Fields marked with an asterisk (*) are mandatory.

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Are the responses approved or endorsed by your organization?

Yes

Comments on the "Discussion paper"

General comments : Please comment on the clarity and comprehensiveness of the approach

Although the process of developing the papers (Discussion, Introduction, and Tool) is described, there is no disclosure of conflicts of interest for those who were involved in drafting the papers. This should be included as part of the documents.

The definitions of conflict of interest (items 9, 10 and 11) confuse conflict of interest with bias. For example, the academic literature on conflicts of interest does not refer to “potential” conflicts of interest. The conflict of interest exists, but there is a potential for bias (1,2,3). This confusion occurs throughout the document. For example, the last sentence of #11 would be more accurately written as “A conflict of interest does not necessarily mean that the individual involved is BIASED, but the perception of potential BIAS may create a negative image.”

We support the principles outlined in item #18.

We support the 6 steps included in the tool (pages 4-5). For the risk assessment (Step 2), it would be useful to give examples of unacceptable risks, such as having a relationship with an organization with a well documented history of unethical behaviour (such as the tobacco industry). A link to Table 1 in the Tool would provide examples of such risks. Under transparency (step 6), the member state should explain publicly why a risk is acceptable (ie, worth the benefit) and what measures (if any) have been taken to mitigate the risk.

There is an important omission in the discussion paper. There is no description of who should conduct the risk assessments. The risk assessment should not be conducted by an individual or group that would be

directly involved in the relationship with the external actor. A number of organizations (universities, Cochrane, etc.) have designated a committee to assess risks related to conflicts of interest and implement management strategies (Boyd and Bero, 2007; Boyd 2004d). We suggest that any conflict of interest policy of a Member State should describe the process for conducting the risk assessment. We recommend that a committee with relevant knowledge of the nutrition field be convened and that the committee members be free of conflicts of interest.

1. Institute of Medicine, The National Academies of Science. Conflict of Interest in medical research, education and practice. 2009. B Lo and M Field, editors. The National Academies Press.
2. Bero L. Addressing bias and conflict of interest among biomedical researchers (Viewpoint). JAMA, 2017, 317 (17) 1723-1724.
3. Bero L and Grundy Q. Why having a (non-financial) interest is not a conflict of interest (Perspective) PLoS Biology, PLoS Biol, 2017, 14(12): e2001221. doi:10.1371/journal.pbio.2001221
4. Boyd, E, and Bero, L. An analysis of university conflict of interest committee decisions. Science and Engineering Ethics, 2007; 13: 415-435.
5. Boyd, EA, Lipton, S, and Bero, L. Implementation of financial disclosure policies to manage conflicts of interest, Health Affairs 2004; 23: 206-214.

Specific comments

The term “at arm’s length” (item 13) could be clarified by stating that one entity should not be involved in the decision making of the other entity. For example, a charity board that includes members of the parent company and makes decisions about how board money is spent would not be “at arm’s length.”

Comments on the "Introductory paper"

General comments : Please comment on the clarity and comprehensiveness of the introductory paper

The definitions of conflict of interest (items 9, 10 and 11) confuse conflict of interest with bias. For example, the academic literature on conflicts of interest does not refer to “potential” conflicts of interest. The conflict of interest exists, but there is a potential for bias. This confusion occurs throughout the document. Recent literature provides a discussion of interests, conflicts of interest and bias (1, 2, 3).

We support the principles outlined on page 7 of the document. In particular, we agree with principle #6: engagement can be successful if “conducted on the basis of evidence, as well as transparency, independent monitoring and accountability.” However, the introductory document could make a stronger statement about how evidence itself can be manipulated by non-state institutions, especially private sector entities. Thus, policy makers must be sceptical of the source of evidence, recognize that conflicts of interest are not always disclosed, and assess evidence for any risks of bias. Private sector entities can influence the research agenda, design, conduct and reporting of evidence (4, 5).

As suggested in the document (page 8), the monitoring and evaluation of policy should not involve any organizations that have a commercial interest in the outcome of the evaluation as this is a conflict of interest that cannot be managed and must be eliminated.

1. Institute of Medicine, The National Academies of Science. Conflict of Interest in medical research, education and practice. 2009. B Lo and M Field, editors. The National Academies Press.
2. Bero L. Addressing bias and conflict of interest among biomedical researchers (Viewpoint). JAMA, 2017, 317 (17) 1723-1724.
3. Bero L and Grundy Q. Why having a (non-financial) interest is not a conflict of interest (Perspective) PLoS Biology, PLoS Biol, 2017, 14(12): e2001221. doi:10.1371/journal.pbio.2001221
4. Odierna, D, Forsyth, S, White, J and Bero, L. The cycle of bias in health research: A framework and toolbox for critical appraisal training. Accountability in Research. 2013; 20:2, 127-141. doi: 10.1080/08989621.2013.768931.PMID: 23432773
5. White, J, Bero, LA. Corporate manipulation of research: Strategies are similar across five industries, Stanford Law & Policy Review. 2010; 21(1):105-134.

Specific comments

Appendix 4: Under the tactic, “shape the evidence base on diet and public health related issues,” an additional mechanism should be added to mechanism column for this tactic. The additional mechanism is industry’s attempts to influence the standards by which evidence is evaluated by policy makers. For example, the tobacco industry formed a coalition of a number of industries to influence standards for evidence used to support government documents in the United States (1).

1. Baba, A, Cook, D, McGarity, T, and Bero, L. Legislating “Sound Science”: Role of the tobacco industry, American Journal of Public Health, 2005; S1: S20-S27.

Comments on the "Tool"

General comments : Please comment on the clarity and practical value of the tool

The document notes that the 6 steps of the risk-benefit assessment should be made by “the national authority” (page 3). The document should further specify that this risk-benefit analysis should not be conducted by an individual or group that would be involved in the proposed relationship. Ideally, the 6 steps should be conducted by a committee that has relevant expertise in assessing conflicts of interest and knowledge of the state institution’s mission (1,2). Using an independent, dedicated group to assess conflicts of interest is particularly important for Step 3 (Balancing the risks and benefits) as this qualitative assessment is subjective.

We support providing examples of exclusionary criteria (Table 1), but this table should be mentioned in the Discussion and Introductory papers as well. These papers currently suggest that all types of engagement are potentially acceptable as they do not give examples of circumstances under which engagement of the Member State with non-state individuals or institutions is unacceptable.

We also recommend including “lack of alignment with public health goals or nutrition goals” as an exclusionary criterion. This is currently mentioned as a caution (page 15), but it is unclear why the Member State would want to engage with a non-state actor who failed to align with their public health goals. In fact, the document is contradictory because page 5, Step 1 states “It is crucial that the engagement with an external actor is initiated only if it will help advance the nutrition or public health goal.” All of the documents need to indicate clearly and consistently that it is unacceptable to engage with non-state actors who do not align with public health goals.

1. Institute of Medicine, The National Academies of Science. Conflict of Interest in medical research, education and practice. 2009. B Lo and M Field, editors. The National Academies Press.
2. Bero L. Addressing bias and conflict of interest among biomedical researchers (Viewpoint). JAMA, 2017, 317 (17) 1723-1724.

Specific comments