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Agenda Item 10 **NFSDU/39 CRD/13**

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

Comments of Philippines, Tanzania, Thailand, United States of America and African Union

PHILIPPINES

General

The Philippines appreciates the discussion paper on trans fatty acids (TFA) prepared by Canada.

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 toverify that this new proposed levelis 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.

Specific

RATIONALE:

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 consumption increases coronary heart diseast (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.

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 per100 mL of the finished product.

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 extisting 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.

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 & 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.

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TANZANIA

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: Tanzania support the proposed levels

Rationale: Transfatty acids have a negative health effect in terms of Cardio Vascular Diseases (CVDs) and thus in helping consumers make informed decision and protect them from false claims the level as proposed will go a long way in to achieve the objective.

THAILAND

General comments

In principle, we agree with the Discussion Paper on Claim for "Free" of Trans Fatty Acids".

Specific comments

Proposal for conditions for a "free" of Trans Fatty Acids (TFAs) claim

We would like to confirm our previous comments supporting the Canada's proposal on the definition for the claim of TFA free as follows:

1. We agree with the proposal 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).

2. And, we agree with the proposal for the claim for free of TFAs 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 proposed 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]

[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.

UNITED STATES

The United States of America thanks Canada for preparing this Discussion Paper on a Claim for "free" of *trans* fatty acids (CX/NFSDU 17/39/9) and is pleased to provide the following comments. 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 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). The United States supports the proposed conditions for the saturated fatty acid (SFA) content as part of a

proposed “free” claim for *trans* fatty acids. The United States also supports clarifying the definition for *trans* fatty acids and suggests considering the WHO Guidelines on PUFA when released.

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.

While the three proposed current analytical methods may measure *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.

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).	**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.
Limitations of methods	**None of the data are directly associated with specific collaborative 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 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.**	**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.**

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: **African Union** supports the proposed levels

Rationale: Transfatty acids have a negative health effect in terms of Cardio Vascular Diseases (CVDs) and thus in helping consumers make informed decision and protect them from false claims, the level as proposed will contribute to achieving the public health objective of preventing/minimizing CVDs.