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PART 4/6

**COMMISSION STAFF WORKING DOCUMENT**

**IMPACT ASSESSMENT**

*Accompanying the document*

**Commission Regulation (EU)**

**amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in animal fat, in foods intended for the final consumer**

{C(2019) 2902 final} - {SEC(2019) 187 final} - {SWD(2019) 161 final}

## United States



### Policy status

	Existing	Proposed/ considered
Legislation	X	
Voluntary measures	X	
Labelling	X	
Consumer information	X	

### Description of existing measure(s)

<b>Type of measure</b>	Legislation/voluntary measures/labelling/consumer information
<b>Description of measure</b> (if legislation paste exact text of legislation)	<p><b>Mandatory ban.</b> In November 2013 the FDA made a <i>preliminary determination</i> that partly hydrogenated oils are not Generally Recognised as Safe (GRAS) for use in foods, followed by a 60 day public comment period. Then, in June 2015, the U.S. Food and Drug Administration (FDA) announced that partly hydrogenated oils were no longer generally recognized as safe and that their use in foods would be phased out of the U.S. market by June 2018.<sup>560</sup></p> <p>Release of 2005 <b>Dietary Guidelines</b> for Americans which included recommendations on trans fat intake.</p> <p><b>Mandatory nutrition labelling.</b> Since 2006, USA manufacturers must list trans fats on the nutritional fact panel of foods and certain dietary supplements (FDA issued a final rule on July 11, 2003).<sup>561</sup> More specifically, they must list the quantity of trans fatty acids in a serving of the food product (but not % of daily value as at this time there was no scientific basis for trans fat consumption). On December 1, 2014, the FDA also published a final rule for <b>menu labelling</b> requirements which specified that written nutritional information (including trans fat content) for standard menu items be available for consumers who ask to see it, and that on menus and boards, and that a statement regarding the availability of the nutritional information is present on menus and menu boards.<sup>562</sup> On May 20, 2016, the FDA announced new Nutrition Facts labels for packaged foods to reflect new scientific information. Among other things, including design changes, calories from fat is being removed (although trans fat content must still be listed).<sup>563</sup></p> <p><b>State level initiatives:</b> In recognition of the limits of federal regulation and a growing</p>

<sup>560</sup> <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

<sup>561</sup> <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/trans-fatty-acids-europe-where-do-we-stand>

<sup>562</sup> <https://www.federalregister.gov/documents/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food>

<sup>563</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm385663.htm>

concern regarding the health risks of trans fat consumption, state and local governments began introducing a variety of legislative proposals to restrict the use of artificial trans fats from 2003. California was the first US state to ban restaurants from using trans fats:

**California trans fat ban.** Approved on July 25, 2008, this requires all food facilities in the state, except public school cafeterias, to stop using artificial trans fats by January 2011.<sup>564</sup> It was expected to affect more than 88,000 restaurants, bakeries, delicatessens, cafeterias and other food service facilities.

Many other states have or are presently considering statewide trans fat bans. Examples are Connecticut, Florida, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, South Carolina, Tennessee, Vermont, and Virginia, among others.<sup>565</sup>

#### Local level initiatives:

**Legislation** banning the use of artificial trans fats in restaurants has been passed in New York City, Albany, Nassau and Westchester Counties in New York; King County (Seattle), Washington; Philadelphia, Pennsylvania; Stamford, Connecticut; Boston, Brookline, and Cambridge, Massachusetts; and Baltimore and Montgomery County, Maryland.<sup>566</sup> The New York City ban acted as a catalyst for other jurisdictions. The New York City action was adopted in Dec 2006 and came into effect in July 2008<sup>567</sup>. It restricted all food service establishments from using, storing or serving food that contained PHVO with a total of 0.5g or more trans fats per serving.

#### **Voluntary agreements**

In 2004, Tiburon, California (pop. 8,962) became the first community in the US to eliminate the use of artificial trans fats in restaurants pursuant to a voluntary agreement - all restaurants in Tiburon vowed to switch to cooking with trans fat-free oils. In February 2008, San Francisco began implementing a voluntary artificial trans fat elimination programme.

In Multnomah County (Portland), Oregon, public health officials and the Oregon Restaurant Association collaborated to create a program to voluntarily phase out artificial trans fat use in restaurants and educate consumers about healthier eating.<sup>568</sup>

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<sup>564</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>565</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>566</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>567</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm385663.htm>

<sup>568</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<p><b>Scope of measure</b></p>	<p><b>NYC action</b> – Any food in a food service establishment that contained PHVO with a total of 0.5g or more trans fats per serving.</p> <p><b>Labelling measure</b> – all packaged foods and dietary supplements.</p> <p><b>PHO ban</b> – all food products.</p>
<p><b>FBOs covered</b></p>	<p>NYC action is one of the few actions that targets food prepared outside of the home. It covers all food service establishments using, storing or serving food.<sup>569</sup></p>
<p><b>Derogations</b> (e.g. low fat products, local products)</p>	<p>Foods prepared outside of the home are unaffected by labelling requirements.<sup>570</sup> Some pre-packaged foods and dietary supplements are also exempt if: they come from a retailer with annual gross sales of not more than \$500,000, or with annual gross sales of foods or dietary supplements to consumers of not more than \$50,000; or if the person claiming the exemption employs fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a 12-month period.<sup>571</sup> In addition, products that have less than 0.5g of trans fats per serving don't have to be labelled as containing trans fats.</p> <p>For menu labelling requirements, chain retail food establishments with less than 20 locations are exempt.</p> <p>For the partly hydrogenated oil ban:</p> <ul style="list-style-type: none"> <li>• “any interested party may seek food additive approval for one or more specific uses of partly hydrogenated oils with data demonstrating a reasonable certainty of no harm of the proposed use(s).”<sup>572</sup> The Grocery Manufacturer’s Association argued in a petition to the FDA (filed on October 1, 2015) that continued low-level use of partly hydrogenated oils (1.5% of energy per day) is safe and should be allowed. Sources of partly hydrogenated oil that should be allowed include partly hydrogenated oils manufactured from the following vegetable oils: soy, cottonseed, coconut, canola, palm, palm kernel and sunflower oils, or blends of these oils. Acceptable small-scale usage includes adding partly hydrogenated oil as an anti-caking, anti-dusting and free flow agent; a lubricant or release agent; an emulsifier; and a processing aid or solvent for fat soluble ingredients. Arguably submitting such a proposal is a gamble because the GMA estimates that the formal review process for its petition could take two or more years – if it is rejected they will have one year to meet compliance deadline. No response has yet been issued by the FDA.<sup>573</sup></li> <li>• The use of partly hydrogenated oils as raw materials used to synthesise other ingredients is also outside the scope of the partly</li> </ul>

<sup>569</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm385663.htm>

<sup>570</sup> <https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/trans-fatty-acids-europe-where-do-we-stand>

<sup>571</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm053857.htm>

<sup>572</sup> <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

<sup>573</sup> [https://cspinet.org/sites/default/files/attachment/gma\\_trans\\_fat\\_fap\\_executive\\_summary\\_8-5-15.pdf](https://cspinet.org/sites/default/files/attachment/gma_trans_fat_fap_executive_summary_8-5-15.pdf)

	<p>hydrogenated oil ban, as are ingredients that contain only naturally occurring trans fats.</p> <ul style="list-style-type: none"> <li>• It also does not include the use of conjugated linoleic acid (CLA) as a food ingredient, or partially hydrogenated methyl ester of rosin as these do not fit the partly hydrogenated oil definition.<sup>574</sup></li> </ul>
<p><b>Share of SMEs involved</b> <i>(in case of voluntary measures)</i></p>	<p>No information found.</p>
<p><b>Length and characteristics of transition period</b></p>	<p>After the 2015 announcement that partly hydrogenated oils are not Generally Recognised as Safe (GRAS), the FDA set a compliance period of three years to allow food companies to <b>either</b> reformulate products without partly hydrogenated oils and/or petition the FDA to permit specific uses of partly hydrogenated oils.<sup>575</sup></p> <ul style="list-style-type: none"> <li>• Food labelling: In May 2016, the U.S. Food and Drug Administration finalized the Nutrition Facts and Supplement Facts Label and Serving Size final rules and set the compliance date for July 26, 2018, with an additional year to comply for manufacturers with annual food sales of less than \$10 million. After those rules were finalized, industry and consumer groups provided the FDA with feedback regarding the compliance dates. After careful consideration, the FDA determined that additional time would provide manufacturers covered by the rule with necessary guidance from FDA, and would help them be able to complete and print updated nutrition facts panels for their products before they are expected to be in compliance. On June 13, 2017, the FDA announced its intention to extend the compliance date for the Nutrition Facts Label final rules. The FDA will provide details of the extension through a Federal Register Notice at a later time.<sup>576</sup> The framework for the extension will be guided by the desire to give industry more time and decrease costs, balanced with the importance of minimizing the transition period during which consumers will see both the old and the new versions of the label in the marketplace.</li> <li>• For the menu labelling requirements, the original compliance date was December 2016 (2 years after final rule), however a new final rule in December 2016 changed the compliance date to May 5, 2017. This has subsequently been updated to May 7, 2018.<sup>577</sup></li> <li>• California trans fat ban: introduced in July 2008, restaurants are required to use oils, margarine, and shortening with less than half a gram of trans fat per serving by January 1, 2010 for all food items except deep-fried baked goods. Donuts and other deep-fried baked goods will be prohibited from containing artificial trans fat after January 1, 2011.<sup>578</sup></li> </ul>

<sup>574</sup>

<sup>575</sup> <https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm449162.htm>

<sup>576</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm385663.htm>

<sup>577</sup> <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm515020.htm>

<sup>578</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: <http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

	<ul style="list-style-type: none"> <li>• New York trans fat ban: the regulation allowed restaurants six month (by July 1, 2007) to switch to oils, margarines, and shortening used for frying and spreading, and eighteen months (by July 1, 2008) to replace artificial trans fat used in baking and deep-frying of bakery goods<sup>579</sup>.</li> </ul>
<p><b>Arrangements for measure enforcement and compliance monitoring</b></p>	<p>California trans fat ban: for enforcement purposes, every food facility must maintain the label of any food that is, or contains, any fat, oil, or shortening, and is stored, distributed, served by, or used in the preparation of food by the facility. Health inspectors then review the labels when they conduct regular food safety inspections. Violation of the law is punishable by a fine of between \$25.00 to \$1,000.00.<sup>580</sup></p> <p>New York trans fat ban: violations of the regulation don't count towards an establishment's food service inspection score, but violations will be posted on the health department's website and are subject to re-inspection. Violators are subject to fines of \$200.00 to \$2,000.00, depending on an establishment's number of prior violations.<sup>581</sup></p>
<p><b>Rate of compliance/participation and favouring conditions</b></p> <p>(in case of voluntary measures)</p>	<p>New York trans fat ban: Based on inspections after the first phase of the ban, the City estimated that 94% of affected food service establishments were in compliance.<sup>582</sup></p>
<p><b>Tests used to assess trans fats content</b></p>	<p>There are two methods approved by the FDA for measuring fatty acid composition in the food on food labels (April 2007 article):<sup>583</sup></p> <ul style="list-style-type: none"> <li>• Gas chromatography, Association for Official Analytical Chemists method 996.06; and</li> <li>• Attenuated total reflection–Fourier transform infrared spectroscopy (ATR-FTIR), American Oil Chemists' Society method Cd 14d-96.</li> </ul>

<sup>579</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>580</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>581</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>582</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at:

<http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>583</sup> <file:///C:/Users/32040/Downloads/2231.full.pdf>

<b>Steps taken to raise consumer awareness</b>	<ul style="list-style-type: none"> <li>• A <b>guidance document</b> was provided in 2005 to coincide with the labelling legislation. The aim was to help consumers better interpret the new food labelling and make more conscious food choices. The document was produced by the US Department of health and Human Services and the US Department of Agriculture.<sup>584</sup></li> <li>• In addition, one report found that reporting on trans fats has been persistent over many years, but sharply peaked about the same time as Federal regulations made it mandatory to label the trans fats content of foods.<sup>585</sup></li> <li>• Through the labelling regulation, the FDA regulates the statements that food companies are allowed to make on product packages regarding the level of particular nutrients in food. Prior to 2004, such claims were rarely made, but food and beverage products with a “no trans fats” claim showed a marked upward trend beginning in 2004. FDA issued the regulation requiring disclosure of trans fats on the nutrition label in 2003 (to be implemented in 2006). Expressed as a percentage of all food and beverage products introduced, those with a “no trans fats” claim became an increasingly important component of all product introductions, peaking at 10.9 percent in 2009. Compared with the number of other commonly used nutrient claims made on food packages, “no trans fats” claims surpassed low/no/reduced cholesterol claims in 2004 and low/no/reduced sugar claims in 2005. Moreover, in 2008, the percentage of new products with a “no trans fats” claims exceeded those with no/low/reduced fat claims for the first time (see appendix 5 for graph).<sup>586</sup></li> </ul>
<b>Guidance provided to affected businesses</b>	<p>Guidance provided by the FDA for small businesses:  <a href="https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053479.htm">https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053479.htm</a>.</p> <p>The FDA also have a general food labelling guide for industry:  <a href="https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm">https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm</a></p> <p>And a labelling guide for restaurants and retail establishments selling away-from-home foods:  <a href="https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053455.htm">https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053455.htm</a></p> <p>New York trans fat ban: to assist affected restaurants with compliance, the New York City Department of Health and Mental Hygiene created a Trans Fat Help Centre, including a hotline and website. They also held many workshops to teach food preparers how to adapt recipes to substitute trans fat-free oils for partially hydrogenated vegetable oils and vegetable shortening and distributed educational brochures.</p>
<b>Effectiveness of the measure</b>	<p>See section 1.2 below for impact of measures in detail.</p>

<sup>584</sup> <https://health.gov/dietaryguidelines/dga2005/document/pdf/dga2005.pdf>

<sup>585</sup> [https://www.ers.usda.gov/webdocs/publications/44672/18236\\_eib95.pdf?v=41192](https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192)

<sup>586</sup> [https://www.ers.usda.gov/webdocs/publications/44672/18236\\_eib95.pdf?v=41192](https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192)

**Describe (if any) other measures that are currently being considered**

No information found.

## TFAs in foods and diets

### **TFAs content in food**

(by product, if available please distinguish by trans fats source – iTFA and rTFA, and partly hydrogenated oil)

See Appendix 4 for info. on contribution of certain foods to total trans fat intake for Americans (1994-1996).

### **Variation in TFAs content in food after implementation of measure**

Results from multiple studies show **clear decrease in trans fats content** of food after measures introduced:

- The most recent data on trans-fat intake in the US (2012) suggests that **over two thirds of trans fats** from industrially produced partially hydrogenated oils have already been taken out of the American diet.<sup>587</sup>
- Where trans fats labelling on packaged foods was mandated in 2006, a **49% reduction** (1.9 to 0.9 g/serving) in the trans fats content was reported in an assessment of 360 packaged foods between 2007 and 2011. Some products (e.g., doughnuts, French fries) were reformulated much more rapidly compared with other categories (e.g., popcorn).<sup>588</sup>
- Another study found a similar decrease in the trans fat content of food over time.<sup>589</sup> This study looked at the changes in trans fat and saturated fat in major brand name US supermarket and restaurant foods that were reformulated between 1993-2006 and 2008-2009. They identified 83 reformulated products (58 supermarket foods and 25 restaurant foods). **Trans fat content was reduced to less than 0.5 g per serving in 95% of the supermarket products analysed and 80% of the restaurant products analysed**; mean absolute reductions were 1.8 g per serving (84 percentage points) and 3.3 g per serving (92 percentage points), respectively.
- Another study looking at the fat contents of US snack foods in response to mandatory trans fat labelling analysed the composition data of over 5000 chip and cookie products introduced for sale between 2001 (pre-labelling) and 2009 (post-labelling). Results showed that the **shares of chip and cookie**

<sup>587</sup> D. Doell, D. Folmer, H. Lee, M. Honigfort & S. Carberry. Updated estimate of trans fat intake by the US. Food Additives & Contaminants. 2012. Available online at: <http://www.tandfonline.com/doi/abs/10.1080/19440049.2012.664570>

<sup>588</sup> Arcand, J., Scourboutakos, M. J., Au, J. T., & L'abbe, M. R. (2014). trans Fatty acids in the Canadian food supply: an updated analysis. *The American journal of clinical nutrition*, ajcn-088732.

<sup>589</sup> <http://www.nejm.org/doi/full/10.1056/NEJMc1001841#t=article>



**introductions containing partially hydrogenated vegetable oil declined by 45 and 42 percentage points, respectively.**<sup>590</sup>

- Another study looked at the average trans fat contents of all new product introductions and for those containing positive levels of trans fats (see Annex 7 for a breakdown) – results showed that it is relatively rare for any new product introductions to contain trans fats and when products do contain trans fat, average trans fat content is a relatively small share of recommended fat intake.<sup>591</sup>
- However, while the evidence collected by FDA show that many foods have been reformulated to remove partly hydrogenated oils, there are two main food categories with partly hydrogenated oils that remain on the market: foods for which consumers have alternatives containing lower levels of trans fat (e.g., cookies, baked goods, microwave popcorn, frozen pizza, frozen pies, shortening) and foods for which consumers have limited or no choice of an alternative containing a lower level of trans fat (e.g., ready-to-use frostings, stick margarine).<sup>592</sup>
- See Additional References: graph shows the decrease in the amount of trans fats found in products with the highest trans fat content (2005-2010).

**New York ban:**

- Comparison of trans fats and saturated fat content of fast-food customer purchases in NYC restaurants pre-2007 and 2009 (after NYC ban) showed that there was a statistically significant net decrease in combined trans fats and saturated fat content in food purchases ((1.86 g overall mean decrease (13.7 to 11.9 g)) attributed to reformulation and new offerings; mean trans fats content per purchase decreased by 2.4 g (from 2.9 to 0.5 g), whereas mean saturated fat content per purchase increased by 0.55 g (10.8 to 11.4 g) after the implementation of the action. The observed decreases in the trans fats content of food purchases benefited similarly customers living in high- and low-income neighbourhoods.<sup>593</sup> In addition, purchases with zero grams of trans fat increased from 32% to 59%.
- In 2008, when the New York City restaurant ban was in full effect, estimated restaurant use of artificial trans fat for frying, baking, or cooking or in spreads had decreased from 50% to less than 2%. Replacement fats also tended to be healthier (in major restaurant chains total saturate fat plus trans fat in French fries decreased by over 50%).<sup>594</sup>

**Future projections of trans fats content in food**

No information found.

<sup>590</sup> <https://www.ncbi.nlm.nih.gov/pubmed/22314147>

<sup>591</sup> [https://www.ers.usda.gov/webdocs/publications/44672/18236\\_eib95.pdf?v=41192](https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192)

<sup>592</sup> <https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for>

<sup>593</sup> Angell SY, Cobb LK, Curtis CJ, Konty KJ, Silver LD. Change in trans fatty acid content of fast-food purchases associated with New York City’s restaurant regulation: a pre-post study. *Ann Intern Med* 2012; 157: 81-6 pmid: 22801670.

<sup>594</sup> Angell SY, Silver LD, Goldstein GP, Johnson CM, Deitcher DR, Frieden TR, et al., et al. Cholesterol control beyond the clinic: New York City’s trans fat restriction. *Ann Intern Med* 2009; 151: 129-34 pmid: 19620165.

(e.g. a major FBO pledged to reduce trans fats content in own products)

**Trans fats intake**

(if available please report data by trans fats source – industrial trans fats and ruminant trans fats, age and socio-economic group, and partly hydrogenated oil contribution)

Mean daily intake of TFAs from intrinsic sources (i.e. meat, milk, dairy and other products), is 1.042 g/day (0.46 %en/day) among the US 2+ y.<sup>595</sup>

**Variation in trans fats intake after implementation of measure**

Multiple references show clear decrease in trans fats intake after measures introduced:

- At the time of the 2003 labelling proposed rule, the FDA estimated that the daily mean intake of TFAs from partly hydrogenated oils among adults 20 years of age and older was 4.6g/day (2% energy/day) and total partly hydrogenated oil from both animal and partly hydrogenated oil sources was 5.8g/day (2.6% energy/day).<sup>596</sup> In 2010, the FDA estimated the mean trans fat intake for the US population aged 2 years or more who consumed one or more of the processed foods identified as containing partly hydrogenated oils to be 1.3g/p/d (0.6% of caloric intake). **This suggests a significant decrease in mean dietary intake of industrially produced trans fats since the July 2003 final rule.**
- In 2010, the FDA also prepared an estimate for a high-intake scenario by assuming that trans fat was present at the highest level observed for all foods within a particular food category based on label surveys or analytical data. For this scenario, they estimated the mean intake to be 2.7 g/p/d (1.2 percent of energy) and the 90th percentile intake to be 5.4 g/p/d (2.4 percent of energy) for the U.S. population aged 2 years or more.
- In 2012, the FDA, using survey data, updated the 2010 intake estimate of trans fats from partly hydrogenated oils for those food categories that were identified as major contributors to the dietary intake of trans fat, as well as for those categories where we have noted progress in reformulation. For this most recent estimate, they calculated the mean intake to be 1.0 g/p/d (0.5 percent of energy) and the 90th percentile intake to be 2.0 g/p/d (1.0 percent of energy) for the U.S. population aged 2 years or more.
- The FDA also prepared an estimate for a high-intake scenario by assuming that trans fat was present at the highest level observed for all foods within a particular food category based on the label survey. For this scenario, they estimated the mean intake to be 2.1 g/p/d (1.0 percent of energy) and the 90th percentile intake

<sup>595</sup> [https://cspinet.org/sites/default/files/attachment/gma\\_trans\\_fat\\_fap\\_executive\\_summary\\_8-5-15.pdf](https://cspinet.org/sites/default/files/attachment/gma_trans_fat_fap_executive_summary_8-5-15.pdf)

<sup>596</sup> Department of Health and Human Services. Tentative determination regarding partially hydrogenated oils; request for comments and for scientific data and information.

to be 4.2 g/p/d (1.9 percent of energy) for the U.S. population aged 2 years or more. **The change since 2010 is not significant but it does suggest a continued downward trend.** Specifically, there was a **decrease observed in the intake of trans fat in the refrigerated dough, savory snacks, and frozen pizza categories,** consistent with the lower levels of trans fat observed in the label survey.

- Although trans fat intake has decreased overall since the 2003 trans fat intake estimate, individuals with certain dietary habits may still consume high levels of trans fat from certain brands or certain types of food products (e.g., refrigerated biscuits, ready-to-use frostings, certain brands of frozen pizzas, and certain brands of microwave popcorn), which could contain several grams trans fat per serving. As noted previously, for those consumers who consistently choose these products, the daily intake of added trans fat is approximately twice as high as that for the consumer who does not choose only the foods containing the highest levels of trans fat within a particular category (2.1 g/p/d vs. 1.0 g/p/d).
- Additionally, scientists at the CDC recently studied the change in levels of four major trans fatty acids in the blood of U.S. non-Hispanic white adults from 2000 to 2009, and reported a 58 percent average decrease during that timeframe.<sup>597</sup>

**Information on national consumer awareness of TFAs issues** (e.g. terminology, impact of food choice)

The American Heart Association conducted an online consumer research survey in the spring of 2006 with a national sample of 1000 adults 18 to 65 years of age. Results of this market research indicate that when asked if they had heard of the term “trans fats,” 84% of the respondents said yes. However, close to half (47%) of the respondents lacked understanding of the health effects of trans fats.<sup>598</sup> Results were even lower for partly hydrogenated oils (68% had heard of the term and 67% lacked understanding). Fewer than half of those surveyed could identify any one food as typically containing trans fats, even when asked to choose from a list of foods. The top food identified as containing trans fats was doughnuts (44% of consumers). This compares with the higher knowledge that consumers exhibited regarding foods they thought contained saturated fats. Approximately 70% of consumers surveyed could correctly identify at least 3 foods containing saturated fats from the same list of foods.

## Measure impacts

### Business responses and costs

**Number of business that reformulated their products**  
(if possible)

In New York City, by 2008 an estimated 98 percent of restaurants were not using ingredients containing industrially-produced trans fat, compared with 50 percent in 2005.<sup>599</sup> Many food manufacturers have reformulated their products in the United States to address the need for trans fatty acid reduction. According to the Grocery

<sup>597</sup> <https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for>

<sup>598</sup> <https://www.ncbi.nlm.nih.gov/pubmed/19167956>

<sup>599</sup> <https://www.federalregister.gov/documents/2013/11/08/2013-26854/tentative-determination-regarding-partially-hydrogenated-oils-request-for-comments-and-for>

*differentiate by large and small companies)*

Manufacturers Association and/or company press releases, as of January 2007, food manufacturers that have made significant efforts to reduce or eliminate partially hydrogenated oils/fats from their product portfolios include Campbell Soup Co, ConAgra Foods, General Mills, The Hershey Company, The J.M. Smucker Co, Johnson & Johnson, Kellogg Co, Kraft Foods, Nestle, PepsiCo, Proctor & Gamble, Sara Lee Corp, The Schwan Food Co, and Unilever.<sup>600</sup>

**Evidence of FBO sector facing specific challenges**

Some comments as part of the call for comments in response to the 2015 final determination regarding partially hydrogenated oils identified the following challenges:

- The **oil industry** will need a minimum of three years to fully commercialise the various oils capable of replacing partly hydrogenated oils in food; and it could take several additional years to reformulate after the development of the new oils.
- The **food industry** would prefer to replace partly hydrogenated oils with domestically produced vegetable oils (e.g., high-oleic soybean oil) rather than palm oil, but time is needed to commercialize these options. Some comments stated that sudden demand for palm oil would pose challenges for obtaining sustainably-sourced palm oil, as the current market would likely not be able to meet the demand.
- Other comments indicated that the time needed for removal of partly hydrogenated oils is dependent on the product category. A number of comments indicated that the **baking industry** will have difficulty replacing the solid shortenings used in bakery products. Other comments indicated difficulties in the categories of cakes and frostings, fillings for candies, chewing gum, snack bars, and as a component of what the comments termed minor use ingredients, such as for use in coatings, anti-caking agents, encapsulates, emulsifiers, release agents, flavors, and colors.
- Other challenges to partly hydrogenated oil removal include the need for new transportation infrastructure (e.g., terminals, rail cars, barges, and storage facilities), packaging changes, and disruption of international trade.
- A number of comments noted challenges faced by **small businesses**, such as access to alternative oils, inability to compete for supply, fewer resources to commit to research and development, and effect of ingredient costs on growth of the business.
- Another comment stated that **small businesses** would need at least 5 years due to their limitations in research and development expertise, inability to command supply of scarce ingredients, and economic pressures of labelling changes.

Comments from the **American Institute of Baking (AIB)**:<sup>601</sup>

Challenges faced by the baking sector in moving to trans fatty free solutions:

- Finding substitutes that have the same functionality e.g. extending shelf-life, improving texture. The challenge is particularly large in the manufacture of cakes, cookies, biscuits, pie crusts, pastries and doughnuts.
- In the food service environment, restaurants and bakeries also have to go through extensive recipe reworking and product testing

<sup>600</sup> <https://www.ncbi.nlm.nih.gov/pubmed/19167956>

<sup>601</sup> file:///C:/Users/32040/Downloads/2231.full.pdf

to ensure trans fat free products meet taste, texture and shelf life standards.

- Particular challenge related to finding trans fat-free shortenings without increasing saturated fat. In food manufacturing and food service, many companies that made a switch to trans fatty acid-free alternatives for their baked goods chose shortenings made with palm oil or butter.

The **restaurant industry** raised several objections to trans fat bans including:

- Customers would be dissatisfied with the taste and texture of trans fat free foods;
- National chain restaurants worried that local trans fat bans would interfere with their national product distribution systems or harm their nationwide brand image if products tasted differently in some states;
- The costs of switching to alternative fats were too onerous and would result in higher food costs being passed onto consumers, as well as a disproportionate burden being placed on small, independent restaurants;
- Restaurants would replace trans fats with products high in saturated fat; and
- A rejection was made on philosophical grounds, with the complaint that such laws are paternalistic and it is not the role of government to dictate restaurants' business decisions and consumers' food choices.

However, data shows that **most of these concerns have been refuted**. Consumers have apparently not missed the presence of trans fat in food restaurants; sales of French fries, donuts, and other fried, formerly trans-fat laden fast foods have not decreased significantly in the localities that have implemented trans fat bans; and the costs of switching to trans fat-free alternatives have not resulted in higher restaurant prices. In addition, trans fat-free alternatives have been readily available to restaurants because cooking oil and seed companies anticipated the shift away from hydrogenated oils years before trans fat bans went into effect. Companies began investing in research and accelerating production of trans fat-free alternatives in the 1990s, when the first major studies were released revealing the health risks of trans fat consumption.<sup>602</sup>

***For which oils/fats was there a reduction in use and with what were they replaced?***

The two most common partly hydrogenated oils currently used by the food industry are partially hydrogenated soybean oil and partially hydrogenated cottonseed oil.<sup>603</sup>

It is estimated that roughly 80% of the trans fats Americans consume is from partially hydrogenated vegetable oil.<sup>604</sup>

<sup>602</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: <http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

<sup>603</sup> <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

<sup>604</sup> Public Health Law Center (2008) Trans fat bans: Policy options for eliminating the use of artificial trans fats in restaurants. Available online at: <http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-policy-trans-fat.pdf>

A 2014 study specifically looking at cookies in the US and Canada found that 71% of US cookies contained more than one oil ingredient.<sup>605</sup> In the US, the main fat ingredient was PHVOs in 2006 but by 2012 it was palm oil. By 2012 only 8.3% of cookies in the US used PHVOs as the main oil ingredient. However, many of the shortenings - most of which were made up of hydrogenated fat in combination with another type of oil - included smaller quantities of PHVOs: in the US 31% included PHVOs.<sup>606</sup>

**Costs of changes in products and processes**

*(if possible differentiate by type of cost and include figures)*

**See Additional References for table of costs and benefits for labelling measures.**

**PHO removal:** The FDA conducted an economic analysis, reported in the 2015 Final Determination regarding partially hydrogenated oils, which estimated the net present value over 20 years of quantified costs to the action will be USD\$6.2 billion, with a 90 percent confidence interval of \$2.8 billion to \$11 billion. They estimate the net present value of 20 years of benefits to be \$140 billion, with a 90 percent confidence interval of \$11 billion to \$440 billion. Expected NPV of 20 years of net benefits (benefits reduced by quantified costs) are \$130 billion, with a 90 percent confidence interval of \$5 billion to \$430 billion.<sup>607</sup> **See annex 2 for table of costs and benefits of partly hydrogenated oil removal.**

A prior piece of work in 2013 by Bruns placed the total first year costs of eliminating partly hydrogenated oils from the food supply at \$8 billion, with several hundred million in costs recurring in out-years.<sup>608</sup> This was made on the assumption that all products containing partially hydrogenated oils will require a reformulation and will also cost 2 percent more as a result of ingredient changes, and that consumers currently using partially hydrogenated oils must also learn new cooking methods and pay more for substitutes. The net present value of these costs over 20 years is about \$12 billion at a 7 percent discount rate and \$14 billion at a 3 percent discount rate. The document provided a breakdown by type of cost:

Costs for businesses:

- **Reformulation.** A major producer of processed foods reported that reformulating in less than a year cost \$25 million for 187 product lines, or \$134,000 per product, and after the reformulation the products were fully competitive, with no significant change in price, consumer acceptance, or shelf life. Furthermore, the study estimated that one-time product reformulation cost a total of \$2.7 billion. If producers had two years to reformulate rather than one year, the one-time costs of reformulation would fall to \$2.3 billion. With three years, the costs would fall to \$1.3 billion. This drop in costs is because producers often reformulate products for their own reasons, and required reformulations are less expensive if they can be combined with

<sup>605</sup> <https://www.ifama.org/resources/Documents/v17ia/Hooker-Downs.pdf>

<sup>606</sup> <https://www.ifama.org/resources/Documents/v17ia/Hooker-Downs.pdf>

<sup>607</sup> <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

<sup>608</sup> [http://www.hpm.com/pdf/blog/Reference\\_46\\_Estimate\\_of\\_Cost\\_and\\_Benefits\\_PHOs.pdf](http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf)

planned reformulations. However allowing additional time for reformulation was calculated as reducing public health benefits more than reducing industry costs. (These cost estimates only consider processed, packaged foods that bear a Nutrition Facts label. However they estimate that reformulation costs for fast food and food prepared in restaurants, bakeries and other retail food establishments should be lower than for processed, packaged foods).

- **Relabelling.** The average cost of relabelling is about \$7,000 per UPC if the change must be made in one year, according to the FDA relabelling model. This means that the one-time relabelling costs would be about \$200 million. If producers had two years to relabel rather than one year, the one-time costs of relabelling would fall to about \$60 million, because many label changes could be coordinated with planned label changes. With three years, the costs would fall to about \$40 million.
- **Expected price increases in products because of ingredient substitution.** The 2006 Report of the Trans Fat Conference Planning group lists availability of substitute ingredients as one of the biggest concerns with reformulation. Although the report predicted that supplies of replacements would be readily available at similar prices four years after the report was written, we estimate the costs that would be incurred if substitute ingredients cost 50 percent more, and the partly hydrogenated oils used in packaged food currently account for 4 percent of the price consumers pay for food products, meaning that the total amount spent on these packaged foods would increase by 2 percent. Assuming a 2% increase, the study estimated a total economic cost of \$340 million each year. The Net Present Value (NPV) of 20 years of increased product costs, discounted at 7 percent, is \$3.6 billion. These costs are likely a low estimate as they do not include food products served in restaurants.

Costs to consumers include:

- **Cost to consumers for changing recipes.** Consumers spend about \$120 million each year on vegetable shortening. Assuming that substitute ingredients cost them 50 percent more, consumers would have to spend \$60 million more per year for the more expensive ingredients for their recipes. The NPV of 20 years of these increased costs, discounted at 7 percent, is \$630 million. Substitute ingredients may require different cooking methods or recipes. If 50 million households currently cook or bake with partly hydrogenated oil-containing ingredients, and it takes an average of three hours to learn how to cook with replacement ingredients, then consumers would spend 150 million hours adjusting to the removal of partly hydrogenated oil-containing ingredients from the food supply. If this time is valued at the average hourly compensation of \$31, then the cost of this adjustment would be \$4.7 billion. The total cost to consumers for changing recipes would then be \$5.3 billion.
- **Consumers not being able to enjoy products and recipes that cannot be successfully reformulated.** There may be some loss of consumer surplus as a result of their removal from the market. However, producers of vegetable shortening should be able to produce substitute shortenings that contain only fully hydrogenated and non-hydrogenated vegetable oils, because such products have been available in the past at a similar cost. We are unable to estimate a cost for this potential issue.

NPV, \$Billions, discounted over 20 years at	7%	3%
1. Reformulation Costs	\$2.7	\$2.7
2. Relabeling Costs	\$0.2	\$0.2
3. Ingredient Substitution Costs	\$3.6	\$5.0
4. Cost to Consumers for Changing Recipes	\$5.3	\$5.6

Another study by Cohen in 2014 provided a cost effectiveness value for the trans fat ban, namely the unit cost incurred by the ban per QALY gained.<sup>609</sup> They calculated a cost effectiveness value of between \$16,000 to \$35,000 per QALY.

**Cost of understanding/learning the measure for FBOs**

Information not found.

### Consumer prices and choice

**Evidence of changes in the price of reformulated products**

See section on costs of products and processes above.

**Evidence of price differences between products with iTFAs and alternatives**

See section on costs of products and processes above.

A 2014 study looking at the changing trans fat content and price of cookies in the US and Canada concluded that price was significantly related to the presence of trans fat in cookies: trans-fat free cookies were more expensive than those with trans fats.<sup>610</sup> Median price per 100 grams was \$US 0.75 (interquartile range: USD 0.46, USD 1.48) in US cookies containing trans fat as compared to USD 1.36 (interquartile range: USD 0.82, USD 2.66) in cookies without trans fat (p<.001).

**Evidence of changes in the range, quality or taste of products available**

One study looked at the percentage of successful new products with and without trans fats.<sup>611</sup> It found that trans fat-free products were more successful in 9 out of 16 food categories in which comparisons are possible (See Annex 6 for the breakdowns).

<sup>609</sup> Cohen, J. (2014) Commentary: FDA's proposed ban on Trans Fats: How do the costs and benefits stack up? Clinical Therapeutics; volume 36, No.3. Available at: [http://www.clinicaltherapeutics.com/article/S0149-2918\(14\)00016-2/pdf](http://www.clinicaltherapeutics.com/article/S0149-2918(14)00016-2/pdf)

<sup>610</sup> <https://www.ifama.org/resources/Documents/v17ia/Hooker-Downs.pdf>

<sup>611</sup> [https://www.ers.usda.gov/webdocs/publications/44672/18236\\_eib95.pdf?v=41192](https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192)



<b>Evidence of changes in TFAs consumption</b>	See above
<b>Effect on consumer information and awareness</b>	See above

**Health effects**

**Evidence of benefits on consumer health**

*(if possible differentiate by age and socio-economic group)*

The reformulation that has occurred because of the labelling rule achieved about 5/7 of the benefit of eliminating industrially produced trans fatty acids from the diet, preventing about 8,000 to 18,000 deaths per year. Elimination of industrially produced trans fatty acids from the diet would save an additional 3,000 to 7,000 lives from coronary heart disease annually according to CDC estimates.<sup>612</sup>

Monetizing the lives saved, along with the value of the nonfatal illnesses and medical expenses prevented, yields an estimated benefit of \$14.7 billion dollars per year, starting three years after the elimination of partially hydrogenated oils from the food supply. Over a 20-year period, eliminating partly hydrogenated oils from the food supply would generate benefits of about \$117 billion discounted at 7 percent, or 242 billion discounted at 3 percent. Subtracting costs from benefits yields an estimated \$105 billion in net benefits over 20 years, discounted at 7 percent, or \$228 billion discounted at 3 percent:<sup>613</sup>

Expected Annual Benefit	Value, 7% discount rate	Value, 3% discount rate
5,000 fatal heart attacks prevented	\$8.8 billion	\$12.0 billion
15,000 nonfatal attacks prevented	\$5.3 billion	\$7.3 billion
Medical Costs Saved	\$0.6 billion	\$0.7 billion

However, using more recent research (a 2009 article in the European Journal of Clinical Nutrition) which updates the estimate of harm caused by partly hydrogenated oils, the research team updated their estimates as follows:

Expected Annual Benefit	Value, 7% discount rate
15,000 fatal heart attacks prevented	\$27.1 billion
58,000 nonfatal attacks prevented	\$20.8 billion
Medical Costs Saved	\$2.2 billion

Using this data, the total Net Present Value of 20 years of these benefits is about \$399 billion. If only the benefits of the lowest

<sup>612</sup> [http://www.hpm.com/pdf/blog/Reference\\_46\\_Estimate\\_of\\_Cost\\_and\\_Benefits\\_PHOs.pdf](http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf)

<sup>613</sup> [http://www.hpm.com/pdf/blog/Reference\\_46\\_Estimate\\_of\\_Cost\\_and\\_Benefits\\_PHOs.pdf](http://www.hpm.com/pdf/blog/Reference_46_Estimate_of_Cost_and_Benefits_PHOs.pdf)

estimate of 3,000 lives saved was counted, with no value placed on nonfatal illnesses prevented, the benefits would be \$5.3 billion annually, generating a NPV of \$42 billion. The research team tested the pessimistic assumption that all products would require a critical reformulation, with the extremely pessimistic assumption that the consumer price of packaged food with partly hydrogenated oils would increase by 10 percent. In this case, the total NPV of costs of this action would be \$28 billion. Subtracting these high costs from the low benefits of \$42 billion gives net benefits of about \$14 billion.

New York Trans fat ban: a June 2017 study found that between 2002 and 2013, there was an additional 6.2% decline in hospital admissions for myocardial infarction and stroke among populations living in counties with vs without trans-fatty acid restrictions. The decline in events reached statistical significance three or more years after restrictions were implemented.<sup>614</sup>

**Evidence of change in saturated fats intake**

A study<sup>615</sup> investigating levels of trans fat and saturated fat in major brand-name US supermarket and restaurant foods that were reformulated (83 products: 58 supermarket foods and 25 restaurant foods) showed that **between 1993-2006 and 2008-2009, the amount of trans fat decreased, and 65% of the supermarket products and 90% of the restaurant products had levels of saturated fat that were lower, unchanged, or only slightly higher (<0.5 g per serving) than before reformulation.** The average content of saturated fat in supermarket foods increased slightly owing to increases in one third of the products analyzed; the average content of saturated fat in restaurant foods actually decreased. Reductions in levels of trans fat nearly always exceeded any increase in levels of saturated fat; after reformulation, the overall content of both fats combined was reduced in 90% (52 of 58) of the supermarket products and 96% (24 of 25) of the restaurant products, with average total reductions of 1.2 g and 3.9 g per serving, respectively.

A second study also suggested that **products with no trans fats are healthier overall.**<sup>616</sup> Products reformulated to reduce trans fats content may be compensated by an increase in saturated fat to preserve the taste of the product. However, we find that in all categories except sweet spreads, the products with trans fats have more saturated fats and more calories than the products without trans fats. The study concluded that their research suggests that if the labeling regulations led companies to reformulate products to reduce trans fats, they did not compensate with higher levels of saturated fats, sodium, or calories (see Annex 8 for a breakdown). Another study looking at the fat contents of US snack foods in response to mandatory trans fat labelling analysed the composition data of over 5000 chip and cookie products introduced for sale between 2001 (pre-labelling) and 2009 (post-labelling).<sup>617</sup> Despite a decrease in trans fat content, in cookies, there was an increase of 0.49 (98 % CI 0.01, 0.98) g in the average saturated fat content per

<sup>614</sup> Brandt EJ, Myerson R, Perrillon MC, Polonsky TS. Hospital Admissions for Myocardial Infarction and Stroke Before and After the Trans-Fatty Acid Restrictions in New York. *JAMA Cardiol.* 2017; 2(6): 627-634.

<sup>615</sup> <http://www.nejm.org/doi/full/10.1056/NEJMc1001841#t=article>

<sup>616</sup> [https://www.ers.usda.gov/webdocs/publications/44672/18236\\_eib95.pdf?v=41192](https://www.ers.usda.gov/webdocs/publications/44672/18236_eib95.pdf?v=41192)

<sup>617</sup> <https://www.ncbi.nlm.nih.gov/pubmed/22314147>

30 g serving and an increase of 9 (98 % CI 3, 15) % in the average ratio of saturated to total fat. No statistically significant changes in fat content were observed in chips.<sup>618</sup>

New York Trans fat ban: **Preliminary analyses suggest that replacement of artificial trans fat has resulted in products with more healthful fatty acid profiles.** For example, in major restaurant chains, total saturated fat plus trans fat in French fries decreased by more than 50%.<sup>619</sup>

Another study also found that a statistically significant decrease in trans fat content of restaurant food was not combined with a commensurate increase in saturated fat. The final sample included 6969 purchases in 2007 and 7885 purchases in 2009. Overall, mean trans fat per purchase decreased by 2.4 g (95% CI, -2.8 to -2.0 g; P < 0.001), whereas saturated fat showed a slight increase of 0.55 g (CI, 0.1 to 1.0 g; P = 0.011). Mean trans plus saturated fat content decreased by 1.9 g overall (CI, -2.5 to -1.2 g; P < 0.001). Mean trans fat per 1000 kcal decreased by 2.7 g per 1000 kcal (CI, -3.1 to -2.3 g per 1000 kcal; P < 0.001). Purchases with zero grams of trans fat increased from 32% to 59%.<sup>620</sup>

### **Competition, innovation and trade**

<b>Effect on competition in the domestic market</b>	No information found.
<b>Changes in trade of affected goods</b>	No information found.
<b>Effect on innovation among suppliers (i.e. reformulation and/or changes in production processes)</b>	No information found.

### **Administrative burdens**

<b>Number of businesses required to provide information</b>	No information found.
<b>Evidence of</b>	See section above on costs of processes

<sup>618</sup> <https://www.ncbi.nlm.nih.gov/pubmed/22314147>

<sup>619</sup> Angell, S. Y., Silver, L. D., Goldstein, G. P., Johnson, C. M., Deitcher, D. R., Frieden, T. R., & Bassett, M. T. (2009). Cholesterol control beyond the clinic: New York City's trans fat restriction. *Annals of Internal Medicine*, 151(2), 129-134.

<sup>620</sup> Angell, S. Y., Cobb, L. K., Curtis, C. J., Konty, K. J., & Silver, L. D. (2012). Change in Trans Fatty Acid Content of Fast-Food Purchases Associated With New York City's Restaurant RegulationA Pre-Post Study. *Annals of Internal Medicine*, 157(2), 81-86.

<p><b>economic burden associated with compliance for FBOs</b></p> <p><i>(obtain cost data if possible)</i></p>	
<p><b>Evidence of authorities' effort to enforce/monitor measure</b></p> <p><i>(obtain cost data if possible)</i></p>	<p>From the FDA final decision for the trans fat ban: "Although we are mindful of the need to focus our enforcement efforts, those needs do not change the underlying law or FDA's legal authority. Food that is adulterated may be subject to seizure and distributors, manufacturers, and other parties responsible for such food may be subject to injunction. We recognize that manufacturers who have previously added partly hydrogenated oil to food, rather than other parties such as distributors who merely receive and sell finished foods, are the members of the food industry who will be most directly affected by this order, and we intend to focus our outreach and enforcement resources accordingly."<sup>621</sup></p>

**Environmental impacts**

<p><b>Evidence of any environmental costs or benefits</b></p>	<p>From the Final Determination regarding partly hydrogenated oils: "We have carefully considered the potential environmental effects of this action. We have determined, under 21 CFR 25.32(m), that this action "is of a type that does not individually or cumulatively have a significant effect on the human environment" such that neither an environmental assessment nor an environmental impact statement is required."<sup>622</sup></p>
<p><b>Evidence of increase in demand for palm oil / other ingredients</b></p>	<p>No information found.</p>
<p><b>Effects on deforestation resulting from variation in demand of ingredients</b></p> <p><i>(e.g. palm oil, soy)</i></p>	<p>No information found.</p>

**Additional references**

<sup>621</sup> <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

<sup>622</sup> <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/trans-fatty-acids-europe-where-do-we-stand>

Otite FO, Jacobson MF, Dahmubed A, Mozaffarian D. Trends in trans fatty acids reformulations of US supermarket and brand-name foods from 2007 through 2011. *Prev Chronic Dis* 2013;10:E85.

*Costs and benefits of menu labelling and vending machine rules (in millions)*

	<b>Rate</b>	<b>Potential benefits</b>	<b>Estimated costs</b>	<b>Net benefits</b>
Total for Labelling (menu and vending rules) over 20 years*	3	\$9,221.3	\$1,697.9	\$7,523.4
	7	6,752.8	1,333.9	5,418.9
Annualized for Labelling (menu and vending rules) over 20 years*	3	601.9	110.8	491.1
	7	595.5	117.6	477.9
Total for Menu Labelling over 20 years	3	9,221.3	1,166.8	8,054.5
	7	6,752.8	932.8	5,820.0
Annualized for Menu Labelling over 20 years	3	601.9	76.9	525.01
	7	595.5	84.5	510.99

\* Benefits for the vending machine labelling rule are not quantified and are not counted in these values.

Source: <https://www.federalregister.gov/documents/2014/12/01/2014-27833/food-labeling-nutrition-labeling-of-standard-menu-items-in-restaurants-and-similar-retail-food>

*Costs and benefits of partly hydrogenated oil Removal, USD Billions*

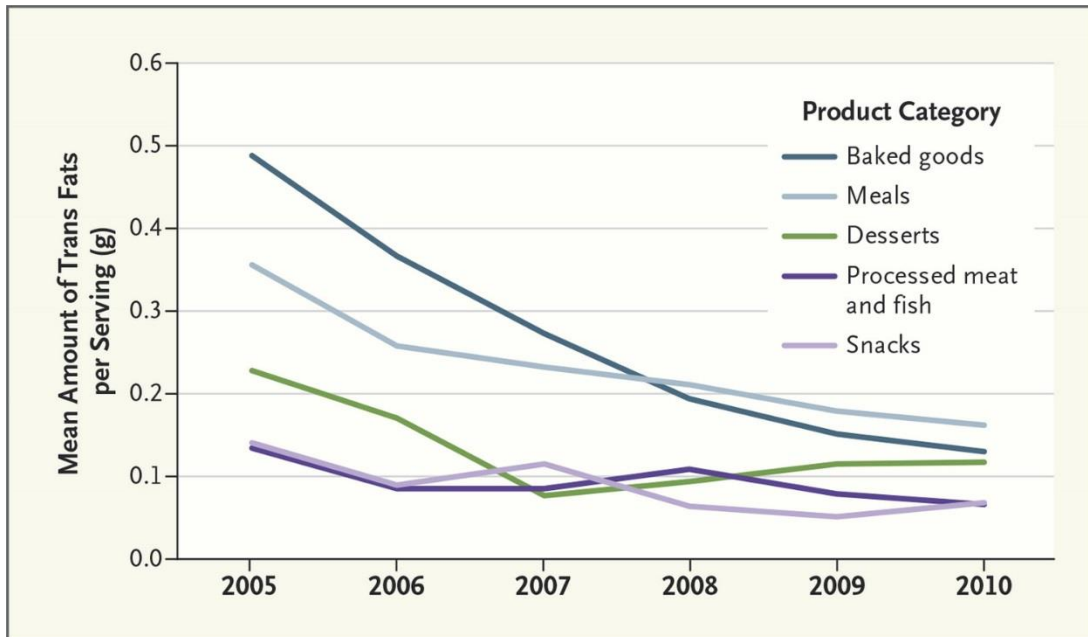
<b>20-Year net present value of</b>	<b>Low Estimate</b>	<b>Mean</b>	<b>High Estimate</b>
Costs *	\$2.8	\$6.2	\$11
Benefits	11	140	440
Net Benefits *	5	130	430

\* This does not include some unquantified costs, see the economic estimate memo (Ref. 17) for discussion.

Source: <https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils>

	Rate	Potential benefits	Estimated costs	Net benefits
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Amount of trans fats found in products with the highest trans fat content (2005-2010)



Data are calculations from the U.S. Department of Agriculture Economic Research Service, which are based on data from the Mintel Global New Products Database.

Source: <http://www.nejm.org/doi/full/10.1056/NEJMp1314072#t=article>

*Contribution of Various Foods to Trans Fat Intake in the American Diet (Mean Intake = 5 .84 g) (data collected 1994-1996)*

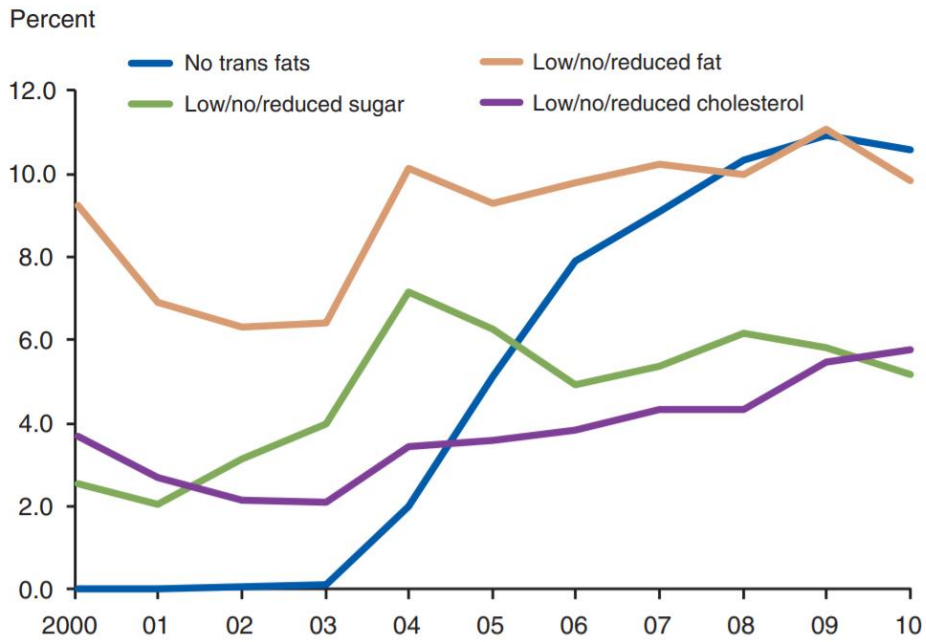
The major dietary sources of trans fats listed in decreasing order. Processed foods and oils provide approximately 80 percent of trans fats in the diet, compared to 20 percent that occur naturally in food from animal sources. Trans fats content of certain processed foods has changed and is likely to continue to change as the industry reformulates products.

Food Group	Contribution (percent of total trans fats consumed)
Cakes, cookies, crackers, pies, bread, etc.	40
Animal products	21
Margarine	17
Fried potatoes	8
Potato chips, corn chips, popcorn	5
Household shortening	4
Other <sup>a</sup>	5

<sup>a</sup> Includes breakfast cereal and candy. USDA analysis reported 0 grams of trans fats in salad dressing.

Source: Adapted from Federal Register notice. *Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Final Rule and Proposed Rule*. Vol. 68, No. 133, p. 41433-41506, July 11, 2003. Data collected 1994-1996.

Figure 4  
**Percentage of new products with a "no trans fats" claim compared with other leading nutrient claims, annually, 2000-10**



Source: USDA, Economic Research Service calculations based on Mintel Global New Product Database data.

Figure 5  
**Percentage of new products with a "no trans fats" claim, by product category, 2004-10**

