidance documents, all data, information and methodologies on which guidance is based should be made publicly available for review by any interested party.</u>

Draft conflict-of-interest disclosure form UNEP/SPP-CWP/OEWG.3/2/Add.5

The WHO Declaration of Interests for WHO Experts form (Available at: https://cdn.who.int/media/docs/default-source/air-pollution-documents/doi_en_form_blank8ba6ab2c-dd62-49a9-914d-aacb4f7ebec7.pdf?sfvrsn=387a7953_5) provides as follows:

'All experts serving in an advisory role must disclose any circumstances that could represent a **potential conflict of interest** (i.e., any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). You must disclose on this Declaration of Interests (DOI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you have been asked to participate in or contribute towards and any interest that could be affected by the outcome of the meeting or work. You must also declare relevant interests of your immediate family members (see definition below) and, if you are aware of it, relevant interests of other parties with whom you have substantial common interests and which may be perceived as unduly influencing your judgement (e.g. employer, close professional associates, administrative unit or department). Please note that not fully completing and disclosing all relevant information on this form may, depending on the circumstances, lead WHO to decide not to appoint you to WHO advisory bodies/functions in the future.'

By comparison, the SPP draft conflict of interest (COI) disclosure form:

- Does not include potential COIs which 'may reasonably be perceived to affect' the declarant's
 objectivity, which is an important factor in 'maintaining public confidence in, the Panel's
 deliverables and processes.'
- Does not specifically require disclosure of interests which may potentially impact the
 declarant's independence, focusing instead on objectivity and the possibility of creation of
 unfair advantage or resulting in material gain related to the work of the Panel. This could
 undermine 'the objective of the Panel (which) requires that special attention be paid to issues
 of independence and potential bias in order to maintain the integrity of, and public confidence
 in, the Panel's deliverables and processes.'
- Requires disclosure of (a) interests that could 'significantly' impair the declarant's objectivity. It is unclear how significance should be assessed, but this implies a higher threshold of impairment and declarants may decide not to declare interests that may impact their objectivity in carrying out their duties and responsibilities for the Panel on the basis that they do not consider that impact to be a significant impairment. A more robust and transparent process would be to require disclosure of all interests which may be perceived as unduly influencing the declarant's judgement (as in the WHO form) and for the interests declared to be independently assessed e.g. by the SPP Secretariat or COI committee to determine whether objectivity (or independence) could be impacted or impaired in a way that could impact the work of the Panel or public perception of it.
- Requires disclosure of interests that could (b) 'create an <u>unfair advantage</u> for you or any person or organization, <u>and which could result in your securing a direct and material gain</u> through outcomes related to a Panel process.' This appears to require that both an unfair advantage and a direct material gain for the declarant are created, which is a narrow interpretation of COI and a high threshold, and which may not capture all relevant interests. It is also important to note that vested commercial interests may only seek the continuation of business as usual, which may in some circumstances impacted by the Panel's work. Such commercial interests could exercise undue influence on a declarant or impair their objectivity,

but do not create an 'unfair advantage' in favour of a particular person or organization, particularly if the outcome benefits an industry sector.

Requires disclosure only of <u>current employment</u>, <u>engagement or contractual relationships</u> and remuneration or financial support that is being received at the time of the declaration. This declaration does not capture previous recent engagements which may impair or unduly influence the independence or objectivity of a declarant or demonstrate a particular leaning or potential bias, which could be considered in the balance of the Panel (see paragraph 13 of the Conflict of Interest Policy). In contrast, the WHO form requires disclosure of remuneration and research support in the past 4 years and for experts engaged in guideline development also requires candidates to provide a CV.

In the specific questions in the SPP COI form:

- It would be beneficial to clarify what is meant by the 'Panel's work' as individuals may be conflicted in relation to one area of work but not others.
- Part I Question 5 asks whether the declarant 'own(s) any intellectual property interests' that
 might be affected by the Panel's work. Given the range of potential interests in intellectual
 property, this question could be made more comprehensive by rephrasing as 'hold any form
 of interest in intellectual property'.
- Part III Question 12 asks '...would the outcome of the meeting or work <u>adversely</u> <u>affect</u> interests of others with whom you have substantial common personal, professional, financial or business interests,' including close family and associates. This question should cover all impacts, as positive impacts on the interests of the family or close associates of the declarant are also generally considered to create potential conflicts of interest. The WHO DOI form instead asks 'would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests ...' The question should be amended to 'benefit or adversely impact'.
- We strongly recommend that the question regarding close family includes the declarant's spouse or partner.
- The form (and policy) would also be strengthened by including a question on public comments made by the declarant on matters relevant to the panel's work, in particular for the management of actual or perceived bias.

Contacts for Further Information

Kathryn Robertson (robertsonk@who.int) Lesley Onyon (onyonl@who.int)