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Agenda Item 8 **NFSDU/40 CRD 7**

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

Fortieth Session

Berlin, Germany
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PROPOSED DRAFT CLAIM FOR "FREE" OF TRANS FATTY ACIDS

PROPOSAL OF OPTIONS - FREE OF TRANS FATTY ACIDS CLAIM

Presented by the Government of Canada

INTRODUCTION

As the Committee may recall, a request was received from the Codex Committee on Food Labelling (CCFL) to establish conditions to allow for a food to carry a nutrient content claim "free of trans fatty acids". In response, Canada presented a proposal (CX/NFSDU 14/36/10) at the 36th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). However, as issues relating to the reliability and reproducibility of results at the proposed level were raised, it was requested to pursue guidance from the Codex Committee on Methods of Analysis and Sampling (CCMAS). It was also requested to consider the outcome of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) review on saturated fatty acids (SFA) and trans fatty acids (TFA), which was years away from publication at the time. As such, further discussion was deferred to the next meeting. At the 37th Session, CCNFSDU agreed to defer discussion, once again to the next session (REP16/NFSDU, paras 9 and 89) to await the outcome of the NUGAG review, as well as the solicited guidance from CCMAS (REP15/MAS, paras 34-36).

At the 38th and 39th Sessions, the Delegation of Canada presented documents CX/NFSDU 16/38/10 and CX/NFSDU/17/39/9, which contained respectively, a revised proposal based on the feedback from CCMAS and the outcome of the NUGAG systematic reviews. Based on comments received at these Sessions, in particular, those relating to issues with the methods of analysis for TFA, Canada is now proposing at CCNFSDU40, two possible options for consideration by the committee.

BACKGROUND

At the 38th Session of the CCFL, a project document (Appendix V, ALINORM 10/33/22) was presented, which described the planned work on the establishment of claims for sugars, salt/sodium and TFAs.

At their 41st Session, CCFL agreed to request that the CCNFSDU establish conditions for a "free" of TFA claim (para. 37, CX/NFSDU 13/35/2). At the 35th Session of the CCNFSDU, it was decided that the Delegation of Canada would develop a proposal for conditions for a "free" of trans fatty acids (TFA) claim for consideration at the next meeting.

At CCNFSDU36, Canada proposed a level of TFA of 0.1 g per 100 g or per 100 mL or per serving as the maximum value for a TFA free claim. This level was not considered nutritionally meaningful as it contributed no more than 1 kcal per serving (or per 100 g or per 100 mL). This proposed value was consistent with the amount set for the "free" claims described in the Table of Conditions for Nutrient Content Claims, in that the level is nutritionally insignificant, but not set at zero. The value proposed was also the same level that is required for a saturated fat "free" claim. Furthermore, Canada proposed additional conditions for a TFA "free" claim that would require the product to meet the conditions set for "low" in saturated fats, as stipulated within the Table of Conditions for Nutrient Content Claims in the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). This additional criteria was proposed in order to avoid replacement of trans fat with saturated fat in foods that are making a TFA "free" claim.

Comments received from Codex members at the 36th Session of CCNFSDU were generally supportive of the establishment of conditions for a "free" of TFA claim; however, it was recommended to await the outcome of the NUGAG's report and seek advice from the CCMAS about methodology concerns before agreeing on the proposed conditions. Additional recommendations were given on the proposed level, the inclusion of criteria for saturated fat, and the method of analysis. The conclusion of the 36th Session of CCNFSDU was to await the outcome of the NUGAG's report and to take into account the feedback from the CCMAS (REP15/MAS, paras 30-33).

At its 36th session, CCMAS noted difficulty in advising what the lowest level of TFAs current analytical methods could accurately and consistently detect. The Committee determined that this information would depend on the matrix of the product, and that it would not be possible to establish a single level for TFA for all foods, rather, that CCNFSDU would have to develop separate levels for different commodities. At this session, one observer expressed concerns about reproducibility when setting the TFA level at too low of a level. An in-depth analysis in certain matrices (e.g. nutritional formula and some dairy products) has been carried out by ISO, IDF[1] and AOAC[2]; and in a broad range of foods by AOCS[3,4,5,6,7]. The results of these analyses were reviewed by CCMAS, who concluded that precision results (both reproducibility and repeatability variables) were more variable when the total TFA amount was less than 0.1 g/100 g product.

At the 37th Session of CCNFSDU, the Committee agreed to defer the matter to the next session (REP16/NFSDU, paras 9 and 89) as the WHO NUGAG report was not available and concluded that Canada would continue to develop the discussion paper taking into account the outcome of the WHO NUGAG and the response from CCMAS.

Meanwhile, on June 30, 2016, the WHO NUGAG published their anticipated systematic reviews, evaluating the effect of saturated fatty acid [8] and trans fatty acid [9] intake on blood lipids, which were conducted as part of the work to update the WHO guidelines on SFA and TFA intake. The reviews concluded that SFA and TFA intake have a negative effect on the blood lipid profile, including elevation of LDL cholesterol, a well-accepted biomarker for risk of cardiovascular diseases.

At the 38th Session of CCNFSDU, the Committee considered an updated proposal presented by the Canadian Delegates, that in order to carry a claim for "free of trans-fat" the food could contain no more than 1 g of TFA per 100 g of fat and must meet the conditions set for "low" in saturated fats. The revised limit was chosen based on the fats and oils portion of the food, rather than the quantity of food, as originally proposed, to address the requirement previously raised by CCMAS, regarding the need to establish various thresholds for different food matrices. The TFA limit of 1 g per 100 g of fat was proposed based on simulations using Canadian intakes of various food categories and their corresponding TFA content to estimate the impact of those foods on daily intakes of TFA, in both children and adults. The 1 g of TFA per 100 g of fat condition ensures that the 'free of trans-fat' claim excludes foods that provide a nutritionally meaningful amount of TFA. The threshold for nutritional significance was set at 20% of the WHO limit of TFA intake (less than 1% of total energy from TFA) for individuals with high (90th percentile) intakes of that food.

Notably, a level of 2 g of TFA per 100 g of fat was also considered by the Canadian Delegates, in addition to the proposed level of 1 g of TFA per 100 g of fat. However, this value was not retrained as this could result in including foods that could contribute a nutritionally significant amount of TFA to the diet. The simulations using

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[1] ISO 16958: 2015 | IDF 231 Milk, milk products, infant formula and adult nutritionals — Determination of fatty acids composition — Capillary gas chromatographic method. https://www.iso.org/obp/ui/#iso:std:iso:16958:ed-1:v1:en

[2] AOAC Official Method 2012.13: *Determination of labeled fatty acids content in milk products and infant formula.* http://stakeholder.aoac.org/SPIFAN/2012.13.pdf

[3] AOCS Official Method Ce 2b-11: Direct Methylation of Lipids in Foods by Alkali Hydrolysis

[4] AOCS Official Method Ce 1j-07: *Determination of cis-, trans-, Saturated, Monounsaturated, and Polyunsaturated Fatty Acids in Extracted Fats by Capillary GLC.*

[5] AOCS Official Method Ce 2-66: Preparation of Methyl Esters of Fatty Acids.

[6] AOCS Official Method Ce 1h-05: Determination of cis-, trans-, saturated, Monounsaturated and Polyunsaturated Fatty Acids in Vegetable or Non-Ruminant Animal Oils and Fats by Capillary GLC

[7] AOCS Official Method Ce 2c-11: Direct Methylation of Lipids in Foods by Acid-Alkali Hydrolysi

[8] World Health Organization. (2016) Effects of saturated fatty acids on serum lipids and lipoproteins: a systematic review and regression analysis. Systematic review. http://www.who.int/nutrition/publications/nutrientrequirements/sfa_systematic_review/en/

[9] World Health Organization. (2016) Effect of *trans*-fatty acid intake on blood lipids and lipoproteins: a systematic review and meta-regression analysis. http://www.who.int/nutrition/publications/nutrientrequirements/tfa_systematic_review/en/

the Canadian intake data demonstrated that these foods could provide, for an individual with high (90th percentile) intakes of those foods, 20%-37% of the WHO limit of TFA intake.

In response to the revised proposal at CCNFSDU38, there was a general agreement on the modified value of 1 g of TFA per 100 g of fat. However, although they were in support of the level of trans fat, several delegations and an observer did not support the accompanying conditions for "low" in saturated fats citing a recent prospective cohort study in 18 countries (PURE study[10]),which suggested that saturated fat consumption was not associated with CVD and mortality.

In contrast, the Representative of the WHO supported the proposal made by Canada to include the conditions for low in saturated fats, as part of the TFA "free" claim conditions, in order to avoid increasing replacement of TFA with saturated fats. She expressed several concerns with the PURE study, including the interpretation of the results. Among others, a key limitation of the study was the lack of a clear definition of carbohydrates, whose consumption was compared with that of fats in the study. Thus, it was not clear what kinds of carbohydrates were included in the analyses, as the study authors did not differentiate between carbohydrates with detrimental health effects (e.g. free sugars, refined grains) and those with health benefits (e.g. fibre rich wholegrains, legumes, vegetables and fruits). The WHO Representative further specified that the findings from this study should not be used as evidence to promote the consumption of saturated fats.

In response to the revised proposal, some members suggested that it would be more appropriate to set the conditions for a TFA claim per 100 g of food as originally proposed. However, it was previously confirmed by CCMAS that it is not possible to establish a single level of TFA for all foods if the level is set per 100 g of food, based on the variability between food matrices.

Furthermore, some members suggested that the revised proposed level for the TFA "free" claim of 1 g TFA per 100 g of fat cannot be accurately and precisely measured based on the available collaborative study data on the analytical methods. The Committee agreed to send the proposal for comments at Step 3 and to further consider this work at its next session.

Upon further consideration of the precision data associated with the methods provided by CCMAS (Appendix 1), it is clear that there is relatively poor repeatability and reproducibility for several foods that would be likely to make a TFA "free" claim, such as peanut butter, salad dressing, potato chips and oatmeal cookies.

OPTIONS

Due to the fact that analytical techniques are not sensitive enough to measure low concentrations of TFA in low fat foods and certain other matrices, Canada proposes the following two options for the TFA "free" claim for consideration by the committee:

OPTIONS	**Considerations for**	**Considerations against**
Option 1: Set conditions for a "free" of TFA claim as previously proposed at Step 3 in REP18/NFSDU, Appendix VI Conditions (not more than): 1 g of TFA per 100 g of fat; and must meet the conditions for "low" in saturated fats[11]	• International alignment on conditions for a TFA "free" claim which would be based on WHO limit of TFA intake; • May increase incentive for industry to further decrease TFA levels in foods.	• The level of TFA proposed cannot be accurately and precisely measured in certain foods which could lead to inconsistent use of the claim and would present enforcement challenges; • May be misleading as many foods using the claim may never have contained TFA in the first place[12]; • Setting the TFA conditions on 100 g fat is inconsistent with other claims conditions; (based on 100g food) and results in TFA levels per serving that are proportional to the amount of fat in a food.

[10] https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(17)32252-3.pdf

[11] As per the Table conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims*, the conditions for "low" in saturated fats are as follows: 1.5 g saturated fat per 100 g (solids), 0.75 g saturated fat per 100 mL (liquids) and 10% of energy of saturated fat.

Option 2: Do not set conditions for a "free" of TFA claim (i.e. discontinue work on this agenda item)	• No methods currently available to accurately determine in all foods that a product is TFA "free"; • May be misleading as many foods using the claim may never have contained TFA in the first place.	• No international alignment on conditions for TFA "free" claim; • May diminish incentive for industry to further decrease TFA levels in food.

APPENDIX 1: CRD 19 from CCMAS36 (comments of AOCS)

COMMENTS ON DETERMINATION OF *TRANS* FATTY ACID ANALYSIS

These comments cover those already submitted to the 36th session of CCNFSDU as CRD14 and further expand on the precision data contained in AOCS Ce 1j-07 on a number of different matrices covering food and feed.

Methods of Analysis

AOCS Ce 1h-05 was developed in response to the need to determine the level of *trans* fatty acids in refined vegetable oils and fats, both hydrogenated and non-hydrogenated. The method allows the quantification of saturated, and *cis* and *trans* isomers of monounsaturated and polyunsaturated fatty acids present in common vegetable oils and fats. It was published with full precision values for the oils and fats analyzed. It was not intended for use to determine *trans* fatty acid levels in finished foods.

The Method describes the chromatographic conditions necessary to obtain repeatable results. It is to be noted that the method requires that methyl esters of fatty acids are prepared in a prior step. Suitable methods are listed as AOCS Ce 2-66 and ISO 5509.

Subsequent to the development of Ce 1h-05, a method (Ce 1j-07 Determination of *cis, trans,* saturated, monounsaturated and polyunsaturated fatty acids in extracted fats by capillary GLC) was developed to determine the levels of saturated and *cis* and *trans* isomers of monounsaturated and polyunsaturated fatty acids in food samples. This method requires the direct preparation of fatty acid methyl esters according to Ce 2b-11 or Ce 2c-11. Method performance data were developed for 24 complex food/feed matrices taken from the AOAC food composition triangle and are given for both methylation methods when coupled with Ce 1j-07. The use of these method pairs allows the analyst a direct path to the determination of *trans* fatty acids in food products where the source of the fat may be of dairy, marine or vegetable origins.

AOCS would recommend the use of these method pairs (Ce 1j-07 plus either Ce 2b-11 or Ce 2c-11) when determining *trans* fatty acid content in finished foods.

As detailed in the reports of previous meetings, CCMAS decided to wait for the outcome of the above-mentioned method performance studies before deciding on the acceptability of any method for the determination of *trans* fatty acids in foods. At the time, AOCS was unable to share the performance data as they had not been approved by the Uniform Methods Committee for publication. From the associated method performance data it is now clear that the determination of *trans* fatty acids in finished foods requires a skilled laboratory with much expertise in the identification of individual *trans* fatty acid isomers from a variety of oil/fat sources. Misidentification of members of the *trans* fatty acid family is a major problem encountered by analytical laboratories.

The AOCS is concerned that low level of *trans* fatty acids cannot be routinely determined by the average laboratory with any high degree of reproducibility. This situation may lead to confusion in the marketplace and in general trade where products may be deemed to be "*trans*-free" by one laboratory and above the threshold for this claim in another."

Performance data from Ce 1j-07 may be summarized as follows:

Matrix	**Total fat content (FA%)**	**Mean *trans* isomer content %**	**SD Reproducibility**	**Relative SD R %**
Anhydrous milk fat	**88.93**	**5.11**	**0.67**	**13.14**

[12]As per the Codex General Guidelines on Claims:
(vi) Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:
(b) is one which consumers would normally expect to find in the food;

Tallow	**95.21**	**7.14**	**0.30**	**4.20**
Chocolate cake mix	**10.34**	**0.90**	**0.07**	**7.43**
Cheese powder	**28.38**	**7.27**	**0.37**	**5.04**
DHA/EPA fortified infant formula	**27.58**	**0.15**	**0.12**	**78.47**
Extruded dog food	**21.06**	**0.31**	**0.11**	**34.97**
Oatmeal cookie	**18.33**	**0.05**	**0.02**	**44.84**
Evaporated milk	**5.97**	**0.33**	**0.05**	**15.89**
Peanut butter	**51.69**	**0.06**	**0.04**	**75.73**
Yoghurt (plain)	**5.51**	**0.32**	**0.03**	**7.94**
Canned cat food	**5.44**	**0.05**	**0.03**	**49.55**
Butter blend	**67.76**	**2.49**	**0.43**	**17.29**
Whole egg powder	**38.47**	**0.43**	**0.06**	**12.99**
Full fat soy flour flakes	**22.05**	**0.02**	**0.01**	**73.10**
DHA/EPA	**53.66**	**0.68**	**0.23**	**33.82**
Creamy ranch dressing	**44.16**	**0.24**	**0.16**	**65.50**
Potato chips	**34.44**	**0.22**	**0.14**	**62.69**
Cheese powder (dupl)	**28.69**	**7.20**	**0.31**	**4.27**
Frozen cheese pizza	**7.66**	**0.37**	**0.07**	**18.70**
Peanut butter (dupl)	**49.29**	**0.05**	**0.05**	**85.63**