7. WHO guidelines: development and governance

Contents

In focus

At the request of Italy, the Secretariat will submit a report (EB137/5) to the Executive Board in order to enable members to review the process for the development, updating and approval of WHO guidelines. See the original motivation for this item, EB136/1 Add.1.

While the explicit focus of this item is on WHO's guidelines process (see Handbook 2012) the underlying dynamic is an attack by the Sugar Industry on WHO's mandate.

Background

In March 2014 WHO issued a draft guideline suggesting dropping the recommended free sugar intake from a maximum of 10% of total energy intake to 5%. See the WHO Media Release from March 2014 which announced the draft guideline (here). This suggestion remained in the final version of the guidelines which were formally published (here) on 4 March 2015.

On the first day of WHO's Executive Board meeting (EB136, from 26 January 2015) a motion from Italy was announced proposing a supplementary item on the agenda aiming to open up WHO's guidelines development processes to interference by member states. See EB136/1 Add.1. The issue was postponed to EB137.

The Italian motivation highlights the guidelines which will need to be developed by way of follow up to the ICN2 (see PHM comment on Item 13.1 at at WHA68) and was particularly critical of the delay in posting EB136/8, " less than one month before the beginning of the Executive Board and when the agenda had already been circulated". This is an extraordinary attack on Secretariat staff. The Conference finished on the 21 November 2914 and the Secretariat produced and translated the report (as required under EB134(2)) by December 30.

The essence of the Italian proposal is that WHO's guidelines protocols (Handbook 2012) "*should be reviewed and updated in order to take into account a different international commitment by stakeholders, in particular Member States, to make them more reliable by increasing the accountability and transparency of the Organization* …".

While it is true that the Handbook does not require the participation of “Member states and other stakeholders” in guidelines development the guideline in question was exposed for public consultation for a year before the finalised guideline was published. The draft guideline suggesting the dropping the recommended free sugar intake from max of 10% of total energy intake to 5% was published and announced in a press release on 5 March 2014 (here) and the finalised guideline was formally published 4 March 2015 here.

It is not clear what the Italian motivation means by “a different international commitment” nor what additional involvement of ‘stakeholders’ in guidelines development is envisaged. It could involve a requirement for a formal approval by one of the governing bodies before the draft could be promulgated as a formal finalised guideline. To suggest that the involvement of ‘other stakeholders’ in the process needs to be strengthened, above and beyond a year of public exposure/consultation, implies a more direct involvement of industry stakeholders in the deliberations leading to the draft and in evaluating consultation feedback.

While the Italian motivation for the discussion at the EB does not mention the sugar guideline the Under-secretary for Health, Vito De Filippo subsequently explained the Italian decision, claiming that ‘sugar is an essential nutrient’ and argued that reducing sugar intake as a proportion of total caloric intake to 5% was ‘overly restrictive’. (Mr De Filippo did not mention that Italy is a major sugar producer (here); nor did he mention that Italy is host to the world’s largest chocolate producer, Ferrero, owned by Italy’s richest man.)

The world faces an epidemic of NCDs. The scientific evidence is that excessive sugar intake plays a major role in obesity, diabetes, heart disease, caries and other high burden conditions. In its comment on the WHO guidelines, the European Public Health Association pointed to the forthcoming deregulation of the sugar beet industry in Europe leading to increased production and reduced prices which will flow on to cheaper junk food, further driving the rise in NCDs, obesity and overweight, and heart disease. See also the extensive commentary in support of the WHO guidelines by Action on Sugar.

The sugar industry has form when it comes to interfering in national and international policy formation. They seek to buy the researchers, to buy the regulators, and to buy their way into trade negotiations. See four part series of articles by Jonathan Gornall in BMJ earlier this year: 1, 2, 3, 4.

The processes of setting WHO guidelines has carefully guarded against commercial interference. The Italian motion at the WHO’s Executive Board argued that the process of developing WHO guidelines should include opportunities for the ‘adequate involvement’ of Member States (of the WHO) ‘and other stakeholders’ in the development of guidelines. It seems that the motion seeks to make space for the sugar industry to be ‘involved’ in guidelines development. This is a direct attack on a fundamental pillar of WHO integrity.

This is not to say that the WHO guideline reflects a universal scientific consensus. The Canadian Centre for Science in the Public Interest (CSPI) was critical of the guidelines development group for conceiving the guideline around the concept of ‘total sugars’ which

includes fruit sugars as well as 'added sugars', sugars added in production. The CSPI argued that the focus of the guideline should be on sugar added in production (which is the health threat) and there should be no suggestion that consumption of sugar-containing fruit and vegetables should be limited.

Interestingly, this argument corresponds to radical new dietary guidelines developed in Brazil. These use a new classification system based not on food groups, but on the nature, purpose and extent of food processing. There are three kinds of processing, the argument goes. The first and oldest is minimal processing, which does not alter the food, such as methods of preservation like drying. The second adds oils or sugar or salt so that foods are modified – preserved, but less healthy. The third, ultra-processing, became the norm as from the 1980s when global corporations mined wonder-foods such as corn for a welter of chemical ingredients and mixed these up with an array of artificial factory-made food-like substances that added colour, flavour, mouth-feel, shelf-life, and extreme convenience. Just as important – and this is where the new classification method confronts transnational corporations – ultra-processed products are rejected because their 'means of production, distribution, marketing, and consumption damage culture, social life, and the environment'.

PHM Comment

There is scope for legitimate debate about the sugar guidelines but this should not be used to attack the guidelines process and further undermine the reputation of the WHO.

The forthcoming deregulation of sugar beet in Europe, leading to increased volumes and lower prices, underlines the urgency of introducing stringent sugar guidelines which assist public health authorities in addressing the challenges of cheap, globalised, ultra-processed, junk food.

In view of the global commitment to action around non-communicable diseases and associated risk factors it would be extraordinary if WHO were to weaken the integrity of its guidelines processes.

EB137/5 provides a useful summary of the development and core principles of WHO's guidelines process as it now operates. Para 18 summarises current priorities for further development including:

- a centralized, public, web-based repository of all guidelines and background documents;
- effective processes for public consultation during guideline development;
- further elaboration of methods for preparing "emergency guidelines", so that they are produced rapidly and rigorously;
- continuing training for all WHO staff, including those from regional and country offices, in guideline development methods; and,
- evaluation of the clarity and usefulness of WHO guidelines for Member States.

The WHO Handbook for Guideline Development (2012) deals extensively with COI issues facing members of the Expert Panels and Committees. It explicitly covers the potential for

conflict between interest in WHO's public health mandate and interests in "financial, academic and public positions". The need for robust protection of guideline development from such conflicts of interest in relation to individual experts needs to be re-affirmed.

The Handbook does not envisage the formal involvement of 'stakeholders' in the deliberation on guidelines or evaluation of consultation feedback. The Handbook does not consider a scenario in which MS are involved in the decision to finalise a draft guideline.

In para 6 EB137/5 states that:

> *Member States play an important role at two critical points in the guideline development process. First, though governing body resolutions, they provide direction and identify priorities for the selection of topics for WHO guideline development. Secondly, they have the sole authority to decide whether and how to implement WHO guidelines at a national or subnational level, and whether or not to include national or local values and preferences in any implementation programme.*

Neither the Handbook nor EB137/5 address the challenge of member states with COIs, such as Europe in relation to sugar or the USA in reference to the transnational food industry.

It is self-evident that MS will have, from time to time, conflicts of interest between broad public health objectives and other considerations. Indeed the International Sanitary Conferences, the progenitors of WHO, were explicitly convened to manage such conflicts of interest, in this case between trade and health.

There have been many instances where individual Member States have been involved in advancing or protecting the interests of particular corporations or industries and allowing these objectives to over-ride the public health objective as broadly defined in WHO's Constitution. (See PHM commentary on WHO's engagement with non-state actors in relation to WHA67 Item 11.2 here.)

Protecting the norm-setting function of WHO from being undermined by the interests of individual member states in outcomes other than public health, depends on the collective oversight of the Assembly and the Executive Board. It has been accepted to this point that protecting the integrity of WHO norm setting in this respect is best served by the exclusion of 'Member States and other stakeholders' from the deliberations which lead to draft guidelines and the evaluation of consultative input. This principle needs to be reaffirmed.

PHM calls for WHO's governing bodies to defend the integrity of the WHO's norm-setting functions:

- Keep the junk food industry out of the WHO guidelines process;
- Protect WHO's decision-making from member states who are subject to pressure from transnational corporations;
- Recognise that binding global regulation of the junk food industry is necessary to control NCDs.

Draft statement to the Board

Thanks Chair for the opportunity of addressing the Board on behalf of MMI, PHM and TWN (and perhaps IBFAN and many others) regarding the development and governance of WHO guidelines.

We welcome the formalisation of WHO's guideline on dietary free sugar published on 4th March 2015 and including the 'conditional' recommendation of a ceiling on free sugar intake of 5% of daily energy intake.

In view of the global commitment to action around non-communicable diseases and associated risk factors the publication of this guideline is timely and will assist public health authorities to address the challenges of cheap, high energy, ultra-processed, food products. The forthcoming deregulation of sugar beet in Europe, leading to increased volumes and lower prices, underlines the urgency of introducing stringent sugar guidelines.

We note the list of current priorities for further development of the guidelines process listed in para 18 of EB137/5: a web-based repository, guidelines for public consultation, methods for developing emergency guidelines, training for Secretariat staff in guidelines development and evaluation of the clarity and usefulness of WHO guidelines for Member States. We urge the Board to request the Secretariat to proceed as appropriate with these priorities.

We note with concern the proposal in EB136/1 Add.1 that the process of developing WHO guidelines should include opportunities for the 'adequate involvement' of Member States (of the WHO) 'and other stakeholders' in the development of guidelines.

We propose that consultation of draft guidelines with an appropriate consultation period provides appropriate opportunity for Member States and other stakeholders to contribute to guidelines development.

We would be particularly concerned if provision were to be made for the involvement of Member States and other stakeholders in deliberation on guidelines or evaluation of consultation feedback.

It is self-evident that MS will have, from time to time, conflicts of interest between broad public health objectives and other considerations. Indeed the International Sanitary Conferences were explicitly convened to manage such conflicts of interest, in this case between trade and health. There have been many documented instances in more recent times where individual Member States have been involved in advancing or protecting the interests of particular corporations or industries and allowing these objectives to override the public health objective as broadly defined in WHO's Constitution.

Protecting the norm-setting function of WHO from being undermined by the interests of individual member states in outcomes other than public health, depends on the collective

oversight of the Assembly and the Executive Board. It has been accepted to this point that protecting the integrity of WHO norm setting in this respect is best served by the exclusion of 'Member States and other stakeholders' from the deliberations which lead to draft guidelines and the evaluation of consultative input. We urge the Board to reaffirm this principle.

Notes of discussion at EB137

Official summary report of debate at second meeting here.

Document:

- EB137/5 - Report by Secrt
- Handbook 2012 – Secretariat Handbook on Guidelines Development
- PHM pre EB comment

At the request of a Member State, the Secretariat will submit a report to the Executive Board in order to enable members to review the process for the development, updating and approval of WHO guidelines

Chair: Get a copy and read it! I am going to request Secretariat to make it available to all EB members.

Gambia: congratulates the team, it's key and fundamental process, guidelines are used worldwide to guide everyone, the recommendations made by the guidelines particularly emphasis, the AFRO recognize that efficient guidelines is essential for sustainable development, the implement of WHO recommendation, we urge the WHO to continue in this manner. this long process might be seen as slow, we recognize the importance of sustainability.

Malta: Thank you chair. Thanks Secretariat for clear concise and focussed document. Credibility of an organisation depends on transparency of its work. Therefore, there must be no room for such comments (ill comments). The Book that Mme Chair has pointed to us states that protocols for producing a guidelines needs frequent updating. Any initiative that strengthens Organisation's credibility must be enhanced. However gains are never absolute: beware of burdening with demands that slow down the process and render all of this ineffective. Protect this technical process of guideline development from parasitic processes / other interests.

Kazakhstan: thank you we endorse the report and welcomes it, thank governance team, we have everything organized across the world, the widely distributed risk factors related to nutrition for example and other is very important we are willing to become involved in this work, and involve in scientific institutions and academia, what we need is wide evidence based database of information, sometimes we get conflict of interests, we have seen this before when we tried to raise taxes on tobacco, these parties have interest in taxes being as low as possible. "70 yrs ago during 2nd WW, not a single step backwards, protection of the motherland!" We will say the same here!

Kuwait: thank you on behalf of the EMR, we noted with appreciation the report, the report was prepared on the request of the EB, guidelines is one of the core functions of the WHO, WHO should keep its neutrality to keep it's leadership in public health, the guidelines have been revised to make sure no conflict of interests, further work is needed to support member states given more than half of the countries of the region and outside can be in emergency situations, we are sure that all the procedures used to reach these guidelines are scientifically sound, to ensure the highest technical standards neutrality and transparency are essential through all steps of reaching the guidelines.

UK: Not only do I align UK with Malta, but I fully agree. As a technical agency, quality of reports is key WHO work. Maximise transparency and keep free from inappropriate influence. In UK for ex, we are good at writing guidelines free of political and industrial influence.

Korea Republic: Thanks we thank DG for her leadership and commitment keeping WHO neutral and scientific, … In international health matters, one of key things thru which WHO fulfills its mandate is guidance. It would be best for this organisation to remain free of political and industrial influence in its setting of high level technical guidance.

Sweden: Evidence, relevance, transparency. .to ensure the guidelines are of highest quality full review and scan for conflict of interest. Appropriate management of conflict of interest. Areas for improvement: evaluation for impact of guidelines. Is this part of evaluation already referred to in para 8 & 11 in the report? no need for further action by the EB we are ready to adopt the report.

Saudi Arabia: Thank you Madam Chair. We appreciate efforts put into guidelines. Does not require participation of MS into development of guidelines at initial stage. We believe that the consultation of draft guidelines provides adequate contribution of MS to guideline development. We believe that DIRECT involvement of MS could lead to industry implications, and risk of conflict of interest. We need also methods for developing emergency guidelines.

South Africa: very briefly we want to align with AFRO and thank sec, we believe we are on the right track it's important that the guidelines continue to be developed according to sound rules, we are growing so there is room for learning and errors identification, we would like to thank the Secretariat along others.

France: Thank you chair, we also welcome excellent report by Secretariat, which are a core element of action and influence of WHO. In spirit of transparency, we welcome this discussion, the present system of development of WHO guidelines with all the improvements made seems perfectly adapted. We would like to recall how much we are attached to credibility of our organisation, and the scientific independence from any political commercial or other independence. we have had enough occasions over past few days (cf FENSA) to see that it is crucial to secure independence, we don't think it is necessary to talk further.

Pakistan: align with EMRO, appreciate the sec for comprehensive and focus, we believe the process is clear and evidence based, we not only need to protect the technical independence of the WHO we should be aggressive about it, this role should be done well, MS should have a

role in deciding the area and lead it's implementaion, I think in line with other MS we strongly urge the WHO to keep its neutrality above doubts.

China: Chinese delegation appreciates the Secr efforts including devt of guidelines and quality assurance. Attention to developing countries.

Argentina: Argentina takes note of report, very clear in procedures and challenges, applicable to different national and international situations, not only question of control but also legitimacy. Not the same in all case, depending on application. Thanks for high quality and scientific rigour. concerned of attempt of any actor to deviate standards of org. NSA to intervention in design of guidelines to be concern about. Produce solid evidence based criteria; encouraged to continue to protect guidelines process from corporate interests

Brasil: Thanks for report. We want to reiterate that the independence and avoidance of conflict of interest is what we are defending in the reform process.

Thailand: 15 years ago when I was still young… asked mentor please tell me in two sentences what WHO responsibilities, reply it's easy, if you want to know something about PH, WHO know everything but does nothing. Technical agency not implementing agency. Guidelines are core business of WHO; these recommendations are not good, negative implications for my country. evidence to produce guidelines.

(15 yrs ago I asked a Prof to tell me in 2 sentences what is WHO. He said, WHO knows everything but does nothing. It is a technical agency but not an implementation agency. Knowledge production is the core business of WHO. Sometimes I think the guideline is poor, but then I find that it's ok, I don't need to implement. Implementation is also an *art*, you can decide. Since then I worry less about the WHO guidelines and recommendations.)

Chair: I thought Thailand that you would finish with which agency knows nothing and implements everything! (Laughs)

Albania: It is clear concise, describes steps procedures etc of the process of development of guidelines. Developing guidelines is one of core functions of WHO. We note in report some safeguards, to guarantee scientific rigor, independence, manage conflict of interest etc. Therefore we are ready to note the report.

Chair: that concludes list of EB members. no DRC has the floor.

DRC: thank you chair, I wanted to thank Sec for this report which is so important, we align with Gambia, we stress importance of these guidelines, this guidelines is the skeleton that protects that organization from any external trials of influence, thanks sec.

Germany: brief interventions aligns itself with Sweden, thanks on report for topic.

Chair: I will buy you flowers, thank you very much (hahaha!)

Romania: Impact of these guidelines subject to national authority of states. We can discuss member states' management of WHO guidelines. This document also detects several areas still needing improvement. We support a yearly report from EB on progress of guidelines development. Guidelines are meant for clinical practice or public health policy. Clarity on scientific approach of developing them are the value added to their credibility and better applicability.

Italy: thanks EB for having opportunity to discuss, thanks Secr for document good starting point for further work; Italy regards this as essential; considers this item very relevant issue. Efforts made to guarantee independence and transparency made by Secretariat. Recent update for which they thank secretariat. Further improvement possible in guidelines process. More transparency needed, communication process to MS, report to be delivered, and yearly overview on GL for following year. Criteria for prioritization; important to understand general framework for guidelines. Will help in better responding to guidelines. Consultation of MS and other stakeholders necessary. Adopted guidelines have to be based on sound scientific evidence. Transparent approach adopted also by other international organisations will reinforce the WHO, process will include thorough knowledge of MS and stakeholders, this will marginalize low level of evidence. Dedicated website to be used. Thank all MS and Secr for collaboration on the issue and would like to come back on the issue; Mentions scientific evidence as in ICN2 ?!!

Croatia: Thanks secretariat. As many previous speakers stressed, the handbook and the report explain well the existing process of guidelines development. According to report, MS provide direction and provide priorities for selection of guidelines to be written. Especially we emphasize evaluation of clarity and usefulness of WHO guidelines for MS - applicability to national context, regional relevance, and clarity of language. This evaluation is crucial to continual guidelines improvement. We note the report.

Egypt: chair, Dr Chan, delegates, we appreciate and thank and love and all pink coloured flowers for the secretary, different international stakeholders involvement are being taken into account, we align with Italy, as WHO guidelines is developed responding to member states needs, we need to maximise the transparency, we need publishing all the procedures in a dedicated website.

Chair: Promises one handbook to all EB members as they are sticking to time and green traffic lights.

Turkey: thanks for report. Transparency and definition of clear roles and definitions is fundamental. Governance and efficiency. Support on submission to EB on guidelines,

Spain: Thank you chair. We thank Italy for having addressed this question, Spain has no taboos and here I refer to a phrase used by some delegation this morning. It is precisely the importance of this issue that is why we are focussing on it. We consider the ground situation to be adequate, but does not mean that we cannot improve it.

Switzerland: congratulations and thanks, preparing guidelines is fundamental of WHO mandate, it goes without said this should be done in total independence, we would like to congratulate WHO and encourage continuity of transparency, clarification and idea to share with you, we think it's useful for WHO to define clear criteria not emergent needs, EB 137 in paragraph 10. it is essential to determine ahead of time. The world places great deal of trust in this institution - in leading world global health. Needs to continue increasing transparency. Central public registry of all guidelines needed.

Japan: one question to ask the Secr it seems that everybody agrees on transparency. Two questions: how we involve the MS? Also, 2nd question: if we accept Italy's proposal of reporting back to EB, what kind of workload does this create??

USA: very brief everything has been said, endorse comments and suggestions made by Switzerland

Chair: still four more speakers. Let's finish the list so Secretariat can respond.

Norway: on behalf of Finland and Norway, thanks for report, including development of guidelines, setting norms and standards is a cornerstone of this org, this has to be based on sound scientific evidence, we welcome WHO effort to maximize transparency, this increases legitimacy of WHO. GL containing important recommendations. Need of transparency, but involving MS in the process will change the process into a battle ground. GL development should be independent of commercial and private interests, protect WHO from other external improper interests

Serbia: WHO guidelines are of utmost importance for MS and their institutions. Like Italy and other MS we highly appreciate independence and transparency in development of WHO guidelines. Important that all are based on clear scientific knowledge. Need to promote public health objectives as outlined in WHO constitution.

Netherlands: brief; fully aligns with statement made by Sweden.

Australia: thanks Secr for excellent report, we consider current methodology is sound. Independence and transparency of this process are paramount, vital for confidence of MS in WHO. Focus? Par 18 of the report

> *18. In the past seven years, the processes for development and quality assurance of guidelines produced by WHO have substantially improved. To maintain this trend will require further investment. Priorities for development currently include: a centralized, public, web-based repository of all guidelines and background documents; effective processes for public consultation during guideline development; further elaboration of methods for preparing "emergency guidelines", so that they are produced rapidly and rigorously; continuing training for all WHO staff, including those from regional and*

country offices, in guideline development methods; and, as noted above, evaluation of the clarity and usefulness of WHO guidelines for Member States.

Chair: Takes this opportunity to invite Dr. ?? / ADG to respond.

ADG/HIS: Thank you for your kind words of appreciation. Please note that we exclude Thailand from this acknowledgement!! Development of guidelines is one of core constitutional functions of WHO. Many countries do not have capacity to develop guidance and rely on WHO for this function. Ebola is an example of where WHO should be counted on to develop guidelines. Both the process and the quality and timeliness should be improved. Of the many good comments:

Emergency guidelines (Gambia): we are working on this actively.

To Sweden, on the evaluation of guidelines, WHO is currently looking at an eval of ALL documents we produce, and guidelines are included. Where we consult and where we don't consult. In terms of PAST of how MS were involved in guideline developments: sometimes MS nominated to expert panels - we want to make this process clear so there is no doubt as to how where when we consult. No problem to write a retrospective report - but in terms of prospective report: not everything is always planned long time in advance, and even outside of emergency, we need to change according to new evidences in public health and so we need to adapt (so prospective report would be difficult to make). We continue to work at constructive process. We are happy to discuss as suggested by UK about undue influences in developing of guidelines, and look forward to doing this.

Chair: thanks for response. can I suggest to note report. I am going to make a request, we are supposed to move to next item about management and financial matters.

Report noted; item concluded; Italy's requests quietly dropped