Dietitians of Canada
Les diététistes du Canada

Dietitians of Canada response to Health Canada Consultation re:

Notice of Proposal - Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods

JUNE 20, 2017

INTRODUCTION

Dietitians of Canada (DC) is participating in this notice of proposal as a non-governmental health professional organization. We are the pan-Canadian professional association for dietitians, representing almost 6000 members at the local, provincial and national levels. We advocate for food and nutrition policy that supports healthy food environments and we provide information and tools to support healthy eating by Canadians.

Dietitians appreciate the leadership and vision of Health Canada in launching the Healthy Eating Strategy and commend the comprehensive approach taken, including this notice of proposal that will impact food environments, food marketing, food labelling and food policy/regulation.

SUMMARY

DC agrees with Health Canada's intent to implement a prohibition on the use of Partially Hydrogenated Oils (PHOs) in foods by adding PHOs to Part 1 (substances which, if present in food at any level, would result in the food being declared as adulterated) of the List of Contaminants and Other Adulterating Substances in Foods (incorporated by reference into Division 15 of the *Food and Drug Regulations)* and that this prohibition take effect in the summer of 2018.

As outlined in Health Canada's document, consumption of PHOs deteriorates cardiometabolic health, thus exacerbating the risk of chronic diseases, including type 2 diabetes and cardiovascular disease. *Trans* fats (TFA) in PHOs are shown to have significant negative impact on human health. We believe this proposed regulation will enhance elimination of PHOs in the food supply.

DC suggests that Health Canada include in their documentation the following to clarify that the Iodine Value (IV) of a fat or oil is not a direct measure of the TFA content, but is a measure of the degree of unsaturation.

DC supports Health Canada's revised proposed definition of PHOs in the *Food and Drug Regulations* and notation:
"Those fats and oils that:

a. *have been hydrogenated, but not to complete or near complete saturation, and*
b. *have an iodine value (IV) greater than 4"*

Note that both conditions "a" and "b" of the proposed definition must be met in order for a fat or oil to be considered a PHO. Ingredients which do not satisfy both conditions are excluded from the scope of the proposed definition.

DC requests that Health Canada identify the method of determination of the IV (i.e. ISO 3961 or equivalent) to make it clear.

DC is pleased that Health Canada has clarified that the proposed definition:

- applies to PHOs used in foods destined for human consumption.
- applies to PHOs added to foods for minor use applications or technical purposes such as processing aids, pan release agents, etc.

and has clearly identified the following exclusions:

- PHOs used as raw materials to synthesize other ingredients as well as ingredients derived from PHOs so long as the trans fatty acids present in the raw materials are not found in the final food;
- conjugated linoleic acids;
- partially hydrogenated methyl ester of rosin;
- ingredients that contain only naturally occurring trans fats (e.g., non-hydrogenated ruminant sources);
- and ingredients or foods containing trans fats which have been introduced inadvertently as an outcome of high temperature processing. (Non-hydrogenated refined fats and oils generally contain *trans* fatty acids as an unavoidable impurity as a result of high-temperature processing, at levels typically below 2 percent[1].)

[1] *Kodali, D. R. and G. R. List, Eds.,* Trans *Fats Alternatives, AOCS Press, Champaign, IL, p. 34-35, 2005.*

DC also supports the inclusion in the *Food and Drug Regulations* of the proposed definition of fully hydrogenated oils (FHOs):

"Those fats and oils that:

a. *have been hydrogenated to complete or near complete saturation, and*
b. *have an iodine value (IV) of 4 or less"*

As with the proposed definition for PHOs, both conditions "a" and "b" of the definition must be met in order for a fat or oil to be considered a FHO.

DC requests that Health Canada further describe FHOs with an IV of 4 or less to contain *TFAs* at levels similar to non-hydrogenated refined fats and oils (less than 2 percent[2]).

It is noted that both the definition for the PHOs and the FHOs is consistent with the definition set out by the United States Food and Drug Administration (US FDA) in its Final Determination Regarding Partially Hydrogenated Oils[3].

DIETITIANS OF CANADA RECOMMENDATIONS

The following is a list of DC's recommendations for implementation of this proposal:

1. **Establish research platform and aim to produce transparent and clear guidance on suitable fats and oil substitutes**
2. **Implement meaningful and routine trans fat monitoring in the Canadian marketplace, to ensure levels remain low, even after the implementation of PHO prohibition**
3. **Apply proposed regulation equally to all foods, domestic and imported, retail and food service**
4. **Plan for the eventual removal of 'trans fat' from the Nutrition Facts table**
5. **Increase the number of food products required to carry a Nutrition Facts table**

[2] *USDA National Nutrition Database for Standard Reference, Release 23, 2010;* http://www.ars.usda.gov/Services/docs.htm?docid=8964.
[3] *https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils*

Details and explanations to support DC recommendations:

1. Establish research platform and aim to produce transparent and clear guidance on suitable fats and oil substitutes

Alternatives to partially hydrogenated fats and oils are being developed, modifying the physical properties of oils and fats and making novel fats. The Health Canada consultation and its notice of proposal documents make reference to the recent WHO meta-regression analysis[4] (2016) which concluded that replacing the same amount, calorie for calorie, of trans fat from PHOs with monounsaturated fatty acids (MUFA) or polyunsaturated fatty acids (PUFA) led to beneficial changes in blood lipid levels, including LDL-cholesterol as well as the ratios of total/HDL-cholesterol and LDL/HDL-cholesterol, with PUFA showing the strongest beneficial effects while the effects of replacing trans fat from PHOs with saturated fatty acids led to less beneficial changes in blood lipids compared to replacing them with unsaturated fatty acids. However, fats and oils are being developed and used to replace much of the PHOs in processed foods are being modified chemically or enzymatically to meet product and ingredient functionality.

Alternatives to the use of partially hydrogenated fats have precipitated the development of novel fat components, as well as increasing the demand for oils such as palm oil, coconut oil, and oils from newer seed varieties that produce high oleic oils which are more shelf stable. Neither Health Canada's consultation document (or the current proposal) nor the WHO report[5] address alternatives to partially hydrogenated fats that have similar functional properties.

The removal of partially hydrogenated fats from the food supply requires the food industry to find alternatives that provide similar functionality as partially hydrogenated fats.

Processed fats and oils are important functional ingredients in foods. Different functionalities (e.g., mechanical strength, laminating and shortening ability) require specific compositions that may not be found in a single natural fat or oil. Melting behaviour, solid fat content, and fat crystal habit or network are important factors in creating food such as margarine and shortenings; whereas, decreasing polyunsaturated fatty acids to increase oxidative stability is important for frying oil. In some cases, a blend of oils with high PUFA and MUFA content, with smaller amounts of natural sources of saturated fat, such as butter or lard, could produce a combination that is both functional in its properties and would have no greater impact on risk for heart disease than some other fats and oils that have

[4] World Health Organization. (2016). Effects of trans-fatty acid intake on blood lipids and lipoproteins: a systematic review and meta-regression analysis. Available from: http://apps.who.int/iris/bitstream/10665/246109/1/9789241510608-eng.pdf

[5] Brouwer, IA. Effect of trans-fatty acid intake on blood lipids and lipoproteins: a systematic review and meta-regression analysis. Geneva: World Health Organization; 2016.

undergone processing. Consumers could be receptive to such blends, especially since effects on metabolism are more likely to be well understood – which may not be the case for some novel fats currently present in food products in the marketplace.

Modification methods for oils and fats include: blending, fractionation, hydrogenation, interesterification (chemical or enzymatic) and genetic improvement.

- Blending is a process whereby different base-stocks are mixed together to obtain a specific composition, consistency or stability in the final product. (These base stocks may include: interesterified oils and fats, fractions from winterized or fractionated oils or partially or fully hydrogenated oils or high oleic soybean or canola oils.)
- Fractionation (either solvent or dry) separates fats and oils into two or more fractions with different melting points. It may also be used to remove minor components such as waxes in oils.
- Partially hydrogenated oils were semi-solid, stable during deep frying, had a long shelf-life and had excellent functionality BUT formed trans fatty acids and are being removed from processed foods.
- Interesterification is a chemical reaction that induces the rearrangement of fatty acids within and between triacylglycerols. Interesterification can be carried out using a chemical catalyst or an enzyme. Sodium methoxide is generally used as a catalyst in chemical esterification, while lipases are used in enzymatic esterification. Chemical interesterification is a random reaction while enzymatic interesterification can be random or regiospecific.
- Genetic modification has produced oils with specific compositions such as high saturated, high monounsatuared or low polyunsaturated fatty acid contents which can be used in the formulation of shortening, margarine and frying oils. Another new development is microalgal oils.

Novel or designer interesterified fats (structured lipids) can be created. The utility of interesterified fats for functional properties for the food industry is clear. The health implications of long-term consumption of interesterified fatty acids are less well understood.

A key question for dietitians (and other health care professionals) is 'What are the estimates of the amount and types of interesterified fats in the diet?' A modelling exercise[6] performed to predict fatty acid intake in the United States subsequent to the replacement of trans fatty acid containing oils in foods identified 25 food categories representing 79% of the total trans fat intake from NHANES 1999-2002 intake data. Twelve of these categories (50% of the total trans fatty acid intake) were identified as those for which trans fatty acid containing oils would be replaced by palm oil

[6] Lefevre M, Mensink RP, Kris-Etherton PM, Petersen B, Smith K, Flickinger BD. Predicted changes in fatty acid intakes, plasma lipids, and cardiovascular disease risk following replacement of trans fatty acid containing soybean oil with application-appropriate alternatives. Lipids 2012;47:951–62.

(some of which would be interesterified and interesterified fat made from fully hydrogenated soybean oil). These researchers predicted mean increases in intake of palmitic and stearic acid.

Differences in the metabolism of different saturated long chain fatty acids (LCFAs) (16:0 and 18:0) have been noted, in relation to infant formula research. Human milk fat contains 20 to 25% palmitic acid (about 70% is esterified to the sn-2 position), while palmitic acid in vegetable oils is esterified to *sn-1* and sn-*3*. Palmitic acid is released from *sn-1* and sn-*3* positions in free fatty form acid after digestion by gastric and pancreatic lipases. In this form, it is not as readily absorbed and can bind to calcium, forming calcium soaps which are excreted. Palmitic acid in the *sn-2* position (as it is in human breast milk) is more easily absorbed. Calcium soaps may contribute to comparatively harder stools and losses of both calcium and palmitic acid [7,8.]

The Technical Committee on Dietary Lipids of the North American Branch of the International Health Sciences Institute sponsored a workshop to discuss the health effects of interesterified fats, identify research needs, and outline considerations for the design of future studies. The new publication by Mensink and colleagues[9] summarizes the current available knowledge on many important issues related to interesterified fats, including the food science of interesterified fats, estimation of interesterified fats in the diet, lipid and glucose metabolism, inflammatory and postprandial responses, longer-term effects on fasting parameters, and inflammatory and hemostatic markers. Gaps in knowledge exist regarding the metabolic fate and potential health effects of longer-term consumption of interesterified fats. Outstanding questions must be answered regarding the effects of interesterification on modifying certain aspects of lipid and glucose metabolism, inflammatory responses, hemostatic parameters, and satiety. The workshop panel of experts concluded that the following areas warrant further investigation:

1. Effects of structured lipids on chylomicron size or apolipoprotein composition and metabolism
2. The fate of lipids from interesterified compared with physical blends of oils in mixed triglycerides (TGs), including the ability of sn-2–SFAs to incorporate in fasting HDL phospholipids and their impact on HDL-phospholipid structure and function
3. Effects of mixed compared with interesterified lipids on postprandial inflammatory markers in the intestine, plasma leukocytes, vascular endothelium, and adipose tissues in light of their various roles in metabolic diseases

[7] Marangon AG, Ghazani SM Trends in Interesterification of Fats and Oils 2012. Power point presentation - ILSI North America. ilsina.org/wp-content/uploads/sites/6/2016/06/PPT1Marangoni-June-2012.pdf

[8] Mu H, Porsgaard T. The metabolism of structured triacylglycerols. ProgLipid Res 2005;44:430–48.

[9] Mensink RP, Sanders TA, Baer DJ, Hayes, KC, Howles PN, and Marangoni A. The Increasing Use of Interesterified Lipids in the Food Supply and Their Effects on Health Parameters 2016;Adv in Nutr 7:719-29 doi:10.3945/an.115.009662

4. Fate of LCFAs from native compared with interesterified TG presentations by methods to determine whether there are acute postprandial differences in tissues, fate, and/or metabolism that have not been apparent until now
5. Whether interesterified lipids may have local effects influencing inflammation
6. Effects of interesterified medium chain /intermediate chain FAs (e.g.,C12–C14)
7. Direct comparisons of stearic-rich compared with palmitic rich interesterified fats, with careful attention to absolute and relative abundance of the sn-2–FA, particularly 16:0, 18:0, 18:1, and 18:2 over a range of percentage energy intakes
8. Differential effects of interesterified fats between normal weight, overweight, and obese subjects
9. Influence of higher-melting-point fats produced by interesterification on the secretion of gut peptides involved in hormonal
10. Signaling in the postprandial period that play roles in insulin sensitivity and metabolic diseases (GLP, GLP-1)
11. Examination of the rate of gastric emptying after consuming fats with a high melting point, by use of ultrasound analysis of stomach volume, postprandially
12. Long-term effects of interesterified fats on markers of inflammation, hemostatic parameters, and satiety

It is essential that these research gaps be addressed in order to understand the longer-term effects of interesterification on human health. Health Canada must support research to answer these important questions and other identified knowledge gaps in a timely fashion.

2. Implement meaningful and routine trans fat monitoring in the Canadian marketplace, to ensure levels remain low, even after the implementation of PHO prohibition

Monitoring for all foods, domestic, imported, retail and foodservice is critical. The ban of PHOs in Canada can succeed with a meaningful and routine monitoring program. The mandatory labelling in 2006 led to significant reductions in the amount of *trans* fat found in foods typically known to have high levels of *trans* fat. We know this because the *trans* fat content of those foods was monitored. Unfortunately, the monitoring stopped in 2008/2009. An independent assessment of TFA in the food supply in 2011 indicated 97% of food met the recommended TFA limits set by the Trans Fat Task Force[10]. In addition to monitoring, raising public awareness of when and how the ban will take effect will be important.

[10] Krenosky S, L'Abbe M, Lee N, Underhill L, Vigneault M, Godfroy S, and Ratnayake N. 2012. Risk Assessment of Exposure to Trans Fat in Canada. International Food Risk Analysis Journal. 2 1-15.

Abdelmagrid and associates[11] assessed temporal changes in circulating plasma trans fatty acids (TFAs) in a population of young healthy Canadian adults over 7 consecutive years. Their results showed "consistent declines in total TFAs from 2004 to 2009, which paralleled changes in food labelling, voluntary reformulation to reduce partially hydrogenated vegetable oil and lower estimated food intake of TFAs by Canadians. Although levels of 16:1t9 and 18:1t11 declined from 2004 to 2010, levels of 18:1t9 and 18:1t10 were only lower from 2005 to 2009. Consequently, total TFAs were lower in 2009 relative to 2004, but not different in 2010, suggesting that young Canadians may remain vulnerable to partially hydrogenated vegetable oil exposure and that there is a need for further monitoring of specific food categories and vulnerable populations". According to the authors, these results indicated a need for "prospective monitoring of dietary intake and assessment of plasma TFAs" and suggested that "continuous monitoring of TFAs in the food supply is warranted".

One could further conclude that there may well be need for continuous monitoring of *all* fats in the food supply – industrially-produced and naturally present, given new types of fat being introduced as replacements for TFAs and/or as novel fats for specific functional purposes. In this way, prospective data would be available to use as Canada examines the impacts of the ban on PHOs as well as other changes, including intended and unintended presence of different fats, changes in blood levels and indicators of risk to health, as well as disease trends.

It is important for Health Canada to have a clear understanding of the designer and novel fats being used in place of the PHOs, the foods that contain these designer fats and the level of exposure of segments of the Canadian population.

We recommend monitoring of FHOs in the food system and their use, especially when blended with oils, since these blends will contain some *trans* fats.

It will be important to not only monitor foods that have Nutrition Facts table (NFt), but to monitor stock fats that are used by the restaurant and food service sector and by bakeries and delis.

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[11] Abdelmagid SA, Neilson DF, Badawi A., El-Sohemy A, Mutch DM, Ma DWL. Circulating concentrations and relative percent composition of trans fatty acids in healthy Canadian young adults between 2004 and 2010: a cross-sectional study. CMAJ 2017(February 15); 5(1): E130-E136.

3. Apply proposed regulation equally to all foods, domestic and imported, retail and food service

The Health Canada prohibition of PHOs in foods should also apply to foods prepared and consumed from food service establishments. Thirty percent of the Canadian food dollar is spent on foods consumed outside of the home, in cafeterias/restaurants making this an important sector to consider. The regulatory guidance document should extend to monitoring of stock products, as well as providing guidance for appropriate frying fats (to eliminate as much as possible the formation of oxidized products, aldehydes, and cyclic monomers).

4. Plan for the eventual removal of 'trans fat' from the Nutrition Facts table

DC reiterates its recommendation that Health Canada plan for the removal of the *trans* fat declaration from the Nutrition Facts table (NFt), *after* 1) the regulation prohibiting the use of PHOs as a food ingredient (including processing aids) is in effect and fully implemented, and 2) the monitoring program confirms PHOs, as the current major source of *trans* fat in foods, are removed from the food supply.

Our rationale for this recommendation is to prevent unintended consequences of maintaining *trans* fat on the NFt. In particular, nutritious foods with natural *trans* fat content (e.g., dairy products, ruminant meats) could be perceived as 'unhealthy' by the public, since they would continue to have some *trans* fat. While the consumer is aware of the negative impact of *trans* fat, the distinction between natural trans fat and PHO *trans* fat is complex and may not be completely understood by the population.

The current scientific evidence indicates that ruminant trans fatty acids (rTFAs) have not been associated with detrimental health effects in amounts customarily consumed. In the recently published systematic review by the WHO on the effect of TFA on blood lipids[12], there was no significant impact of rTFA on Total:HDL and LDL:HDL ratios (with any replacement source), which are considered more important for assessing CVD risk than LDL or HDL alone. In addition, no significant impact of rTFA on triglycerides was reported[12]. Another meta-analysis of 13 RCTs showed no adverse effects of rTFA of up to 4.19% of energy on Total:HDL or LDL:HDL ratios[13]. Furthermore, the findings of a recent meta-

[12] Brouwer, IA. Effect of trans-fatty acid intake on blood lipids and lipoproteins: a systematic review and meta-regression analysis. Geneva: World Health Organization; 2016.

[13] Gayet-Boyer C, Tenenhaus-Aziza F, Prunet C, et al. Is there a linear relationship between the dose of ruminant trans-fatty acids and cardiovascular risk markers in healthy subjects: results from a systematic review and meta-regression of randomised clinical trials. Br J Nutr. 2014;112(12):1914-1922

analysis of prospective cohort studies commissioned by WHO[14], indicate that, unlike industrial TFAs which clearly increase CVD risk (as assessed by hard clinical endpoints), rTFAs are not associated with CVD risk, with even a suggestion of a beneficial effect.

DC reiterates that the other option which could be implemented immediately would be the exclusion of all naturally occurring trans fat (ruminant) from the definition of trans fats for the purposes of the Nutrition Facts table.

5. Increase the number of food products required to carry a Nutrition Facts table

The current Food & Drug Act allows for exemptions of many processed foods, such that these do not carry a NFt on their package nor is this information available at the point of purchase (or on a website). Many of the foods exempted are now produced from standard recipes in central processing plants, so this information could easily be provided. This would apply particularly to foods portioned at the deli counter of major grocery chains and baked goods that are finished in the in-store bakery. As well, NFt information should be mandatory for all chain restaurants where recipes are standard – available at point of purchase and on the chain's website. The requirement to carry a NFt and List of Ingredients will be a more transparent indication of what fats and other components are in the food products.

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[14] de Souza RJ, Mente A, Maroleanu A, et al. Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. BMJ. 2015;351:h3978.