CODEX ALIMENTARIUS COMMISSION

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Agenda Item 9 **CX/NFSDU 16/38/10**

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

Thirty-eighth Session

Hamburg, Germany

5 – 9 December 2016

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 (CCNFSDU). As issues related to the reliability and reproducibility of results at the proposed level were raised, as well as it was requested that 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. At the 37th Session, CCNFSDU agreed to defer discussions again to its next session (REP16/NFSDU, paras 9 and 89) so as to await the outcome of the WHO Nutrition Guidance Expert Advisory Group (NUGAG).

2. The Delegation of Canada has since updated the following proposal for revisions to the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) based on the feedback from the Codex Committee on Methods of Analysis and Sampling (CCMAS) and the outcome of the NUGAG systematic reviews.

BACKGROUND

3. 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.

4. At its 41st Session, CCFL agreed to request the CCNFSDU to establish conditions for free of TFAs 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 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 the 36th Session of CCNFSDU were generally supportive of the establishment of conditions for a "free" of TFA claim, with recommendations from eight members and one observer to await the outcome of the NUGAG 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:

- There was no consensus amongst members regarding the proposed value (0.1 g per 100 g/mL) (two members supported and two members and two observers objected). One of the members who did not support the proposed value suggested instead to use the lowest possible level based on scientific evidence and to add a condition with regards to the overall energy requirement (e.g. <1% of energy).
- Two observers commented that the proposed value was not scientifically justifiable and would be difficult to implement for the vegetable fats and oil sector as these products contain natural amounts of TFA/SFAs. One of the observers expressed support for using the Canadian value for TFA free claim (0.2 g per serving)

and they also proposed the limit of 2 g per 100 g fat in the final food. One other member commented that the proposed levels of TFA should not be higher than that for saturated fatty acids as per intake recommendations.

- There were a couple of comments received which did not support the claim containing per serve conditions.
- Not many comments were received regarding the inclusion of conditions for saturated fats as part of the trans fat "free" claim. Of those received however, two members supported the inclusion for "low" in saturated fats. One member suggested that the combined trans and saturated fat content should be taken into consideration for the free from claim. One member did not support the inclusion and one observer mentioned that many countries where TFA-free claims are currently allowed do not include criteria for saturated fat.
- One member further proposed that the Committee request that CCFL consider adding criteria on trans fat to the saturated fat-claims to avoid replacement of saturated fat with trans fat in foods that are low/free from saturated fats. Currently a footnote to the saturated fat and cholesterol claims state that trans fat should be taken into consideration where applicable with no further guidance as to what threshold should be considered appropriate.
- One member noted that the method of analysis currently adopted for TFAs for the purposes of the *Guidelines for Nutrition Labelling* (AOCS Ce 1H-05) was only suitable for certain types of oils and fats and was not intended for use to determine TFA levels in finished foods. One member and one observer had concerns regarding the accuracy/precision and reproducibility issues with the two methods proposed by Canada. Another member noted the method selected should be practical and internationally accepted. One observer suggested using the method pairs (Ce 1j-07 and either Ce 2b-11 or Ce 2c-11) to determine TFA levels in finished foods. It was also noted by one observer that the ISO-IDF method was recently accepted as an AOAC method and should also be considered.

7. The conclusion of the 36th Session of CCNFSDU 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).

8. At its 36th session, CCMAS 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 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, IDF[1] and AOAC[2], and CCMAS reviewed some results as summarized in CRD 16 (Appendix 1). Based on this data, the lowest total TFA amount that was quantified in an adult nutritional formula product was 0.009 g/100 g product (SDr <10% and SDR <40%) whereas the lowest amount of TFA (18:1 trans) was 0.003 g/100 g product (SDr <13% and SDR <36%). Precision results (both reproducibility and repeatability variables) were more variable when the total TFA amount was less than 0.1 g/100 g product. The ISO/IDF method was officially published November 1, 2015. Another observer provided data on TFA levels measured in a variety of products based on a different suggested method (Ce 1j-05). According to this observer, precision data were similar for both methods (Ce 1j-05 and AOAC 2012.13) but should be interpreted cautiously when assigning a limit of quantification. The results are included in Appendix 2.

9. At the 37th session of CCNFSDU, the Committee 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.

10. 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 Calorie diet, this would mean less than 2.2 g of TFAs. On June 30, 2016, the WHO published

[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

two systematic reviews which assess the effect of SFA[3] and TFA[4] 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.

PROPOSAL

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

11. 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* (CAC/GL 23-1997).

12. 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

13. At the 36th Session of CCMAS, the Committee considered the request from CCNFSDU on the lowest level of TFAs that current analytical methods can accurately as well as consistently reproduce. As outlined earlier, the Committee indicated it would be too difficult for them to provide a single level for TFA for all foods. They indicated their preference to use a food matrix approach and recommended CCNFSDU develop separate levels for different commodities.

14. Canada notes that establishing levels of a nutrient to meet a level referred to as "free" based on the food matrix is not consistent with how the conditions are set for any other nutrient content claims. "Free" claims are generally set based on amounts of nutrients that are nutritionally insignificant or trivial in relation to current dietary recommendations, rather than based on the level of the substance found in a given food matrix. In the Table of conditions for nutrient content claims described in the *Guidelines for Use of Nutrition and Health Claims,* the amounts for the "free" claims of other macronutrients are set on a basis of 100 g of food or per 100 mL for liquids.

15. At the 36th Session of CCNFSDU, one observer proposed to set the limit for TFAs based on the fats and oils portion of the food (e.g. amount of TFA per 100 g of fat). Although this option is not consistent with the way conditions for other nutrients are referenced in the *Guidelines for Use of Nutrition and Health Claims*, it would help alleviate the question of matrices, which was raised by CCMAS. In order to do so however, an appropriate threshold needed to be determined.

16. Canada is proposing a value set at 1 g per 100 g of fat. This 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 Table 1 in Appendix 3). It has to be noted that depending on the actual portion size and number of portions consumed per day, the overall contribution of a food to the total daily intake of trans fat may vary. 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. The proposed level of 1 g per 100 g of fat would also be readily measurable with current, well-established analytical methods. The measurement on a per g of fat has an inter-lab variability rate of about 20% and within-lab variability rate of 7-10% for fat samples with a content of

[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/

[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.

total trans fat around 1%[6]. Given the non-avoidable inter-lab variability, it is advisable that the trans fat content measurement is performed by more than a single lab for foods with a total trans fat content close to the limit of 1%.

17. We had also considered setting a condition for trans fat to be at 2 g of TFA per 100 g of fat, as recommended by an observer at CCNFSDU36. However, this value was not retained because its contribution to the daily TFA intake could be substantial, with some foods contributing up to or more than 20% of the maximal daily trans fat intake for individuals having high intakes of those foods (see Table 2 in Appendix 3).

SATURATED FAT CONDITIONS

18. 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.

19. 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.

20. The recently published systematic review by the WHO confirms that saturated fatty acids have negative effects on the blood lipid profile. Based on multiple regression analysis, when SFA intake was reduced by replacing it with intake of other fatty acids (*cis*-PUFA or *cis*-MUFA), there was a significant decrease in total cholesterol, LDL-cholesterol, total cholesterol to HDL-cholesterol ratio, LDL-cholesterol to HDL-cholesterol ratio, and in ApoB levels. When SFA intake was increased by the replacement of unsaturated fatty acids with SFA, there was an opposite effect (significant increase in total cholesterol, LDL-cholesterol, total cholesterol to HDL-cholesterol ratio, LDL-cholesterol to HDL-cholesterol ratio, and in ApoB levels). There also was a consistent and linear relationship between a reduction or increase in SFA intake (ranging from 1.6 to 24.4% of total energy) and effect on serum lipids and lipoproteins. The results of the regression analysis suggested increasing SFA intakes from a start point of less than 10% of total energy intake has a negative effect on the overall serum lipoprotein profile. Similarly, reducing SFA intakes to less than 10% of total energy intake may have additional benefits in terms of improving the overall serum lipoprotein profile when replacing SFA with unsaturated fatty acids.

21. Based on this evidence, Canada feels it is important to keep the conditions for saturated fats as part of the trans fat "free" claim. Accordingly, the proposed condition includes a condition for "low in" saturated fats[7] 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.

OTHER OPTIONS CONSIDERED

22. Canada had considered setting a condition for trans fat to be at 0.2 g of TFAs per 100 g/mL of food. The proposed amount would have been consistent with the amounts set for the other "free" claims described in the Table of conditions for nutrient content claims (which are all low levels, but not zero). In addition, it would have allowed some refined oils containing inadvertently produced TFAs (e.g. olive oil) to still be considered as 'trans fat free'[8]. Considering the data provided by IDF/ISO/AOAC at CCMAS (Appendix 1) as well as AOCS (Appendix 2), this level would be more reliably detectable and reproducible in various food matrices relative to the previously proposed level (0.1 g per 100 g/mL of food) at CCNFSDU34. However, our stimulation analysis (Appendix 3), showed that many categories of foods would be contributing, for individuals with high daily intakes of those foods, more than 1/5th of the maximal intake of trans fat maximum daily limit suggested by the WHO.

23. Canada had also considered setting a condition for trans fat to be at less than 0.2 g of TFAs per 100 g/mL and/or per serving of stated size of the food. A condition per serving would provide a more realistic and achievable

[6] American Oil Chemists' Society. Re-approved 2009. 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] 1.5 g saturated fat per 100 g or 0.75 g per 100 mL and 10% of energy of saturated fat

[8] Ratnayake, N and Zehaluk, C. Trans Fatty Acids in Foods and their Labelling Regulations", pp1-32 in Healthful Lipids http://www.crcnetbase.com/doi/abs/10.1201/9781439822289.pt1.

target for foods usually consumed in amounts less than 100 g/mL such as fats and oils. However, as the serving size approach would not be consistent with the conditions set for other macronutrients in the *Guidelines for Use of Nutrition and Health Claims*, this option was not retained. As well, there was no support at CCNFSDU36 for the claim to contain per serve conditions.

24. As mentioned earlier, the most recent guidance from the WHO is to limit intakes of TFAs to less than 1% of total energy. At the 36th Session of CCNFSDU, one member country recommended including an energy requirement as part of the condition. This suggestion was not further considered however, as it is a daily recommendation for the overall diet and not for an individual food.

METHODS OF ANALYSIS FOR TFA

25. Canada agrees with the general comments made at CCNFSDU36 and CCMAS36 that the method of analysis for determining TFAs should be practical and internationally accepted as well as being reliable and consistently reproducible. The method should also be able to accurately identify individual isomers.

26. Based on the comments received at CCNFSDU36/CCMAS36, there are three options available for recommendation to the CCMAS, depending on the food matrix:

Product	**Method**		
	ISO 16958/IDF 231/ AOAC 2012.13	**AOCS Ce 1h-05 and AOAC 996.06**	**AOCS Ce 1j-07 and Ce 2b-11/Ce 2c-11**
Dairy and ruminant products/fats	✓		✓
Adult nutritionals	✓		
Infant Formula	✓	✓	Ce 2b-11 only
Samples containing vegetable oils		✓	
Samples containing marine oils or other oils with long chain polyunsaturated fatty acids			✓ (Ce 1i-07 is recommended instead of 1j-07)
Samples with unknown fat sources			✓

27. The **ISO 16958 | IDF 231** International Standard specifies a single method for the quantification of all labelled fatty acids in milk and milk products, infant formula and adult nutritionals. A collaborative study in accordance with ISO 5725 was completed and the standard was published in 2015 (Refer to Appendix 1). The ISO/IDF method is equivalent to the recently accepted **AOAC official method 2012.13**: *Determination of labeled fatty acids content in milk products and infant formula*. In this method, the determination of TFA is performed by direct transesterification in food matrices, without prior fat extraction, and is applicable to liquid samples or reconstituted powder samples with water having total fat ≥ 1,5 % m/m. The fat extracted from products containing < 1,5 % m/m fat can also be analysed with the same method after a preliminary fat extraction. This method has not been validated for use in other foods.

28. The **AOCS official method Ce 1h-05** is used for refined vegetable or non-ruminant animal origin oils and fats, but is not suitable for dairy, ruminant, marine, or long chain polyunsaturated fats and oils, or products supplemented with conjugated linoleic acid. The collaborative study data reported for this method is restricted to fats/oils (e.g. lard, oil, shortening, etc). However, Ce 1h-05 when used in combination with **AOAC 996.06**[9] can be used to detect TFAs (as well as other fatty acids) in foods. The AOCS method is for the optimized analysis of the TFA profile by GC analysis using the Flame Ionisation Detection approach and the AOAC method is used for fat extraction. These methods are both cited for use in infant formula in STAN 234-1999 and commonly used for nutrition labelling purposes. AOAC 996.06 was revised in 2001 to include improved gas chromatography (GC) analysis of the fatty acid profile so that the method includes both extraction of fat from foods and low levels of detection.

29. It was noted by an observer at CCNFSDU36 that **Ce 1j-07** was developed after Ce 1h-05 to measure saturated fatty acids and cis/trans-isomers of unsaturated fatty acids food in extracted fats. This method provides a single capillary GC procedure using Flame Ionisation Detection and can be used for nutrition labelling purposes. It is

[9] AOAC Official Method 996.06 Fat (Total, Saturated, and Unsaturated) in Foods http://files.instrument.com.cn/bbs/upfile/2008622221856.pdf

applicable to fats derived from dairy and ruminant products but not for products containing both dairy and vegetable fats. In addition, the method can be used for fat samples where the source of fat is unknown. The observer suggested that Ce 1j-07 be paired with **Ce 2b-11** or **Ce 2c-11**, which are both methods used to prepare fatty acid methyl esters. The AOCS official method Ce 2b-11 is applicable for fat-containing matrices (e.g. food stuffs, beverages, tissues, and oils) and Ce 2c-11 is only required when Ce 2b-11 does not release all fatty acids quantitatively. The use of the method pairs (Ce 1j-07 and Ce2b-11/Ce 2c-11) allows a direct path to determine TFAs in food products. Performance data from the observer for a variety of food products was shared at CCMAS36 (Appendix 2) and shows that the degree of variability was lower for products containing more than 2% of TFA.

30. We welcome further discussion by the Committee to decide one final method to propose to the CCMAS.

MATTERS TO REFER TO OTHER COMMITTEES:

CCMAS

31. The Committee should consider asking CCMAS to verify that our new proposed levels are measurable with the recommended analytical methods described above.

OTHER CONSIDERATIONS:

32. Considering the comments received about possible methodological issues with detecting low levels of trans fat in different types of food CCNFSDU may want to ask CCFL to revisit the conditions for the “free” of saturated fatty acids claim.

APPENDIX 1: CRD16 from CCMAS36

(comments from AOAC, IDF and ISO)

Trans fatty acids

Performance characteristics of the trans fatty acids method currently under standardization with ISO/IDF & AOAC in reply to CCNFSDU request to CCMAS about the lowest level of TFAs that current analytical methods can accurately detect as well as consistently reproduce.

Title of the method

Determination of Fatty Acids in Milk Products, Infant Formulae and Adult/Pediatric Nutritional Formula Products

Method description

This ISO/IDF International Standard/AOAC Final Action Method specifies a single method for the quantification of all labelled fatty acids. This includes groups of fatty acids (i.e. TFA, CLA, SFA, MUFA, PUFA, omega-3, omega-6, omega-9) and/or individual fatty acids (i.e. LA, ALA, ARA, EPA, DHA) in milk products, infant formulae and adult/pediatric nutritional formula products (i.e. all forms made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch and amino acids, with and without intact protein) containing milk fat and/or vegetable oils, supplemented or not supplemented with long chain polyunsaturated fatty acids (LC-PUFA).

The determination is performed by direct trans esterification of fatty acids in food matrices, without prior fat extraction. Consequently, it is applicable to liquid and powder samples. Products containing less than 1,5 % fat and dairy products like soft or hard cheeses with FFA level ≤ 1 mmol/100g of fat can be analyzed after preliminary fat extraction using methods described in the standard.

The method is particularly adapted to quantify low levels of trans fatty acids coming from partially hydrogenated oils (C18:1 trans), deodorized vegetable oils (C18:2 trans, C18:3 trans) and/or trans fatty acids naturally present in ruminant fats (C18:1 trans, C18:2 trans). The method can be used for checking compliance of 'trans fat free' labeled products with regulatory limits.

Collaborative study results for trans fatty acids

A collaborative study in accordance with ISO 5725 with 18 participants from 9 countries was performed on 12 samples.

The calculated precision parameters SDr% and SDR% are presented in Table 1 and Table 2[10].

The lowest total trans fatty acids amount (sum of C18:1 trans, C18:2 trans and C18:3 trans) was quantified in an adult nutritional formula product at a level of 0.009 g trans FA/100 g product, with SDr<10% and SDR<40%. The lowest amount of trans fatty acid (18:1 trans) was quantified in an adult nutritional product at a level of 0.003 g C18:1 trans/100 g product, with SDr<13% and SDR<36%.

Method status

• IDF/ISO/AOAC publication expected end of 2015

[10] *Note:* Reported results for some of the individual fatty acids (which also contribute in summated values) showed to be erroneous (*i.e.* deviating response factors of instrument, co---elution, wrong peak identification or integration, errors in reporting). Precision parameters for low *trans* fatty acid amounts calculated from proficiency tests organized in 2014 using the same material (e.g. infant formula products included in the collaborative study) were two times lower than values found with the collaborative study.

Table 1: *Summary of calculated precision data for the determination of trans fatty acids in dairy products, Infant formula and pediatric and adult nutritional products. Fatty acid amounts are expressed in g/100 g product.*

Products	Fat %	Results	C18:1 *trans*	C18:2 *trans*	C18:3 *trans*	total *trans*
Milk products	3.5 to 100.0*	**Range**	**0.134 - 4.131**	**0.031 - 0.888**	**no present**	**0.167 - 5.056**
		SD r%	2.9 - 5.3	2.7 - 10.5		2.8 - 3.7
		SD R%	6.8 - 9.9	29.0 - 36.7		8.7 - 11.2
Infant formulae and Adult/Pediatric Nutritional Formula products	3.4 to 28.4	**Range**	**0.003 - 0.034**	**0.003 - 0.056**	**0.003 - 0.047**	**0.009 - 0.109**
		SD r%	5.7 - 13.4	6.9 - 9.8	5.7 - 26.8	5.4 - 16.6
		SD R%	16.4 - 36.2	11.0 - 34.5	28.5 - 72.9	21.3 - 42.5

*fat extracted from cheese having 13.3% fat

Table 2: *Summary of calculated precision data for the determination of total trans fatty acids amount in dairy products, Infant formula and pediatric and adult nutritional products. Results (Mean) are expressed in g total trans fatty acids/100g product)*

Products	n	Mean	SD r%	SD R%
Cheese	12	**5.056**	3.4	11.1
Butter	17	**4.235**	3.0	10.4
Full cream	17	**1.624**	3.7	11.0
Full cream Milk powder	17	**1.032**	3.4	11.2
Full Liquid milk	17	**0.167**	2.8	8.7
Infant Formula Milk based powder	17	**0.109**	6.4	29.2
Infant Formula Partially Hydrolyzed Soy powder	18	**0.091**	16.6	40.0
Infant formula	17	**0.073**	9.8	32.9
Adult Nutritional Milk Protein powder	15	**0.056**	13.0	23.5
Infant Formulan Ready to drink (liquid) Milk based	17	**0.027**	8.0	21.3
Adult Nutritional Ready to drink (liquid) High fat	11	**0.010**	10.0	42.5
Adult Nutritional Ready to drink (liquid) High protein	16	**0.009**	5.4	38.5

APPENDIX 2: CRD19 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
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

APPENDIX 3: SIMULATION OF % ENERGY INTAKE FROM TRANS FATTY ACIDS FOR DIFFERENT AGE POPULATIONS DEPENDING ON THE CRITERIA CHOSEN FOR A TRANS-FAT FREE CLAIM

(CANADIAN DATA)

Simulations were made for a limit set at 1 g / 100 g of fat and 2 g/100 g of fat for the following age groups: adults 18 years and older, children 4-8 years, children 9-13 years, and children 14-18 years.

For children, two activity levels (influencing estimated energy requirements) were analyzed: sedentary and active. Since the results were very similar for both groups, only one set of data (sedentary children, as the worst case scenario) are presented.

The portions of foods typically consumed are based on the Canadian Community Health Survey (CCHS)[11] 2004 data, and matched to trans fat content in foods data published by Arcand *et al.,* (2014)[12], where possible. Portions at the 50th, 90th and 95th percentile were used for the simulations, but only the 90th percentile data are presented below.

The criterion used to determine whether the contribution of a food to the total TFA intake was considered as nutritionally meaningful was that the food, when consumed in typical amounts for consumers with relatively high intakes (90th percentile), provided 1/5 or more of the maximal TFA intake (expressed as % energy intake as per the WHO recommendation of 1%).

Approximations/limitations of the modelling work:

- Average estimated energy requirements (EER) were calculated for children age groups by averaging the EER of each age within that age group (e.g. for 14-18 y old, EER for 14y, 15y, 16y, 17y, and 18y were averaged) EER for males and females were also averaged. This was done to match the age groups in the CCHS intake data. It has to be noted that the average EER for each of the 3 children age groups is not weighted (does not take into account the proportion of children with a given age within the age group).
- The estimated %E intake from trans fat for sedentary children may possibly be overestimated because average intakes of foods for a given age group were used, rather than intakes specific to sedentary children (which may possibly be smaller). In the case of active children, the estimated %E intake from trans fat may possibly be underestimated (the actual food intakes may be higher than the average intakes used for the estimation). Nevertheless, in both cases, similar results were obtained (pointing towards the choice of 1g/100g fat as the condition for the claim).
- For adults, an arbitrary value of 2, 000 kcal/day was chosen as an EER.

[11] Health Canada and Statistics Canada. Canadian Community Health Survey, Cycle 2.2, Nutrition (2004). Nutrient intakes from foods. http://www.hc-sc.gc.ca/fn-an/surveill/nutrition/commun/index-eng.php

[12] Arcand, J., Scourboutakos, MJ., Au, J.TC, and L'Abbe, M. trans Fatty acids in the Canadian food supply: an updated analysis. Am J Clin Nutr (2014) doi: 10.3945/ajcn.114.088732

Table 1. TFA Content set at 1 g TFA /100 g fat for selected foods*

FOOD	Adults		Children (4-8y)		Children (9-13y)		Children (14-18y)	
	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)
	P90		P90		P90		P90	
Bread with additions	121.5	7	99.39	8	125.00	8	141.95	8
Brownies and other squares (<5% of total fat as TFA)	94.0	8	N/A	N/A	N/A	N/A	N/A	N/A
Cereal, instant hot, flavoured	351.6	8	300.81	11	342.83	10	311.95	7
Cheesecake	124.00	10	93.09	12.2	124.00	13	209.57	18
Chicken wings, cooked and uncooked	230.1	13	132.49	12	180.54	13	229.05	13
Cookies, social tea/sugar type	63.0	5	70.00	8	72.37	7	80.00	6
Cooking oil	23.50	10	14.99	10	18.67	10	20.55	9
Desserts, baked	124.00	8	93.09	9.6	124.00	10	209.57†	14
Fish and seafood, seasoned and stuffed	213.0	4	139.82	4.4	170.08	4	195.56	4
Lard and shortening (<2% of total fat as TFA)	23.5	11	16.82	12	N/A	N/A	27.63	12
Margarine	28.30	9	28.30	14	28.30	11	25.83	8
Pasta and noodles with sauce, canned and dry	394.2	7	278.71	8	349.01	8	407.93	8
Pasta, stuffed, frozen	394.16	11	285.22	12	349.01	12	407.93	11
Pies and crisps	124.0	8	93.09	9.7	124.00	10	209.57†	14
Potatoes	181.44	4	151.93	6	173.19	5	189.56	4
Poultry, breaded, cooked and uncooked	257.7	13	138.56	11	210.83	13	245.53	12
Rice and grains, canned and dry, seasoned	448.4	4	293.39	4	386.62	4	512.48	5
Soup, non-cream, ready to serve	629.1	3	421.74	3	N/A	N/A	590.59	2
Sweet buns	121.5	9	99.39	11	125.00	11	141.95	10
Tortilla and wraps	114.0	3	86.00	4	114.00	4	127.52	4

* Foods included in the table are those reported to contain 2% TFA on a fat basis and a few additional foods
†: Food intake data with a coefficient of variation (CV) from 16.6% to 33.3% in CCHS; interpret with caution.
N/A: data not available

Table 2. TFA Content set at 2 g TFA /100 g fat for selected foods*

FOOD	Adults		Children (4-8y)		Children (9-13y)		Children (14-18y)	
	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)	Typical portion consumed (g per person per day)	Percent of maximal limit of TFA intake (1% energy)
	P90		P90		P90		P90	
Bread with additions	121.50	13	99.39	17	125.00	17	141.95	15
Brownies and other squares (<5% of total fat as TFA)	94.00	15	N/A	N/A	N/A	N/A	N/A	N/A
Cereal, instant hot, flavoured	351.63	17	300.81	22	342.83	20	311.95	15
Cheesecake	124.00	21	93.09†	24	124.00	26	209.57†	35
Chicken wings, cooked and uncooked	230.12	27	132.49	24	180.54	26	229.05	26
Cookies, social tea/sugar type	63.00	9	70.00	16	72.37	13	80.00	12
Cooking oil	23.50	21	14.99	21	18.67	20	20.55	18
Desserts, baked	124.00	16	93.09†	19	124.00	20	209.57†	28
Fish and seafood, seasoned and stuffed	213.00	9	139.82†	9	170.08	8	195.56	8
Lard and shortening (<2% of total fat as TFA)	23.49	21	16.82	23	N/A	N/A	27.63	25
Margarine	28.30	18	28.30	28	28.30	22	25.83	16
Pasta and noodles with sauce, canned and dry	394.16	15	278.71	16	349.01	16	407.93	15
Pasta, stuffed, frozen	394.16	22	285.22	25	349.01	24	407.93	23
Pies and crisps	124.00	17	93.09†	19	124.00	20	209.57†	28
Potatoes	181.44	8	151.93	11	173.19	10	189.56	9
Poultry, breaded, cooked and uncooked	257.67	26	138.56	21	210.83	26	245.53	25
Rice and grains, canned and dry, seasoned	448.43	8	293.39	8	386.62	9	512.48	9
Soup, non-cream, ready to serve	629.11	5	421.74	5	N/A	N/A	590.59	5
Sweet buns	121.50	17	99.39	22	125.00	22	141.95	20
Tortilla and wraps	114.00	7	86.00	8	114.00	9	127.52	8

* Foods included in the table are those reported to contain 2% TFA on a fat basis and a few additional foods
Cells highlighted in red represent ≥ 1/5 (20%) of maximal trans fat intake
†: Food intake data with a coefficient of variation (CV) from 16.6% to 33.3% in CCHS; interpret with caution.
N/A: data not available