

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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Agenda Item 10

CX/NFSDU 17/39/9

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

Thirty-ninth Session

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4 – 8 December 2017

DISCUSSION PAPER ON CLAIM FOR “FREE” OF TRANS FATTY ACIDS

(Prepared by Canada)

INTRODUCTION

1. 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”. 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 (CCNFSDU36). As issues related to the reliability and reproducibility of results at the proposed level were raised, it was requested that Codex Committee on Methods of Analysis and Sampling (CCMAS) advice on methodological issues be sought, as well the outcome of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) review on saturated fatty acids (SFA) and trans fatty acids (TFA) be considered, it was decided to defer discussion to the next meeting. CCNFSDU37 agreed to defer discussions again to its next session (REP16/NFSDU, paras 9 and 89) so as to await the outcome of NUGAG and the reply from CCMAS (REP15/MAS, paras 34-36).

2. At CCNFSDU38, the Delegation of Canada presented document CX/NFSDU 16/38/10 which contained a proposal for revisions to the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997) based on the feedback from CCMAS and the outcome of the NUGAG systematic reviews. Canada has since updated the proposal based on comments received at CCNFSDU38 and based on a more detailed analysis of the methodology by CCMAS.

BACKGROUND

3. At CCFL38, 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.

4. CCFL41 agreed to request the CCNFSDU to establish conditions for a free of TFA claim (para. 37, CX/NFSDU 13/35/2). At CCNFSDU35, it was decided that the Delegation of Canada would develop a proposal for conditions for a “free” of TFA claim for consideration at the next meeting.

5. At CCNFSDU36, Canada proposed a level of trans fat (0.1 g per 100 g or per 100 mL or per serving). This level was considered nutritionally insignificant as it only contributed up to 1 kcal. As well, it was consistent with the amounts set for the other “free” claims described in the Table of conditions for nutrient content claims (which are all insignificant, but not zero). It was also based on a level that was the same as that stated for the saturated fat “free” claim.

6. Comments received from Codex members at CCNFSDU36 were generally supportive of the establishment of conditions for a “free” of TFA claim, with recommendations to await the outcome of the NUGAG’s report and seek advice to the CCMAS about methodology. Other recommendations were given on the proposed level, the inclusion of criteria for saturated fat as well as regarding the method of analysis. The conclusion of CCNFSDU36 was to await the outcome of the NUGAG’s report and to take into account the reply from the CCMAS (REP15/MAS, paras 30-33).

7. CCMAS36 noted difficulty in advising what the lowest level of TFAs current analytical methods could accurately detect as well as consistently reproduce. The Committee mentioned 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

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all foods, but 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 some matrices had been carried out by ISO, IDF¹ and AOAC², and CCMAS reviewed these results.

8. CCNFSDU37 agreed to defer the matter to the next session (REP16/NFSDU, paras 9 and 89) and that Canada would continue to develop the discussion paper taking into account the outcome of the WHO NUGAG and the reply of CCMAS.

9. The most recent guidance from the WHO is to limit intakes of trans fats to less than 1% of energy. For an adult consuming a 2,000 kilocalorie diet, this would mean less than 2.2 g of TFAs. On June 30, 2016, the WHO published two systematic reviews which assess the effect of SFA³ and TFA⁴ intake on blood lipids as part of the work to support the updating of WHO guidelines on SFA and TFA intake. The reviews indicated that saturated fatty acid and *trans*-fatty acid intake have a negative effect on the blood lipid profile, including elevation of LDL cholesterol, a well-accepted biomarker for risk of cardiovascular diseases.

10. At CCNFSDU38, Canada proposed a level of trans fat of “1 g per 100 g fat”. As well, Canada proposed that the product would also have 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* (CXG 23-1997).

11. A few comments were received from Codex members at CCNFSDU38 on the above proposals which were generally supportive of the establishment of conditions for a “free” of TFA claim. In particular:

- Five members and two observers supported the proposal of including a “free” claim, with three members supporting the proposed level (1 g per 100 g fat) and the remaining two preferring a level of “0.2 g per serving” and “0.2 g per 100 g/mL of food”, respectively.
- One member did not support the proposed level because they believed it could not be accurately and precisely measured;
- Two observers did not support a “free” of TFA claim. The first recommended that the conditions should be reconsidered and only focus on reduction of TFAs from partially hydrogenated oils and fats (e.g. 1 g of trans fatty acids from partially hydrogenated oils and fats per 100g of fat). The other observer noted that the threshold should be based on actual consumption and a level that is nutritionally relevant. This observer instead preferred the criteria Canada has applied nationally (not more than 0.2 g TFA/serving).

12. With respect to the proposed conditions of use on saturated fatty acid levels, comments were as follows:

- Two members supported the proposed inclusion of SFA conditions, with one member recognizing that some countries already included conditions for SFA content for a “free” TFA claim.
- One member strongly objected to the inclusion of conditions for “low” in saturated fats noting there was increasing evidence suggesting different health outcomes between trans fatty acids and saturated fatty acids;
- Although recognizing that the reason to include limits on both fatty acids is to avoid TFA reduction accompanied by an increase in SFAs, one observer noted that voluntary removal of partially hydrogenated oils in margarines did not result in an increase in saturated fat content.

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 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/

⁴ 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/

13. Lastly, regarding the methods of analysis for TFA, only comments from one member and one observer were received. Comments suggested that there are accuracy and detection issues with some of the current analytical methods, including the lack of multi-laboratory collaborative study data. The observer supported requesting CCMAS to review the suitability of the proposed methods to support the claim.

PROPOSAL

Conditions for a “free” of Trans Fatty Acids (TFAs) Claim

14. It is proposed that an entry for a claim of “free” of TFAs be inserted between Saturated Fat and Cholesterol within the Table of conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims* (CXG 23-1997).

15. In order to carry a trans-fat free claim, Canada is proposing that the food should contain no more than 1 g per 100 g of fat and must meet the conditions set for “low” in saturated fats as stated in the Table below.

Component	Claim	Conditions (not more than)
Trans fatty acids	Free	1 g per 100 g of fat And must meet the conditions for “low” in saturated fats ⁵

RATIONALE/JUSTIFICATION

16. Canada has proposed a value set at 1 g per 100 g of fat. Setting the limit based on the fats and oils portion of the food, although not consistent with the way conditions for other nutrients are referenced in the *Guidelines for Use of Nutrition and Health Claims*, alleviates the question previously raised by CCMAS about having various thresholds for different food matrices.

17. The proposed value was determined based on modelling using Canadian intakes of various categories of foods and their trans fat content to estimate impact on total daily intakes of trans fats for both adults and children (see Appendix 3 of CX/NFSDU 16/38/10⁶). The 1 g per 100 g fat condition is proposed to ensure that a given food does not contribute to more than 1/5th of the maximal trans fat intake (1% of total daily energy as suggested by the WHO) for individuals with high (90th percentile) intakes of that food.

18. It should also be noted that the proposed level applies to all trans fatty acids (including naturally occurring and industrially produced). The current status of scientific knowledge does not allow drawing a firm conclusion on the relative effects of ruminant versus industrial trans fats on blood lipids and risk of coronary heart disease.

SATURATED FAT CONDITIONS

19. The WHO Global Strategy states that recommendations for populations and individuals should include direction on limiting energy intake from total fats and shifting fat consumption from saturated fats to unsaturated fats and towards the elimination of TFAs. Given that there is a link between trans fat and saturated fat consumption and coronary heart disease, many countries have moved towards implementing strategies and tools to lower excessive trans and saturated fat intakes.

20. Currently, some countries have started to introduce nutrient content claims for TFAs to encourage the reformulation of foods and to provide manufacturer means to promote lower contents of TFAs in their foods. However, some countries that have or are considering provisions for TFAs claims have also included conditions for the food in relation to its saturated fat content due to their negative impact on cardiovascular health. There is also concern that placing undue emphasis on the reduction of TFAs, without consideration for the saturated fatty acid content may lead to manufacturers replacing TFAs with saturated fats. One

⁵ 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.

⁶ Discussion Paper on Claim for “Free” of Trans Fatty Acids (CX/NFSDU 16/38/10): http://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-38%252Fnf38_10e.pdf

observer at CCNFSDU38 noted this was not the case for margarine with the removal of partially hydrogenated oils; however, it may not preclude other industries from doing so.

21. The most recently published systematic review by the WHO confirms that saturated fatty acids have negative effects on the blood lipid profile.

22. Based on this evidence, and general support from CCNFSDU members, Canada is proposing to retain the conditions for saturated fats as part of the trans fat “free” claim. Accordingly, the proposed claim includes a condition for “low in” saturated fats⁷ as per the Table of conditions for nutrient content claims in the *Guidelines for Use of Nutrition and Health Claims*. A product claiming to be TFA-free should therefore also have low levels of saturated fat.

METHODS OF ANALYSIS FOR TFA

23. Canada agrees with the general comments made at CCNFSDU36, CCMAS36 and CCNFSDU38 that the methods of analysis for determining TFAs should be practical and internationally accepted as well as being reliable and consistently reproducible.

24. Based on the comments received at CCNFSDU36/CCMAS36, Canada had presented to CCNFSDU38 three options available for recommendation to the CCMAS, depending on the food matrix: 1) ISO 16958/IDF 231/AOAC 2012.13, 2) AOCS Ce 1h-05 and AOAC 996.06, and 3) AOCS Ce 1j-07 and Ce 2b-11/Ce 2c-11. We welcomed further discussion by the Committee to decide on one final method to propose to the CCMAS.

25. Very few comments were received at CCNFSDU38 regarding the methods of analysis for TFAs, as mentioned earlier. The concerns expressed by one member and observer were regarding accurate detection issues with some of the current analytical methods, including the lack of availability of multi-laboratory collaborative study data. The Committee had agreed to request CCMAS to review if the three methods were applicable to TFA as defined in both the *Guidelines on Nutrition Labelling* (CXG 2-1985) and the WHO definition – at least one double bond in the trans configuration - at the level of 1 g per 100 g of fat.

26. At CCMAS38, it was agreed that the PWG on endorsement of methods of analysis and sampling would consider this work. Following discussions after CCMAS38, a table summarizing the methodology and validated results was drafted by a CCMAS Member and reviewed by AOCS (refer to Appendix 1). Based on the table, the proposed methods can detect the levels of the proposed claim.

⁷ 1.5 g saturated fat per 100 g or 0.75 g per 100 mL and 10% of energy of saturated fat

APPENDIX 1: Review of Methodology for Determining Trans Fatty Acid Content

- CCMAS supports the determination of trans fat based on reporting grams/ 100g of fat rather than grams/ 100g of food (or product)

Food Type	Examples	Method	Principle	Validation Information	Special Comments
Nutritional Formula	Infant formula	AOAC 2012.13 ISO 16958:2015 IDF 231:2015 OR AOCS Ce 2b-11 coupled with Ce 1j-07 ¹	Direct trans-esterification GC-FID Direct trans-esterification (Alkaline hydrolysis and methylation) ² GC-FID	0.010 – 0.073g/ 100g product 0.15g/ 100g total fat (equivalent to approx. 0.04g/ 100g product)	Powdered or liquid DHA/EPA fortified infant formula (in multiple matrix study)
	Adult nutritional formula	AOAC 2012.13 ISO 16958:2015 IDF 231:2015	Direct trans-esterification GC-FID	0.006 – 0.010g/ 100g product	
Dairy Products	Butter, Cheese, Milk, etc.	AOAC 2012.13 ISO 16958:2015 IDF 231:2015 OR AOCS Ce 2b-11 coupled with Ce 1j-07 ¹	Direct trans-esterification GC-FID Direct trans-methylation (Alkaline hydrolysis and methylation) ² GC-FID	0.17 – 5.06g/ 100g product 0.32 – 7.27% total fatty acids	Powder or liquid Dairy-based fat Powder or liquid
Ruminant fats	Tallow	AOCS Ce 2b-11 coupled with Ce 1j-07 ¹	Direct trans-methylation (Alkaline hydrolysis and methylation) ² GC-FID	0.24 – 7.14% total fatty acids	Also successful for: Egg powder Creamy Ranch Dressing Chocolate cake mix Peanut butter Potato chips
Vegetable oils	Canola oil, Sunflower oil, etc.	AOCS Ce 2-66 and Ce 1h-05 ³	Methylation followed by GC-FID	0.06 – 45.01% total fatty acids	Commodity oils and fats (including hydrogenated fats)

Marine oils and fats	Micro-encapsulated oils, or other long-chain polyunsaturated fatty acids in food matrices	AOCS Ce 2b-11 coupled with Ce 1j-07 ¹	Direct trans-methylation (Alkaline hydrolysis and methylation) ² GC-FID	0.00 - 0.68% total fatty acids	Micro-encapsulated DHA/EPA DHA/EPA fortified orange juice
Non-ruminant based fats	Lard	AOCS Ce 2-66 and Ce 1h-05 ³	Methylation followed by GC-FID	0.90% total fatty acids	
Specialised food types Foods where fatty acids are not quantitatively released by alkaline hydrolysis alone	Oat-based foods	AOCS Ce 2c-11 coupled with Ce 1j-07 ¹	Acid digestion followed by alkaline hydrolysis and methylation ⁵ GC-FID	0.06 – 0.31% total fatty acids	Oatmeal cookie and all matrices studied using Ce 2b-11

¹ AOCS Ce 1j-07 was validated on 22 matrices from the AOAC food composition triangle in separate studies using the methylation strategies of AOCS Ce 2b-11 and Ce 2c-11. These procedures can be used when the source of fat is unknown, ruminant based, or dairy based.

² AOCS Ce 2b-11 does not require prior extraction of the fat or fatty acids.

³ AOCS Ce 1h-05 is not suitable for dairy, ruminant or marine oils

⁴ AOCS Ce 1i-07 was developed to improve the accuracy of the determination of long-chain polyunsaturated fatty acid content such as omega-3's or individual unsaturated fatty acids present in high amounts in marine and single cell oils.