CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 7 **CX/NFSDU 18/40/8-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Proposed Draft NRV-NCD for EPA and DHA long chain omega-3 fatty acids Replies to CL 2018/66 - NFSDU

Comments of, Australia, Brazil, Canada, Colombia, Ecuador, Ghana, Iran, Jamaica, New Zealand, Norway, Peru, Philippines, Sri Lanka, United States of America, CRN, EU Speciality Food Ingredients, FoodDrinkEurope, GOED, IADSA

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/66-NFSDU issued in September 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENTS	
The country believes it is important to take account of the criteria of the World Health Organisation, which in 2003 established convincing associations for reduced risk of CVD include consumption of fruits (including berries) and vegetables, fish and fish oils (eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)), foods high in linoleic acid and potassium, as well as physical activity and low to moderate alcohol intake. Therefore, it suggests that it is essential to boost consumption of foods that contain EPA and DHA, especially as the leading causes of death are CVD and other non-communicable diseases. Ecuador agrees with the four planned recommendations, especially with recommendation 3 to continue using the terms "convincing, generally acceptable, probable, possible and insufficient", as defined in the Joint FAO/WHO Expert Consultation for the purpose of establishing NRV-NCD in line with the general principles. It also agrees with recommendation 4 to consider whether it is necessary to initiate a discussion about a review of the criteria for evidence that complies with the definition of convincing/generally accepted. References World Health Organisation. Diet, nutrition and the prevention of chronic diseases. WHO technical report series; 916. http://www.who.int/nutrition/publications/obesity/WHO_TRS_916_spa.pdf2003.	**Ecuador**
In the current context and after all the previous discussions and consultations, we support this recommendation.	**Iran**
The Philippines supports the proposed recommendations on the proposed Draft Nutrient Reference Value for diet-related non-communicable diseases (NRV-NCD for Eicosapentanoic acids (EPA) and docosahexanoic acids (DHA) Long Chain Omega-3 Fatty Acids based on currently available body of scientific evidencce.	**Philippines**
Sri Lanka agrees with the recommendations.	**Sri Lanka**
CRN having participated actively at the annual CCNFSDU meetings and via the eWG's request to submit substantive comments, is in agreement with the assessment by the chairs of the eWG, and notes that to date, there has been a lack of consensus by the CCNFSDU delegations. The contrasting perspectives as to the quality of the evidence available in support of the EPA and DHA effect on CHD mortality suggest that further discussion on the EPA and DHA long-chain fatty acid Nutrient Reference Value - Non-Communicable Disease (NRV-NCD) endpoints should be postponed until new evidence becomes available for review and incorporation into the assessment. Further, CRN does not think that Recommendation's 2, 3, or 4 should be addressed at the present time.	**Council for Responsible Nutrition**
IADSA welcomes Recommendation 1 to postpone further discussion on NRV-NCD on EPA/ DHA. It is clear that at present it is not possible to achieve consensus in the Committee. If the Committee decides to agree to Recommendation 1, IADSA considers that there is no need to address Recommendations 2, 3 and 4 at this present time.	**International Alliance of Dietary/Food Supplement Associations**
Recommendation 1: **Taking into consideration that no consensus has been reached on quality of evidence collected in support of the EPA and DHA effect on CHD mortality, to postpone further discussion of the NRV-NCD for EPA and DHA until new convincing/generally accepted evidence becomes available.**	
Australia supports the recommendation to postpone further discussion of the NRV-NCD for EPA & DHA. The Committee might also want to seek clarification from NUGAG on their definition of CHD death and cardiac death in the systematic review of RCTs In regards to the second part of the recommendation, as Australia does not support the discussion continuing, we therefore also do not see the need or value in seeking clarification from NUGAG at this time.	**Australia**

We consider that it is not reasonable to postpone further discussion of the NRV-NCD for EPA and DHA until new convincing/generally accepted evidence becomes available. In our opinion, the work should be finished at CCNFSDU40 since the NUGAG systematic reviews clearly states that there is no convincing or high level of evidence for the relationship between EPA/DHA intake and risk reduction of mortality/fatal CHD events, which is the health outcome under discussion to establish an NRV-NCD for EPA/DHA. So, the criterion 3.2.2.1 of General Principles was not met. Brazil also considers that it is not necessary to seek clarification from NUGAG. We note that during the CCNFSDU39 there was a side-event on evidence reviews on n-3 polyunsaturated fatty acids (PUFA) conducted by NUGAG where the clarifications have already been provided. Moreover, the systematic reviews of NUGAG have been published in Cochrane (Abdelhamid et al. 2018). In this matter, the article clearly states which were the types of outcomes measured.	**Brazil** .
Canada agrees that at this time there is not sufficient evidence to establish an NRV-NCD for EPA and DHA and that work on this item should be halted until new convincing/generally accepted evidence becomes available. The NUGAG report found that “There is no evidence that LCn3 fats alter risk of cardiovascular deaths in either primary or secondary prevention of CVD, and there is no suggestion that studies at lower risk of bias, those with longer duration or using higher doses offer more benefit.” The results were similarly unconvincing for benefits related to CHD deaths, CHD events, or stroke. Canada agrees that CCNFSDU should request clarification from NUGAG on their definition of CHD death and cardiac death in the systematic review of RCTs. It was unclear if sudden cardiac death was included in cardiac death. In addition, there was no rationale included to explain the way outcome data was chosen from relevant studies: “We included data reported as coronary deaths, or where these were not reported, IHD death, fatal MI or cardiac death (using the first of these available in any study).” It was unclear why all the various outcomes relevant to coronary heart disease death were not summed as was done for the outcome of cardiovascular death: “Where a trial did not report cardiovascular death, but deaths from individual cardiovascular causes these were summed.”	**Canada**
Colombia agrees and supports the recommendation.	**Colombia**
We support the recommendation to seek clarification from NUGAG to help attain consensus on matters.	**Ghana**
Jamaica is in agreement with seeking clarification from NUGAG on their definition of CHD death and cardiac death in the systematic reviews of RCTs. Further discussions can be postponed on the discussion of the NRV-NCD for EPA and DHA until new convincing generally accepted evidence becomes available. However, for consistency in the information available, Jamaica's position on the recommendation is that the NRV-NCD for EPA and DHA reflect the currently available evidence with provisions to revise as soon as more current, convincing, generally accepted evidence becomes available. Especially taking infants and young children into consideration since EPA and DHA are usually added to formulations targeting this vulnerable population.	**Jamaica**
New Zealand considers that the currently available evidence is not convincing/generally accepted in characterising the relationship between EPA and DHA and CHD mortality, as required by the first item of Section 3.2.2 of the Annex to CAC/GL 2-1985. As such, New Zealand agrees that discussion on the possible NRV-NCD for EPA and DHA is postponed/discontinued until new evidence becomes available.	**New Zealand**
We agree with the proposal to postpone further discussion of the NRV-NCD for EPA and DHA until new evidence is available.	**Norway**
Peru agrees that it is necessary to find more scientific evidence regarding the consumption of EPA/DHA and cardiovascular protection; however, it believes the information that is currently available is important. Given the lack of consensus regarding the quality of the evidence gathered to support the effect of EPA and DHA on mortality as a result of ischemic heart disease, we recommend postponing the debate on the NRV-NCD for EPA and DHA until new convincing/generally recognised evidence is available. We also recommend that the Committee ask NUGAG to clarify the definitions of death due to ischemic heart disease and death of cardiac origin used in the systematic review of the randomized clinical trials. RESPONSE:	**Peru**

Peru supports the recommendation to postpone the debate/discussion on this topic. However, it believes that the available scientific evidence is important to support the adoption of the NRV-NCD for EPA and DHA. Peru also recommends attempting to clarify the definitions of death due to ischemic heart disease and death of cardiac origin used in the systematic review of the randomized clinical trials.	
Though the Philippines is supportive of the proposed NRV-NCD for EPA and DHA Long Chain Omega-3 Fatty Acids at 250 mg based on collected scientific evidence when this new work was introduced, we are in agreement with the following recommendations with modification:	**Philippines**
We are of the opinion that if the WHO Nutrition Guidance Advisory Group RCT reviews found no convincing evidence for a causal relationship between EPA and DHA and CHD event/CHD mortality, it is premature to consider establishing NRV-NCD for EPA and DHA at this point. Even the EWG did not reach consensus whether the available evidence was sufficient to establish NRV-NCD for these fatty acids. We believe that it is prudent to hold the discussion until new convincing/generally accepted evidence is available. It is relevant to continue to seek clarification on NUGAG's definition of CHD death and cardiac death in the systematic reviews of RCT.	**Philippines**
The USA supports the recommendation to cease discussion of the NRV-NCD for EPA and DHA. The USA would support further discussion if new evidence that impacts the totality of evidence becomes available. The USA notes the methods section of the published review of RCTs (Abdelhamid et al. Omega-3 fatty acids for the primary and secondary prevention of cardiovascular disease. Cochrane Database of Systematic Reviews 2018, Issue 7. Art. No.: CD003177) define CHD mortality as the first of the following list reported: coronary death, ischaemic heart disease (IHD) death, fatal MI, cardiac death. Authors reported that cardiac death was used only when no other outcomes in this category were available, and explained that they conducted a sensitivity analysis that omitted cardiac death because the outcome potentially includes other causes of death in addition to CHD, such as cardiomyopathies and congenital and valvular heart diseases.	**USA**
EU Specialty Food Ingredients supports Recommendation 1 to postpone further discussion on the NRV-NCD for EPA and DHA until new convincing/ generally accepted evidence becomes available.	**EU Specialty Food Ingredients**
In the current context and after all the previous discussions and consultations, we support this recommendation.	**FoodDrinkEurope**
GOED supports the recommendation to postpone further discussion on this agenda item, despite our opinion that the totality of the available scientific evidence supports the adoption of an NRV-NCD for EPA+DHA for inclusion in the Guidelines on Nutrition Labelling (CAC/GL2-1985). It's clear from the consultations and discussions over the last three years that there is a lack of necessary consensus to adopt an NRV-NCD EPA+DHA. While GOED supports the postponement of further discussion, there should be a clear and reasonable definition of the threshold of evidence required to resume future discussion. To this end, GOED's support of this recommendation is tied to its support of Recommendation #4 – "To consider if discussion needs to be initiated on reviewing criteria of the evidence that meets definition of convincing/generally accepted." In addition, GOED suggests discussing the use of a variety of evidence grading terminologies in order to accommodate a wider range of reviews. GOED also supports seeking clarification from NUGAG on its definition of CHD death and cardiac death in the systematic review of RCTs published as "Omega-3 fatty acids for the primary and secondary prevention of cardiovascular disease ". It is GOED's opinion that among the potential reasons for the risk reduction for CHD deaths not reaching statistical significance is that relevant fatal CHD events were missed due to its definition of CHD mortality. Curiously, NUGAG adopted a prioritization scheme for CHD mortality in its review of RCTs that differed from its review of the observational evidence, presented at CCNFSDU39, but so far not published.	**GOED**

Recommendation 2 **To initiate new work on revision of the General Principles addressing the following: - Amending item 3.2.2 to account opinions of RASBs that considered not to set intake reference values for nutrients reviewed for establishing an NRV-NCD.**	
Australia is not clear on the intent of this recommendation. We have interpreted the recommendation to be related to the text below from paragraph 3.2.2 in the Annex to the General Principles. We understand the intent of the recommendation is to clarify that the full range of evidence available can be taken into account by the Committee when considering: if a nutrient might be suitable for a NRV-NCD and the basis for the NRV-NCD. This consideration would include evidence from RASBs that undertook an appropriate review process and did not set an NRV-NCD. At the moment the text is silent on this as it states: 3.2.2 Selection of Nutrients and Appropriate Basis for NRVs-NCD The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD: • Relevant convincing13/ generally accepted14 scientific evidence or the comparable level of evidence under the GRADE classification15 for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g. adults). • Public health importance of the nutrient-non-communicable disease risk relationship(s) among Codex member countries. Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to the general population. Daily intake reference values from FAO/WHO or recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake. Australia could support consideration of a minor amendment to the text to clarify. The amendment would clarify that: any recent review conducted by FAO/WHO or a RASB, which concluded that the evidence did not support setting a value, can be included in the consideration. We also note the absence of a value should not be because the RASB chose not to assess the evidence.	**Australia**
We would appreciate some clarification about the rationale used to propose a revision of the item 3.2.2 of the CAC/GL 2-1985 “Annex - General Principles for Establishing Nutrient Reference Values for The General Population” In this regard, we consider that the item 3.2.2 of the General Principles do not preclude accounting the opinion of RASBs which had not find sufficient evidence to set intake reference values for nutrients reviewed for establishing a NRV-NCD. Those opinions should be considered as an indication that it is not possible to set a quantitative NRV-NCD for the nutrient in accordance with the General Principles. Brazil also highlights that the criteria set in the Annex to CAC/GL 2-1985 have already been applied by CCNFSDU to set NRV-NCD for sodium, potassium and saturated fats. Therefore, we do not consider it appropriate to reopen the discussion on the criteria for establishing NRV-NCD.	**Brazil**
Canada agrees that CCNFSDU should consider if new work should be initiated on revision of the General Principles to amend item 3.2.2 to take into account the opinions of RASBs that did not set intake reference values for nutrients reviewed with the purpose of establishing an NRV-NCD. We agree that those RASBs that did not find sufficient evidence to establish a recommended daily intake for EPA and DHA provided a rationale for their conclusions which should not be disregarded in the NRV-NCD assessment.	**Canada**
Yes, Colombia supports the proposal to take into account the opinions of the recognized competent scientific bodies that do not establish intake values for EPA / DHA for definition of the NRV-NCD for EPA/DHA, under the consideration that impartiality must be guaranteed of the technical discussion and try to have all the scientific evidence available.	**Colombia**
We support the recommendation	**Ghana**
We support this recommendation: Indeed, all results including inconclusive evidence have to be taken into account to decide on	**Iran**

whether to establish an NRV-NCD.	
Jamaica is in agreement with initiating new work on revision of the General Principles addressing the amendment of item 3.2.2.	**Jamaica**
New Zealand does not support amending the General Principles specifically Section 3.2.2. of the Annex. New Zealand strongly supports the consideration of recognised authoritative scientific bodies (RASBs) that have conducted a primary evaluation of the evidence but not established a reference value to be considered in establishing both an NRV-R and an NRV-NCD. The text within Section 3.1 has previously been interpreted correctly to evaluate all relevant RASBs in their independent advice on daily intake reference values, regardless of whether a dietary intake reference value was then established. For example in the 2015 Session of CCNFSDU, the Committee agreed not to establish NRV-R for chromium or chloride due to the limited evidence and diverging RASB opinions on the establishment of a dietary intake value for those elements (REP16/NFDSDU). Furthermore, the text within Section 3.1 of the Annex should be read in conjunction with the definition of a RASB in Section 2 of the Annex. A RASB as used in these Principles refers to an organisation supported by a competent national and/or regional authority(ies) that provides independent, transparent, scientific and authoritative advice on daily intake reference values through primary evaluation of the scientific evidence upon request and for which advice is recognised through its use in the development of policies in one or more countries. There is no specification that the advice must result in a daily intake reference value, the results of the evaluation of scientific evidence could result in advice not to derive a daily intake reference value. This was the case of the Scientific Opinion on Dietary Reference Values for chromium, where it was concluded that setting an adequate intake level for chromium was not appropriate. New Zealand also notes that, the general principles on the selection of suitable data sources to establish an NRV (Section 3.1) clearly articulates that relevant daily intake reference values provided by FAO/WHO that are based on a recent review of the science should be the primary source in establishing Codex NRVs (CAC/GL 2-1985, Annex).	**New Zealand**
We believe that the principles as they are worded now in section 3.1, implies that only established daily intake reference values should be taken into consideration when establishing NRVs. In order to enable all relevant independent reviews of the science performed by RASBs to be taken into account, irrespective of whether the review concludes with establishing a daily reference value or not - we are of the opinion that a change in the wording of section 3.1 should be considered.	**Norway**
Peru agrees that a new revision of section 3.2.2 of the general principles should be initiated to establish the NRV-NCD, taking account of the associations already identified in previous studies in which reference values were not established. A new review of the general principles should address the following: • The amendment of section 3.2.2 so that, when establishing NRV-NCD, the opinions of the RASB that decided not to establish daily intake reference values for the revised nutrients are taken into account. RESPONSE: Peru agrees that a new revision of section 3.2.2 of the general principles should be initiated to establish the NRV-NCD, taking account of the associations already identified in previous studies in which reference values were not established. This includes a complete review of the available scientific evidence including studies that do not establish an intake reference value.	**Peru**
We support this recommendation to consider the opinions of other RASBs that did not set intake reference values for nutrients under consideration in establishing NV-NCD. It would be enlightening to consider their arguments which could be relevant in the establishment of NRV-NCD. However, we believe that the relevant change in the text should be made in section 3.1 of the General Principles, which is applicable to both NRV-R and NRV-NCD, instead of section 3.2.2, which is applicable only to NRV-NCD. The contention that those RASBs that did not find sufficient evidence to establish an NRV-NCD for EPA/DHA had rational argumentation in doing so, may very well apply to	**Philippines**

discussions of NRV-R. While we are discussing initiating new work on the revision of the General Principles, it would be practical and less time-consuming in the long run to recommend amending 3.1 allowing for the inclusion of RASBs that did not set reference intakes values, whether for nutrition labelling or for reduction of disease risk, in anticipation of future work on establishing NRVs-R and NRVs-NCD.	
The United States does not support new work on revision of the General Principles to amend item 3.2.2.2. The USA views criterion 3.2.2.2 to include systematically reviewed evidence from RASBs that consider quantitative intakes for a NRV-NCD as part of the totality of evidence, regardless of whether a dietary intake reference value was established or not.	**USA**
We support this recommendation: Indeed, all results - including inconclusive evidence - have to be taken into account to decide on whether to establish an NRV-NCD.	**FoodDrinkEurope**
GOED supports this recommendation, because it includes a review of the totality of the available scientific evidence and the omission of opinions of RASBs who did not establish reference intake values introduces bias into the process. Thus said, should consideration of reviews from RASBs in which a reference intake value was not established require amending item 3.2.2, then GOED supports such change. Since this issue is not specific to EPA+DHA, the work in this recommendation can be pursued regardless of the outcome of recommendation #1.	**GOED**
Recommendation 3 **To continue using the terms convincing, generally acceptable, probable, possible and insufficient as defined in the Joint FAO/WHO Expert Consultation1 for the purpose of establishing NRV-NCD according to the General Principles.**	
Australia notes that while the WHO has adopted the use of GRADE, the FAO has not. We support the agreement of the EPA/DHA NRV-NCD electronic working group (eWG) that the CCNFSDU should continue to use the terms convincing, generally acceptable, probable, possible and insufficient as defined in the 2002 Joint FAO/WHO Expert Consultation. We also re-iterate that we do not support the proposal to use the GRADE classification only as limiting to GRADE may exclude several current and future high-quality reviews prepared by certain RASBs from being considered. We note the eWG agreement that the current wording of the first criterion in 3.2.2 of the General Principles allows for the use of both the convincing-insufficient approach as well as the GRADE classification, and both should be used where appropriate.	**Australia**
We support continuing using the terms convincing/ generally accepted or the comparable level of evidence under the GRADE classification as stated in item 3.2.2 of CAC/GL 2-1985 (Annex - General Principles for Establishing Nutrient Reference Values for The General Population).	**Brazil**
Canada agrees that it is appropriate to continue using the terms convincing, generally acceptable, probable, possible and insufficient as defined in the Joint FAO/WHO Expert Consultation for the purpose of establishing NRV-NCD according to the General Principles.	**Canada**
Colombia agrees to continue with the use of the terms "convincing", "generally recognized", "probable", "possible" and "insufficient" defined in the joint FAO / WHO expert consultation, and suggests that clarity be these terms, as opposed to the equivalence of the degrees of evidence suggested by the Grading of Recommendations, Assessment, Development and Evaluation -GRADE model. In the GRADE system, the quality of the evidence is classified as high, moderate, low and very low. The strength of the recommendations is based not only on the quality of the evidence, but on a series of factors such as the balance between risks and benefits, the values and preferences of patients and professionals, and the consumption of resources or costs.	**Colombia**
We support the recommendation.	**Ghana**
For the time being, it would be probably better to keep the current terms ‘convincing, generally acceptable, probable, possible and insufficient’ as defined in the Joint FAO/WHO Expert Consultation for the purpose of establishing NRV-NCD according to the General	**Iran**

Principles, waiting for clearer conclusions on the best methodology to finally adopt. Experts should look at all the different previous documents, the GRADE method and the previous method, understand which publications should be excluded/included based on GRADE methodology, to be able to conclude.	
Jamaica is in agreement with this recommendation.	**Jamaica**
New Zealand supports the current drafting of 3.2.2 and no revisions are deemed necessary.	**New Zealand**
We consider it important that the General principles continue to refer to both systems for evaluating scientific strength of evidence. Consequently, we support to continue using the terms "convincing, generally acceptable, probable, possible and insufficient" as defined in the Joint FAO/WHO Expert Consultation 2003, for the purpose of establishing NRV-NCDs.	**Norway**
Peru does not believe it is necessary to discard the studies that have already been conducted without GRADE; however, it would be advisable to standardise the GRADE rating in the new studies.	**Peru**
Peru supports the recommendation, as the use of "convincing", "generally recognised", "probable", "possible" and "insufficient" is acceptable for studies that did not use the GRADE system during their deliberations, but the exclusive use of GRADE may be restrictive and does not take account of studies by other RASB that contributed to the totality of the available scientific evidence.	**Peru**
To continue using the terms relevant/convincing/generally accepted, scientific evidence or the comparable level of evidence under the GRADE classification, and both should be used where appropriate, for the purpose of establishing NRV-NCD in the General Principles.~~*convincing, generally acceptable, probable, possible and insufficient* as defined in the Joint FAO/WHO Expert Consultation.[1] for the purpose of establishing NRV-NCD according to the General Principles.~~ The Philippines still prefers to use the terms convincing/generally acceptable, probable. Possible and insufficient as defined in the Joint FAO/WHO Expert Consultation for the purposes of establishing NRV-NCD according to General Principles. These terms have been consistently used in other Codex documents (e.g. Codex Guidelines on Health and Nutrition Claims). Further, there maybegray areas on level of evidence which are considered as convincing in the new GRADE Classification of WHO. Other scientific evidence that did not use the GRADE classification should also be considered. However, we propose that the statement be revised as follows: • To continue using the terms relevant/convincing/generally accepted, scientific evidence or the comparable level of evidence under the GRADE classification, and both should be used where appropriate, for the purpose of establishing NRV-NCD in the General Principles Section 3.2.2 of the General Principles prescribes the use of both convincing,insufficient approach and the GRADE classification in evaluating the strength of evidence in the selection of nutrients for the establishment of NRVs-NCD. The recommendation, in its present form, implies abandoning the use of GRADE classification.	**Philippines**
The United States supports the Chairs recommendation to continue to these terms. The United States notes that 3.2.2 as written provides for comparable level of evidence which allows for updates to the science of systematic review such as GRADE and recalls the Committee decision to advance the General Principles (REP13/NFSDU para 46-50).	**USA**
• Experts should look at all the different previous documents, the GRADE method and the previous method, understand which publications should be excluded/included based on GRADE methodology, to be able to conclude.• For the time being, it would be probably better to keep the current terms 'convincing, generally acceptable, probable, possible and insufficient' as defined in the Joint FAO/WHO Expert Consultation for the purpose of establishing NRV-NCD according to the General Principles, waiting for clearer conclusions on the best methodology to finally adopt.	**FoodDrinkEurope**
GOED supports this recommendation. The use of the criteria convincing, probable, possible and insufficient are acceptable for use, but the use of only GRADE-based descriptions is too restrictive in that it may eliminates the ability to consider reviews from other RASBs, who contribute to the totality of the available scientific evidence.	**GOED**

While GRADE provides a way to evaluate the strength of evidence for each type of study, it does not provide a good way to combine these assessments. In addition, GRADE ignores all other evidence, including the effect on biomarkers or plausible mechanistic explanations. The strength of GRADE over other systems is that it separates the strength of evidence from the strength of recommendation, and leaves these decisions to different groups of people, with different expertise. Focusing on only strength of evidence misses the point, and leaves the recommendations in the hands of data analysts instead of the public health experts and risk assessors, who are the ones with the necessary expertise to evaluate the balance between risks and benefits of any given intervention. Since this issue is not specific to EPA+DHA, the work in this recommendation can be pursued regardless of the outcome of recommendation #1.	
Recommendation 4 **To consider if discussion needs to be initiated on reviewing criteria of the evidence that meets definition of convincing/generally accepted.**	
Australia assumes this recommendation also applies to paragraph 3.2.2 and is based on suggestions from some eWG members that further discussion may be required to specify which level of evidence in the GRADE classification is comparable to the term convincing as defined in the 2002 Joint FAO/WHO Consultation. Australia does not support this recommendation. We agree with the view that this is outside the scope of the current work and terms of reference.	**Australia**
In our opinion, the level of evidence quality under the GRADE classification that corresponds to “relevant convincing/generally accepted scientific evidence” is high. As stated in CX/NFSDU 18/40/8, the eWG members have expressed their view that the evidence studied in the NUGAG systematic reviews for the relationship between EPA and DHA and CHD mortality (LOW to MODERATE under the GRADE classification) could not be considered as the relevant convincing/generally accepted scientific evidence or as the evidence of comparable level under the GRADE classification, as required to establish an NRV-NCD. So, we consider that it is not necessary to initiate a discussion on reviewing criteria of the evidence that meets definition of convincing/generally accepted.	**Brazil**
Canada does not believe that CCNFSDU needs to discuss this item further. Canada’s interpretation is that high quality evidence as per the GRADE approach is equivalent to “relevant convincing/generally accepted scientific evidence”.	**Canada**
Colombia agrees that this debate be opened against the criteria for reviewing the evidence that is part of the definition of "convincing / generally recognized", taking into account that: 1. The definition of "convincing / generally recognized" was adopted since the report of the international group of experts in 2003, it is considered necessary to update it. 2. These degrees of solidity of the evidence are based on those used by the Global Fund for Cancer Research, and although they were modified by the Expert Consultation, the starting point should be more specific in relation to NRV- ENT.	**Colombia**
We support the recommendation.	**Ghana**
We support the initiation of this discussion: It is very important to have a common understanding and full clarity on the criteria of evidence meeting the definition of “generally accepted” scientific evidence. . The GRADE system has of course to be considered in this discussion, but if the conclusion is that it is not the most appropriate one, a specific work on this aspect of the methodology has to be conducted.	**Iran**
It is always prudent to conduct revisions of established definitions to ensure they remain current. Against this background, Jamaica is not opposed to consideration being given for initiating discussions on reviewing criteria of the evidence that meets definition of convincing/generally accepted.	**Jamaica**

New Zealand does not consider this a priority at this time. This piece of work would be out of scope of this eWG and would need to be considered by the Committee as new work. It is our view that the current drafting of 3.2.2 allows the Committee to consider evidence using the GRADE classification system and requires it to be equivalent to relevant convincing/generally accepted scientific evidence. To date the Committee has been able to effectively conduct these assessments against the WHO Guidelines for sodium and potassium in the establishment of their relevant NRV-NCD, and has decided not to establish an NRV-NCD for EPA and DHA based on the NUGAG's assessment of the quality of evidence. In the future it may be appropriate to specify the levels of evidence under the GRADE classification that can be considered equivalent to convincing or generally accepted. However, it would be preferable to do this with an example that is being actively considered by the Committee. The Committee may need to consider not only the quality of evidence but also the classification of the strength of the recommendation as assigned by the WHO. Reference EFSA. Scientific Opinion on Dietary Reference Values for Chromium. EFSA Journal. 2014;12(10):3845	**New Zealand**
We agree to consider a further discussion in order to specify which level of evidence in the GRADE classification that is comparable to convincing/generally accepted.	**Norway**
Peru agrees that a debate should be initiated regarding the criteria for a review of the evidence to establish a clear balance between the definition of "convincing" and "generally recognised". It should be examined whether it is necessary to initiate a debate about the criteria for a review of the evidence regarding the definition of "convincing" and "generally recognised". RESPONSE: Peru supports the recommendation, as it is necessary to have a balance between the GRADE classification and other rating methods with the aim of being able to consider all of the available scientific evidence.	**Peru**
We are in agreement that discussion should be considered to review the criteria of evidence that meet the definition of convincing/generally accepted while waiting for new evidence on causal relationship between EPA and DHA and CHD In view of the implementation of both convincing-insufficient approach and the GRADE classification in evaluating scientific evidence in support of the NRV-NCD nutrient selection, it is imperative to clarify the definition of convincing/generally accepted evidence and the comparable level of evidence under the GRADE classification.	**Philippines**
The United States view is that the level of evidence quality is specified in 3.2.2 thus does not support further discussion at this time. The United States views the first criteria in 3.2.2 of 'Relevant convincing/ generally accepted scientific evidence' (WHO Technical Report Series 916 2002) as comparable to a 'High' level of evidence under the GRADE classification (WHO Handbook for Guideline Development 2nd ed.) for the relationship between a nutrient and noncommunicable disease risk. These terms both conceptually address the most rigorous quality of evidence from RCTs and observational studies by accounting for study limitations (e.g. subject dropout rate, duration, lack of blinding), inconsistency of results, indirectness of evidence, imprecision (e.g. due to limited size and events), and reporting bias (e.g. publication bias).	**USA**
We support the initiation of this discussion: it is very important to have a common understanding and full clarity on the criteria of evidence meeting the definition of "generally accepted" scientific evidence. The GRADE system has of course to be considered in this discussion, but if the conclusion is that it is not the most appropriate one, a specific work on this aspect of the methodology has to be conducted.	**FoodDrinkEurope**
GOED supports this recommendation as mentioned previously in its comment to The first item of Section 3.2.2 of the Annex to CAC/GL 2-1985 acknowledges and accommodates a range of evidence grading	**GOED**

methodologies by accepting “relevant convincing,” “generally accepted,” “or a comparable level of evidence under the GRADE classification.” Without accommodation of a variety of generally accepted evidence grading terminologies, only evidence evaluated using GRADE will ever enter deliberations. Given that GRADE has not been globally adopted by all relevant RASBs and does not reflect all elements of a cause and effect relationship, the restriction to only GRADE-based evaluations effectively eliminates consideration of any other RASB relevant evidence review and curtails an evaluation of the totality of the available scientific evidence. Since this issue is not specific to EPA+DHA, the work in this recommendation can be pursued regardless of the outcome of recommendation #1.	