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ARTICLE

International Food Risk Analysis Journal

Risk Assessment of Exposure to *Trans* Fat in Canada

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Received 24 July 2012; final version received 19 October 2012

Abstract *Trans* fats are undesirable because they raise LDL-cholesterol and lower HDL-cholesterol levels in the blood, which can lead to an increased risk of coronary heart disease. In the mid-1990's, researchers estimated that Canadians had one of the highest average *trans* fat intakes in the world, estimated to be approximately 3.7% of energy. The World Health Organization recommends that average intakes of *trans* fats should be less than 1% of total energy. As such Canada has pursued a multi-faceted approach to decrease *trans* fat levels in Canadian foods. Initiatives undertaken include: mandatory nutrition labelling, the establishment of a multi-stakeholder *Trans* Fat Task Force to develop recommendations and strategies to eliminate *trans* fat in Canadian foods, and most recently the monitoring of industry's efforts in reducing *trans* fats from their food products. Collectively, these initiatives have proven successful as average *trans* fat intakes have been reduced to 1.42% of overall energy. Further reductions in *trans* fat levels in the Canadian food supply are needed to meet the target of 1% of energy, the associated public health objectives, and the protection of vulnerable populations.

Keywords *Trans* fat, Risk Assessment, Intakes, Food Supply, Monitoring

1. Introduction

The objectives of this paper are: 1) to summarize the findings from authoritative bodies on the health risks associated with *trans* fat intakes, 2) to describe the findings from monitoring *trans* fat levels in foods in Canada undertaken by Health Canada from 2005-2009 and the resulting estimates of *trans* fat intakes by Canadians, and 3) to characterize the health risks associated with such intakes.

1.1 What is Trans Fat?

Trans fat or *trans* fatty acids (TFAs) are chemically defined as unsaturated fatty acids containing a carbon-carbon double bond in the fatty acid chain in the "*trans*" position (Figure 1) [1], [2].

As depicted in the illustration, in the "*trans*" configuration the hydrogen atoms are on opposite sides of the double bond resulting in a fatty acid chain that is straight [1], similar to saturated fats in that way. In contrast, when the hydrogen atoms are in the "*cis*" position, as in the case of oleic acid, they are on the same side of the double bond. This causes a bend or a kink in the fatty acid chain [1]. Straight chains are more easily

compacted than bent chains and result in a less fluid material. Most natural unsaturated fatty acids are found in the *cis* position, including oleic acid, linoleic acid, α-linolenic acid, and the marine fatty acids [2]. Partial hydrogenation converts many unsaturated double bonds from a *cis*- to a *trans*-configuration (called geometric isomerization). This process also often induces changes in the double bond position to a different carbon in the fatty acid chain (called positional isomerization) [2].

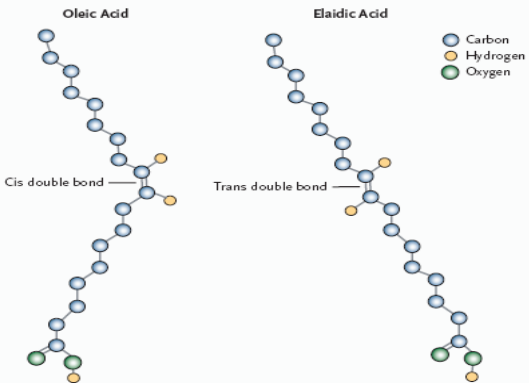

Figure 1. Structure of *Cis* and *Trans* Fatty Acids [1]

1.2 Sources of Human Exposure to Trans Fat

Trans fats are formed during the partial hydrogenation of unsaturated fat. Vegetable oils are hydrogenated to increase their melting point so that they are solid or semi-solid at room temperature. Partially hydrogenated oils (PHO) are used to make shortenings and margarines for processing, baking, and frying. Generally, products made with PHOs have a longer shelf life than if made with liquid oils and are more stable and break down less easily under conditions of high temperature heating. *Trans* fats can also be found at low levels in fully hydrogenated oils and in refined oils [3].

Trans fats are also found naturally at relatively low levels, historically between 2-5% of the total fat content in ruminant-derived foods (for example, beef, dairy products, lamb) [4]. Recent data from Health Canada research indicated that TFA levels measured in some dairy products (cheese, butter, milk, and cream) range from 4.2%-7.4% of total fats [4]. The level of fat in these samples ranged from 10% (half-cream product) to 80% (salted butter) [4]. The highest levels were found in cheese and butter [4].

2. Hazard Characterisation: Health Hazards of *Trans* Fat

Trans fats are not essential, are not required for any specific body function, and provide no known benefit to human health. The adverse effects on heart health are well known [1], [2], [5]. *Trans* fat raises LDL-cholesterol (LDL-C) and lowers HDL-cholesterol (HDL-C) levels in the blood. Elevated levels of LDL-C and lowered levels of HDL-C are risk factors in the development of coronary heart disease (CHD). Dietary TFAs are considered to pose an even greater risk to health than saturated fats (SFAs) since SFAs raise both LDL-C and HDL-C levels [5]. Furthermore, evidence from both controlled trials and observational studies indicates that TFAs from partially hydrogenated sources adversely affects multiple cardiovascular disease risk factors, not only blood cholesterol profiles [5], [6], [7].

Health Canada has adopted the recommendations of the US-Canada Panel on Macronutrients of the U.S. National Academies' Institute of Medicine (IOM), published in 2002, with respect to intakes of *trans* fat [8]. Therefore, the hazard identification and characterization of TFAs upon which this risk assessment is based was done by this Panel. This was supplemented by reference to the work of the World Health Organization (WHO) [2], [9].

Based on their assessment of the evidence linking TFAs to coronary heart disease available at that time [10], [11], the IOM Panel recommended that TFA consumption be as low as possible while consuming a nutritionally adequate diet [5]. The IOM also noted that it would be difficult to lower *trans* fat intakes to 0% energy since a nutritionally adequate diet would contain some naturally occurring TFAs [5]. No Adequate Intake or Recommended Dietary Allowance was set for TFAs because they have no nutritional function. Also, no, Tolerable Upper Intake Level (UL) was set because any incremental increase in TFA intake was found to increase CHD risk [5]. The Panel also stated that because the intake of TFAs and LDL-C is a positive linear relationship, even very low intakes of TFAs may increase the risk of CHD [5]. It was determined that there was a dose-dependent relationship between TFAs and the LDL-C:HDL-C ratio when the results from nine randomized studies were combined and the magnitude of this effect was greater for TFAs than with SFAs [5], [11]. Furthermore, when there was a direct comparison in six of the trials, the effect of TFAs on the ratio of LDL-C to HDL-C was statistically significantly larger than that of SFAs [11]. It was concluded that these studies provided definitive evidence that TFAs raise this ratio more than do SFAs [5], [11].

Subsequently, in 2003, the World Health Organization (WHO) advised that diets should provide a very low intake of TFAs; that is, average intakes of TFAs should be less than 1% of total energy [9]. Given the uncertainty about whether health effects differ between naturally occurring TFAs and industrially produced TFAs and the analytical difficulty in distinguishing these, the WHO did not distinguish between these sources in making the 1% recommendation [6].

In November 2008, the Food and Agriculture Organization (FAO) and the WHO convened a meeting to review the major developments in the field of fatty acids in human nutrition. It was recognized by experts that the current recommendation, average *trans* fat intakes of less than 1% of total energy, may need to be revisited in light of the fact that it does not fully take into account the distribution of intakes [12]. Thus, the removal of partially hydrogenated fats and oils from the human food supply may be needed to protect certain groups from having dangerously high intakes [12].

In support of the expert consultation held in November 2008, a scientific update [6] which included the most recent data as well as earlier studies available on heart health effects of TFAs was published in the European Journal of Clinical Nutrition's Supplement entitled "WHO Scientific Update on *trans* fatty acids". This update considered evidence from both controlled and observational studies for the effects of *trans* fat consumption on CHD. The authors summarized the results of over twenty controlled studies and several meta-analyses (conducted in 2003 and 2006) focussing on the effects of TFAs on blood lipids and lipoproteins. The adverse effects of TFAs on LDL-C and HDL-C were clearly demonstrated: they increased LDL-C, decreased HDL-C, and increased the ratio of total-cholesterol to HDL-C [6]. The same authors report in a separate paper their own meta-analyses of 13 controlled trials conducted from 1982 until 2007. They report that for each 1% energy replacement of TFAs with SFAs, monounsaturated fats (MUFAs) or polyunsaturated fats (PUFAs), the total-cholesterol:HDL-C ratio decreased by 0.31, 0.54 and 0.67, respectively [7].

A limitation of these types of studies, acknowledged by the authors, is that they are generally short term, high dose, and in generally healthy individuals. Ethical concerns limit the possibility of longer term trials, when almost certain harm will occur in individuals subjected to a high *trans* fat intervention. The authors also reviewed observational studies examining the correlation between *trans* fat consumption and CHD, in both prospective and retrospective study designs. These types of studies have different limitations, such as difficulty in adjusting for confounding risk factors, reliance on dietary estimates, and change in dietary habits over time. Seven retrospective and five prospective studies were summarized. Five of the retrospective and four of the prospective studies showed a clear association between *trans* fat consumption and CHD events. A meta-analysis of just the four prospective cohort studies estimated a 17%, 21% and 24% lower risk of CHD for every 2% of energy from *trans* fat intake that is replaced with SFA, *cis* MUFA and *cis* PUFA, respectively [7].

The evidence from controlled trials or observational studies provide concordant data that consumption of *trans* fat from PHO adversely affects multiple cardiovascular risk factors and contributes significantly to increased risk of CHD.

3. Exposure Assessment

3.1 Historical Intakes and Sources of TFAs in Canada

In Canada, scientists raised concerns about the potential detrimental effects of TFAs and the levels in the Canadian diet as far back as the 1970s, recommending that the *trans* fat levels not increase [13], [14]. The evidence at the time was largely from animal studies and was inconclusive. However, the use of PHO continued to increase. Partially hydrogenated oils were attractive to the food industry in the manufacture of margarines, shortenings and the preparation of commercial baked products because of their better functional properties, longer shelf life, oxidative stability and semi-solidity [1], [2]. Also, they were promoted as an alternative to butter and other animal fats and tropical oils which were the fats most associated with having negative health attributes at that time. By the mid-1990's, researchers estimated that Canadians had one of the highest average *trans* fat intakes in the world, estimated to be approximately 8.4 g/day or 3.7% of energy [15]. This estimate was made using both dietary intake data and analysis of human milk samples. Foods that were contributing to the high *trans* fat intakes included crackers, margarines, shortenings, donuts, cookies, pie shells, breaded chicken, cake mixes and cakes, french fries, sauces, and gravies [16], [17]. Detailed fat analysis of over 200 locally and nationally available foods indicated that the TFA levels in some foods reached as high as 50-56% TFA as percent of total fat [16]. The variability of TFA levels in certain food categories was quite large as well [16]. In light of one of the highest intakes of *trans* fat in the world, Canada became the first country in the world to require the declaration of *trans* fat in nutrition labelling. The regulations requiring the mandatory declaration of *trans* fat were promulgated in December 2002 and came into effect for most prepackaged foods in December 2005 [18].

The availability of *trans* fat information on the Nutrition Facts table helped draw the attention of consumers and public health professionals to the presence of TFAs in prepackaged foods, which resulted in a significant reduction of the *trans* fat content of these foods [19], [20], [21]. However, there was also interest expressed by Canadian health organizations that more actions were needed to ensure that *trans* fat levels were reduced across the food supply.

Therefore, in light of this increased interest and in response to other factors [22], in 2005, a multi-stakeholder task force was established to study *trans* fat in the Canadian food supply. The mandate and the final report of the *Trans* Fat Task Force (TFTF), "*TRANS*forming the Food Supply", were published on Health Canada's website [23].

Among the analyses conducted for the Task Force in 2005 was a new estimate of *trans* fat intake. *Trans* fat composition values and intakes were obtained from the Canadian Nutrient File (CNF) archived records, from the Nutrition Survey System (NSS) databases used during this time period, as well as data files from three Provincial nutrition surveys. The analyses indicated that average intakes of TFAs by Canadians in 2005 had decreased to 4.4g/day from the previous high of 8.4 g/day as of 1995 [24]. This level was, nevertheless, still well above the WHO recommendation of less than 1% of overall energy intake (approximately 2.2 g/day).

In response to the TFTF's final report, which called for a regulatory approach to limit the levels of TFA in the Canadian food supply [23], in June 2007, it was announced that the food industry would have two years to achieve, on a voluntary basis, limits of 2% of total fat content for vegetable oils and soft, spreadable margarines and 5% of total fat content for all other foods [25]. Additionally, it was announced that progress would be monitored by Health Canada [25], [26]. These limits were established with the aim of achieving an average Canadian intake of 1% of energy as *trans* fat, as recommended by the WHO [23].

The *Trans* Fat Monitoring Program (TFMP) was established to analyze the TFA content of foods, focussing on those foods known to contribute high levels of TFAs to the Canadian diet. The primary objective of the program was to assess the food industry's performance in reducing TFAs in their products to meet the 2% and 5% limits, rather than to gather data to estimate changes in intake. Foods that were monitored over the 2-year period included pre-packaged foods, bakery products and desserts, margarines, shortenings, and foods from fast food and restaurant chains. Results were obtained from laboratory analyses conducted in three Health Canada laboratories as well as by label review and were released approximately every 6-7 months on the Health Canada website. Details and full results of the TFMP can be found in Appendices A and B.

3.2 Changes in Food Sources of TFAs as shown by the TFMP

Overall, results obtained from the TFMP from 2005-2009 indicate that through the voluntary approach, industry has made progress in reducing TFA levels in their products while not increasing saturated fat content [26], [28]. More than 1100 food items were analyzed over the two year monitoring period and it was found that approximately 75% of those foods analyzed and reviewed using label data were meeting the 2% and 5% limits that were recommended by the TFTF and adopted by Health Canada [28] (see Appendix B).

The results also demonstrated that, as of 2008-2009 as reported in the 4th data set, there remain certain segments of the food supply that are not fully meeting the targets [26], [28]. For example, products that could still be found to contain high levels of TFAs (from 5%-67% *trans* fat of total fat) included hard margarines, garlic spreads, shortenings, coffee whitener, garlic bread, soft margarines, desserts, and bakery products (cookies, donuts, croissants, tarts, pies, brownies) [26], [28].

3.3 Current Trans Fat Intakes in Canada

The 2008 average intake of TFAs by Canadians was estimated using data obtained from the Canadian Community Health Survey (CCHS) Cycle 2.2 on Nutrition (2004), data collected from the TFMP, and by making certain assumptions regarding TFAs in the food supply. This allowed Health Canada to verify that these estimates, which were done for the TFTF based on earlier provincial data, were still valid using more current, nationally representative data. The methodology employed and the resulting estimate of *trans* fat intakes in Canada are described below.

3.3.1 Methodology

The CCHS Cycle 2.2 was a nutrition-focussed survey carried out by Statistics Canada that included data from over 33,000 respondents from all provinces, excluding the territories [31]. For this survey, a 24-hour recall was completed on all respondents, with a repeat recall done on a subset of over 10,000 respondents. This analysis included respondents aged one year and over; respondents with null or invalid recalls and breastfed children were excluded.

Trans and saturated fat composition values were obtained for a number of foods at two time points: 2004 and 2008. *Trans* and saturated fat composition values for 2004 were obtained from the archived records of the CNF [32] and from the NSS databases used during this time period. *Trans* and saturated fat composition values for 2008 were obtained from laboratory analyses of food products as part of the TFMP. The 2008 *trans* fat composition estimates were calculated as the average for the brands sampled for a given food, taking the average weighted by sales volume when available.

Trans and saturated fat composition values when available were applied to foods reported in the CCHS Cycle 2.2 and all recalls were then combined to obtain the total *trans* and saturated fat consumed by respondents during their recall day. Usual intake distributions were estimated using the Software for Intake Distribution Estimation (SIDE) [33], and the age-sex groups were pooled for the 2008 data as they were in the 2005 modelling conducted for the TFTF [23].

Population weights were applied to obtain representative estimates. The Bootstrap replication method was used to calculate standard errors for the estimates of *trans* fat intake distributions [34]. Reliability rules based on the Coefficient of Variation (CV) were applied to identify estimates of marginal reliability (16.6% < CV ≤ 33.3%) and to suppress estimates of unacceptable reliability (CV > 33.3%). The Bootstrap replication method accounts only for the sampling error. There are other sources of error not quantified in this report such as respondents misunderstanding questions or answers being incorrectly processed. In particular, the methodology does not propagate to the population estimates the potential variation between the nutrient composition of brands of products consumed by respondents. As a result, care must be exercised in interpreting the standard errors and confidence intervals (CI) estimated in this report.

3.3.2 Results

For all Canadians aged one year and above, average *trans* fat intakes (from all sources) were estimated to be 3.44 ± 0.03 g/day or 1.42 ± 0.01 % of energy [28]. Figure 2 depicts the decline in average *trans* fat intakes (g/day) by Canadians since 1995 and compares the intakes to the WHO recommended limit. On average, while *trans* fat intakes of Canadians have dropped by 1.5 g/day or 0.8% of energy since 2004, they are still above the WHO recommended limit of 1% of overall energy.

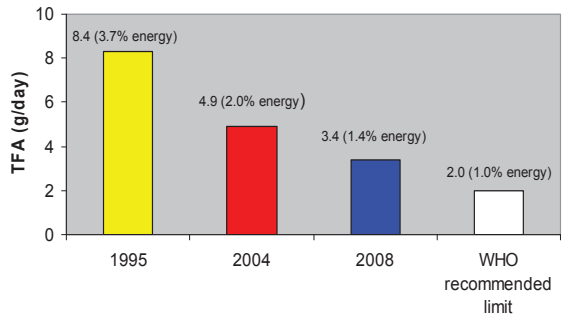

Figure 2. Average *trans* fat intakes (g/day) of Canadians 1 year and above in 1995, 2004, and 2008 vs. the World Health Organization's (WHO) recommended limit.

Average intakes of *trans* fat (as % of energy) by Canadians were calculated for certain age-sex groups and are listed in Table 1 [28]. The 2008 data shows that the sub-group that appears to have the highest intake of *trans* fats on a % energy basis is children; the same observation is made from the 2004 data. According to Table 1, current average *trans* fat intakes for children (1-8 years) are equivalent to 1.55-1.57% of overall energy. Another sub-group with high levels of *trans* fat intakes appears to be women 71 years and above, whose average *trans* fat intakes are equivalent to 1.47% of overall energy.

DRI age-sex group	Sample Size	*Trans* % of Energy	
		2004	2008
Children 1-3y	2117	2.07	1.55
Children 4-8y	3235	2.31	1.57
Boys 9-13y	2080	2.31	1.54
Boys 14-18y	2288	2.25	1.53
Girls 9-13y	1980	2.32	1.54
Girls 14-18y	2277	2.17	1.52
Males 19-30y	1804	2.01	1.40
Males 31-50y	2596	1.94	1.38
Males 51-70y	2550	1.89	1.36
Males 71+y	1520	1.92	1.44
Females 19-30y	2017	2.05	1.39
Females 31-50y	2755	1.94	1.39
Females 51-70y	3201	1.87	1.36
Females 71+y	2610	1.96	1.47
All Adults 19+y	19053	1.94	1.39
All Person 1+y	33030	2.01	1.42

Table 1. Estimated *trans* fat intakes as percent of energy in 2004 vs. 2008 in different age-sex groups in Canada [28]. The results contained in this table are based on the Canadian Community Health Survey – Cycle 2.2 on Nutrition, Statistics Canada, 2004.

The usual intake distributions of *trans* fat (as % of energy) were also calculated for certain age-sex groups (Table 2) [28]. The 95th percentiles for all age-sex groups have dropped from approximately 3.00% in 2004 to 2.12% in 2008. The 95th percentile for males 51 years and older is the highest at 2.30% of overall energy. The 5th percentile for both boys and girls 9-18 years of age are reported to be 1.22% and 1.06% of energy. This indicates that almost all children and teenagers exceed the *trans* fat limit of 1% energy intake recommended by the WHO.

Estimations were also calculated for average saturated fat intakes. The results indicate that average saturated fat intakes have remained constant since 2004 [28]. For all Canadians aged one year and above, saturated fat intakes are estimated now to be on average, 25 g/day which is the same estimate from 2004 [28]. This suggests that many food manufacturers are replacing TFAs with mono- and poly-unsaturated fats and not with saturated fat. This was confirmed through the scientific assessment of the full fatty acid profile of the foods that were included for analysis in the TFMP [28].

Age-Sex	Sample Size	Year	Percentile						
			5th	10th	25th	50th	75th	90th	95th
Boys 9-18y	4368	2004	1.55	1.70	1.96	2.27	2.62	2.96	3.18
		2008	1.22	1.20	1.34	1.51	1.71	1.91	2.04
Girls 9-18y	4257	2004	1.58	1.71	1.94	2.22	2.53	2.82	3.00
		2008	1.06	1.15	1.30	1.49	1.73	1.96	2.12
Males 19-50y	4400	2004	1.16	1.31	1.58	1.92	2.29	2.67	2.91
		2008	0.90	0.99	1.15	1.36	1.59	1.81	1.96
Males 51+y	4070	2004	0.96	1.11	1.40	1.80	2.27	2.78	3.12
		2008	0.71	0.82	1.03	1.31	1.66	2.04	2.30
Females 19-50y	4772	2004	1.27	1.40	1.65	1.95	2.30	2.64	2.85
		2008	0.92	1.00	1.16	1.36	1.59	1.82	1.97
Females 51+y	5811	2004	1.10	1.24	4.50	1.84	2.23	2.63	2.89
		2008	0.79	0.89	1.08	1.33	1.64	1.96	2.18

Table 2. Usual distributions of estimated *trans* fat intakes as percent of energy in 2004 vs. 2008 in different age-sex groups in Canada [28]. The results contained in this table are based on the Canadian Community Health Survey – Cycle 2.2 on Nutrition, Statistics Canada, 2004.

The estimates of *trans* fat intake were calculated using the monitoring data that was analyzed until late 2008/early 2009. More recently a Cost Benefit Analysis (CBA) was commissioned by Health Canada to estimate the potential costs and benefits of further efforts to reach the target of 1% [35]. Interviews conducted as part of the CBA indicated that some other companies were ready to roll out new products that were meeting the *trans* fat limits in a matter of weeks or by the end of 2009 [35]. Thus, it is possible that there were additional reductions in *trans* fat intakes resulting from food reformulation since the 1.42% of energy estimate was calculated. However, decreases in *trans* fat intake are not expected to be as large as in past years, since most companies that expressed their intent to voluntarily reduce TFA content in their foods have already done so. Therefore, the authors of the CBA decided to assume that further reductions since the last data collection would occur at half of the average rate of the previous 4 years (from 2.01% to 1.42% of energy intake over four years, or approximately 0.15% per year, and then an approximate reduction of 0.075% energy). Based on this assumption, the average *trans* fat intake would be estimated at 1.35% of energy (with an 80% confidence interval of 0.92% to 1.93%) in 2009 [35], a year after the completion of the monitoring program, which is still above the WHO recommendation of 1% of energy. In children, the 2009 average *trans* fat intake would be estimated at 1.49%.

If we were to continue with the assumption that there have been additional reductions in *trans* fat intakes since the 1.42% of energy estimate was calculated, and that additional reductions continued at the same rate of 0.075% energy per year, the estimated *trans* fat intakes in 2012 would be 1.12% of energy and 1.27% of energy in children. However, in estimating the anticipated health benefits of the reductions in *trans* fat intake, the CBA assumed that there would not be any further reductions in *trans* fat intakes in Canada beyond the 2009 levels, i.e. over 2010-2029 [35], based on interviews with food industry stakeholders about their intent to make further reductions in *trans* content of foods. Therefore, assumptions of similar reductions beyond 2009 as in previous years have not been substantiated. Further analysis would be required to confirm whether suitable alternative ingredients for troubled sectors have been developed and whether or not there has been uptake of alternatives in these sectors leading to further reductions.

3.4 Additional Considerations

3.4.1 Availability of High TFA Foods

Among the foods that remain high in TFA are some house brand products that are still made with PHO and do not meet the recommended *trans* fat limits [26, [28]. There are at least three examples of the same margarine manufacturer producing two lines of margarines, one that contains *trans* fat and one that is *trans* fat-free [26], [28]. The continued marketing of high TFA products such as soft margarines, shortening, hard margarines, and bakery products that have TFA content up to 21%, 31%, 40%, and 45% of total fat, respectively, is of particular concern since these categories of foods have been and continue to be top contributors to *trans* fat intake by Canadians [16], [17], [26], [28].

3.4.2 Food Service Establishments

The beneficial impact of Canadian nutrition labelling regulations on alerting consumers to the levels of *trans* fat does not extend to foods sold in restaurants and food service establishments as the nutrition labelling regulations only apply to prepackaged foods. Recently it was reported that most Canadians eat out (48%-74%) or order take-out (20-67%) about once per week [36] and on

a given day, one out of four adults and children in Canada eats or drinks a food or beverage in a fast food outlet [37]. This figure is likely higher since the report also indicated that an additional 23% consumed food in some other combination (either something prepared at a restaurant, bar, school and non-school cafeteria, etc.) [37]. Furthermore, information from nutrition surveys indicates that 22% of the average *trans* fat intake of Canadian adults (and as much as 31% in the case of males aged 19 to 30 years) is provided by foods consumed away from home, often in fast food restaurants and other food service environments [23]. Results from the TFMP suggest that while a number of popular fast-food and family restaurant chains in Canada have been successful in decreasing TFA levels, there are still establishments that continue to offer menu items high in TFAs [26], [28].

3.4.3 Analysis of specific sub-populations and socioeconomic considerations

Besides overall estimates of exposure in the population, the potential for some groups to have higher exposure to *trans* fat needs to be considered. As noted in the exposure assessment section, exposure in children tends to be higher than exposure in adults on the basis of percent energy.

Another potentially vulnerable population includes people living in remote areas such as the Canadian Inuit population. Over the last five decades or so, Inuit populations have transitioned from a traditional, marine diet to one which incorporates more processed foods, typical of a western diet. Foods containing industrially produced TFAs offer qualities that are required for processed foods in remote communities, namely, storability at room temperature and a longer shelf-life. A recent dietary survey conducted in 2004-2005 in Inuit populations from Nunavik, Canada and Greenland indicated that on average, store-bought foods accounted for 75% and 84% of energy intakes, respectively [38]. This study showed that while the contribution of energy from store-bought foods was comparable between the two Inuit populations, the average *trans* fat intakes among the Nunavik Inuit were three times higher than those of the Greenland Inuit (as measured by the fatty acid composition of erythrocyte membrane phospholipids) [38]. Furthermore, while Inuit youth consumed a significantly higher proportion of store-bought foods than their elders (90% of calories vs. 70% of calories) in both populations, erythrocyte TFA levels were similar across all age groups in Greenland Inuit, while in Nunavik youth had significantly higher erythrocyte TFA levels than their elders (0.67% vs. 0.39%). The study reported that the availability of good quality store-bought foods, at least as it relates to *trans* fat, was better for the Greenland Inuit because most industrially produced foods sold in Greenland are imported from Denmark, where a *trans* limit of 2% of total fat has been imposed since 2003 [38].

While familiarity with the food product is a factor influencing Canadians' food buying practices [39], one of the top factors influencing food buying decisions is cost [36], [39]. Research shows a negative relationship between price and the SFA and TFA contents of margarines [40]. It was reported that margarines sold on the Canadian market that are lower in SFA, TFA, and the sum of SFA+TFA, cost significantly more than margarine with higher levels of these fats [40]. Additionally, despite controlling for confounding variables such as package size, store type, and brand, this relationship was still seen [40]. More recent data is consistent with this price disparity among high and low TFA margarines [41]. In 2002, those that were "*trans*-fat free" (i.e. less than 0.2 g of *trans* fat per reference amount and serving of stated size and low in saturated fats) cost $4.62 per kg and those that were not "*trans*-fat free" cost $3.05 per kg. In comparison, in 2006 those that were "*trans*-fat free" cost $5.10 per kg and those that were not "*trans*-fat free" cost $3.55 per kg [41]. Similar research indicates that nutritionally improved products tend to be higher in price [42] which is of a particular concern for lower income groups. Budget constraints have a significant influence on lower income groups making them very price sensitive. The implication is that these groups will be likely to have a higher exposure to *trans* fat through their selection of lower priced foods [43].

4. Risk Characterization

Coronary heart disease is among the leading causes of death in Canada contributing to approximately 50,000 annual deaths [44]. The heart health effects of TFAs are well known: they raise LDL-cholesterol and lower HDL-cholesterol, which leads to increased risk of CHD. Even very low intakes of TFAs may increase the risk of CHD [5].

In prospective cohort studies reviewed by Mozaffarian and Clarke, each 2% energy replacement of *trans* fat with monounsaturated or polyunsaturated fat lowered the CHD risk by 21% or 24%, respectively [7]. Based on these rates (and using the more conservative estimate of *trans* fat intake based on the interviews summarized in the 2009 CBA [35]), reducing the average *trans* fat intakes of children from 1.49% to 1% of overall energy would decrease the CHD risk by 5-6%. Reducing the average *trans* fat intakes of adults from 1.35% (using the more conservative *trans* fat intake estimate) to 1% of overall energy would decrease the CHD risk by 3-4%.

Population-attributable risks based on epidemiological data, such as those mentioned above, may overestimate

the true effect of eliminating a risk factor owing to other unrelated (competing) risk factors [45], [46]. Therefore further estimates of decreased risk were obtained from controlled trials and short term clinical studies. On the basis of predicted changes in the total-cholesterol:HDL-C ratio from controlled trials, according to Mozaffarian and colleagues, 3% of CHD events could be averted when *trans* fat intakes are reduced from 2.1% energy to 1.1% energy [1]. As cited by the Food and Drug Administration, findings from other short-term feeding trials that measured changes in serum lipids (LDL+HDL), showed a 0.184%, 0.287% and 0.296% reduced risk of CHD for each 0.1% of energy replacement of TFAs with SFAs, MUFAs or PUFAs, respectively [47]. This equals an average 2.6% reduction in the risk of CHD for every 1% energy replacement of TFAs with SFAs, MUFAs and PUFAs [((0.184% + 0.287% + 0.296%) /3)*10 = 2.6%].

To account for the range of published estimates using clinical trials measuring changes in serum lipids, an average of the two estimates, 2.6% and 3.0%, is taken. Thus, there is an estimated reduction in CHD risk of 2.8% for each 1% of energy replacement of TFAs with SFAs, MUFAs or PUFAs (in equal proportions).

Using the average estimate of 2.8%, on the basis of the changes in cholesterol levels alone, decreasing the average *trans* fat intakes of children from 1.49% to 1% of overall energy would decrease the CHD risk by 1.37%. Reducing the average *trans* fat intakes across all ages from 1.35% to 1% of overall energy would decrease the lifetime CHD risk by 0.98%. According to the CBA commissioned by Health Canada that factored in the reduced risk of CHD along with annual growth rate of heart attack cases in Canada, this further reduction of average *trans* fat intake to 1% of energy is conservatively estimated to prevent an average of 12,354 heart attack cases in Canada over 2010-2029 [35].

5. Conclusion

Collectively, the monitoring program results indicate that, while there are a large number of foods on the market in most categories meeting the 2% and 5% *trans* fat limits recommended by the TFTF, there were still some foods that contain high levels of TFA [26], [28].

The progress made by the industry to reformulate and decrease the TFA content of their products has been reflected in an overall decrease in the *trans* fat intakes of Canadians. However, the estimated average *trans* fat intake for Canadians in 2008 at 1.42% of energy continues to be above the WHO recommendation that average *trans* fat intake be limited to less than 1% of total energy. It also confirms that the average *trans* fat intakes of Canadians could reach 1% of total energy if most products were reformulated to meet the 2% and 5% limit.

Despite the progress made by industry to reduce the *trans* fat content of their foods, there remain foods in the Canadian market place that contain high levels of *trans* fat. Further reductions in *trans* fat levels in the Canadian food supply are needed to meet the target of 1% of energy, the associated public health objectives, and the protection of vulnerable populations.

6. Acknowledgements

The authors would like to thank: William Yan, Maya Villeneuve, Claude Gagnon, Isabelle Rondeau, Brian Lampi, Zeshawn Awan, Amanda Whitfield, Michael Masotti, Valerie Casey, Dayani Mohottalage, William Lillycrop, Mary Meleta, Lynn Wong, Tran Ng, Yu Gao, Keri Kwong, Shirley Chalouh, Peter Pantazopoulos, Hasantha Gunaratna, Richard Blagden, Veronica Roscoe, Tom Krakalovich, Gary Neumann, and Gary Lombaert for their extensive and invaluable contributions to the various aspects of this paper. The authors would also like to thank Lydia Dumais, Kevin Cockell, and Lisa Pavone for their helpful reviews.

APPENDIX A - *Trans* Fat Monitoring Program

On June 20, 2007, Health Canada adopted the recommendations of the TFTF with respect to the amount of TFA in foods and announced the *Trans* Fat Monitoring Program [25]. The Minister of Health called on the food industry to achieve the 2% and 5% limits within two years [25].

Health Canada has been analyzing TFAs in foods intermittently since the 1970's, focusing then on margarines [13]. The analysis of TFAs in foods increased at the time the TFTF was established in order to support their work. The *Trans* Fat Monitoring Program was established following the announcement of the Minister in June 2007 to analyze the TFA content of foods that were, as indicated by earlier surveys, significant sources of TFAs, i.e. foods with high levels of TFAs or foods with lower levels of TFAs that were consumed in large quantities by a large number of consumers.

For prepackaged foods, the individual products that were chosen for laboratory analysis were representative of the majority of products sold within a particular food category. In most cases, they represented a group of products that covered approximately 80% of the market share (as volume share). Market share data was purchased from AC Nielsen [27]. Bakery products that were predominantly unlabelled items from various grocery stores were also chosen for laboratory analysis since they represent foods that were previously identified as significant sources of TFAs [16], [17], [23]. Items were collected from major grocery stores that represented retail chains found across Canada.

Foods from the major fast food chains, family restaurants, donut/coffee shops, and restaurants serving various ethnic cuisines underwent laboratory analysis as well. A smaller sample of foods were also collected and analysed from small and medium-sized family and quick service restaurants, as well as cafeterias located in institutions. All laboratory analyses were conducted from 2005-2009.

For the label review, the food categories chosen were those that were previously identified as significant sources of TFAs [16], [17], [23]. The individual products within each of these categories were selected based on market share data. Collectively, groups of products represented more than 99% of the market share (as volume share). However, certain products were not collected because previous monitoring data suggested that the levels of TFAs were already low in these products and so a label review of these products was not repeated. All food labels were collected for label review in March and October 2008 from major grocery stores from across Canada (Toronto, ON; Scarborough, ON; Vancouver, BC; Halifax, NS; and Montreal, QC).

Three Health Canada laboratories (Ottawa, Toronto, and Winnipeg) performed the collection and laboratory analyses as well as the label review. The full details of the sample collection, analytical methods, quality assurance program, were posted on the Health Canada website along with the data [26], [28].

Briefly, the food samples were analysed by the Association of Official Analytical Chemists (AOAC) Method 996.06 [29], the recommended method for TFA analysis in Canada. This laboratory procedure and methodology is used to determine the total fat and fatty acids in a wide variety of foods that require nutrition labelling in Canada and the United States.

Item	Total samples	Number of samples meeting	Number of samples not meeting	Percent of samples meeting	Percent of samples not meeting	Min. % TFA*	Max % TFA
cookies	79	53	26	67	33	0.0	33.3
crackers	62	58	4	94	6	0.0	33.3
popcorn	22	18	4	82	18	0.0	50.0
pizza	6	4	2	67	33	2.2	9.8
coffee whitener	17	8	9	47	53	0.0	66.7
garlic spreads	6	2	4	33	67	0.6	17.2
garlic bread	11	6	5	55	45	0.9	25.1
bread	21	21	0	100	0	0.4	3.3
muffins	2	2	0	100	0	0.5	1.9
snacks	90	84	6	93	7	0.0	28.6
chicken products	6	5	1	83	17	2.0	19.0
hard margarines	6	0	6	0	100	35.7	44.5
soft margarines	37	23	14	62	38	0.5	32.8
shortening	4	2	2	50	50	3.8	30.9
lard	4	4	0	100	0	1.1	2.0
baked packaged desserts	87	73	14	84	16	0.0	28.6
granola bars	21	17	4	81	19	0.3	17.5
instant noodles	22	22	0	100	0	0.0	0.9
frozen potatoes	21	20	1	95	5	0.0	37.5
frozen packaged desserts	49	36	13	73	27	0.0	22.2
snack pudding	27	21	6	78	22	0.0	33.3
appetizers	109	93	16	85	15	0.0	40.9
entrées/dinners	85	69	16	81	19	0.0	12.5

Table 3. Results of prepackaged foods collected and analysed (label review and laboratory analysis) from 2005-2008.
* For samples that were laboratory analyzed, the 0.0% indicates that the level of *trans* fat detected was below the limit of detection. For samples that underwent label review, the 0.0% indicates the amount of *trans* fat that is declared on the label and thus subject to labelling regulations (including rounding).

Item	Total number of samples	Percent of samples not meeting TFA limit	range of TFA in samples (as % of total fat)
hard margarines	6	100	35.7-44.5
garlic spreads	6	67	5.1-17.2
shortening	4	50	30.6-30.9
coffee whitener	17	53	13.3-66.7
garlic bread	11	45	11.5-25.1
soft margarines	37	38	14.7-32.8
pizza	6	33	7.3-9.8
cookies	79	33	6.7-33.3

Table 4. Prepackaged food with high levels of TFAs.

The data were presented alphabetically by food category in a standard format and included the sampling date, the percentage of total fat in the food, as well as TFA and SFA content as a percentage of total fat. All results were posted on the Health Canada website. Results from the 1st, 2nd, 3rd, and 4th set of *trans* fat monitoring data were released in December 2007, July 2008, February 2009, and September 2009 respectively [26] and published in 2009 [28]. The results presented in this risk assessment include data from all four data sets.

APPENDIX B - *Trans* Fat Monitoring Program Results

Prepackaged Foods

In total, 792 prepackaged foods (not including the repeated items) were collected and analysed (by label review and laboratory analysis) from 2005-2008. The food categories included are listed in Table 3. Based on the most recent results, approximately 76% (or 655 out of the 792) of prepackaged foods analyzed are meeting the 2% and 5% *trans* fat limits. The food categories with the highest percentages of items now meeting the limits include: instant noodles (100%), lard (100%), muffins (100%), breads and buns (100%), frozen potatoes (95%), crackers (94%), snacks (93%), baked packaged desserts (84%), popcorn (81%), and granola bars (80%). The food categories with the lowest percentages of items now meeting the *trans* fat limits include: hard margarines (0%), garlic spreads (33%), shortenings (50%), coffee whitener (47%), garlic bread (55%), soft margarines (62%), pizza (67%), and cookies (67%).

The TFA content of some foods is still quite high, with levels as high as nearly 70%. For example, the TFA content of some coffee whiteners ranges from 13.3%-66.7%, the TFA content of some popcorn products ranges from 20.0%-50.0%, and the TFA content of some soft margarines ranges from 14.7%-32.8%. Other high TFA-containing foods are listed in Table 4.

Market share for most of the foods that are still high in TFAs is marginal except for the cookies that are not meeting the *trans* fat limits, which collectively represent close to 10% of the market (as volume share). Also, the high TFA-containing soft margarines represent approximately 16% of the market and the high TFA-containing hard margarines represent close to 30% of the market. The proportion of the market that these foods actually represent is likely higher since the market share of house brands, which is unknown for individual products, has not been included. There are a number of house brand products that are still using PHO and as such are not meeting the *trans* fat limits.

In all other cases, the food products that are higher than the *trans* fat limits represent less than 5% of the market. For example the snack products collectively represent less than 1% of the market, the popcorn products collectively represent less than 3% of the market, and the garlic spreads collectively represent less than 0.5 % of the market.

Bakery products from grocery stores:

The *trans* fat monitoring program analysed 81 bakery products from various grocery stores. The results from the bakery products analyses indicate that the following were meeting the 5% TFA limit: 25% of croissants (n = 16), 45% of danishes (n = 11), 36% of pies (n = 11), 67% of tarts (n = 15), 43% of cakes (n = 14), 45% of brownies (n = 11), and 33% of donuts (n = 3). The details can be found in Table 5.

On average, out of the total of 81 bakery products, 46 (or 58%) were meeting the *trans* fat limit of 5% of total fat. The TFA content of those 46 items that were still high in TFAs ranged from 5.4% TFA (tart) to 39.2% (danish) and 43.7% TFA (croissant). Thus, the levels of certain bakery products remain quite high. There are however examples of low *trans* fat bakery products in each category, some with levels as low as 0.6% TFA, indicating that it is possible to reformulate and produce low *trans* fat products of all types, including croissants and tarts.

Item	Total samples	Number of samples meeting	Number of samples not meeting	Percent of samples meeting	Percent of samples not meeting
croissants	16	4	12	25	75
danishes	11	5	6	45	55
pies	11	4	7	36	64
tarts	15	10	5	67	33
cakes	14	6	8	43	57
brownies	11	5	6	45	55
donuts	3	1	2	33	67

Table 5. Results of bakery items collected from grocery stores.

Item	Fat (% by weight of food)	TFA (% of total fat)	SFA (% of total fat)	TFA + SFA (% of total fat)
croissants	20.6	0.7	45.1	45.8
croissants	20.5	43.7	18.9	62.6
danishes	13.1	1.0	44.6	45.6
danishes	9.3	39.2	22.9	62.1
blueberry pie	14.4	0.8	46.3	47.1
lemon meringue pie	8.6	29.0	22.5	51.5
butter tart	18.9	0.6	41.0	41.6
fruit tarts	10.0	23.0	39.4	62.4
chocolate cake with icing	25.6	0.8	46.2	47.0
chocolate cake	13.7	27.1	32.2	59.3
brownies	14.8	0.7	32.6	33.3
brownies	9.9	26.2	21.9	48.1
donut	17.7	3.4	45.1	48.5
donut	27.8	26.0	33.5	59.5

Table 6. Data indicating the sum of *trans* fat + saturated fat decreasing in low *trans* fat bakery products.

Bakery products are known to require a hard fat to maintain functional characteristics. One such substitute for *trans* fat is saturated fat. The data, as reported in Table 6, indicates that while saturated fat in some of the low *trans* fat bakery products have increased, in each case the sum of *trans* fat + saturated fat is much lower than the high *trans* fat bakery products. This suggests that a much lower amount of saturated fat is required to produce a comparable product. There are also examples of low *trans* fat bakery products with low saturated fat levels as well, indicating the replacement of TFAs with other fats such as monounsaturated and polyunsaturated fats.

The results also indicate that the majority of the products that are high in *trans* fat, and thus not meeting the limit, do not have a Nutrition Facts table. These include in-store bakery products that are exempt from nutrition labelling requirements. Specifically, 62 products were not labelled with Nutrition Facts tables versus 19 products that were labelled with Nutrition Facts tables. As indicated in Table 7, of the 62 products not labelled, 38 of (61%) were high in *trans* fat. Whereas out of the 19 products that were labelled eight (42%) were high in *trans* fat.

Foods from restaurants serving various ethnic cuisines:

Rates of meeting the *trans* fat limit were high for many menu items from restaurants serving various ethnic cuisines, including Thai, Vietnamese, Caribbean, Chinese, Japanese, and East Indian. In total, 70 menu items were collected from 16 different establishments and 63 (or 90%) of those items were meeting the TFA limit. Foods collected and analysed included fried foods and those that are pastry-based such as: naan bread, samosa, Chinese cookies, mooncake, General Tao's chicken, fried beef and pork, roti, egg rolls, and spring rolls.

Foods from fast food chains, family restaurants, and coffee shops:

Foods collected and analyzed from 2006-2008 included: french fries, chicken products (such as chicken nuggets and chicken strips), fish products, onion rings, donuts, cookies (including biscuits and croissants), miscellaneous (cheese sticks, hash browns), desserts, muffins, pizzas, and pizza dipping sauces.

Item	Total samples	Number of samples meeting	Number of samples not meeting	Percent of samples meeting	Percent of samples not meeting
labelled	19	11	8	58	42
unlabelled	62	24	38	39	61

Table 7. Bakery items labelled and unlabelled that are high and low in *trans* fat.

Item	Total samples	Number of samples meeting	Number of samples not meeting	Percent of samples meeting	Percent of samples not meeting
pizza	13	13	0	100	0
pizza dipping sauce	8	8	0	100	0
muffins	18	17	1	94	6
ethnic foods	70	63	7	90	10
popcorn	17	15	2	88	12
miscellaneous	11	9	2	82	18
french fries	90	71	19	79	21
chicken products	95	75	20	79	21
fish products	25	19	6	76	24
onion rings	12	9	3	75	25
desserts	35	23	12	66	34
cookies	13	6	7	46	54
donuts	35	10	25	29	71

Table 8. Results of foods collected from fast food chains and family restaurants.

In total, 355 fast foods items (not including repeated items) were collected and analysed from 2006-2009. Based on the most recent results included in Table 8, on average 75% or 260 out of the 355 fast food items meet the 5% *trans* fat limits. The fast food product categories with the highest percentages that meet the limits include: pizzas (100%), pizza dipping sauces (100%), muffins (94%), miscellaneous fast foods (82%), french fries (79%), and chicken products (79%). Some of the fast food product categories with the lowest percentages that meet the limits are donuts (29%), cookies (46%), and desserts (66%). The *trans* fat content in some of these foods is still quite high. For example, croissants and donuts collected from donut shops were reported to be as high as 44% *trans* fat and 56% *trans* fat, respectively, and a fried fish product from a popular family restaurant was reported to be as high as 42% *trans* fat.

Results from the monitoring program indicate that many of the top fast food and top family restaurant chains in Canada have been successful in reducing *trans* fat from menu items that have been previously high in *trans* fat. Revenues for these establishments, according to the 2007 Foodservice and Hospitality top 100 report [30], range from $25.5 million to $4.2 billion. Revenues for establishments that are still offering menu items that are high in *trans* fat range from $47 million to $474.6 million [30].

Foods from cafeteria in institutions (high schools, hospitals, college campuses, and nursing homes):

One hundred and four items from cafeterias in institutions such as high schools, hospitals, college campuses, and nursing homes were collected and analysed. While this was a small sample, it helped provide a baseline of the levels of TFAs in these types of establishments since many of these foods are not considered to be prepackaged and are exempt from the nutrition labelling regulations. Foods were collected from institutions in the following cities across Canada: Victoria, British Columbia; Winnipeg, Manitoba; Ottawa, Ontario; Montreal, Quebec; and Charlottetown, Prince Edward Island.

Foods that were collected included french fries, chicken products (such as chicken nuggets and chicken strips), fish products, onion rings, cookies, margarines, desserts, and muffins.

On average 67% or 88 out of the 104 items meet the 2% and 5% *trans* fat limits. The food categories with the highest percentages now meeting the limits include: muffins (100%), chicken products (80%), and cookies (76%). Foods categories that had low percentages of items but are now meeting the limits were margarines (25%), fish products (50%), and desserts (63%). These details are reported in Table 9. The TFA content in some of these foods is still quite high. Specifically, the TFA content of the 24 items that were still high in *trans* fat ranged from 5.3% (onion rings served in hospital cafeteria) to 29% (scones served in high school) to 47.0% (chicken fingers served in nursing home).

Item	Total samples	Number of samples meeting	Number of samples not meeting	Percent of samples meeting	Percent of samples not meeting
french fries	21	15	6	71	29
chicken products	15	12	3	80	20
cookies	29	22	7	76	24
muffins	22	22	0	100	0
onion rings	3	2	1	67	33
fish	2	1	1	50	50
margarines	4	2	2	50	50
desserts	8	5	3	63	37

Table 9. Results of foods collected from institutions (cafeteria in hospitals, on college campuses, in high schools).

The results show that foods served in cafeteria in institutions are not meeting the limits as well as foods served in other food service establishments such as restaurants and fast food chains. Two of the top food service providers/caterers are serving foods that are still high in *trans* fat, namely margarines (24% TFA and 26% TFA), cookies (20% TFA), and french fries (13% TFA) in nursing homes and on college campuses. The revenue for two of the top food service providers/caterers ranges from 485 million to $707 million [30].

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