External Expert and Stakeholder Panel
Scoping of WHO Guidelines on Saturated-Fatty Acid and Trans-Fatty Acid Consumption

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Public comments and WHO action or response on scope of guidelines on trans-fatty acid consumption

№	Comment	Times stated	WHO action or response
	Population		
1	Add subgroup by race		to be considered by NUGAG
2	General healthy adult and child populations should be considered.		noted
3	Particular attention should be given to the elderly, in light of current demographic changes in many countries.	2	subgroup by age already considered
4	Older adult aged 60 is missing; it should be ≥60	2	noted
5	Guidelines for people with pre-existing metabolic abnormalities should only be considered when confounding influences, especially drug treatment, can be excluded.		subgroup on health status included to be considered by NUGAG
6	The general population consists of a substantial and rapidly growing number of people with an early heart disease event and diabetes. The effects of dietary fatty acids could have a different impact for these people compared to those without any prior disease or condition. The committee could consider looking at these important subgroups in the population.		subgroup on health satus included to be considered by NUGAG
7	It would be also interesting to include pregnant and breast-feeding women as they have different nutritional needs.	5	subgroup added to be considered by NUGAG
8	Should focus on adolescent		subgroup by age already considered
9	Consider adding by baseline physical activity level, including sedentary lifestyle		subgroup added to be considered by NUGAG
10	Consider adding infancy		subgroup added to be considered by NUGAG
11	To have more subpopulations, e.g. by baseline hypertension status and by baseline glucose status		subgroup on health satus included to be considered by NUGAG
12	Meaning of baseline nutritional status is unclear. What standards will be used?		clarified
13	It may also be useful to sort the data by birth weight, baseline body weight, visceral adiposity, and physical activity.		subgroup added to be considered by NUGAG

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14	Age: This new guideline evaluation starts from the age of 2 years (24 months), and includes children of 2-13 years in one population category, i.e. children. However, considering that: - Young children of 2-3 years are at an age and have requirements closer to those of 1-2 years children than to those of 4-13 years children. The intake of milk (rich in SFA) and other foods of 2-3 years old children is closer to that of 1-2 years children than that of 4-13 year old children. The children of 2-3 years are often included in disease risk assessment studies covering the age range of from 1-5 years, rather than in those of broader age range of 2-13 year studies. Therefore we think it may be more appropriate to consider the risk of SFA exposure for young children categories covering the age range of 1-3 years (not included in the present table), rather than the broad age of 2-13 years population.	2	noted and to be addressed at NUGAG
15	Baseline nutritional status should be exemplified: vegans, usual energy intake, alcohol intake...	3	clarified
16	TFA only pertinent to country where commercially hydrogenated fat forms a major dietary fat of the population concerned.		noted
17	All population age groups should be included in the TFA recommendation		infancy subgroup added to age categories for consideration at NUGAG meeting
18	Reduce risk of cardiovascular disease including stroke, myocardial infarction and coronary heart disease and reduce serum total cholesterol/LDL cholesterol/triglycerides, hypertension, and other NCD as cancer and diabetes, quality of life, risk of overweight is less than 1% of total caloric or value of total energy, . This range is affected by gender, baseline nutritional status and type of macronutrient that replaces the TFA in the diet		noted
19	The influence of physical activity and intra- and inter-individual variation in responses to dietary change must be assessed before advice to the general population can be considered. Evidence of the safety of any proposed dietary advice, including to vulnerable groups, must be available before advice may be given to the general public.Guidelines should not assume that the whole human population can be given the same advice unless there is evidence that this is the case. In light of the difficulty in achieving dietary change, advice should not require greater changes than necessary. Therefore, it is unsatisfactory to give advice to the general public that is only necessary for particular vulnerable groups. If necessary, different advice should be aimed at different groups.		The guideline process will attempt to determine the recommended levels within the context of a nutritional adequate diet for the general population and will consider potential adverse effects in making that decision
	Intervention		
20	add subgroup dy duration of exposure	2	subgroup added for consideration at NUGAG

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21	Need to consider the influence of changes in consumption of the different trans fatty acids when substitution is with other types of fat and other macronutrients.		already considered
22	In the subgroup analysis instead of using the cut-off points 2 % energy, 1 % energy, 0.5 % energy and 0 % energy, a continuous range from 5 % energy to 0.5 % energy should be considered. This range represents realistic population intakes. Given the presence of TFA in dairy foods as well as foods that contain refined vegetable oils such as bottled oils and vegetable fat spreads sold in supermarkets, 0 % energy TFA is practically unachievable. A continuous range instead of pre-determined cut-off points would also allow setting the recommended intake range/cut-off.	2	added for consideration at NUGAG meeting
23	Q1. Most adverse effect observed for TFA in human feeding trials was observed from 1-4 % energy. In 2003, WHO recommended that the TFA in the diet should not exceed 1% energy, therefore, the 1 % energy TFA cut off should be used instead of having a few cut off ranging from 0-2 % energy.		Please note WHO is revising and updating guidelines based on the new WHO Guideline Review Committee Handbook.
24	Q6. This question is pertinent to countries where hydrogenated edible oil forms a major dietary fat in the population.		noted
25	Q7. The cut off is not practical because TFA occurred naturally in the meat of ruminant and their dairy products.		noted and added for consideration at NUGAG
26	Q8-9. These questions are inappropriate as the TFA are form naturally in the rumen of the animals concerned.		noted
27	For carbohydrates, there should be differentiation between patterns of intake of the different types of carbohydrates, including simple carbohydrates (concentrated sweets) or refined carbohydrates and unrefined and/or complex carbohydrates from fruits, vegetables, whole grain, and high-fiber foods such as legumes and nuts.	6	noted and added for consideration at NUGAG
28	Consider adding questions related to the effect of specific classes of fatty acid isomers (18:2n-6 isomers, 18:3n-3 isomers, cis-18:1 positional isomers).	2	noted and added for consideration at NUGAG
29	I suggest to include conjugated linoleic acid isomers(9-cis, 11-trans CLA and 10-trans, 12-cis CLA) as well.	3	noted and added for consideration at NUGAG
30	TFA intake of less than 1%E reduced industrial TFA intake to 0%E		noted
31	Reduced the % intake to at least 0.5%.		noted and added for concideration at NUGAG
32	Regarding ""reduced TFA intake throught replacement with carbohydrates"", please add after ""carbohydrates"" this phrase: "", according to their chemical form"".	4	added for consideration at NUGAG meeting

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33	Assessing effects of consuming 0%E ruminant TFA is unrealistic		noted and added for consideration at NUGAG
34	In general diminish the percentage of energy supplied by the TFA to less than 2% at the lowest possible level or MUFA or PUFA replace carbohydrates or high of TFA acid reduces the risk of cardiovascular disease including stroke, myocardial infarction and coronary heart disease and reduce serum total cholesterol/LDL cholesterol/triglycerides and other NCD as cancer and diabetes		noted
35	Replacements for TFA must also provide the food functionality that TFA provide - hardness. SFA will also provide hardness, but neither MUFA nor PUFA will do this. Therefore, replacing TFA with MUFA or PUFA is not practical in foods requiring a specific hardness.	2	noted
36	In reference to the levels of TFA as percent of energy that are being examined, Vesper HW, et al. 2012 JAMA 307:562 indicates that there has been a significant decrease in TFA consumption from 2000 to 2009. Uauy R. 2009. Eur J Clin Nutr 63:568 indicates that Finland and Norway have reduced TFA to 0.5-0.8 percent energy. WHO should focus on interventions that use lower intakes.		noted
37	Concern about eliminating all TFA from diet without considering the source of TFA		Source of TFA (ruminant vs. industrial) is a potential subgroup that will be considered by NUGAG
38	Different definitions of TFA exist: at least one trans double bond; only trans double bonds. We think it is important to define the TFA definition that will be used for the TFA guidelines in the PICO questions.		Comment noted and a definition of TFA in the background section added
	Comparator		
39	The comparitor seems to be low fat vs high fat intake. The problem with this is that the effect of SFA reduction will depend on what replaces it as energy in the diet (other types of fat, protein or carbohydrates, and among the latter, the nature of the protein and carbohydrate). So it is a very difficult question to address		Noted and the replacement of TFA with other sources of energy are already considered in the scope.
40	Other types of fat and other macronutrients		noted
41	We suggest that the type of macronutrient which replaces TFA in the diet is considered for all outcomes.	2	Noted and the replacement of TFA with other sources of energy are already considered in the scope.
42	Normal TFA intake	2	noted
43	Usual TFA intake		noted
	Outcomes		
44	Add overweight and obesity (defined by BMI cut off by age) for both children and adult	3	noted and added for consideration at NUGAG

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45	Add waist to hip ratio	2	noted and added for consideration at NUGAG
46	Changes in risk indicators such as LDL but also changes in hard clinical end-points such as diagnosed coronary events. In addition, it is crucial to have evidence on total mortality outcome in order to establish safety of any changes in trans fatty acid intake suggested by the guidelines.		already considered
47	We assume that the effects on serum total cholesterol/ LDL cholesterol will be be looked at together with effects on serum HDL cholesterol, and that total / HDL cholesterol ratio, the most powerful predictor of CHD risk in population studies, will also be addressed.	7	noted and added for consideration at NUGAG
48	Include prediabetes risk or insulin resistance risk. In clinical trials, saturated and trans fatty acids are shown to increase insulin resistance, whereas monounsaturated and polyunsaturated and omega-3 fatty acids do not have an adverse effect.	3	noted and added for consideration at NUGAG
49	How would you account for risk of cigarette smoking and exposure to second hand smoking?		To be described in review of evidence
50	Consider including alcohol intake for adults?		noted and added for consideration at NUGAG
51	The category " inflammatory bowel disease" is very broad, might need to add types (e.g., common forms -- Crohn's disease and ulcerative colitis, or less common forms -- ischaemic colitis and Behcet's disease).		noted and added for consideration at NUGAG
52	Consider specifying types of cancers	2	noted and added for consideration at NUGAG
53	Quality of life is very much subjective. How it'll be defined?	2	noted and added for consideration at NUGAG
54	How will Nutritional adequacy of the diet be measured?	3	noted and added for consideration at NUGAG
55	Children/Adolescents11. Cancer incidence12. Nutritional adequacy of the dietAdults / Older adults15. Cancer incidence, mortality, morbidity18. Nutritional adequacy of the diet		noted and added for consideration at NUGAG
56	Total Cholesterol, Serum HDL Cholesterol & Serum LDL Cholesterol		already considered
57	Regarding ""Children / Adolescents"", and ""Adults / Older adults"", please add C-reactive protein, interleukin-6	2	noted and added for consideration at NUGAG
58	Regarding ""Adults / Older adults"", please add Body Fat Distribution		noted and added for consideration at NUGAG
59	Regarding ""Adults / Older adults"", please add Adiposity	3	NUGAG
60	Regarding ""Adults / Older adults"", please add Intra-abdominal fat	3	noted and added for consideration at NUGAG

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61	Please add another subgroup: Pregnancy and Breastfeeding (Outcome: labor complications; Outcome: children's growth: weight, length, head circumference -at birth time OR during lactation-)	3	noted and added for consideration at NUGAG
62	Children /Adolescents :Prioritize weight, body mass index , nutritional adequacy of the diet Serum total cholesterol, Serum LDL cholesterol, quality of life and other adverse effects.		Already considered and prioritization will occur at NUGAG
63	Adults / older adults: Prioritize Cardiovascular disease incidence, mortality, morbidity, Coronary heart disease incidence, mortality, morbidity Stroke incidence, mortality, morbidity myocardial infarction incidence, mortality, morbidity Serum total cholesterol, Serum LDL cholesterol, Nutritional adequacy of the diet, weight, body mass index, Systolic blood pressure, Diastolic blood pressure, cancer events mortality , morbidity, quality of life and other adverse effects.		Already considered and prioritization will occur at NUGAG
64	A recent IOM report (IOM Committee on Qualifications of Biomarkers, Surrogate Endpoints in Chronic Disease. 2010. Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease. National Academies Press, Washington, DC, USA) concluded that LDL cholesterol is an appropriate surrogate endpoint for some statin drug interventions, but not for CVD interventions in foods. How will this WHO review take into account the IOM view that effects of foods on CVD cannot be evaluated based on LDL and HDL, alone?		WHO will look at the entire body of evidence and look not only at one outcome but multiple outcomes to work with NUGAG to generate a guideline
	Other comments		
65	One of the difficult questions facing the committee is whether a distinction should be made between ruminant trans fatty acids, CLA and industrial trans fatty acids. There is an important new study about this from the United States Department of Agriculture Human Nutrition Research Center at Beltsville, Md. This study has not yet been published in full, but the essential data are available on the internet. We have completed a systematic review of the effects of CLA and ruminant fats, including the USDA study, one week ago, and we might be able to provide the committee with that paper, if the committee so desires.		noted and added for consideration at NUGAG
66	As Asian population is higher risk than their western counterparts, evidence should looked into whether they require a different cut-off than the other population.		world geographical region already considered
67	Current UK TFA intake is well below the UK maximum 2% dietary energy recommendation. Population SFA intakes remain greater than maximum recommendations. Recommendations to reduce TFA should not suggest increases to SFA intake that would increase intakes above current levels. Scoping should ensure that assessments, and resulting guidance, do not lead to unintended negative consequences. As such, consideration of the source of replacement nutrient components should be given within the assessment criteria.		To be described in review of evidence

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68	TFA-PICO questions should specifically address replacement of trans 18:1 isomers with 16:0.		noted and added for consideration at NUGAG
69	In practice, TFA are not replaced with specific fatty acids. Partially hydrogenated vegetable oils (PHVO) are replaced with other available fats and oils. So what are the nutritional and health properties of the available replacement fats and oils? Do PHVO based fats and oils contain nutritionally important non-isomeric fatty acids that may be present at much lower levels in available replacement fats. Recommendation: In addition to questions related to replacing TFA with specific FA, consider adding questions related to replacement of PHVO based fats and oils with other commonly available fats and oils.Examples: What is effect of replacing margarine and shortening with commonly available semi-solid animal (ie tallow, butter, lard) and vegetable (ie Shea, Ghee) fats and oils? Is butter a healthier fat than soft tub PHVO based margarine? Is lard a healthier fat than a PHVO based shortening?		Noted however the aim of these guidelines are to generate nutrient consumption guidelines and therefore the guidelines on consumption of specific foods is outside the scope of this guideline.
70	TFA only pertinent to country where commercially hydrogenated fat forms a major dietary fat of the population concerned.		noted
71	It would be inaccurate to generalise about the effects of a single nutrient without considering the food matrix. I recognize a “whole food” approach as a most appropriate approach.	3	comment noted but outside the scope of current guideline.Also please note that the guidance on how to translate the nutrient recommendations to dietary practice is provided in other work area which is implemented by WHO, i.e. food-based dietary guidelines.
72	A truly zero level of trans is close to impossible.	4	noted and added for consideration at NUGAG
73	observational studies and randomized trials indicate that TFA consumption adversely affects multiple risk factors for chronic diseases, including 1. numerous blood lipids and lipoproteins, 2. systemic inflammation, 3. endothelial dysfunction, and possibly insulin resistance, diabetes,4. and adiposity.		noted and all outcomes to be considered for prioritization by NUGAG

Public comments and WHO action or response on scope of guidelines on trans-fatty acid consumption

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74	Research indicates food manufacturers and restaurants have significantly reduced if not eliminated trans-fatty acids. Similar to saturated fatty acids, IFT recommendations the PICO questions consider the macro and micro nutrient food compositions of products that have reduced or eliminated trans-fatty acids. Research on trans-fatty acid consumption should also examine the scientific and technological opportunities and obstacles to further reducing or eliminating trans-fatty acids in the food supply, particularly in dairy and meat products.		Please note WHO is revising and updating guidelines based on the new WHO Guideline Review Committee Handbook. This methodology takes into account components such as feasibility when developing the guideline.
75	Its shocking to see that all faty acids with a trans bond are considered in the same group. In literature effects of elaidic and vaccenic (both C18:1 trans) on cardiovascular disease are completely different! Rumenic acid (C18:2 9cis 11trans) has a conjugated double bond which bends the molecule. Therefore it is chemically and biologically completely different from C18:1 trans molecules. Why should completely different molecules be assigned to one group of trans fats but not for saturated fats? Because their effects on plasma cholesterol? Statins, torcetrapib, rosiglitazone, estrogens and ezetimibe all influence cholesterol plasma levels by another mechanism. Only the HMGCoA reduyctase inhibition by statins protect against cardiovascular disease. Trans fats do induce cardiovascular disease, but very unlikely due to its effect on plasma cholesterol: Its effect on plasam cholesteorl is about 10 times too small for that!		noted and added for consideration at NUGAG
76	teniendo en cuenta que la leche materna contiene un porcentaje de grasas trans y algunas carnes como las de rumiantes siempre en una dieta existirá algun porcentaje de aporte dado por estos nutrientes. Lo importante es lograr el nivel mas bajo posible para evitar el desarrollo de las enfermedades no transmisibles relacionadas con el sindrome metabolico, el cáncer y la diabetes.		noted
77	In scoping question 1.a., for many of the diseases listed, the available data will be insufficient or no association will be found. Final recommendations should clearly state such findings.		According to the WHO Handbook for Guideline Development, if an outcome is prioritized, the results of the systematic review of the evidence will be made available.
78	Scoping question 1b: We suggest adding food source of TFA (industrial vs. ruminant), chain length of TFA, smoking, physical exercise, baseline body weight, birth weight.		noted and added for consideration at NUGAG
79	Because many outcomes will be examined, we would suggest to specify which are the more critical to decide on the guidelines.		Outcomes will be prioritized by NUGAG
80	To our knowledge it will be difficult to answer the draft PICO questions (point 2) outside the field of cardiovascular diseases.		noted