CODEX ALIMENTARIUS COMMISSION

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Agenda Item 9 **CRD 10**

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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECCIAL DIETARY USES

Thirty-eighth Session

Hamburg, Germany, 5 – 9 December 2016

DISCUSSION PAPER ON CLAIM FOR "FREE" OF TRANS FATTY ACIDS

Comments of India, Indonesia, Kenya, Malaysia, Nigeria, United States of America, African Union, IDF and IFMA

INDIA

Specific Comment:

India suggests the health claim for "Free" of Trans Fatty Acids may be made when the Trans fat is less than 0.2 g/serving of food.

Rationale: Based on the National Regulations.

INDONESIA

Indonesia would like to thank Canada for preparing the discussion paper and supports the development of conditions for a "free" of TFA claim. Indonesia proposes a level at 0.2 g of TFAs per 100 g/mL of food to be consistent with the amounts set for the other "free" claims in the CAC GL 23-1997 Guidelines for Use of Nutrition and Health Claims.

KENYA

We support in principle work on this subject and the recommendation to adopt 1 g per 100g of fat as the basis for transfatty acids free claim on all products.

MALAYSIA

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

Malaysia supports the proposal by Canada 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).

Malaysia also supports Canada's proposal that in order to carry a trans-fat free claim, the food should contain no more than 1 g per 100 g of fat.

On the other hand, Malaysia strongly objects the proposal that conditions for the TFA-free claim must meet the conditions set for "low" in saturated fats.

Malaysia reiterates our previous position that saturated fatty acids (SFAs) and TFAs are two independent fatty acid classes which are not linked to each other in any way or form and each exhibits different characteristics and physiological effects as well as metabolic outcomes. The detrimental health effects of TFAs have been well established.

Malaysia notes that Canada has also asserted that two recently-published systematic reviews highlighted by WHO (2016) confirms that saturated fatty acids have negative effects on the blood lipid profile, including total cholesterol/HDL cholesterol ratios and LDL cholesterol/HDL cholesterol ratios and ApoB levels.

However, it is pertinent to point out that the two systematic reviews were based on surrogate or intermediate markers and it is important not to ignore the increasing number of systematic reviews and meta-analysis that were based on actual cardiovascular disease risks which are hard clinical end-points (CHD and stroke).

This includes a recent systematic review and meta-analysis of observational studies looking at Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes by de Souza et al, 2015. The review reported that saturated fats are not associated with all cause mortality, CVD, CHD, ischemic stroke, or type 2 diabetes.

A point to note from the authors was that NUGAG members have looked at the results presented and that WHO agreed to the publication of this systematic review in a scientific journal because it serves as the background evidence review for updating WHO guidelines on saturated and trans fatty acids and should therefore be available widely.

Prior to the above publication, there has been increasing evidence suggesting that SFAs may not be the causative agent for CHD risk and that not all SFAs impact plasma cholesterol adversely (de Oliviera Otto et al., 2012). Current scientific evidence does not support the traditional diet-heart paradigm which relates the consumption of SFAs and coronary heart disease (CHD) (Mozaffarian, 2011). Indeed evidence from meta-analysis on cohort studies by Skeaff & Miller (2009) on SFAs and CHD, suggest that the intake of SFAs was not significantly associated with CHD mortality and events based on 5% total energy increment in SFAs intake. Moreover, the meta-analysis by Siri Tarino et al. (2010a) concludes that prospective epidemiologic studies do not associate dietary SFAs with increased risk of CHD or CVD. Similarly, a recent meta-analysis of some 50 observational studies and 17 randomised controlled trials reported no link between SFAs and cardiovascular disease risks (Chowdhury et al., 2014). Furthermore, as pointed out by Siri Tarino et al. (2010b), the relative effect of dietary SFAs on CVD risk factors needs to be evaluated, taking consideration of the changing paradigms associated with CVD risk factors.

There is also insufficient evidence to support the association of SFAs with a cluster of metabolic risk factors, as no clear association has been reported between dietary fat and blood pressure, endothelial function, inflammation, fibrinolysis, or insulin sensitivity (Sanders, 2009) and diabetes (Melanson et al., 2009; Micha & Mozaffarian, 2010).

In addition, it is crucial to highlight that plasma cholesterol are carried by LDL particles which comes in a continuum of many of sizes, divided into 4 major sub-classes in the density range 1.019-1.060 g/ml; namely LDL-I (large buoyant, 1.019-1.023 g/ml), LDL-II (intermediate, 1.024-1.034 g/ml), LDL-III (small dense, 1.034-1.044 g/ml) and LDL-IV (very small dense, 1.044-1.060 g/ml). Krauss and colleagues (Krauss, 1991; Berneis and Krauss, 2002) have simplified this to define two LDL phenotypes; so-called Pattern A individuals who are characterized by a predominance of large buoyant LDL particles in plasma whilst Pattern B individuals have a predominance of small dense LDL particles. It is the small, dense LDL particles which are much more atherogenic as these can easily penetrate the arterial wall, get oxidized and engulfed by phagocytes which later burst forming fatty streaks. On the other hand, large buoyant LDL particles are much less harmful.

It must be highlighted that current scientific research shows that saturated fats induce large LDL particles which are deemed less harmful compared to trans fats and refined carbohydrates (Dreon et al, 1998; Mauger et al., 2003).

The effects of dietary fats on LDL particle size must be considered when reviewing the effects of dietary fats on risk of cardiovascular disease. Therefore, whilst it is reasonable to include trans fatty acids in the Table of Conditions for Nutrient Content Claims, the proposal to include a low saturated fat content for a trans-free claim is not only illogical, but may not represent the true effect on the hard clinical end-points. The fact that “saturated fats” and “trans fats” are two completely different entities, with significantly different impacts on CHD and stroke mortality, as well as on LDL particle size in circulation, should not be ignored. However, the impact of trans on lipoprotein particles is not fully documented but we take cognizance of this emerging science that could further show a real time need to separate effects of trans from saturates.

In addition the effects of trans fatty acids go beyond their impact on plasma cholesterol and lipoproteins. There are additional heath challenges due to trans which made them a unique nutrient target to be eliminated from the human diet. These additional health challenges which are seen with trans but not similarly manifested or impacted by consumption of saturated fats/fatty acids, include increase in diabetes, obesity trends being higher, impacting fetal development in pregnant women, and adverse cardiac health apart from hyperlipidemia.

This clearly states that trans and saturates cannot be linked in any labeling effort since their health outcomes are so significantly different from each other.

Therefore, the current proposal to associate TFAs with saturated fats takes a step backwards and will do significant injustice to the scientific principles already well-established on the differences between TFAs and SFAs.

In view of the above, Malaysia does not support the proposal that the trans-fatty acid free claim must meet the conditions for ‘low’ in saturated fat.

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NIGERIA

Nigeria supports the proposal for a claim "free" of Trans Fatty Acids be inserted between saturated fat and cholesterol within the table of conditions for nutrient content in the Guidelines for Use of nutrition and Health Claims (CAC/GL 23- 1997).

Nigeria also support the proposal that food should contain not more than 1g per 100g of fat and must meet condition "low" in-saturated fat. The proposed level is in line with WHO Guideline.

Rationale: Transfatty acids (TFA) have a negative health effect. A number of studies have shown an association of TFA consumption and increased risk of Cardiovascular Diseases (CVDs). Hence it is important to help consumers make informed decision and protect them from false claims by establishing the proposed level for TFA.

UNITED STATES OF AMERICA

The United States is of the view that the proposed level of 1 g *trans* fat per 100 g of fat cannot be accurately and precisely measured based on the available collaborative study data on the analytical methods. The United States recognizes the strong evidence for relationships between *trans* fat intake and saturated fat and increased LDL-cholesterol concentration, a surrogate endpoint for coronary heart disease risk. The United States therefore recognizes the importance of declaring the amount of *trans* fat on the food label to assist consumers in maintaining health dietary practices, and when possible relevant nutrient content claims. The United States also recognizes that some countries include conditions for saturated fatty acid (SFA) content along with the provision for a "free" claim for *trans* fatty acids.

However, the Codex List of Methods has not yet identified methods for measuring *trans* fat in foods. The precision data on the *trans* fat methods have relative standard deviation (RSD) values that are too high to allow the methods to be fit for purpose. The methods work well in some foods, but not well in others. It is the U.S. view that the current analytical methods, including the combinations referred to in this Discussion Paper (ISO 16958/IDF 231/AOAC 2012.13, AOAC 996.06 and AOCS Ce 1h-05, and AOCS Ce 2b-11/Ce 2c-11 and AOCS Ce 1j-07) generally do not allow for the determination of the proposed level and below in foods (Table 1). Accurate determination may be achievable for specific foods and in specialized labs with highly trained and experienced analysts.

The first method (ISO 16958/IDF 231/AOAC 2012.13) describes a direct transesterification method for the determination fatty acids in milk products, infant formulas, and adult/pediatric nutritional formulas which contain milk fat and/or vegetable oils and may be supplemented with oils rich in long chain polyunsaturated fatty acids (PUFAs). Results of the collaborative study were expressed by groups of fatty acids (e.g., total *trans* fat, PUFAs, SFAs). Over the concentration range of 0.008 to 5.056 g *trans* fat/100 g product in the ISO-IDF materials, minimum and maximum RSD_R (%) values were 8.69 and 32.92, respectively. None of the data were directly associated with specific collaborative study samples. ISO 16958/IDF 231/AOAC 2012.13 is applicable only to liquid or reconstituted powder samples, and has not been validated for solid food matrices. Therefore, it is not possible to determine whether this method is suitable for determination of *trans* fat at levels of <1% in foods.

The second method combination (AOAC 996.06 and AOCS Ce 1h-05) involves the sample preparation procedures of AOAC 996.06 combined with AOCS Ce 1h-05 for the analysis of fatty acid methyl esters (FAME) by gas chromatography with flame ionization detection (GC-FID).

- AOAC Official Method 996.06 presents multi-laboratory precision data for the analysis of total, saturated, and monounsaturated fat, but not for *trans* fat (Tyburczy et al., 2013) [1] There are no multi-laboratory collaborative study data available for the determination of total *trans* fat in foods when samples were prepared according to AOAC 996.06.
- AOCS Ce 1h-05 is appropriate for the analysis of vegetable and non-ruminant fats and oils, but not appropriate for the analysis of dairy, ruminant, or marine oils, oils containing long chain PUFA, or products supplemented with conjugated linoleic acid. AOCS Official Method Ce 1h-05 presents multi-lab validation data for the determination of *trans* fat in 10 edible fats and oils. For oils with a

[1] Tyburczy C, Mossoba MM, Rader JI. Determination of *trans* fat in edible oils: current official methods and overview of recent developments. *Anal Bioanal Chem* 2013;405:5759-5772.

high *trans* fat content (11.62–45.01 % of total fat), Horrat[2] [i.e., precision] values ranged from 0.79 to 2.02, indicative of acceptable method performance for these samples. For oils with a low *trans* fat content (0.06–1.00 % of total fat) the Horrat values exceeded 2.65. The collaborative study did not include any samples with a *trans* fat content in the range of 1.00–11.62 % of total fat, a range that includes many refined, bleached, and deodorized edible oils (Tyburczy et al., 2013).

The third method combination (AOCS Ce 2b-11/Ce 2c-11 and AOCS Ce 1j-07) involves the sample preparation procedures of AOCS Ce 2b-11/Ce 2c-11 with AOCS Ce 1j-07 for the analysis of FAME by GC-FID.

- AOCS Ce 2b-11/2c-11 combined with AOCS Ce 1j-07 was recently evaluated in a multi-laboratory collaborative study which involved 22 different food matrices. Horrat values were <2.00 for only 4 (22%) of the 18 matrices for which this parameter could be calculated. Among the samples studied, only two had low *trans* fat values (chocolate cake mix, 0.90%; plain yoghurt, 0.32%) and Horrat values of < 2. Thus, the collaborative study data that would support a 1 g *trans* fat per 100 g fat cut-off are limited to data from only two samples. The observation that Horrat values ranged from 2.87 to 14.8 for the majority of the study samples indicates the unsuitability of this method for the determination of *trans* fat at levels < 1% of total fat for all but two products (Tyburczy et al., 2013).

Table 1. Comparison of Analytical Methods for the Determination of Total Trans Fat

Method Characteristics	**ISO16958 / IDF231 / AOAC 2012.13**	**AOAC 996.06 and AOCS Ce 1h-05**	**Ce 2b-11/Ce 2c-11 and AOCS Ce 1j-07**
Scope and Applicable Matrices	liquid or reconstituted powder samples of milk products, infant formulas, and adult/pediatric nutritional formulas	AOAC 996.06 - fat (total, saturated, and unsaturated) in many food matrices, including dairy products and cheese. AOCS Ce 1h-05 - fatty acid composition in vegetable and non-ruminant oils and fats.	AOCS Ce 2b-11/Ce 2c-11 - fatty acids in many food matrices. AOCS Ce 1j-07 - *cis*-, *trans*-, saturated, monounsaturated, and polyunsaturated fatty acids in extracted fats, including those derived from dairy and ruminant products.
Protocols for: **Sample preparation** **and** **Measurement**	Direct transesterification to FAME, then analysis by GC-FID	**AOAC 996.06** - applicable to most food matrices. **AOCS Ce 1h-05 –** GC-FID	**AOCS Ce 2b-11/Ce 2c-11** – many food matrices. **AOCS Ce 1j-07 –** GC-FID
Collaborative Study Data for Total TFA	**AOAC 2012.13** 6 samples (i.e., cream, butter, cheese, infant formula powder) and 6 samples from SPIFAN/AOAC (i.e., adult nutritional powder or liquids, infant formula powders or liquid). **None of the data are directly associated with specific collaborative**	**AOCS Ce 1h-05:** 10 edible fats and oils.	**AOCS Ce 1j-07** : 22 samples - Total fat values varied from 0.11% (DHA/EPA-fortified orange juice) to 95.2% (tallow). Total *trans* fat (as % of total fat) varied from 0.02% (full-fat soy flour flakes) to 7.27% (cheese powder). Four samples contained 0.00% *trans* fat. **The collaborative study data that would support a 1 g *trans* fat per 100 g fat**

[2] The empirically accepted Horrat range is 0.5 to 2.0 with values > 2.0 indicating a need for further method optimization or analyst training.

	study samples and it is not possible to determine whether this method is suitable for determination of *trans* fat at levels of < 1% in foods.	**There is a minimal amount of available collaborative study data and limited sample matrix applicability**.	**cut-off are limited to data from only two samples.**

The findings from multi-lab validation studies, such as those discussed above, are a more appropriate source of information about the analytical method than what occurs with specific analysts within a specific lab. Based on the above information, it is the U.S. view that there are no reliable analytical methods to support a "free" *trans* fat claim at this time.

AFRICAN UNION

Issue: Discussion paper on Trans fatty acids to include a level of 1 g per 100g of fat

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).

Comment: The AU supports the proposed levels

Rationale: Trans fatty acids (TFA) have a negative health effect. A number of studies have shown an association of TFA consumption and increased risk of Cardiovascular Diseases (CVDs). Hence it is important to help consumers make informed decision and protect them from false claims by establishing the proposed level for TFA.

IDF – International Dairy Federation

IDF (International Dairy Federation) would like to reiterate its previous comments that **the proposed Claim for "free" of trans fatty acids is not supported by the dairy industry.**

It is strongly recommended that any consideration of claims related to trans fatty acids be reconsidered in the context of reduction of *trans fatty acids from partially hydrogenated oils and fats*.

As per the 2009 WHO Scientific Update on trans fatty acids, it is recommended that industrially produced trans fatty acids should be virtually eliminated from the food supply. These have been found to be associated with adverse effects on blood lipoprotein profiles and coronary heart disease, and have no known nutritional benefit (Uauy R et al, 2009). Such recommendations continue to be supported by recently published evidence.

One systematic review and meta-analysis commissioned by WHO and published in a peer reviewed journal in July 2015 on trans fatty acids and health outcomes, showed that total trans fatty acid intakes are associated with all-cause mortality (RR 1.34; 95%CI: 1.16-1.556) and coronary heart disease mortality (RR 1.28; 95%CI: 1.09-1.50). In the systematic review, it was also found that **industrial, but not ruminant, trans fats were associated with coronary heart disease mortality** (RR 1.42 vs 0.93) (de Souza RJ et al 2015). The authors conclude that the association between total TFA and CHD is most consistently driven by industrial TFA, probably because of their higher levels of intake (de Souza et al 2015). In another review, a daily intake of 5 g of primarily industrial TFA was associated with a 29% increased risk of CHD whereas no such association was found for a daily intake of 4 g of ruminant TFA (Stender et al., 2008).

Last summer the WHO Expert Advisory group released a second systematic review focusing solely on blood lipid profiles which found that replacement of trans fatty acids from any source with cis-polyunsaturated fatty acids consistently lowered total cholesterol. The systematic review included a total of 16 RCTs, 12 of which examined the effects of industrial TFAs, only 4 of which included ruminant TFAs While the evidence for an effect of reducing total and industrial TFA intake by replacement with other fatty acids or carbohydrates was high, the evidence for an effect on blood lipids of replacing ruminant TFA with cis-MUFA, cis-PUFA, SFA or carbohydrates on most outcomes was judged to be GRADE LOW (due to serious inconsistency and imprecision). The authors concluded that the (lack of) effects observed for ruminant studies may actually have been a result of differences in dose rather than type of TFA. Furthermore, Brouwer (2016) noted that the number of studies on rTFA is small because "it is difficult to design diets comprising natural, unmodified foods with high intakes of rTFA. This suggests that in current real-world settings, intakes of ruminant TFA are generally low, which would correspond to a small resulting risk of negative health effects"(Brouwer 2016).

The WHO Global Strategy on Diet, Physical Activity and Health background documents refers to partially hydrogenated oils and fats when considering trans fats intake in the context of cardiovascular health. Thus the ingredients of concern are trans fats derived from partially hydrogenated oils and fats ('*To promote*

*cardiovascular health, diets should contain very low levels of trans fatty acids (hydrogenated oils and fats'**No index entries found.**)* (WHO 2003).

Regulatory and public health body approaches in the EU and US have focused on reduction/ elimination of partially hydrogenated vegetable oil consumption and not reduction of ruminant TFA consumption.

Furthermore, despite dairy providing TFAs, 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). This adds to the evidence that fat present in dairy is not detrimental for cardiovascular health. Overall, if TFA labelling encouraged reduced intakes of dairy, this may lead to unintended negative health outcomes.

Therefore, if any condition of use would be chosen by the Committee on a claim about trans fat, and based on elements stated, IDF proposes the following changes to the Canadian proposal in point 12

Component	**Claim**	**Conditions (not more than)**
Trans fatty acids **from partially hydrogenated oils and fats**	Free	1 g of **trans fatty acids from partially hydrogenated oils and fats** per 100g of fat And must meets the conditions for "low" in saturated fats[5]

Finally, IDF has concerns about the suitability of the set of methods mentioned in the Canadian proposal for the coverage of the whole range of food products. The now published ISO 16958|IDF 231:2015/AOAC 2012.13 has been validated on milk, milk products, infant formula and adult nutritionals and in principle could be applied to other foods. This may be relevant as in Appendix 2 with the Discussion Paper AOCS raises concerns about the reproducibility of the AOCS methods at low levels of trans fatty acids:

> *"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."*

However, to determine whether ISO 16958|IDF 231:2015/AOAC 2012.13 can be used to verify compliance with a TFA-free claim, further validation studies are required to verify its applicability to other foods and to estimate performance characteristics (repeatability and reproducibility) for such other foods. We note that the IDF|ISO/AOAC method can both measure in g/100 fat and g/100 product. We would support requesting CCMAS to review the suitability of the proposed methods to support this claim.

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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL regarding trans fats in foods and in the overall diet of the Union population https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_trans-fats-report_en.pdf

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IFMA – International Federation of Margarine Associations

Specific comments

PROPOSAL (FROM CANADA)

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

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]

[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.

IFMA GLOBAL POSITION:

- We welcome the proposal of the government of Canada to the Codex Committee on Nutrition and Foods for Special Dietary Uses to establish a definition and criteria for use of the claim "Free from Trans Fatty Acids".
- As both TFA sources in the diet, ruminant TFA and non-ruminant TFA have the same detrimental effect on health (Brouwer IA, 2016), the conditions set out for a TFA free claim should apply on both sources of TFA (ruminant and non-ruminant TFA) in the food products.
- Claims must be relevant and understandable to consumers, based on scientific evidence and focused on helping consumers make healthier food choices.
- A "Free from Trans Fatty Acids" claim should therefore only be used **in an environment where information about TFA content in all foods is provided**, to ensure that consumers are not misled about the TFA content of foods that do not, or are not permitted to use the claim.
- The most appropriate way to set a threshold for a claim is per 100ml/100g/portion of food product- as originally proposed by Canada - as this is related to the actual food consumed. Per 100g FAT relates to an ingredient and is therefore not directly related to the TFA content of the actual food consumed, - hence the REAL amount of TFA consumed in "TFA Free" foods could vary considerably.

- We wish to propose thresholds that better reflect the real relationship between a food item, it's TFA content and the contribution to the diet coming from that food and thus enable meaningful communication to the consumer:
    - **Trans Fats (TFA) levels: no more than 0.2 g per serving;**
    - **Saturated fats (SFA) levels: no more than 30-33% of SFA of total fat, and no more than 30-33% of energy per serving from SFA.**

RATIONALE / JUSTIFICATION

Overall approach for "*trans* fat free" claim:

- The possibility to claim "*trans* fat free" on products should help consumers make healthy food choices and provide an incentive for food manufacturers to reformulate, leading to a meaningful reduction in consumer TFA intake from all sources and, ultimately, a tangible public health benefit.
- Partially hydrogenated oils with significant levels of TFA have typically been used for their technological & texturing properties in products. Examples include cookies, cakes, chocolate and confectionary products, fries, pop corn, and fast food. It should be noted that voluntary reformulation efforts by the industry has resulted in a significant reduction of non-ruminant TFA content in major geographies like the EU and US.
- According to the claim conditions proposed in the Discussion Paper, only the category of products already low in fat (read SFA) could make the claim; this is less relevant from a public health point of view (Stender et al., 2012).
- Restricting the use of TFA-free claims to products also qualifying for "low SFA" claims would be counter-productive: many of the products mentioned above would be excluded from making a TFA-free claim based on their saturated fat content including vegetable oils which are recommended by National Dietary Nutrition Guidelines.
- Moreover, proposed values are also much more restrictive than the values certain jurisdictions have applied for years:
    - Eg CANADA:
        1. <0.2 g TFA per SERVING and per REFERENCE AMOUNT
        2. < 2.0 g [SFA+TFA] per SERVING and per REFERENCE AMOUNT
            a. Or per 100 g, if the food is a prepackaged meal
        3. < 15% ENERGY from [SFA + TFA]

Conditions of use on TFA levels

- We do not see the rationale for choosing 1g TFA per 100g FAT as a threshold as this is lower than the level that FEDIOL advises (2 g TFA/100g FAT), taking into account the refining of liquid oils and hydrogenation of oils and fats. It is therefore unclear if this claim could be used in some of the categories where it could be most helpful to consumers.
- The threshold should be based on actual consumption and a level that is nutritionally relevant. Consideration of levels in individual ingredients is therefore less meaningful for a claim (i.e. grams of TFA per 100g FAT), and deviates from the approach used for other 'free-from' claims as already noted (in para 22). This approach may be useful for setting a legal limit for products but that is beyond the stated scope of this work, which is to set a definition and conditions of use for a 'free-from' claim. This work should not be used as a back-door to set legal limits for products.
- IFMA supports the TFA-free claim criteria that Canada itself has applied for years: 0.2g TFA/ SERVING. A typical 10 gram serving of spread that meets the proposed 0.2 gr/serving would deliver less than a tenth of the WHO/FAO population nutrient intake goals for trans fatty acids of <1 E% (FAO report, Geneva 2008).

Conditions of use on SFA levels

- We do understand that the reason to include limits on **both** TFA and SFA content for the TFA-free claims is to avoid TFA reduction accompanied by SFA increase.
- However, voluntary PHVO removal in the margarine category over the past 20 years has demonstrated that reduction of TFA can be done without an increase in saturated fats content. This approach has led to a decrease in population TFA intake (Wesdorp et al 2014).

- In addition, the results of two North-American studies confirmed that supermarket and restaurant foods decreased TFA without concomitantly increasing SFA (Ratnayake 2009; Mozaffarian 2010)
- The proposed SFA condition is focusing on very low SFA level (per 100g product). Scientifically the balance with unsaturated fats is much more relevant. E.g. oils such as canola oil would not be able to make the low TFA claim, as SFA = 7g/100g (irrespective of MUFA+PUFA being >91g/100g). This condition ignores recommendations such as the US dietary guidelines stating that people should eat more non-tropical vegetable oils.
- The strict SFA condition would considerably reduce the incentive for manufacturers to remove TFA. For example, a Canadian study has shown that many types of foods that likely contain TFA such as cookies, muffins, pizza, crackers and popcorn contain more than 1.5g SFA per 100g food and would never be able to qualify for a TFA-free claim (Ratnayake 2009).
- IFMA therefore suggests adaptation of conditions of use regarding SFA: the product claiming TFA-free should meet conditions to fit in a healthy diet in the context of fatty acids. **We suggest the following conditions of use regarding saturated fats for the trans fat free claim**, consistent with the WHO/FAO recommendations on fatty acids, the International Choices Criteria, and in line with the latest criteria of the Nordic Keyhole and Finnish Heart Foundation:
    - no more than 30-33% of SFA of total fat, and no more than 30-33% of energy per serving from SFA.

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