



Toward the Prohibition of Partially Hydrogenated Oils in the Canadian Food Supply

Consultation Document



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A. Introduction

Purpose

Health Canada is proposing to prohibit the use of partially hydrogenated oils (PHOs), the main source of industrially produced *trans* fatty acids (*trans* fats), in foods sold in Canada. Although significant progress has been made to reduce *trans* fats in prepackaged foods and restaurant foods in Canada, there are some remaining food categories that may contain high levels of industrially produced *trans* fats. These foods include some commercially baked goods (e.g., cookies), shortenings, and margarines.

Furthermore, subpopulations such as children and teens, Canadians in remote areas, and price sensitive consumers have been identified as being at risk for higher *trans* fat intakes.

The purpose of this proposal is to effectively reduce *trans* fats in the food supply to the lowest level possible. It will also help achieve the public health objective of reducing *trans* fat intake by the great majority of Canadians to less than 1% of total energy intake. Achieving this target would lead to an overall reduction in risk of coronary heart disease (CHD) among the general population. This document outlines the rationale underpinning this proposal and solicits feedback from interested and affected stakeholders and consumers.

Current context

The consumption of *trans* fats increases CHD risk. The World Health Organization (WHO) recommends that *trans* fat intake, from both naturally occurring and industrially produced sources, should be less than 1% of total energy intake. Since the early 2000s, Health Canada has pursued a multi-faceted approach aimed at reducing the *trans* fat intakes of Canadians including mandatory *trans* fat labelling, setting voluntary targets for processed foods, and establishing an active monitoring and open reporting program to measure industry's progress toward meeting the voluntary targets. Although these initiatives have proven successful in reducing *trans* fat levels in the Canadian food supply, some foods still contain high levels of industrially produced *trans* fat, namely PHOs. This can be a health concern for Canadians who choose these foods regularly.

On October 24, 2016 the Minister of Health launched a [Healthy Eating Strategy](#) for Canada (the Strategy)(1), which included several food and nutrition commitments identified in her [2015 Mandate Letter](#) from the Prime Minister of Canada (2). The Strategy unites Health Canada's ongoing nutrition efforts and successes to date with new, complementary initiatives to help create a food environment that makes healthier eating choices easier for Canadians. The Strategy is part of the Government of Canada's broader commitment to promoting public health and healthy lifestyles (1). One of the key objectives under the Strategy is to improve the nutritional quality of the Canadian food supply (1). To help achieve this objective, Health Canada is proposing to amend the *Food and Drug Regulations* to prohibit the use of PHOs in any food sold in Canada.

B. Background

What are *trans* fats? What are partially hydrogenated oils?

Fats in foods are made up of two different types of fatty acids: unsaturated (e.g., mono- and poly-unsaturated) and saturated. In general, plant oils tend to be higher in unsaturated fatty acids making them liquid at room temperature, while animal fats (e.g., butter) and tropical oils (e.g., palm or coconut oil) tend to be higher in saturated fatty acids making them more solid at room temperature. *Trans* fats are a type of unsaturated fatty acid that are found naturally in some animal-based foods and can also be industrially produced (3).

Naturally occurring *trans* fats are formed by bacterial transformation of unsaturated fats in the digestive tracts of ruminant animals. This results in *trans* fat levels in dairy and ruminant meat products ranging from 0.5 to 8% of total fat (4, 5).

Industrially produced *trans* fats can be formed inadvertently during the commercial oil refinement process due to exposure of oil to high temperatures, typically at levels between 0.2 to 2.4% of total fat (5). However, the major source of industrially produced *trans* fats in the food supply are PHOs, which are produced via a process called partial hydrogenation. PHOs are often used in the manufacture of foods such as margarines, shortenings and baked goods because they improve texture and increase shelf life (6). The *trans* fat content of PHOs typically ranges from 25 to 45% of the oil (7).

What are the health risks of consuming *trans* fat?

Heart disease is one of the leading causes of death in Canada, resulting in approximately 50,000 deaths in 2012 (8). Large observational population studies have shown that the risk of CHD is substantially increased with increasing intakes of *trans* fat (encompassing both industrially produced and ruminant sources) (9, 10). The main mechanism through which *trans* fats increase CHD risk is by altering blood lipid levels. *Trans* fats elevate blood levels of "bad" (low-density lipoprotein (LDL)) cholesterol, lower blood levels of "good" (high-density lipoprotein (HDL)) cholesterol, and increase the ratio of total/HDL-cholesterol (11). The detrimental effects of *trans* fats on blood lipids have a continuous dose-response relationship (11) meaning any incremental increase in *trans* fat intake increases CHD risk (3). In addition to CHD, the current scientific evidence suggests positive associations between *trans* fat intake and the risk of stroke (12, 13, 14) as well as all-cause mortality (15, 16).

What are the current scientific recommendations for *trans* fat intake?

Based on current scientific evidence regarding the adverse health effects of *trans* fats, several authoritative health bodies have recommended limiting their consumption. The Institute of Medicine (IOM) advised that *trans* fat consumption should be as low as possible while consuming a nutritionally adequate diet (3). In 2003, the WHO recommended that the mean population intake of *trans* fat should be less than 1% of total energy intake, encompassing both naturally occurring and industrially produced

trans fats (17). In 2008, a WHO Scientific Update concluded that this recommendation needed to be revisited such that it encompassed the great majority of the population and not just the population mean in order to protect vulnerable populations from having high *trans* fat intakes. In this update, it was recognized that this could be accomplished by the virtual elimination of PHOs from the food supply (18, 19).

Replacements for partially hydrogenated oils

The replacement of PHOs with alternative food ingredients would lower CHD risk, but the choice of replacement ingredients needs to consider the effects on CHD risk or CHD risk factors. A recent meta-regression analysis conducted for the WHO (2016) concluded that replacing the same amount, calorie for calorie, of *trans* fats 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. 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 (11).

What is the Canadian context?

In the 1990s, Canadians had one of the highest *trans* fat intakes in the world, with average intakes estimated to be approximately 3.7% of energy (20, 21). Since the early 2000s, Health Canada has pursued a multi-faceted approach aimed at reducing the *trans* fat intakes of Canadians. This started with providing more information to consumers on the *trans* fat content of prepackaged foods by passing regulations in 2002 making it mandatory to display the amount of *trans* fat in the Nutrition Facts table on food labels. At the same time, regulatory criteria were put in place to allow claims such as “*trans* fat free” to be listed on product labels to help guide consumers toward healthier alternatives.

In 2005, a multi-stakeholder *Trans* Fat Task Force was established by Health Canada to develop recommendations and strategies to reduce industrially produced *trans* fats in Canadian foods to the lowest level possible. The Task Force published a [final report](#) in 2006 that recommended a regulatory approach be taken to limit levels of *trans* fats in the food supply to 2% of total fat content for vegetable oils and soft spreadable margarines and 5% of total fat content for all other foods. Full compliance with the targets established by the Task Force would be expected to result in an average *trans* fat intake of 1% total energy as recommended by the WHO in 2003 (22).

On June 20, 2007, the then Minister of Health called on the food industry to voluntarily achieve the 2% and 5% limits within two years. In order to monitor the food industry’s progress toward meeting the voluntary targets, Health Canada established the [Trans Fat Monitoring Program](#) (TFMP) in 2007. This two-year program analyzed the *trans* fat content of over 1100 foods known to contribute high levels of *trans* fat to the Canadian diet (23).

Data published over the last decade suggest that initiatives to decrease the *trans* fat consumption of Canadians have been highly effective. In fact, a 2007 assessment by Health Canada estimated that average *trans* fat intakes for all Canadians (age one year and older) had decreased to 1.42% of total energy (24). A subsequent study of Canadian nursing mothers showed a decline in the *trans* fat concentrations in human milk samples collected between 2009 and 2011, suggesting that intakes have further declined since the 2007 assessment, at least in this population (25). These findings are consistent with the results of the TFMP, which showed that by 2009 approximately 75% of prepackaged foods and nearly all restaurant foods that were monitored met the voluntary targets. Furthermore, a 2011 survey of approximately 10,000 prepackaged and restaurant foods on the Canadian market found that 97% of foods met the voluntary targets for *trans* fat (26).

Despite this progress, as of 2011 there were still certain food categories that continued to have large proportions of foods not meeting the *trans* fat targets. For prepackaged foods, these categories included dairy-free cheeses, frosting, coffee whiteners, lard and shortening, shortbread cookies and refrigerated dough, and for restaurant foods these included biscuits, scones and cookies (26). Also in 2011, a [risk assessment](#) conducted by Health Canada showed that some subpopulations were at risk for higher *trans* fat intakes. Vulnerable groups included children and teens, Canadians living in remote areas, price-sensitive consumers (i.e., lower income groups) and those who regularly consumed foods remaining high in *trans* fat (27).

The Minister of Health has committed to bring in tougher regulations to eliminate industrially produced *trans* fats in the food supply as per the [2015 Mandate Letter](#) from the Prime Minister of Canada (2). In response to this commitment, Health Canada launched in May 2016 a [Call for Data](#) to collect information on the current use of PHOs in the food supply (28). Data was submitted by seven manufacturers, two fats and oil processors, one restaurant, two industry associations and one academic. Many respondents indicated that they were moving away from PHO use and none of the data received supported the need to maintain allowance for PHO use (see **Appendix** for further details). However, the response rate was low and may not provide a comprehensive picture of the Canadian food supply.

C. Proposed approach and Consultation

Proposed approach

In order to achieve the public health objective of reducing the *trans* fat intake of the great majority of the population to less than 1% of total energy intake, **Health Canada is proposing to amend the [Food and Drug Regulations to prohibit the use of PHOs in foods sold in Canada](#).**

Under this proposal, PHOs are defined as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4. The iodine value (IV) of a fat or oil is not a direct measure of *trans* fat content but relates to the extent of unsaturation. In general, oils and fats with an IV of 4 or less contain *trans* fats at levels similar to non-hydrogenated fats and oils.

Recognizing that prohibiting PHOs will require certain manufacturers to reformulate their products, Health Canada is proposing that a 12-month transition period be provided following the adoption into regulation of the prohibition. This should provide sufficient time for impacted industry stakeholders to reformulate their products and/or exhaust existing stock. With regard to product reformulation, Health Canada urges industry to consider, wherever possible, the use of more healthful alternatives (e.g., unsaturated rather than saturated fats).

The proposal aligns with global efforts toward the elimination of PHOs in foods. In fact, the WHO has called for the elimination of industrially produced *trans* fats from the global food supply in response to the rise in the prevalence of non-communicable diseases (19). In June 2015, the U.S. Food and Drug Administration (FDA) issued a [final determination](#) that PHOs are no longer Generally Recognized as Safe (GRAS) in food due to health risks associated with *trans* fat consumption. Manufacturers have until 2018 to reformulate products to remove PHOs (29). In EU countries, there is currently no legislation regulating the content of *trans* fats in foods. However, select countries (e.g., Denmark, Austria, Hungary) have regulations restricting their content. In December 2015, the European Commission concluded that setting a legal limit for industrially produced *trans* fat content would be the most effective measure for reducing intake in terms of public health, consumer protection and compatibility with the international market (30).

Consultation

Health Canada values the input Canadians and interested and affected stakeholders have on its proposed policies. We welcome your comments and feedback on the proposed approach to prohibit the use of PHOs in foods, particularly on the following key aspects:

1. Do you support Health Canada's proposal to prohibit the use of PHOs in foods? Please explain.
2. Do you have any comments/concerns with the proposed definition for PHOs? Please explain.
3. Do you have any comments/concerns with the proposed transition period of 12 months following adoption into regulation of the prohibition? Please explain.

To submit your input, please visit the [Consultation on banning partially hydrogenated oils in foods](#) (31). A summary report on what we heard will be published following the consultation. If unpublished information is submitted, it will remain the property of the submitting organization or individual and its confidentiality will be safeguarded in so far as it is possible to do so within current regulations governing such issues. To safeguard privacy, you should ensure that any written comments you may provide are sufficiently general that you cannot be identified as the author and that individual identities are not disclosed.

D. Conclusion

Comments received will help inform decisions on the best approach to prohibit PHOs from the Canadian food supply and achieve the public health objective of having the great majority of Canadians with *trans* fat intakes below 1% of total energy intake.

E. Openness and Transparency

The Government of Canada is committed to [openness and transparency](#). Health Canada will support this commitment by making more information available to Canadians and provide more opportunities to participate in discussions on government policies and priorities (32). Formal written submissions in response to this consultation will be summarized in a report (e.g. Summary of Comments, What was Heard Report) that will be made publicly available. However, the individual submissions may be released upon request under the *Access to Information Act*.

All other [correspondence and all meetings](#) with stakeholders will be published monthly online in list format including the organization name, date, subject and purpose of correspondence or meeting. This includes correspondence and meetings in which opinions and information (including requests for information) are relayed with the intent to inform the development of policies, guidance or regulations related to healthy eating initiatives (33). For more information on Health Canada's new approach to openness and transparency please visit [Transparency of stakeholder communications for healthy eating initiatives](#) (32).

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G. Appendix

PHO Data Call Summary, Summer 2016

Food category	Company										
	A	B	C	D	E	F	G	H	I	J	K
Bakery											
Biscuits/cookies					2			18			1
Bagels					2						
Doughnuts					1						
Beverage											
Prepared beverages					3						
Beverage mixes (e.g. powdered)					3	13					
Confectionary/Snack foods											
Candy											2
Candy bars											2
Confectionary toppings					1						
Dessert toppings											2
Puddings			23								
Popcorns			1								
Whipped toppings					2						
Fats and Oils											
Margarines							17			12	3
Margarine bases										8	
Oils (canola, soy)		5									
Shortenings							3			38	1
Other											
Bacon bits											1
Dips											6
Cereal	X										
Croutons											2
Frozen entree						2					2
Frozen meats/fish (prepared)									15		1
Rice side dish											25
Sauces						8					
Soups			2								
Spreads							1				
Stuffing											2
Unspecified				X							
Legend											
	Company has indicated that PHOs will be removed by 2018										
X	Number of products not provided										

Note: Data provided by one industry association and one academic not included due to lack of detail.