

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 7

NFSDU/43 CRD14

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

Forty-third Session

Düsseldorf, Germany

7 – 10 March with report adoption by virtual mode on 15 March 2023

PRIORITIZATION MECHANISM / EMERGING ISSUES OR NEW WORK PROPOSALS

Comments by European Union, Malaysia, Mali, Niger, Nigeria, Republic of Korea, Vietnam, EUVEPRO, ENSA and IMACE, Fediol, Helen Keller International, IDF, IMACE, IPA, ISO

EUROPEAN UNION

The European Union and its Member States (EUMS) would like to thank Germany and Canada for preparing the Draft Guideline for the preliminary assessment to identify and prioritize new work for CCFNSDU.

General comments

The EUMS note that some committees have developed or are in the process of developing their own approach and tailored criteria for managing work priorities.

While the EUMS greatly appreciate the efforts of all committees engaging in work management enhancement processes, the EUMS feel that a more detailed overview of all existing procedures in committees and a centralised access to all existing prioritisation criteria and methodologies would be beneficial for Members wishing to propose new work that addresses their needs in Codex.

For that purpose, all prioritisation mechanisms and other work practices that have been developed on this issue should be collated in one single place. Such place could be the practical guidance for new work proposals that the Codex secretariat has been tasked to draft.¹

Specific comments

The draft guideline proposes that when assessing new work and trying to identify priorities, four basic criteria are taken into account. In addition to the four criteria proposed, the EUMS would like to see that consumers' interests are sufficiently protected and taken into account, therefore the EUMS propose the addition of one more criterion: "Impact on consumers' interest".

Furthermore, by the prioritization exercise the EUMS noted that new work proposals might eventually also negatively impact certain criterion, thus the EUMS recommend that introducing negative impacts in the decision tree should be considered.

MALAYSIA

Malaysia appreciates the good effort by Germany and Canada to facilitate discussion on the discussion paper on the Draft Guideline for the Preliminary Assessment and Identification of Work Priorities for CCFNSDU.

Generally, Malaysia agrees with the proposed revised draft guidelines and decision tree for the preliminary assessment and prioritization of new work proposals for CCFNSDU. However, Malaysia proposes that paragraph 9 to be given further consideration.

Paragraph 9

Malaysia would like to reiterate our opinion as in the 1st eWG (2022), that the requirement for the choice of the respective impact level (high, medium or low) should be accompanied by a detailed rationale and supported by **available scientific and validated data** to be rather rigid and may require validation by accredited organisations. We are of the opinion that it suffices for the respective impact level (high, medium or low) to be accompanied by a detailed rationale and supported by **available scientific and/or other appropriate data**.

¹ REP22/EXEC2, paragraph 118 (iii)

All pertinent references for these data should accompany the assessment and can be scrutinised by members. Malaysia therefore proposes changes in bold as follows:

9. The prioritization criteria (para. 6) should be addressed in a self-assessment as part of the new work proposal. The choice of the respective impact level (high, medium or low) should be accompanied by a detailed rationale and supported by available scientific and/or other ~~validated~~ **appropriate** data. Pertinent references should accompany the assessment.

MALI

Contexte

Le CCEXEC70 a recommandé que tous les comités du Codex élaborent une approche pour la gestion de leurs travaux (REP15/EXEC Para 22). Le CCEXEC75 a spécifiquement invité le CCNFSDU à prévoir un mécanisme de fixation des priorités afin de mieux gérer ses activités (REP18/EXEC2-Rev.1 Para 19(i)). Sur la base de cette orientation, le secrétariat du CCNFSDU a présenté, lors du CCNFSDU41, un document de travail consacré à ce mécanisme, lequel a été accepté par le Comité. Lors du CCNFSDU42, le Comité a créé un GTE chargé de réviser les directives provisoires pour l'évaluation préliminaire et l'identification des activités prioritaires afin de préparer une proposition de mécanisme révisée pour la fixation des priorités,

destinée à être utilisée à titre expérimental et qui sera présentée pour examen au CCNFSDU43. Le GTE a finalisé son travail et a élaboré une version provisoire des directives en vue de son examen par le CCNFSDU43.

Position: Le Mali est favorable à l'adoption de la version provisoire des directives relatives à l'évaluation préliminaire visant à identifier et à classer par ordre de priorité les nouveaux travaux du CCNFSDU, sous réserve des améliorations suivantes:

But: Supprimer le mot « suivant » et lire la déclaration comme suit: « La directive suivante est destinée à aider le comité du codex sur la nutrition et les aliments diététiques ou de régime (CCNFSDU) à identifier et à classer par ordre de priorité les nouveaux travauxParagraphe 6: Il convient de donner des explications sur la signification des termes « faible, moyen et élevé ». Pour cela, il faudrait se référer au paragraphe 9 pour obtenir des conseils.

Paragraphe 6: (impact du commerce): Remplacer le mot « entraves » dans la colonne pour plus d'informations par « obstacles » afin de respecter l'accord OMC/OTC qui reconnaît les normes Codex dans le commerce alimentaire international.

Paragraphe 6: (impact mondial): Il est indispensable de clarifier la description figurant dans la colonne des informations complémentaires afin d'éviter toute ambiguïté quant à son interprétation. Il est proposé que la déclaration se lise comme suit: « Dans quelle mesure la proposition peut-elle résoudre, atténuer, prévenir ou réduire de manière significative un problème mondial lié à la santé de la population cible, aux pratiques commerciales et à la sécurité alimentaire? »

NOUVELLES PROPOSITIONS DE TRAVAIL CX/NFSDU 23/43/7

Contexte

Le GTE qui travaille sur la version provisoire de la directive relative à l'évaluation préliminaire visant à identifier et à classer par ordre de priorité les nouveaux travaux à entreprendre par le CCNFSDU à l'issue du document, conformément aux directives du CCNFSDU42, a publié une lettre circulaire invitant les États membres à soumettre des propositions de nouveaux travaux en se servant de la version provisoire de la directive. Le Comité a reçu deux demandes concernant des propositions d'amendements à apporter au texte en vigueur du Codex et quatre nouvelles propositions de travaux à effectuer par le Comité.

Position: Le Mali est favorable aux nouveaux travaux tels qu'ils ont été soumis au Comité.

Justification: Les États membres partis ont soumis un document de projet détaillé, un document de travail et une auto-évaluation, conformément aux instructions données dans version provisoire des directives pour l'évaluation préliminaire visant à identifier et à classer par ordre de priorité les nouveaux travaux du CCNFSDU.

NIGER

Contexte

Le CCEXEC70 a recommandé que tous les comités du Codex élaborent une approche pour la gestion de leurs travaux (REP15/EXEC Para 22). Le CCEXEC75 a spécifiquement invité le CCNFSDU à prévoir un mécanisme de fixation des priorités afin de mieux gérer ses activités (REP18/EXEC2-Rev.1 Para 19(i)). Sur la base de cette orientation, le secrétariat du CCNFSDU a présenté, lors du CCNFSDU41, un document de travail consacré à ce mécanisme, lequel a été accepté par le Comité. Lors du CCNFSDU42, le Comité a créé

un GTE chargé de réviser les directives provisoires pour l'évaluation préliminaire et l'identification des activités prioritaires afin de préparer une proposition de mécanisme révisée pour la fixation des priorités, destinée à être utilisée à titre expérimental et qui sera présentée pour examen au CCNFSDU43. Le GTE a finalisé son travail et a élaboré une version provisoire des directives en vue de son examen par le CCNFSDU43.

Position : Le Niger est favorable à l'adoption de la version provisoire des directives relatives à l'évaluation préliminaire visant à identifier et à classer par ordre de priorité les nouveaux travaux du CCNFSDU, sous réserve des améliorations suivantes :

But : Supprimer le mot « suivant » et lire la déclaration comme suit : « La directive suivante est destinée à aider le comité du codex sur la nutrition et les aliments diététiques ou de régime (CCNFSDU) à identifier et à classer par ordre de priorité les nouveaux travaux ».

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Paragraphe 6 : (impact mondial) : Il est indispensable de clarifier la description figurant dans la colonne des informations complémentaires afin d'éviter toute ambiguïté quant à son interprétation. Il est proposé que la déclaration se lise comme suit : « Dans quelle mesure la proposition peut-elle résoudre, atténuer, prévenir ou réduire de manière significative un problème mondial lié à la santé de la population cible, aux pratiques commerciales et à la sécurité alimentaire ? »

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Position : Le Niger est favorable aux nouveaux travaux tels qu'ils ont été soumis au Comité.

Justification : Les États membres partis ont soumis un document de projet détaillé, un document de travail et une auto-évaluation, conformément aux instructions données dans version provisoire des lignes directrices pour l'évaluation préliminaire visant à identifier et à classer par ordre de priorité les nouveaux travaux du CCNFSDU.

NIGERIA

Background CCNFSDU in response to the recommendation by CCEXEC to consider a prioritization mechanism to better manage its work established an EWG to revise the Draft guideline for the preliminary assessment and identification of work priorities. The EWG also prepare a Revised proposed prioritization mechanism for use on trial basis for consideration by CCNFSDU43.

As at 30 September 2022 six new work proposals were received in response to CL 2020/30-NFSDU.

Recommendation for Action by Nigerian Delegates

A physical working group will hold on Monday 6 March 2023 at same venue to consider the report of the EWG on the prioritization mechanism to better manage the work of CCNFSDU and do a case-by-case review of all new work proposals submitted in response to CL 2020/30- NFSDU. It will also consider a discussion paper on General guidelines on nutrient profiles. The report of the PWG will be considered under this item and will be made available as a CRD prior to the session.

Comment: Nigeria supports the six new work proposals presented.

Justification: Comprehensive project documents/ new work proposals have been submitted following discussion papers by the concerned member

REPUBLIC OF KOREA

Proposal 2.2: The Republic of Korea agrees with the need for new work on the development of guidance and general principles to manage the internationally consistent nutritional composition of alternative protein foods derived from plants, bacteria, insects, and fungi.

The Republic of Korea agrees with the Draft Guideline for the preliminary assessment to identify and prioritize new work for CCNFSDU.

VIETNAM

1. Regarding to the new work proposals in light of the prioritization mechanism, Vietnam supposes that development of harmonized probiotic guideline for use in food and food supplements is necessary to ensure and sustain quality probiotic products on a global scale. So Vietnam proposes the Committee to consider and support the new work proposal of this issue to submitted for approval by CAC 46.
2. Regarding to the new work proposal for Guidelines including General principles for the nutritional composition of foods and beverages made from plant-based and other alternative protein sources, Vietnam in the opinion that due to the lack of consistent policies for plant-based and other alternative protein sources food and beverages may have impact to trade and public health. Having the nutritional composition guidelines for these products is necessary at that time. So Vietnam supports to approve the new work proposal of this issue.

EUVEPRO, ENSA AND IMACE

EUVEPRO (European Vegetable Protein Association), ENSA (European Plant-Based Foods Association) and IMACE (European Margarine Association) welcome the increased inclusion of plant-based foods and beverages in **balanced diets comprising all key nutrients**, as encouraged by dietary guidance recommendations around the world, and support high quality and safety standards for these products. Nonetheless, it is essential to establish a clear understanding of what falls under the categories of plant-based and animal-derived foods and beverages before developing any Guidelines including general principles for the nutritional composition of food and beverages made from plant-based and other alternative protein sources (proposal 2.2 from the United States of America and Canada, [CX/NFSDU 23/43/7](#)).

- **Plant-based foods definition**

The lack of a universally accepted definition can possibly mislead consumers and manufacturers. As a step towards addressing this lack of harmonised definition, the [ISO plant-based foods working group](#) is currently developing a definition for plant-based foods and criteria for plant-based foods labelling and claims. The ISO standard for plant-based foods will be published in 2024.

- **Nutritional equivalence with animal products**

The proposal aims to define nutritional composition criteria for plant-based foods based on “nutritional equivalence” with the corresponding animal-derived foods. However, in order to define nutritional criteria for plant-based alternatives to animal protein foods and beverages, it is first necessary that the composition and properties of the corresponding animal-derived foods are also defined in a standard, including nutrients of concern, so that it is clear what the plant-based foods are being compared to in a uniform and unambiguous manner. A **review of the current Codex Alimentarius commodity standards** should be conducted to identify gaps, and new work initiated to create the missing standards before nutritional composition guidelines can be developed for plant-based foods.

For instance, animal-derived burgers and meat sausages are all **lacking nutritional composition requirements or Codex Standards**. The Codex standard for Fermented Milks (CXS 243) does not include nutritional composition requirements for sugars, and the Codex standard for Cheddar (CXS 263) does not include nutritional composition requirements for protein levels. Plant-based alternatives of these products are widely produced, but without any nutritional composition criteria, there is no benchmark to compare the composition of the animal-derived and plant-based counterparts.

In addition, for plant-based foods and their animal-based counterparts to achieve true nutritional equivalence, this would include **nutrients of concern** as well as positive nutrients, which is not possible in some cases. In many jurisdictions around the world, foods are bound by law to contain less than 2g trans fat (from non-animal sources) per 100g fat, in line with the World Health Organization’s recommendation within its REPLACE Trans Fat Programme. In all cases, TFA from animal sources is exempted. It should be noted that dairy butter contains almost 3% trans fat and some meats contain up to 9% trans fat. Thus, the plant-based sector would not be allowed to achieve nutritional equivalence, as it would mean increasing trans fat levels above the legal limit.

- **Varied plant-based diets**

It is also key to highlight that plant-based foods comprise a wider range of products other than meat or dairy alternatives, thus they should not be limited to this classification. These foods are chosen by consumers for a variety of reasons, increasingly **environmental concerns** and their different nutritional profiles, often to be consumed alongside meat and dairy products.

Indeed, while many people are cutting back on their consumption of animal-derived products when embracing more plant-based diets, most consumers still consume animal products alongside plant-based products seeing these products as complementary rather than substitutes to animal products. According to a [2018 IPSOS survey](#), vegans account for 3% of the global population, while vegetarians and pescatarians account for 8%. The majority of the global population remains omnivorous or flexitarian, with 87% of people occasionally or regularly consuming both meat and dairy products.

Therefore, we recommend the proposal on the Guidelines including general principles for the nutritional composition of plant-based foods and beverages to be rescinded or ranked as low priority among the new Codex work proposals, on the basis of the prioritisation mechanism implemented to better manage the work of CCNFSDU:

1. Impact on the health of the target group

The proposal notes that most plant-based foods have lower **protein content** than their animal counterparts. Contrarily, the World Resources Institute Working Paper "[Shifting Diets for a Sustainable Food Future](#)" shows that total protein intakes in all markets surveyed exceed recommended intakes. This trend is especially visible in developed countries, with protein intakes almost doubling the required needs in the USA, Canada and Europe. The data also shows that for all markets, plant sources provide almost all required protein intake. For a significant portion of the Western population consuming a varied and plant-based balanced diet, the likelihood of protein deficiencies remains thus very low.

Moreover, concerns raised in the proposal about particular nutrients (e.g., sodium) are not unique to alternative proteins and are not best addressed through guidance for this subset of foods based on nutritional equivalence to animal proteins.

2. Impact on food safety

The impact on food safety of the increased consumption of plant-based foods and beverages was identified as low in the Canada-US proposal. Indeed, the alleged nutritional deficiencies outlined in the proposal do not meet the definition of food safety.

3. Impact on trade practices and global impact

While establishing global guidance for the nutritional composition of plant-based foods could lead to more harmonised international regulations, such guidelines could limit the diversity and innovation of plant-based food products, especially those developed by small and medium enterprises (SMEs). Indeed, continued innovation is the best way to address any nutritional shortcomings in alternative protein products, and premature nutrient composition guidance may impede future advancements and breakthroughs in this area.

Prescriptive nutritional guidelines may also not be appropriate for all populations and could contribute to a one-size-fits-all approach to nutrition that does not consider cultural, and socio-economic factors. In addition, the proposal would introduce heightened regulation for plant-based foods where such regulation does not exist for the meat and dairy counterparts they are compared to, which could constitute a technical barrier to trade under WTO rules. Requiring nutritional equivalence for plant-based foods and their animal-based counterparts further cements their status as "like products," meaning that unequal regulatory treatment (only introducing nutritional criteria for plant-based foods) is certainly a Technical Barrier to Trade.

Therefore, while harmonisation of international regulations is important, we must ensure that it does not come at the expense of diversity, innovation, and cultural considerations.

Key conclusions

- The plant-based food category currently lacks a universally accepted definition, so the scope of the proposal is unclear.
- Standards of Identity are required for all animal-derived foods to which it is intended to make comparisons. Currently, there are substantial gaps for animal-derived counterparts of popular plant-based foods.
- Animal-derived foods and plant-based foods are not nutritionally equivalent, either in terms of advantageous or disadvantageous nutrients, therefore aiming for nutritional equivalence would be inappropriate. Each have their place in a balanced diet.
- For a significant portion of the Western population consuming a varied and plant-based balanced diet, the likelihood of protein deficiencies remains thus very low. The nutritional guidelines will be in conflict with public health laws and contradict national dietary guidelines.
- Nutritional guidelines should not be a hurdle for innovation and development of new and diverse plant-based products that meet the varied needs and preferences of consumers.
- It is important to offer consumers a variety of plant-based products that cater to their individual needs and preferences, allowing them the freedom to choose what best suits them.

- Unequal regulatory treatment of “like products” constitutes a Technical Barrier to Trade.

FEDIOL

FEDIOL welcomes the overview of the new work proposals as prepared by Germany. FEDIOL would like to bring comments on the proposal for new work 2.3. on the discussion paper on general guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL), as brought up by Costa Rica (co-chaired by Paraguay, the EU and the United States) outlined as from page 47.

General comments:

As a member of the electronic group having worked on the file in the past years and as outlined in our responses to the questionnaire on the subject in 2020, FEDIOL welcomes the discussion paper on general guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL). FEDIOL believes that the overview prepared summarises well the feedback received through the questionnaire and provides a good way forward for next steps.

FEDIOL continues supporting the need for general guidelines on nutrient profiles that are based on sound scientific principles and on data that is robust and of good quality. FEDIOL trusts that general guidance as such would allow flexibility in application of FOPNL to align to local nutrition policies and to meet nutritional specificities in different regions and in different population groups. FEDIOL therefore fully concurs that *nutrient profiling should be based on generally accepted scientific evidence/recommendations on the relationship between diets, dietary patterns, nutrients, NCD risk factors, or other related public health endpoints*. FEDIOL further supports the need for any future guidelines to *include principles and additional guidance on how to establish thresholds and ranges based on scientific evidence as well as on how to establish an evidence-based definition for nutrient profiling*

In addition, FEDIOL considers that guidance on nutrient profiling should take account of nutrients with both “positive” and “negative” dietary and health associations, and not focus only on “negative” nutrients. Nutrient profile guidance must also address the specificities of single ingredient foods as well as composite food products. In this context, definitions of single ingredients vs. composite food products and of portion size would be useful.

FEDIOL therefore supports the setting-up of such a new work as proposed at the CCNFSDU 43 and remains available to contribute to the next steps of such a work.

HELEN KELLER INTERNATIONAL

2.3 General Guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL)

Helen Keller Intl does not support taking up the new proposed work on developing general guidelines to establish nutrient profiles for front-of-pack nutrition labelling (FOPNL).

Helen Keller Intl strongly believes that this work is outside the scope of the Committee and therefore does not recommend that the work continue. The justification for this opinion is as follows:

- This new proposed work on nutrient profiling is beyond the scope of Codex.

The work proposed expands beyond FOPNL to include application of nutrient profiling to other nutrition-related policy actions, such as marketing restrictions, school food environments and feeding, taxation and reformulation incentives. The scope of Codex (based on website) reads as follows: “*The Codex Alimentarius includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius includes provisions in respect of food hygiene, food additives, residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification.*” It is not clear how development of guidelines for nutrient profiling beyond food labelling falls within this scope, as CCFL has noted that no further work is needed from CCNFSDU around nutrient profiling as it relates to FOPNL. It is our belief that any guidance related to nutrient profiling should come from the normative agencies such as WHO and UNICEF and this is not the work of Codex.

- This new proposed work on nutrient profiling is beyond the scope of CCNFSDU.

The Draft Guideline for the Preliminary Assessment to Identify and Prioritize New Work for CCNFSDU (CX/NFSDU 23/43/8 – Appendix 1) states that “*Proposals for new work should be within the terms of reference of CCNFSDU*”. These terms of references include: a) *to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues; b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods; c) to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where*

necessary; d) to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion Codex standards, guidelines and related texts. The new work proposed on nutrient profiling does not a) study a nutrition problem, b) address the nutritional aspects of foods (nutrient profiling does not mandate any formulation of foods, but is a tool used to restrict/promote marketing of foods), c) pertain to foods for special dietary uses, or d) consider or amend or endorse specific nutrition aspects of foods.

In addition to the proposed work on nutrient profiling being beyond the scope of Codex/CCNFSDU, Helen Keller Intl notes the following additional concerns:

- This work is not necessary at this time. At CCFL46, the FOPNL guidelines were finalized. With this, the working group completed their response to the request from CCNFSDU39 for CCFL to consider how nutrient profiling could contribute to FOPNL. As CCFL's work on FOPNL has been completed, there is no requirement for CCNFSDU to work further on the topic of nutrient profiling. Nutrient profiling is a rapidly developing scientific field, and it would be too early for Codex to develop guidance that would quickly be outdated. For example, the proposal states: "*The guideline should include principles and additional guidance for how to establish thresholds and ranges for those components based on scientific evidence. However, the guideline should not establish specific thresholds.*" As evidence around many nutrient profiling models is just beginning to be generated, it is not yet possible to establish principles for various aspects of nutrient profile models based on a systematic review of the evidence. Additionally, the proposal states: "*The guideline should include principles to evaluate and determine effectiveness after implementation against the public health objective(s) for the nutrient profiling model.*" What is implemented is the policy action, for which nutrient profiling is a tool, and not the nutrient profiling itself. These policy actions (e.g. marketing restrictions, school feeding, reformulation, etc) can be effective or not effective based on a range of factors, and so these guidelines would be usable for establishing the 'effectiveness' specifically of nutrient profiling.
- Nutrient profiling must be based on food-based dietary guidelines and these vary significantly from country to country. Therefore, developing global nutrient profiling guidelines will be difficult and should happen at the national level.
- CCNFSDU currently has an extremely challenging workload with multiple high-priority proposals for new work. Given CCNFSDU's limited resources and heavy workload, only new work of the highest priority should be undertaken.

Should the Committee decide to go forward with this work, Helen Keller Intl will provide detailed comments on each element of the proposal.

INTERNATIONAL DAIRY FEDERATION (IDF)

IDF reiterates its comments made in the different discussions at Codex level, either at CCFL or CCNFSDU that any risk management options related to trans fatty acids be considered in the context of reduction of ***industrially produced trans fatty acids***, not all sources of trans fatty acids.

IDF therefore does not consider appropriate to open this new work item on establishing a Nutrient Reference Value (NRV-NCD) for total Trans-Fatty Acids (TFAs), as:

1. This does not distinguish ruminant TFAs from industrially produced TFAs and therefore is not in line with the World Health Organisation (WHO)'s goal to eliminate industrially produced TFAs only from the global food supply.
2. This could inadvertently mislead consumers as to the overall healthfulness of a product and discourage consumption of nutrient dense whole foods such as dairy, which contains inherent ruminant TFAs.

Such measure is not in line with the World Health Organisation (WHO)'s goal to eliminate industrially produced TFAs only from the global food supply:

We continue to point out that WHO REPLACE initiative is targeted to industrially produced trans fatty acids as noted by the WHO representative during the CCNFSDU41 (paragraph 128 – "... As also reiterated in Agenda item 3, the elimination of industrially produced TFA by 2023 was WHO's target and scaled-up actions had been undertaken by WHO and its partners since last year") as well as CCNFSDU 42 (paragraph 9 " ... the accelerated actions to eliminate industrially produced trans fatty acids (TFAs)")

We therefore broadly support measures that aim to continue to specifically reduce intake of industrially produced TFAs (iTFA) in the diet in line with the World Health Organisation (WHO)'s priorities. We believe in measures targeting the main source of industrial TFAs, such as declaring the presence of Partially Hydrogenated Oils (PHOs) in the list of ingredients or ensuring that vegetable oil suppliers are applying best practices to reduce iTFA formation in their products.

An NRV-NCD for total TFA could inadvertently mislead consumers as to the overall healthfulness of a product and discourage consumption of nutrient dense whole foods:

Dairy foods, which contains inherent levels of rTFA and can thus not be reformulated at will, play a key role in human nutrition, especially in childhood (FAO, 2013). Intake of full-fat milk and dairy products is either inversely or not associated with heart disease and stroke (Alexander et al 2016; Qin et al 2015), as well as several cardiovascular risk factors such as blood pressure (Soedamah-Muthu et al 2012), obesity (Rautiainen et al 2016; Lu et al 2016), type 2 diabetes (Drehmer et al 2015; Aune et al 2013), and risk of metabolic syndrome (Chen et al 2015; Kim et al 2015). In addition sufficient dairy foods intake is a readily available intervention that reduces the risk of falls and fractures commonly occurring in older adults (Iuliano et al., 2021), consumption of milk decreases malnutrition, particularly in combating stunting and thinness, and it also has a positive impact on cognitive skills in school children (R. Rana et al., 2022), and higher intakes of total dairy are positively associated with 9– 57% lower risk of inadequate or deficient levels of RBC folate, serum vitamin B6 and serum B12 (Cifelli, Agarwal, et al., 2022). Indeed, milk, cheese and yogurt were found among the top foods that should be prioritised to fill common micronutrients gaps and reduce undernutrition in the current worrying situation of global widespread micronutrient deficiency, where diets are known to be inadequate, particularly in iron, zinc, folate, vitamin A, calcium, and vitamin B12 (Beal & Ortenzi, 2022).

Setting a NRV-NCD without differentiating the source of the TFA will potentially lead to poorer diets. This may result in discouraging consumers from eating dairy products. Milk and dairy foods play a key role in healthy human nutrition and development throughout life, and especially in childhood.

Trans fatty acids (TFA) are a specific type of unsaturated fatty acids. There are two dietary sources of TFA. Industrially produced TFA are formed during the hardening process, called partial hydrogenation of vegetable oils. They are found in various products including spreads, baked goods, fried food and frying fats. Naturally occurring TFA - also referred to as ruminant TFA - are produced by ruminants such as cows and are therefore naturally present in ruminant meat (e.g. beef and lamb) and milk. In dairy products, natural TFA are part of the milk fat.

These sources have different distribution of trans 18:1 fatty acids as show in figure 1. Emerging evidence shows that the biological activities of industrial and ruminant TFA differ, and that certain ruminant TFA (such as rumenic, vaccenic and t-palmitoleic acids,...) may be associated with beneficial health effects in humans (Wang, 2013). For example, the findings of the meta-analysis of prospective cohort studies commissioned by WHO (de Souza, 2015) showed that “Ruminant trans-palmitoleic acid was inversely associated with type 2 diabetes”

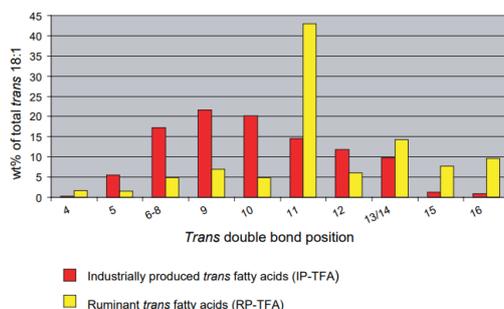


Figure 1: Isomeric distribution of trans-octadecenoic acids in industrially produced and ruminant trans fat (mean wt% of trans-18:1 fatty acids) (S Stender, 2008)

The detrimental effects of **industrial TFA** on heart health are well accepted:

- The FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition concluded in 2010: “There is convincing evidence that TFA from commercial partially hydrogenated vegetable oils (PHVO) increase CHD risk factors and CHD events – more so than had been thought in the past. There is also probable evidence of an increased risk of fatal CHD and sudden cardiac death in addition to an increased risk of metabolic syndrome components and diabetes.” (FAO, 2010)
- A 2015 systematic review and meta-analysis commissioned by WHO, reported: “Consistent with the findings of a previous meta-analysis of observational studies, our study [...] found that industrially produced, but not ruminant derived, trans fats are associated with risk of CHD...” (de Souza, 2015)
- A 2016 WHO Scientific update on TFA also confirmed: “The results of this meta-regression analysis show clearly and consistently that reducing intake of total or industrial TFA by replacing either with cis-MUFA or cis-PUFA, and to a lesser extent, carbohydrates, improves the lipid and lipoprotein profiles

towards reduced risk of CVD. The results on ruminant TFA studies were less conclusive...” (WHO, 2016)

Consumption of ruminant TFA at doses achievable by the diet alone has no adverse effect on CHD risk. (Uauy R et al 2009) (Gayet-Boyer C et al., 2014) (Kuhnt et al., 2015) (Pipoyan et al 2021) Milk and dairy products contain low amounts of natural TFA. Whole milk contains about 0.08 g of natural TFA/100g of product (i.e < 0.1%), butter contains about 2.6 g/100g (i.e < 3%). A ruminant-specific TFA, trans-palmitoleic acid, has been found to substantially reduce the risk of type 2 diabetes (Mozaffarian et al., 2010; de Souza et al., 2015).

As the intake of industrial TFA substantially decreased in the past decade, total TFA intake went down as well, while the absolute amount of natural TFA eaten from dairy and meat did not change. Stating that the current consumption of natural TFA has increased is misleading; the correct statement is that the relative contribution of natural TFA to the total TFA intake has become higher. Yet, the habitual intake of ruminant TFA is well below the maximum recommended intake of 1 En%.

Following the above outlined arguments we continue to strongly oppose to any proposal targeted to trans fatty acids that does not differentiate the source.

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- **The proposal conflicts with the existing Standards for dairy butter (CXS 279-1971), dairy spreads (CXS 253-2006), and for Fat Spreads and Blended Spreads (CXS 256-1999) due to scope.** In the case of fat spreads and plant-based alternatives to dairy butter, compositional requirements already exist for different products. Compositional requirements on fat content also already exist for the dairy counterparts (Dairy Butter and Dairy Spreads), but not such criteria exist concerning protein content or micronutrient content. All three Standards would have to be revised in order to achieve “nutritional equivalence.”

It should be noted that the 27th session of the Codex Committee on Fats and Oils considered and rejected a proposal to amend CXS256, including changes to requirements on fat quantity and quality. ([REP22/FO](#))

Proceeding with Proposal 2.2 of CX/NFSDU 23/43/7 would entail a revision of the Standard for Fat Spreads and Blended Spreads and redefining the different product categories within it. The scope of the proposal includes foods intended to fulfil the same role as dairy products (including margarines, which for many years, and by many people around the world are used interchangeably with dairy butter).

The proposal also assumes that in-scope products do not include animal-based components. The current Standard for Fat Spreads and Blended Spreads cannot accommodate the conflicted and confused approach that would arise if the proposal is adopted: the Standard includes products with no animal-based components and products with animal-based components, but there is no distinction between the two. As per the Codex Standard, Fat Spreads can contain anything between 0% and 3% milk fat content. The proposal would only target products with 0% milk fat content, meaning that a new subcategory would have to be defined within the Standard.
- **Some plant-based foods already have Codex Standards with compositional requirements.** In the case of fat spreads and plant-based alternatives to dairy butter, compositional requirements already exist within CXS 256 – dictating fat content for different products. Creating new requirements would, again, entail

an overhaul of the existing Standards, otherwise risking creating of redundant or conflicting requirements in a new standard.
- **No nutritional composition requirements for animal-based foods.** Defining nutritional criteria for plant-based foods on the basis of “nutritional equivalence” is not possible, as there are no corresponding

nutritional composition requirements for many of the nutrients identified as concerns in the proposal (e.g. Vitamins A, D, B12, heme-iron, zinc) for animal-based foods, and certainly not negative nutrients like trans fats. As such, there is no universally agreed, formal basis for such criteria. Before proceeding, the composition and properties of each of the corresponding animal-derived foods must also be defined in global Standards, including nutrients of concern, so that it is clear what the plant-based food is being compared to in a uniform and unambiguous manner. A review of current Codex Alimentarius commodity standards should be conducted to identify gaps, and new work initiated to create the missing standards before nutritional composition guidelines can be developed for plant-based foods that are supposed to be alternatives to animal-based foods.

- **“Nutritional equivalence” will either mean breaking WTO principles or breaking public health laws.** The Discussion Paper states that *“Generally, intakes of fibre, folate, magnesium, fat and saturated fat improve with increased consumption of plant-based foods, however there is also a reduction in the intakes of important essential nutrients such as protein, Vitamin A, Vitamin D, Vitamin B12, heme-iron and zinc.”* The Project Document then poses the question: *“Should the composition of these replacement products be based on the nutritional profile of the products they are replacing, in particular those nutrients in the animal-based food that are a significant contributor to meeting dietary adequacy of essential nutrients? Should plant-based and other alternative protein replacement foods be formulated to be nutritionally equivalent to the animal-based foods they are replacing? And, if so, for all nutrients? Or only essential nutrients?”*

Option 1: selective nutritional equivalence based on essential nutrients breaks WTO principles. If the proposal makes nutritional requirements only based on essential nutrients (e.g. Vitamins A, D, B12, heme-iron, zinc), then it **holds plant-based foods to a higher regulatory standard than their animal-derived counterparts**. Plant-based foods and their animal-based counterparts are “like products” (*de facto* if nutritional equivalence is required), and those animal-based foods do not have codified nutritional composition criteria for nutrients

like Vitamins A, D, B12, heme-iron and zinc. Therefore, the proposal would require more stringent regulatory conditions for plant-based foods, meaning unequal treatment of “like products,” constituting a Technical Barrier to Trade.

Option 2: full nutritional equivalence based on all nutrients conflicts with public health objectives, including WHO. Many countries have regulations dictating an upper limit of 2% trans fat content for plant-based or non-animal foods – in all cases, this upper limit does not apply to the corresponding animal-derived foods. Examples include the EU, Brazil, Peru, Chile, South Africa and India. This limit is also recommended by the World Health Organization’s *REPLACE Trans Fat* programme. However, many animal-derived foods contain substantially more than this threshold – for example, all dairy fat contains approximately 3% trans fats, and lamb contains around 9% trans fats. Enforced, full nutritional equivalence based on all nutrients would mean that plant-based foods would exceed the regulatory limit, and public health recommendations for trans fat content in many countries. This would require the reversal of important and effective public health regulations.

- **Undefined scope:** It should be noted that the proposal invokes the concept of “plant-based foods,” seeming to cover all plant-based alternatives to meat and dairy within the scope. This is unfit for regulatory development, given that there is as yet, no agreed global definition of “plant-based foods.” This topic is currently being addressed by ISO, where a Standard for Plant-based Foods is being developed. The lack of an agreed definition of ‘Plant based food’ at this stage means that the proposal cannot proceed.
- **Negative impact on climate and environment.** As per the above, the proposal would introduce unequal regulation between “like products,” with the effect of creating a higher regulatory bar for plant-based foods than for animal-based foods. This stricter treatment would act as a barrier to innovation and market entry for plant-based foods, and disincentivise the uptake of plant-based diets. According to the IPCC’s Special Report on Climate Change and Land, plant-based diets offer a significant emissions mitigation potential. As such, the proposal has negative environmental implications.

Conclusions:

- The scope is not adequately defined, as no regulatory definition yet exists for “plant-based foods.”
- The proposal would require reopening and redefining the Standard for Fat Spreads and Blended Spreads (CXS 256), which has a conflicting scope and already includes nutritional composition criteria.
- The relevant nutritional composition criteria for the corresponding animal-based foods do not currently exist in a suitable form, so no regulatory basis exists to create such equivalence criteria for plant-based foods.

- Tackling nutritional equivalence only on the basis of essential nutrients would mean unequal treatment of “like products,” constituting a Technical Barrier to Trade, against WTO principles.
- Tackling nutritional equivalence on the basis of all nutrients would require public health laws to be reversed, e.g. in the case of trans fats, where plant-based foods could not (and should not) increase their levels to match animal-based foods.

The proposal could have negative impacts on the uptake of plant-based foods and diets, with corresponding negative impacts on climate

THE INTERNATIONAL PROBIOTICS ASSOCIATION (IPA)

Proposal 2.1 Discussion Paper on Harmonized Probiotic Guidelines for Use in Foods and Food Supplements

The International Probiotics Association (IPA) wishes to thank Argentina and Malaysia for drafting the Discussion Paper on harmonized probiotic guidelines for use in foods and food supplements for consideration at the CCNFSDU43, under agenda item 7.

IPA supports starting new work on Codex Guidelines for Probiotics used as an ingredient in food and food supplements (CX/NFSDU 23/43/7, circulated by the Codex Secretariat).

Standards for other uses of microbial cultures have been adopted in Codex, such as the Standard for Fermented Milks (CXS 243-2003) and the General Standard for Cheese (CXS 283-1978) and several standards for specific cheeses. In addition, the term “probiotic” is already used in the Codex Regional Standard for Doogh (CXS 332R-2018) for the Near East region, creating the need to clarify the use of the term by Codex. Ideally terms used in Codex standards should have a Codex definition, as it was noted by the 44th Session of the Codex Committee on Food Labelling (REP18/FL, paragraph 17). Therefore, Codex Guidelines for Probiotics is necessary as new work to ideally provide clarification in criteria and designation, given the expanded use of this ingredient.

Probiotics are live microorganisms increasingly used in a wide variety of food applications. The term “probiotics” is used more and more in several different products, with some products not in line with the commonly referenced FAO/WHO definition. The development of harmonized guidelines could be used by the different countries as a reference for minimal criteria for probiotics and will undoubtedly ensure and sustain the quality of probiotic products and facilitate international trade and enable fair and transparent practices.

High priority

IPA believes that the proposal for new work on Codex Guidelines for Probiotics meets the CCNFSDU prioritization criteria to be ranked as high priority by the ad hoc Working Group for the Establishment of CCNFSDU Work Priorities, at its next meeting on 6 March, and by the CCNFSDU43 under agenda item 7.

IPA supports the self-assessment of the CCNFSDU prioritization criteria contained in the Discussion Paper prepared by Argentina and Malaysia, moreover, taking into account the criteria that have been subsequently reviewed by the Electronic Working Group on the Prioritization Mechanism as follows:

Impact on health of the target group ²:

IPA supports that the proposal for new work on Codex Guidelines for Probiotics has a High positive impact on the health of the whole population

The beneficial effects of probiotics are broadly acknowledged and scientifically demonstrated to play important roles in immunological, digestive and respiratory functions with potential application for health maintenance and wellbeing. Probiotic intervention has the potential to significantly benefit many important health care issues that have a substantial health cost, as seen in various published studies on the health economics of probiotics. Examples of published studies on the health economics of probiotics can be found in Annex I of this document.

Impact on food safety

IPA also considers that the proposal for new work on Codex Guidelines for Probiotics has a positive impact on food safety. Probiotics have a long history of safe use which has been acknowledged already in 2001 by the FAO/WHO Expert Consultation, and by several regulatory organizations, including the European Food Safety Authority, who included typical probiotics species in the list of microorganisms with Qualified Presumption of Safety (QPS) with well-defined generic and specific qualifications.

Impact on trade practice

² Health claims on probiotics are excluded from the scope of this work. Codex horizontal guidelines on claims are framed by the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997).

PA supports that the proposal for new work on Codex Guidelines for Probiotics has a High positive impact on trade practices.

The development of Codex Guidelines on Probiotics will generate the regulatory harmonization of probiotics across the world, contributing to consistent fair trade practices in this area.

Global Impact

Currently, there is regulatory environment divergence that hinder the marketing and promotion of probiotics in different parts of the world. In addition, probiotics are on the regulatory agenda of many countries around the world.

IPA believes that the establishment of Codex high-level principles and guidance will have a High global impact:

- for the consistent interpretation and application of the definition of probiotics to help national authorities develop an appropriate regulatory framework to probiotics, and
- to ensure the consumer access to high quality, functional and safe probiotic foods and food supplements, avoiding consumers being misled.

Scope

IPA supports the scope of the guidelines as proposed in the Project Document in Appendix 3 of the Discussion paper prepared by Argentina and Malaysia.

IPA therefore supports the establishment of harmonized definition, minimum requirements, for the consistent interpretation and application of the definition of probiotics and guidelines in the FAO/WHO consultation (2001), as well as labelling parameters for probiotics, for use as an ingredient in foods, beverages and food supplements on aspects not framed by existing Codex standards.

In this sense, IPA supports the adoption of the Project Document as presented in Appendix 3 of the Discussion Paper on harmonized probiotic guidelines for use in foods and food supplements, that is, Part 2 of the Codex document CX/NFSDU 23/43/7.

About IPA

The International Probiotics Association (IPA) is a global non-profit organization bringing together through its membership, the probiotic sector's stakeholders including but not limited to academia, scientists, health care professionals, consumers, industry and regulators. The IPA's mission is to promote the safe and efficacious use of probiotics throughout the world. Holding NGO status before Codex Alimentarius, and Observer status at ISO, the IPA is also recognized as the unified "Global Voice of Probiotics" around the world.

Annex I – Published Studies on the Health Economics of Probiotics

1. GBD 2016 Causes of Death Collaborators. Global, regional, and national age-sex specific mortality for 264 causes of death, 1980-2016: a systematic analysis for the Global Burden of Disease Study 2016 *Lancet*. 2017;390(10100): 1151-1210. doi:10.1016/S0140-6736(17)32152-9
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THE INTERNATIONAL ORGANISATION FOR STANDARDIZATION (ISO)

With regard to CX/NFSDU 23/43/7, Annex I, Part 2, 2.2 “Guidelines including General Principles for the Nutritional Composition of foods and beverages made from plant-based and other alternative protein sources”, and the Evaluation of Criteria for the Establishment of New Work Priorities, part 4 (c), ISO would like to inform the Codex Alimentarius Commission, and CCFSDU that work is currently in progress to develop a standard to define ‘Plant Based Foods- Terms and Definitions’, and recommends that members and observers take account of this in their deliberations.

A new project was approved in October 2021 as ISO/NP 8700, and a new working group (WG26, secretariat: NEN – The Netherlands) was established under Technical Committee 34 (TC34, secretariat: AFNOR – France) to carry out the work. The project is currently at the Committee Draft stage.

The scope of the work is to specify technical definitions for plant-based foods and the criteria to be fulfilled for:

- plant-based foods;
- plant-based foods ingredients
- plant-based food labelling and claims.

It is not intended to include any detailed criteria or technical guidance for specific food types.

The resulting standard will be applicable to business-to-business and business-to-consumer communication, food trade and to food labelling and claims. The terminology and criteria described will apply only post-harvest/collecting.

It will apply only to foods for human consumption. This document does not apply to animal feed, pet foods, unprocessed fruits and vegetables, packaging material for foods, nor does it cover non-food applications.