

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 8

CX/NFSDU 18/40/9

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

Fortieth Session

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### PROPOSED DRAFT CLAIM FOR “FREE” OF TRANS FATTY ACIDS Comments at Step 3 (Replies to CL 2017/89/OCS-NFSDU)

*Comments of Argentina, Australia, Brazil, Colombia, Costa Rica, Cuba, Ecuador, Egypt, Guinea Bissau, Iran, Malawi, Mexico, New Zealand, Paraguay, Peru, Philippines, Singapore, South Africa, United States of America, FEDIOL, ICGMA and IDF*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/89/OCS-NFSDU issued in December 2017. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

## ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER
<p>In Argentina, the same conditions proposed by Canada for the nutrition claim “free of trans fats” apply (GMC Resolution No. 01/12, Chapter V of the Argentine Food Code - CAA):</p> <ol style="list-style-type: none"> <li>1. Not to contain more than 0.1 g of trans fats: (a) per 100 g or 100 ml for prepared meals as appropriate; or (b) per serving.</li> <li>2. To meet the conditions established for “low in saturated fats”.</li> </ol> <p>The condition established for “low in saturated fats” is:</p> <ol style="list-style-type: none"> <li>1. Not to contain more than 1.5 g of the sum of saturated fats and trans fats: (a) per 100 g or 100 ml for prepared meals as appropriate; or (b) per serving when these are above 30 g or 30 ml; in portions smaller than or equal to 30 g or 30 ml, it shall be calculated on the basis of 50 ml or 50 g.</li> <li>2. The energy provided by saturated fats shall not be more than 10% of the total energy value of the food.</li> </ol> <p>On the other hand, it is stressed that the preparation of food in Argentina is restricted in terms of the trans fats content. In this regard, CAA Seccion 155 tris states that “the content of industrial trans fatty acids in foods shall not be more than: 2% of total fats in vegetable oils and margarines intended for direct consumption and 5% of total fats in the rest of food. These limits do not apply to ruminant fats, including milk fat.”</p>	<p><b>Argentina</b></p>
<p>Given the established association between saturated fats and TFAs and their negative effect on blood lipid profiles and increased risk of cardiovascular disease, Australia supports the inclusion of the conditions for “low” in saturated fat as currently proposed (i.e. not more than 1.5 g per 100 g (solids); 0.75 g per 100 ml (liquids); and 10% of energy of saturated fat). Inclusion of these conditions should avoid any increase in replacement of TFA with saturated fats. We note this is similar (but not entirely consistent) to the requirements in the Australia New Zealand Food Standards Code where food carrying a ‘free of trans fatty acids’ claim in Australia and New Zealand must meet the conditions for a ‘low’ saturated fat claim.</p>	<p><b>Australia</b></p>
<p>Brazil considers that the rationale used to derive the conditions for use “free” of trans fatty acids is consistent. So, we do not have specific comments on these proposed conditions.</p> <p>However, we would like to point out that an effective reduction in the consumption of TFA might require the adoption of other regulatory approaches, such as the mandatory removal of industrial TFA from the food supply or the use of front-of-packaging labelling (FOPL) to help consumers identify foods that have the addition of these substances.</p> <p>In this regard, it should be noted that elimination of industrial TFA is one of the priority actions identified by WHO in its 13th General Program of Work, which will guide the work of the Organization in 2019-2023. Removing these substances from the food supply represents a feasible mechanism for achieving significant reductions in TFA intake at the population level and is considered as an achievable goal (ref 1).</p> <p>Additionally, some delegations and observers have suggested the use of different approaches to label foods with TFA, which includes FOPL (ref 2,3,4). Although this issue is outside the scope of this work, it should be noted that the Codex Committee on Food Labeling (CCFL) is carrying new work on the development of guidelines on FOPL systems and that in the next session it will consider a discussion paper on criteria for the definition of “high in” nutritional descriptors for fats, sugars and sodium.</p> <p>Given the issues raised above, it is important to carefully evaluate the consistency between the proposed conditions for the use the claim free of TFA and the thresholds adopted to ban these or to highlight its presence in foods.</p> <ol style="list-style-type: none"> <li>(1) World Health Organization. Draft guidelines on saturated fatty acid and trans-fatty acid intake for adults and children. 2018</li> <li>(2) Peru. Decreto Supremo N° 017-2017-SA. Decreto Supremo que aprueba el Reglamentode la Ley N° 30021, Ley de Promoción de la Alimentación Saludable . El Peruano, 17 de junhode 2017.</li> <li>(3) Peru. Ministerio de Salud. Manual de advertências publicitarias del reglamento de la Leyn° 30021, Ley de Promoción de la Alimentación Saludable para Niños, Niñas y Adolescentes.2017.</li> </ol>	<p><b>Brazil</b></p>

(4) PAHO. Pan American Health Organization Nutrient Profile Model, 2016.	
<p>Colombia refrains from supporting or rejecting the proposed text, as there was no consensus during the technical discussions because of the divergent positions between the industrial sector and the government sector – health, as explained below:  The Ministry of Health and Social Protection does not support the proposed text because it is not consistent with public health protection policies with respect to the reduced consumption of trans and saturated fats, which are based on the recommendations of the World Health Organisation and based on the evidence of the effects of the consumption of these fats on human health, especially non-communicable diseases. The updated regulation on the requirements for nutritional marking that the Ministry is carrying out calls for the restriction of trans and saturated fats content through the use of the declaration “free of trans fatty acids”, remembering that a healthy diet should consist of a wide variety of nutritional sources and not a single component. In addition, it is considered important for consumers to have clear information so they can make informed buying decisions.  For its part, the industry says that the proposed parameter in the text is restrictive and that there is insufficient evidence regarding a link between the consumption of saturated fatty acids and cardiovascular diseases, as a result of which the declaration should not be conditional based on a low saturated fat content.</p>	<b>Colombia</b>
<p>We support the establishment of conditions for this declaration, and the placement of the declaration in the Table of Conditions for the declarations on nutrient content within the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) as indicated at the footer line of page 1 of the proposal.</p>	<b>Costa Rica</b>
<p>Cuba supports the component on trans fatty acids in the proposed draft text; in the recommendations for the Cuban population, it is recommended that the consumption of trans fats be limited to less than 1% of daily calories.</p>	<b>Cuba</b>
<p>Ecuador notes with concern that a nutritional declaration concerning the content of trans fatty acids (TFA) has been approved, as this type of declaration may cause consumers to think that a product “free of trans fatty acids” is healthy and they may favour such products, even though they may contain high levels of fat, sodium and sugar. For this reason, it believes it is important to use warnings regarding the presence of trans fatty acids in food products and recommendations to avoid or reduce the consumption of these, but not confusing declarations that might not provide clear and precise information.</p>	<b>Ecuador</b>
<p>Egypt agrees the claim for “free” of trans fatty acids as proposed.</p>	<b>Egypt</b>
<p>According to the Table of Conditions relating to nutrient content claims in the Guidelines for Use of Nutrition and Health Claims, the conditions for "low" saturated fat content are as follows: 1.5 g saturated fat per 100 g (solids), 0.75 g saturated fat per 100 ml (liquids) and 10% energy from saturated fat.</p>	<b>Guinea Bissau</b>
<p>Iran support this proposal, as scientifically based. So,  - It is aligned with WHO limit for TFA of 1% Total Daily Energy Intake.  - It will ensure that a given food does not contribute to more than 1/5th of the maximum trans fat intake limit (for individual with high intake of this food).  - Last year, the working group conducted simulations with observed food intake data in different age groups in Canada and TFA analyses in Canadian food. Some countries may have higher TFA content in foods (e.g. in eastern Europe). Therefore, this low limit of 1% (g TFA/ 100g fat) is justified for this claim.  - We could support the proposal that the conditions for the TFA-free claim also include conditions for saturated fat, in order to ensure that a food claiming to be free of TFAs will also be low in saturated fats.</p>	<b>Iran</b>

<p>-Trans-Fat claims should not be made on products where all such foods have the same characteristics, unless this is apparent in the claim. This principle is stated in CAC/GL 1-1979 section 51.1.v but should be reminded in this context.</p>	
<p>We find the Draft Standard acceptable</p>	<p><b>Malawi</b></p>
<p>In Australia and New Zealand a food must contain no detectable trans fatty acids to be eligible for a “free from” claim within the Australia and New Zealand Food Standards Code Standard 1.2.7.  In addition, the food must not contain more than 0.75 g saturated fatty acids/100 mL of liquid food; or 1.5 g saturated fatty acids/100 g of solid food; or no more than 28% saturated fatty acids as a proportion of the total fatty acid content.  If the Committee is supportive of adopting criteria which differ to the approach taken in Australia and New Zealand, we would not oppose the proposed criteria (i.e. the food must not contain more than 1 g trans fatty acids per 100 g of fat and must meet the conditions for “low” in saturated fats) on the basis CCMAS verifies the proposed level is measurable with the recommended analytical methods.  We note that in the Guidelines for Use of Nutrition and Health Claims the criteria for nutrient content claims for saturated fats take into account trans fatty acids and consider that saturated fat should be taken into account in criteria for the claim “free” from trans fatty acids. This is also consistent with the approach in the Australia and New Zealand Food Standards Code.</p>	<p><b>New Zealand</b></p>
<p>We agree with the proposed values regarding the declaration that a product is free from trans fats.</p> <p>We agree with the condition that a product not have more than 1 g per 100 g of fat, and that the product must also meet the condition that it has a low level of saturated fats.</p>	<p><b>Paraguay</b></p>
<p>Singapore supports the proposed conditions (i.e. the food should contain no more than 1g per 100g fat and must meet the conditions set for "low" in saturated fats), for use of the claim, "free" of trans fatty acids in the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997).  Acknowledging WHO's confirmation that saturated fatty acids have negative effects on the blood lipid profile, a food claiming to be TFA free should therefore also have low levels of saturated fat.  The proposed conditions would support WHO's recommendations on the reduction of TFA intake in adults and children as well as on the prevention of increasing saturated fat intake in adults and children.</p>	<p><b>Singapore</b></p>
<p>South Africa agrees with the proposed conditions for a "Free" of Trans fats claim and have already legislation with reference that ... "Where a claim that a foodstuff is "Trans-Fat free" is made on the label or in an advertisement, the content of Trans-Fat shall be less than 1 gram per 100 grams of the total fat or oil in the final product".  The cut-off point for the claim “trans-fat free” was amended to improve the accuracy in terms of what is possible with existing analytical methodology. The preferred method for analyzing the content of trans fatty acids in foodstuffs, other than those from ruminant animals, shall be the latest updated version of AOAC 996.06 or AOCS Ce 1 h-05; or a combination thereof.</p>	<p><b>South Africa</b></p>
<p>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 is of the view that:</p> <ul style="list-style-type: none"> <li>• The three proposed analytical methods do not measure the proposed TFA level in all foods and are may not be globally applicable</li> </ul>	<p><b>United States of America</b></p>

<p>• An accompanying condition for saturated fat is consistent with public health objectives but the U.S. queries whether the proposed condition for 'low' achieves its objective of helping consumers maintain healthy dietary practices because the condition would prevent claims on oils high in unsaturated fatty acids recommended in many national dietary guidelines.</p> <p>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 (Table 1). While the three proposed current analytical methods may detect the proposed level of trans fatty acids, the United States view is that the methods do not accurately and precisely measure the proposed level of 1g per 100 g of fat based on the available collaborative study data on limited food matrices. The methods work well in some foods, but not well in others. Accurate determination may be achievable for specific foods and in specialized labs with highly trained and experienced analysts but may not be globally applicable. The findings from multi-lab validation studies, such as those discussed in Table 1, are a more appropriate source of information about the analytical method than what occurs with specific analysts within a specific lab.</p> <p>The United States is concerned that basing the claim on 100 g of fat versus 100 g of product could potentially limit trans fatty acids 'free' claims on products with low levels of total fat and exclude the use of oils containing low levels of trans fat when use of that oil in the product may be low.</p> <p>The United States supports inclusion of a condition for the saturated fatty acid (SFA) as part of a proposed "free" claim for trans fatty acids, however is concerned that the conditions for 'low' in saturated fats in the <i>Guidelines for Use of Nutrition and Health Claims</i> (CXG 23-1997) may exclude products such as some vegetable oils that are important sources of unsaturated fatty acids, including the essential fatty acids recommended in national dietary guidelines. The United States notes modeling using the proposed trans fat level with various saturated fat thresholds would be helpful to identify which products could bear the proposed claim for the intended purpose of assisting consumers with maintain healthy dietary practices.</p>	
<p>FEDIOL is the European federation representing the interests of the European vegetable oil and protein meal industry. Directly and indirectly, FEDIOL covers about 150 processing sites that crush oilseeds and/or refine crude vegetable oils. These plants belong to around 35 companies. It is estimated that over 80% of the EU crushing and refining activity is covered by the FEDIOL membership structure.</p> <p>FEDIOL, as an observer to the Codex Alimentarius, would like to submit the following comments on the proposed draft conditions for a "free" of trans fatty acids (TFAs) claim in the Guidelines for use of nutrition and health claims (CXG 23-1997)</p> <p>FEDIOL continues to be against the introduction of the "free" TFA claim with the 2 cumulative conditions as proposed for the same reasons as outlined earlier in the process.</p> <p>Why FEDIOL does not support the suggested TFA free claim?</p> <p>Should a TFA "free" claim be pursued, it should be based on available science and should be achievable by industry. This is not the case with this proposal.</p> <p>Firstly, FEDIOL would like to reiterate that setting a TFA free claim at the level of 1g per 100g of fat is not achievable in practice for vegetable oils and fats.</p> <p>Over the past 15 years, FEDIOL members have been supporting industry initiatives to reduce TFA in vegetable oils and fats including reformulation, optimisation of refining processes and Code of Practice. The FEDIOL Code of Practice on refining, in which all the technical parameters have been specified for the quality and safety of refined vegetable oils and fats, ensures that during refining, no more than 2% TFA on fat basis will be formed, including in bottled vegetable oils.</p> <p>All vegetable oils and fats therefore contain an unavoidable low TFA level that in practice is often higher than 1g/100g as suggested in the proposal. Setting a TFA free claim at such a level cannot be implemented in practice by the utmost majority of vegetable oils and fats, sold as such or as an ingredient of food products. And this despite of the fact that most vegetable oils and fats contain levels of TFA that do not present a health issue. Such a TFA free claim would introduce a discrimination for the utmost majority of vegetable oils and fats, which would not be able to meet this threshold and would not be able to reformulate in practice.</p> <p>Secondly, even if some vegetable oils and fats were able to meet the 1g TFA/100g level, they would never be able to meet the</p>	<p><b>FEDIOL</b></p>

<p>cumulative conditions of “low saturated fat claim”.</p> <p>Industry continues to invest heavily in innovation to reduce SAFA content of its products by replacing high saturated fat-containing vegetable oils and fats by other oils higher in MUFA or PUFA, such as high oleic sunflower oil or palm olein.</p> <p>But all vegetable oils and fats contain a natural amount of saturated fat, which is not possible to reduce to the levels indicated in the “low saturated fat claim”. Even canola/rapeseed oil, the vegetable oil with the lowest SAFA content, does not meet the “low saturated fat claim”. There is no option to reformulate bottled oils to lower the SAFA level to such level. Hence, it would create a discrimination for bottled vegetable oils and fats, which would never be able to meet such criteria. It would ultimately undermine industry innovation.</p> <p>As already highlighted in November 2014 and 2016, introducing such claim will furthermore not benefit consumers, as it will not provide incentives for industry to further reduce TFA and saturated fats. No “TFA free” claim are to be expected for products with higher fat content, as none of them will meet the cumulative conditions. This would equally mislead consumers.</p> <p>FEDIOL therefore voices strong concerns on the introduction of the “TFA free” claim as it stands today and considers it inappropriate for the vegetable oils and fats sector.</p>	
<p>ICGMA supports the development of a “Free” of trans fatty acids claim. ICGMA is concerned that the proposed level of 1 g per 100g of fat cannot be accurately and precisely measured. The available collaborative study data demonstrates that the methods work well in some foods but not all. Accurate determination may be achievable for specific foods and in skilled and specialized labs but may not be globally applicable.</p>	<p><b>ICGMA</b></p>

<p><b>SPECIFIC COMMENTS</b></p>	
	<p><b>MEMBER / OBSERVER AND RATIONALE</b></p>
<p>1 g per 100 g of fat</p>	<p><b>Costa Rica</b></p> <p>With respect to the proposed condition (1 g per 100 g of fat) and the footer line 2, Costa Rica would like to express its concern, as no vegetable oil would be able to include such a declaration, as it would not meet the condition of 1.5 g of saturated fat per 100 g (solids), 0.75 g of saturated fat per 100 ml (liquids) and 10% of energy as saturated fat.</p> <p>Justification:</p> <p>The adverse effects of trans fatty acids on lipids that point to an increase in the risk of coronary disease depend on the levels consumed and therefore the daily intake of these should be kept as low as possible. (EFSA, 2018). However, there is some concern because the Codex Standard for Named Vegetable Oils, CODEX STAN 210-1999 indicates the saturated fat content of virtually all of the products it covers, as they naturally contain this nutrient. This implies that, despite efforts not to hydrogenate fats and oils, products that currently have very low amounts of trans fatty acids may not be declared as trans-free because of their naturally occurring saturated fatty acid content. Products such as these are sold on the domestic market without implying that the recommended intake is being exceeded. (R. Monge-Rojas et al., 2017).</p> <p>Therefore, Costa Rica would like to suggest analysing whether the proposed conditions can be met, if they are based on exposure to risk, if they have an analytical methodology that permits verification of the accuracy of these and that they are not detrimental to the reformulation of products but do provide an incentive for this.</p> <p>The aim is to have products that have lower levels of trans fatty acids and saturated fatty acids, levels that can be achieved from a technological standpoint and based on the nature of the product.</p> <p>References:</p>

	<p>EFSA (European Food Safety Authority), 2018. Scientific and technical assistance on trans fatty acids. EFSA supporting publication 2018: EN-1433.16 pp. doi: 10.2903/sp.efsa.2018. EN-1433.  R Monge-Rojas et al., 2017. Progress towards elimination of trans-fatty acids in foods commonly consumed in four Latin American cities. Public Health Nutrition: page 1 of 10 doi:10.1017/S1368980017001227.</p>
	<p><b>Ecuador</b></p> <ul style="list-style-type: none"> <li>• At the global level, it is estimated that the increase in the intake of TFA is responsible for more than half a million deaths annually. The consumption of TFA is strongly associated with an increased risk of developing chronic, non-communicable diseases, as well as an increase in the mortality associated with these diseases. For this reason, the World Health Organisation has suggested eliminating industrially produced trans fatty acids from the food supply.</li> <li>• The labelling of TFA has the potential to help consumers make more informed decisions and may also pressure the food industry to reformulate its products. However, the current declarations provided by the food industry, such as “free of trans fatty acids”, may confuse many consumers, which highlights the need for package labelling that is easy to understand.</li> <li>• The World Health Organisation’s “replace trans fat” strategy shows that, even though the labelling is intended to allow consumers to choose products without TFA, consumers must be aware of the health effects of these products, they must be capable of interpreting the nutritional labels correctly and they must be motivated to do so. In order to help facilitate consumer comprehension, an increasing number of countries are implementing simplified nutritional labelling strategies in addition to the nutritional declaration. It has been observed that declarations regarding health properties, such as “free of trans fats”, may be problematic if the nutritional declarations are used solely to increase the attractiveness of the market for non-healthy foods with high levels of sugar, salt or saturated fatty acids.</li> </ul>
<p>1 g per 100 g of fat</p>	<p><b>Philippines</b></p> <p>The Philippines welcomes the proposed conditions for a trans fat free claim for inclusion in the Guidelines for Use of Nutrition and Health Claims. Based on convincing evidence, the adverse effects of trans fat intake are well demonstrated in scientific reviews and researches including the most recent WHO Systematic Review. We support virtual elimination of trans fatty acids from the diet consistent with the recommendation of the World Health Organization Global Strategy on Diet, Physical Activity and Health. In addition, we suggest that the basis for the proposed levels for trans fat free claim be clarified. We are of the opinion that the lowest possible level for trans fat be considered for the claim “trans fat free” which should be based on current scientific evidence. Though we support the proposed level of 1 g per 100 g fat, we recommend that this be referred to CCMAS to verify that this new proposed level is measurable with the recommended analytical methods before CCNFSDU considers the amount for trans fat free claim. Moreover, we do not support the accompanying condition for low in saturated fat.</p>
<p>And must meet the conditions for “low” in saturated fats<sup>2</sup></p>	<p><b>Philippines</b></p> <p>The deleterious effects of trans fat intake on risks of diet related non-communicable diseases have been well demonstrated in several studies and reviews. There was a 25% increased risk of coronary heart disease risk associated with trans fat intake in a meta-analysis of 4 prospective studies (Mathan et al 2004). Intake of trans fat was also associated with a 33% higher risk of coronary heart disease in all women and a 50% higher risk in those younger than 65 years in a large prospective study with 20 years of follow-up (Hu et al, 2005). The clear association of trans fat with an increase of cardiovascular risk was shown by Atthia-Skhiri et al (2009) in recent epidemiologic studies and meta-analyses of well-designed controlled trials. The evidence that TFA</p>

	<p>consumption increases coronary heart disease (CHD) risk is convincing based on the adverse effects of risk factors and consistent relationships with clinical endpoints. A REGARDS cohort study showed that intake of trans-unsaturated fatty acids (TFAs), even at low levels (~2% of energy), is associated with several adverse outcomes, including dyslipidemia, inflammation, myocardial infarction, and increased cardiovascular mortality (Kiage et al 2013). Teegala et al, 2009 showed that some evidence suggests that TFA consumption may also increase other disease outcomes, but further investigation is warranted to confirm the presence and magnitude of such effect.</p> <p>We support the level of 1 g trans fat per 100 g fat with the recommended analytical methods. We agree that 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. Lastly, we believe that cost effectiveness of this proposed level be considered since it is expected that analysis of trans fat per 100 g fat will be more expensive compared to analysis per 100 g or per 100 mL of the finished product.</p> <p>We do not agree with the proposal to include the condition “low in saturated fat”. The concern of this recommendation is trans fats and not saturated fats. Saturated fatty acids already have a separate recommendation and should not be included. There are recent studies which support this position. The finding of a large prospective cohort study from 18 countries in five continents showed an inverse association between saturated fatty acid intake, total mortality, non-cardiovascular disease mortality, and stroke risk without increase in major cardiovascular disease (CVD) mortality, myocardial infarction and cardiovascular disease mortality (Dehghan, et al, 2017). In contrast to existing dietary guidelines, this cohort study also found that a high carbohydrate intake was linked with higher risk of total mortality. Other recent randomized trials and observational studies support the results of this cohort study on the effect of saturated fats on mortality and risks of CVD. De Souza and co-workers (2015) have shown that trans fats are associated with all cause mortality, CVD, and CHD, while saturated fats are not. Further, Siri-Tarino and co-workers (2010) have shown that there is no link between dietary saturated fat and increased risk of CHD or CVD.</p> <p>There are numerous studies that support our recommendation not to include condition for saturated fat on trans fat free claim. Based on eight carefully controlled studies, it was concluded that trans-fatty acids had the worst effect on blood lipids of all dietary fatty acids (Sacks &amp; Katan, 2002). It is universally accepted that trans-fats are unhealthy and cause coronary heart disease (Ascherio et al., 1996; HSPH, 1999). A systematic review and meta-analysis conducted by Thomas and Mushtaq (2013) concluded that SFA did not increase CVD risk in affluent Caucasian adults. Diets high in trans fat elevate the LDL:HDL ratio and triacylglycerol, LDL, and total cholesterol concentrations (Mensik et al 2003); increase inflammation (Mozafarian et al 2006); and increase cardiovascular disease risk. The systematic review and meta-analysis, published in the Annals of Internal Medicine, included studies involving more than 600, 000 people in 18 countries. The researchers found no association between total saturated fatty acid consumption and coronary risk when they analysed 32 observational studies of fatty acids in dietary intake and 17 observational studies of fatty acid biomarkers. However, total intake of trans fats, found in some processed foods, was associated with coronary disease risk. (Chowdury et al 2014 as cited by Wise, 2014). Trans-fats are clearly harmful. Therefore, it is inappropriate to include condition for “low in saturated fat” in TFA free claim.</p>
<p>1 g per 100 g of fat</p>	<p><b>Malawi</b> 2 g per 100 g of fat</p>
<p><b>Industrially-produced</b> Trans fatty acids</p>	<p><b>IDF/FIL</b></p>

IDF (International Dairy Federation) strongly recommends that any consideration of claims related to trans fatty acids be reconsidered in the context of reduction of industrially-produced trans fatty acids.

REPLACE the WHO action plan targets the elimination of industrially produced trans fatty acids from the food supply. As approximately 540,000 deaths each year can be attributed to intake of industrially produced trans-fatty acids (Wang et al 2016) These trans fats have no known health benefits.

We have noted that the draft WHO Guidelines: Saturated fatty acid and trans-fatty intake for adults and children does not support making a distinction between industrial and ruminant trans-fatty acids. The basis for the decision was that the differences in health outcomes observed in many studies are most likely to be due to differences in dose of trans-fatty acids rather than differences in type of trans-fatty acids.

We do have strong opposition regarding this interpretation, as the report cites evidence of no effect of ruminant trans fatty acid intake on a host of cardiometabolic outcomes.

In addition the WHO draft guidelines on SFA and TFA intakes for adults and children excludes 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.

This 2015 Systematic Reviews (de Souza et al 2015) indicated the following:

- Industrial, but not ruminant, trans fats were associated with coronary heart disease mortality and coronary heart diseases.
- Ruminant trans-palmitoleic acid, considered as a biomarker of dairy intake, was inversely associated with type 2 diabetes. This finding is said to be “quite consistent and compatible with a 26-54% reduction in risk across an estimated threefold intake range.”

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). 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.

The implementation measures targeting food and beverages ‘high’ in trans-fatty acids may well unfairly and detrimentally target milk and dairy products, unless clear distinctions are made in recommendations about industrial produced trans fatty acids, as done for the WHO global plan to eliminate all industrially produced TFA.

Therefore we would suggest that the recommendation be amended to:

References:

Alexander DD, Bylsma LC, Vargas AJ et al. (2016) Dairy consumption and CVD: a systematic review and meta-analysis. *Brit J Nutr* 115:737-750.

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Brouwer IA. Effects of trans fatty acid intake on blood lipids and lipoproteins: A systematic review and meta-regression analysis. Geneva: World Health Organization; 2016.

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1 g of <b>industrially-produced trans fatty acids</b> per 100 g of fat	<p><b>IDF/FIL</b> see previous comments</p>
In addition, compliance with the conditions for meeting the standard “low level” of saturated fats <sup>2</sup> .	<p><b>Mexico</b> According to the World Health Organisation (WHO), in its “REPLACE Trans Fat” guidelines, it is recommended that the consumption of trans fatty acids be limited to less than 1% of total energy intake, which translates to less than 2.2 g/day for a diet consisting of 2,000 calories, as the intake of more than this amount</p>

	<p>is associated with an increase in the risk of coronary disease and mortality. For this reason, eliminating trans fats in industrial production is one of the main challenges for the WHO.</p> <p>Similarly, according to the recommendations of the Pan American Health Organization (PAHO) in its Nutrient Profile Model, a processed or ultra-processed product is classified as “excessive in saturated fats” if in any given quantity of the product the amount of energy (kcal) from saturated fats (g of saturated fats x 9 kcal) is equal to or higher than 1% of the total energy (kcal). Therefore, if the amount of trans fatty acids in 100 grams of fat is 1 gram, the amount of energy from trans fatty acids is 1% and, according to the recommendations of the WHO/PAHO, the product is considered to be “excessive in saturated fats”.</p> <p>Mexico proposes:                  Less than 1 g per 100 g of fat                  In addition, compliance with the conditions for “low level” of saturated fats                  (In accordance with the conditions in the Table for claims on the properties related to nutrient contents in the Guidelines for Use of Nutrition and Health Claims, the conditions for the use of “low level” of saturated fats are as follows: 1.5 g of saturated fat per 100 g (solids), 0.75% g of saturated fat per 100 ml (liquids) and 10% of energy from saturated fat)</p>
<p>In accordance with the conditions in the Table for claims on the properties related to nutrient contents in the <i>Guidelines for Use of Nutrition and Health Claims</i>, the conditions for the use of “low level” of saturated fats are as follows: 1.5 g of saturated fat per 100 g (solids), 0.75% g of saturated fat per 100 ml (liquids) and 10 % of energy from saturated fat.</p> <p><sup>3</sup>Pan American Health Organization / World Health Organization (2016) - Nutrient Profile Model. Washington, DC. Available at (in Spanish): <a href="http://iris.paho.org/xmlui/bitstream/handle/123456789/18622/9789275318737_spa.pdf">http://iris.paho.org/xmlui/bitstream/handle/123456789/18622/9789275318737_spa.pdf</a></p>	<p><b>Peru</b></p>
<p>With the exception of foods that naturally contain saturated fatty acids and that are minimally processed<sup>3</sup>.                  Annex 1                  Composition of fatty acids in sachachi                  Analysis results 1* results 2**                  Saturated fats (LC: 0.01) 4.10 g/100 g 7.2%                  Linoleic acid (C18:2 n6c) (LC: 0.01) 34.07 g/100 g 36.3%                  Linolenic acid (C18:3 n3) (LC: 0.01) 49.23 g/100 g 46.6%                  Polyunsaturated fats (LC: 0.01) 83.30 g/100 g 82.9%                  Trans fatty acids:</p>	<p><b>Peru</b>                  With the exception of foods that naturally contain saturated fatty acids and that are minimally processed<sup>3</sup>.</p>

Trans-6,9,11 isomers (C18:1) (LC:0.01)  
 Trans-9,12 isomers (C18:2) (LC: 0.01)  
 < 0.01 g/100 g  
 < 0.01 g/100 g < 0.01%  
 Source: Analysis of extra virgin sachu inchi by  
 producers  
 \* Testing method: AOAC 996.06, 20th ed. 2016.  
 \*\* Testing method: ISO 5508  
 Fatty acid composition by gas chromatography in  
 olive oil (% of total fatty acids)  
 Fatty acid virgin olive oils  
 C16:0 (palmitic) 7.5-20.0  
 C18:0 (stearic) 0.5-5.0  
 C18:1 (oleic) 55.0-83.0  
 C18:2 (linoleic) 3.5-21.0  
 Trans fatty acids  
 C18:1 T 0.0-0.05  
 C18:2 t+C18:3 T 0.0-0.05  
 Source: Codex Stan 33-1981 (rev. 4:2017; am.  
 2:2013) Standard for Olive Oils and Olive Pomace  
 Oils.  
 Fatty acid composition of virgin olive oil from  
 Peruvian producers  
 YEARS  
 FATTY ACIDS 2007 2008 2015 2015 2016 2016  
 2016  
 Saturated fatty acids 20.00 19.01 21.00 21.449 20.25  
 15.60 18.26  
 Monounsaturated fatty acids 61.65 71.25 51.60  
 66.287 57.10 58.31 65.00  
 Polyunsaturated fatty acids 18.11 9.74 19.95 12.264  
 17.75 23.09 16.75  
 Undetected 0.24 0 7.46 0 4.90 3.00 0.00  
 TOTAL % 100.00 100.00 100.00 100.00 100.00  
 100.00 100.00  
 \* \* \* \* \*  
 Trans fats (g/100 g, sample) <0.007  
 \* Testing method for fatty acids: LABS-ITP-F-002-98  
 Rev. 4, 2003  
 \*\* Testing method for fatty acids: AOAC - 996,06,  
 c41, 19th ed. 2012. Fat (Total, Saturated and  
 Unsaturated) in Foods Hydrolytic Extraction Gas  
 Chromatographics Method.

