

## Should Canada Ban Trans Fats? The Evidence Suggests Not

### Executive Summary

- A bill that bans trans fats in the Canadian food supply has passed the House of Commons.
- Trans fats were created as a healthier replacement for saturated fats.
- The evidence against their use is based on epidemiology, statistical correlations of data that do not demonstrate cause and effect.
- Metabolic studies of trans fats are ambiguous and epidemiological calculations of relative risk can mislead.
- In the rush to publish, researchers are liable to present confidence intervals in the worst possible light and exaggerate their import.
- The relative risk numbers for trans fats from a number of studies are too low to cause alarm.
- Extrapolations of already wobbly risk factors into human body counts are completely unjustifiable.
- The ban will make food more expensive and open Canada to trade retaliation. A better recourse is to encourage a healthy lifestyle and a balanced diet.

### Introduction

On November 18, 2004, the New Democratic Party (NDP) introduced a bill in Parliament which would effectively ban the use of trans fats in the Canadian food industry. The bill was debated for most of that day passed a vote of approval five days later by a margin of 193 to 73.

Health concerns are the primary justification cited for the ban. The main claim is that trans fats are responsible for between 82 and 274 deaths a day, or between 30,000 to 100,000 deaths a year in the United States due to coronary heart disease.<sup>1</sup>

The purpose of this backgrounder is to review and explain the evidence that led to the conclusion that an all-out ban on trans fats is necessary to protect the health of the Canadian public. It will demonstrate that the dangers of trans fats are not scientifically proven, and that the claim that they cause deaths are not based on a chain of proven cause and effect, but rather on assumptions from statistical extrapolations.

### Trans Fats

Trans fatty acids or trans fats are formed when manufacturers turn liquid oils into solid fats, to create products like shortening and hard margarine. Manufacturers create trans fats by means of a process called hydrogenation. In this process, vegetable oils are converted to solid fats simply by adding hydrogen atoms.

Hydrogenation increases the shelf life and flavour stability of foods. Trans fats can be found in a laundry list of items including vegetable shortening, margarine, crackers (even healthy-sounding ones like Nabisco Wheat Thins), cereals, candies, baked goods, cookies, granola bars, chips, snack foods, salad dressings, fats, fried foods and many other processed foods. In total, about 40% of the products found on supermarket shelves contain trans fats.

Trans fatty acids are found naturally in small quantities in some foods including beef, pork, lamb, butter and milk, but most trans fatty acids in a modern diet come from hydrogenated foods.<sup>2</sup> By educated estimates, 5 to 10 percent of the fat in the North American diet and 5 percent of the fat in adipose tissue is trans unsaturated fat.

### The History of Trans Fats

Based on ambiguous evidence, a backlash against saturated fats took hold in the 1970s. Saturated fats are essentially animal fats found in butter, cream and meats. At the time, the public was repeatedly told to consume less such fat to avoid "killer diseases" that were supposedly sweeping the country. The Center for Science in the Public Interest, an influential think tank, directed a successful consumer campaign against saturated fats and advocated their

replacement in diets with partially hydrogenated oils, or trans fats. Now the “experts” at this organization claims that trans fats are far worse.<sup>3</sup>

Which begs the question: if these same experts have been wrong about butter for the past 25 years, why should we believe them now about margarine? Their work is riddled with a striking error in method, one that could apply to almost all commodities. They can reasonably misjudge the ill-effects of saturated and unsaturated fats in parallel ways because they misuse the statistical findings of epidemiology.

## Epidemiology

The first thing to recognize is that *the evidence against trans fats is not science-based*. It is based on a type of research called epidemiology.<sup>4</sup> Its findings are commonly mistaken for science, especially by politicians and the mass media.

Epidemiology is essentially the statistical study of the incidence and distribution of disease in a population. Because it is a form of statistical study, it cannot and should not attempt to prove *cause and effect*.<sup>5</sup> That is not to say it is not useful in studying diseases, especially rare ones. However its findings offer nothing more than a guidepost that may or may not lead people in the labs, who do the real science, in the right direction.

The most important rule to remember about epidemiology and statistics is that *“correlation does not equal causation.”* To illustrate, the following logical error occurs when the concepts are confused: Virtually all heroin addicts drank milk regularly as children. Therefore, drinking milk leads to heroin addiction. The misuse of epidemiological studies typically resonates with that puffy sort of thinking.

In the case of trans fats, we know that they are consumed on a regular basis by a large percentage of the population and also that a lot of people die every year from coronary heart disease. However, that does not automatically mean that one leads to the other; further evidence is required before one can make that claim.

The next elements in the mix are metabolic studies.

## Metabolic Studies

A number of metabolic studies have shown that trans fats have adverse effects on blood lipid levels. They increase LDL (“bad”) cholesterol while decreasing HDL (“good”) cholesterol. This combined effect on the ratio of LDL to HDL cholesterol is double that of saturated fatty acids.<sup>6</sup>

But do increased or elevated levels of cholesterol lead to heart disease and death? The evidence for that conclusion is far from clear. As far back as 1948, the Framingham Heart Study, extensively reviewed since in over 1,000 published reports, showed that high cholesterol was not associated with increased heart disease *after the age of 47*. In fact the study showed the opposite, that after that age those whose cholesterol *went down* actually had the *highest risk of a heart attack*. “For each 1 mg/dl drop of cholesterol there was an 11 percent increase in coronary and total mortality,” reported the study’s authors.<sup>7</sup>

Further to this, from a report on randomized cholesterol reduction trials in a 1993 *British Medical Journal*, “In the pooled analysis, net benefit in terms of total mortality from cholesterol lowering was seen only for trials including patients at very high initial risk of coronary heart disease. In a medium risk group no net effect was seen, and in the low risk group there were adverse treatment effects.”<sup>8</sup>

It should be noted that trans fats consumption only increases LDL cholesterol *temporarily* in healthy individuals and that the more cholesterol in the diet, the less cholesterol the body makes on its own. But, for the sake of argument, let’s assume that elevated levels of cholesterol lead to heart disease and death. Where does that assumption lead?

## Strongest Evidence

According to the Harvard School of Public Health, the strongest epidemiological evidence relating dietary factors to risk of coronary heart disease is provided by prospective investigations. The relation between the intake of trans fatty acids and the risk of coronary disease has now been examined in three large cohort studies, the Health Professionals Follow-up Study (HPFS), the Alpha-Tocopherol Beta-Carotene study (ATBC) and the Nurses Health Study (NHS).<sup>9</sup>

However this data can be properly interpreted, the role of “relative risk” in epidemiological studies must be understood.

## Relative Risk

The goal of an epidemiological study is to determine “relative risk” (RR), and this terms lies at the very heart of the dispute between epidemiology and real science. Relative risk is determined by first establishing a baseline, an accounting of how common a disease (or condition) is in the general population. This general rate is given a relative

risk of 1.0, which means no risk at all, or neutral. An increase in risk would result in a number larger than 1.0. A decrease in risk would result in a lower number, and indicates a protective effect.<sup>10</sup>

The media usually reports RRs as percentages. A RR of 1.40 is usually reported as a 40% increase, while an RR of .90 is reported as a 10% decrease. (In theory, at least. In practice, negative RRs are seldom reported.) One of the most difficult things for non-mathematicians, including most journalists, to understand is that 90% is NOT a large number. It is less than one. What causes conceptual difficulties is that 90% is a large *proportion* (nearly all) but it not a large *increase* (less than a doubling).

These statements from those who work in the field can clarify the matter:

"As a general rule of thumb, we are looking for a relative risk of 3 or more before accepting a paper for publication." – Marcia Angell, editor of the *New England Journal of Medicine*

"My basic rule is if the relative risk isn't at least 3 or 4, forget it." – Robert Temple, director of drug evaluation at the U.S. Food and Drug Administration.

"Relative risks of less than 2 are considered small and are usually difficult to interpret. Such increases may be due to chance, statistical bias, or the effect of confounding factors that are sometimes not evident." – The National Cancer Institute

"An association is generally considered weak if the odds ratio [relative risk] is under 3.0 and particularly when it is under 2.0, as is the case in the relationship of ETS and lung cancer." – Dr. Geoffrey C. Kabat, IAQC epidemiologist

What are examples of really significant risk ratios? Heavy cigarette smoking has an association with lung cancer with a risk ratio of about 20, while aspirin produces a relative risk of 35 for Reye's syndrome in children. This is where epidemiology can be effective – for large risks of comparatively rare diseases.

### **Publication Bias**

The process by which non-alarming risk ratios become publicly alarmist includes a phenomenon called "publication bias." Because negative or near neutral results are almost never published, there is a tendency on average to produce results that appear significant. The research world lives and dies by the axiom "publish or perish." The motivation by career researchers to show significant increases in risk by placing the proverbial "thumb on the scale" is quite strong. This is another reason for never accepting RRs of less than 2.0.

The *Journal of the American Medical Association* actually did a study on this tendency. They determined that "A greater proportion of studies with statistically significant results are published than those with nonsignificant results."<sup>11</sup>

### **Confidence Interval**

A "confidence interval" (CI) is used to determine the precision of the RR. It is expressed as a range of values that would be considered valid, for instance .90 – 1.43. The narrower the CI, the more accurate the study. The CI can be narrowed in many ways, including using more accurate data and a larger sample size.

Confidence intervals are usually calculated to a 95% confidence level. This means the odds of the results occurring by chance are 5% or less. This is another reason why epidemiology is considered to be a crude form of research. Imagine if the brakes on your car failed 5% of the time.

The RR could be any number within the CI. For instance, a RR of 1.15 with a CI of .95 – 1.43 could just as well be a finding of 1.25, a 25% increase, or .96, a 4% decrease, or 1.0, no correlation at all. One should pay close attention to any study where the CI results in a RR that straddles 1.0 even where there is no correlation, the RR is never exactly 1.0, due to the fact that both items are statistical variates.

### **The Risk Numbers in Trans Fat Studies**

Given this understanding of the functions of relative risk, of the phenomenon of publication bias and of confidence intervals, let's turn to the studies cited by the Harvard School of Public Health as showing the strongest epidemiological evidence against trans fats.<sup>12</sup>

1. In the Health Professionals Follow-up Study,<sup>13</sup> the relative risk of coronary heart disease associated with an absolute increase of 2 percent in the intake of trans fatty acids was 1.36 (95 percent confidence interval, 1.03 to 1.81).

This result, while low, is still misleading. The relative risk of 1.36 is a raw result, without any adjustment for other heart disease risk factors. When one adjusts for other risk factors – including age, body mass index, smoking habits,

alcohol consumption, physical activity, history of hypertension or high blood cholesterol, family history of myocardial infarction before age 60, profession, and fibre intake – the already weak relative risk is substantially reduced, by more than 50 percent, and becomes statistically insignificant.

2. In the Alpha-Tocopherol Beta-Carotene Cancer Prevention Study,<sup>14</sup> the relative risk of coronary heart disease associated with an absolute increase of 2 percent in the intake of trans fatty acids was 1.14 (95 percent confidence interval, 0.96 to 1.35).

Again, the result is a weak association that is not statistically significant. Furthermore, this study consisted of 21,930 male smokers. Can you really study dietary factors for heart disease in a population where smoking and its attendant unhealthy consequences is also a risk factor for heart disease? Of course not. Smoking is a confounding factor that will skew the results.

3. In the Nurses' Health Study,<sup>15</sup> The relative risk of coronary heart disease associated with an absolute increase of 2 percent in the intake of trans fatty acids was 1.93 (95 percent confidence interval, 1.43 to 2.61).

As with the Health Professionals Follow-up Study, here we are looking at raw numbers. When they are adjusted for age and other factors, the RR is actually 1.53 (95 percent confidence interval, 1.16 to 2.02) and this is only at the highest consumption rate. While it looks at first glance that it might be statistically significant when considering the high point of the confidence interval of the raw data, it is in reality a very weak association.

Table 3 of the Nurses' Study is also interesting in a number of other ways. It reports no statistically significant association between total fat intake and risk of coronary heart disease, between animal fat intake and risk of coronary heart disease, between saturated fat intake and risk of coronary heart disease, nor between cholesterol intake and risk of coronary heart disease.

In other words, the study basically reports that public reports about the connection between fat consumption and heart disease is not supported by data collected from 90,000 nurses over a period of 20 years. Either the study data is wrong or the public health establishment has been wrong about the association of fat consumption with the risk of heart disease. If the study data is wrong, then we should doubt the trans fat result. If the public health establishment has been generally wrong about fat consumption for the last two or three decades, why should we believe its claims about trans fats consumption?

### **Virtual Body Count**

The 30,000 to 100,000 deaths mentioned in the Harvard School of Public Health report<sup>16</sup> as the result of trans fats consumption are not actually real deaths that have been recorded by physicians or coroners. They are part of what is referred to as a "virtual body-count," derived from a mathematical model containing all of the assumptions in the data just analyzed.

This kind of extrapolation lies at the heart of the error in alarmist interpretations of epidemiological studies. Such a claim adds sizzle and draws attention to a study, and is a simple misdirection akin to the patter used by a conjuror to distract an audience. The Environmental Protection Agency in the United States, for example, used a similar feint with great success when it created an annual 3,000 imaginary corpses from passive smoking, a lie that has had enormous social consequences.

Researchers calculate such conclusions by using what is called the "attributable fraction," which takes a relative risk factor and multiplies it across a large population. Since the relative risk in any study is never exactly one, every such study, no matter how banal, will produce a loss (or saving) of thousands of lives. The larger the population used, the more dramatic the body count.

The flaw is the assumption that relative risk actually increases death rates. It doesn't. No one knows how much trans fat any of the people that died from coronary heart disease actually consumed and no one is yet able to make the clinical evaluation that trans fats caused observed deaths.<sup>17</sup>

In the case of trans fats, the relative risk numbers used to calculate the widely reported fatality rates, which some find so persuasive in the argument to ban them, are 1.07 and 1.31.<sup>18</sup> As stated before, these numbers are far too low to be used to justify such a sweeping recommendation. Due to chance, statistical bias, or the effect of multiple confounding factors, these numbers on relative risk are essentially meaningless. When the confidence interval is factored in, the conclusion that trans fats should be banned is not only foolish, it may also be the opposite of what's really indicated. The ingestion of trans fats may be just as likely to provide a slight protective effect.

### **Conclusions**

A review of the evidence used to push for a ban of trans fats in Canada makes two things abundantly clear. First, there is no scientific evidence to substantiate the claim that the public is at risk because of the presence of trans fats

in their diet. Second, the evidence that is available is so statistically insignificant, open to so many confounding variables and dependant on so many assumptions, speculations and conjectures that it is doubtful that it could be called evidence at all.

These conclusions are troubling because a ban on trans fats will have a substantial impact on the price of food. Alternatives, fats that are free of hydrogenated fats, are available, but only in small and expensive quantities. Each additional attempt to reformulate food or add another label to existing food in response to government mandates or public fears, real and imagined, increases food production costs. These are ultimately passed on to the consumer and has the greatest negative impact on those in our society who can least afford to pay more for their sustenance.

Additionally, a ban on trans fats when there is a lack of scientific evidence to support it may have other repercussions. It leaves Canada vulnerable to sanctions and tariffs by other countries that export to us. Both the NAFTA and WTO trade agreements specifically spell out the need for sound scientific evidence before a country can ban a food product because of health concerns. If there isn't, it is considered a non-tariff trade barrier and the country becomes legally open to trade retaliation.

Mainstream nutrition organizations have been trying to educate consumers for years about the fact that it is the overall diet that is important in weight control and healthy eating, and that other lifestyle factors are important. An unfortunate side effect of the focus on trans fats is that encourages people to obsess about this or that constituent part of a diet rather than the whole diet. The problem isn't this fat or that fat, it's the total amount of fat in one's diet, the total amount of many calories, and whether or one exercises enough to burn them off. A far more sensible recourse than a complete abandonment of any kind of fat is eating a smart balance of different types of foods.

### Recommendations

- 1. Lift the ban.** The Parliamentary ban on the use of trans fats in the Canadian food supply should be lifted immediately.
- 2. Separate researchers and regulators.** Politicians and bureaucrats who take on personal crusades and biased agendas are not above misrepresenting scientific "evidence" to advance a favored policy or appease a special interest group, as appears to have been the case with the ban on trans fats. Research should be designed, conducted, and reviewed by scientists who are totally independent of regulatory agencies or agents.
- 3. Provide for adequate judicial review.** To provide for a check of the use by governments or regulatory agencies of suspect science, the public should be allowed greater leeway to challenge their decisions in a court. Agencies and governments should be required to defend their actions on the basis of a standard of, at least, "substantial evidence."



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## Footnotes

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<sup>1</sup> Harvard School of Public Health Report on trans fatty acids and coronary heart disease, available at <http://www.hsph.harvard.edu/reviews/transfats.html>, and W. C. Willett and A. Ascherio, "Trans fatty acids: Are the effects only marginal?", *American Journal of Public Health* 1994; 84:722-724, available at [http://www.ajph.org/cgi/search?sortspec=relevance&author1=Willett&fulltext=&pubdate\\_year=1994&volume=&firstpage=](http://www.ajph.org/cgi/search?sortspec=relevance&author1=Willett&fulltext=&pubdate_year=1994&volume=&firstpage=)

<sup>2</sup> "Trans Fats: The Science and the Risks," available at <http://my.webmd.com/content/Article/71/81217.htm>

<sup>3</sup> "CSPI's Hypocritical Trans-ition," the Center For Consumer Freedom, available at [http://www.consumerfreedom.com/news\\_detail.cfm/headline/2641](http://www.consumerfreedom.com/news_detail.cfm/headline/2641)

<sup>4</sup> Junk science judo, A Short Course: Epidemiology is Statistics, available at [http://www.junkscience.com/JSJ\\_Course/jsjudocourse/12.htm](http://www.junkscience.com/JSJ_Course/jsjudocourse/12.htm)

<sup>5</sup> Ibid.

<sup>6</sup> Harvard School of Public Health Report, op. cit. and R.P.M. Mensink and M.B. Katan, "Effect of dietary trans fatty acids on high-density and low-density lipoprotein cholesterol levels in healthy subjects." *New England Journal of Medicine*, 1990; 323:439-45, available at <http://content.nejm.org>.

<sup>7</sup> Information on the Framingham Heart Study is available at <http://www.foxnews.com/story/0%2C2933%2C57486%2C00.html>, <http://www.americanheart.org/presenter.jhtml?identifier=4666>, and <http://framingham.com/heart/index.htm>.

<sup>8</sup> "Meta-analysis," *British Medical Journal*, available at [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list\\_uids=8518602&dopt=Abstract](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=8518602&dopt=Abstract), and <http://www.junkscience.com/sep02/Willett-response.htm>. See also: <http://bmj.bmjournals.com/cgi/content/full/321/7267/983>

<sup>9</sup> Harvard School of Public Health Report, op. cit.

<sup>10</sup> See [http://www.junkscience.com/JSJ\\_Course/jsjudocourse/13.htm](http://www.junkscience.com/JSJ_Course/jsjudocourse/13.htm), and <http://www.numberwatch.co.uk/RR.htm>

<sup>11</sup> "Publication Bias and Research on Passive Smoking," *The Journal of the American Medical Association*, available at <http://jama.ama-assn.org/cgi/content/full/280/3/250>. See also [http://www.numberwatch.co.uk/publication\\_bias.htm](http://www.numberwatch.co.uk/publication_bias.htm)

<sup>12</sup> Harvard School of Public Health Report, op. cit.

<sup>13</sup> Health Professionals Follow-up Study, available at [http://bmj.bmjournals.com/cgi/content/abstract/313/7049/84?maxtoshow=&HITS=80&hits=80&RESULTFORMAT=&titleabstract=aspirin+heart&fulltext=heart+prevent&searchid=1075781653386\\_20122&stored\\_search=&FIRSTINDEX=0](http://bmj.bmjournals.com/cgi/content/abstract/313/7049/84?maxtoshow=&HITS=80&hits=80&RESULTFORMAT=&titleabstract=aspirin+heart&fulltext=heart+prevent&searchid=1075781653386_20122&stored_search=&FIRSTINDEX=0)

<sup>14</sup> Alpha-Tocopherol Beta-Carotene study, available at <http://circ.ahajournals.org/cgi/content/full/94/11/2720>

<sup>15</sup> Nurses Health Study, available at <http://content.nejm.org/cgi/content/short/337/21/1491>

<sup>16</sup> Harvard School of Public Health Report, op. cit.

<sup>17</sup> "Body count- The Grand Illusion," available at [http://www.junkscience.com/JSJ\\_Course/jsjudocourse/15.htm](http://www.junkscience.com/JSJ_Course/jsjudocourse/15.htm). See also <http://www.numberwatch.co.uk/2004%20November.htm>

<sup>18</sup> Harvard School of Public Health Report, op. cit.