



## AN ACTION PACKAGE TO ELIMINATE INDUSTRIALLY-PRODUCED TRANS-FATTY ACIDS

### EXECUTIVE SUMMARY

Elimination of industrially-produced trans-fatty acids (TFA) from the food supply is one of the priority targets identified in the draft 13th General Programme of Work, which will guide the work of the World Health Organization (WHO) in 2019-2023. Increased intake of TFA (>1% of total energy intake) is associated with increased risk of coronary heart disease (CHD) events and mortality. Globally, more than 500,000 deaths in 2010 were attributed to increased intake of TFA.

Industrially-produced TFA have no known health benefits. Elimination of industrially-produced TFA is feasible and achievable. During the past decade, various policy actions (including mandatory and voluntary TFA labelling, reformulation, and national

and local TFA prohibitions) have been implemented by countries aiming to restrict the TFA content of food and reduce TFA intake in their populations. Several countries have in fact virtually eliminated industrially-produced TFA from the food supply through implementation of systematic policy actions and monitoring programs.

The REPLACE package serves as a roadmap for countries to implement actions to reduce and eliminate industrially-produced TFA, and outlines six strategic action areas to support the prompt, complete, and sustained elimination of industrially-produced TFA from the food supply.

# REPLACE

REVIEW	PROMOTE	LEGISLATE	ASSESS	CREATE	ENFORCE
dietary sources of industrially-produced trans fats and the landscape for required policy change	the replacement of industrially-produced trans fats with healthier fats and oils	or enact regulatory actions to eliminate industrially-produced trans fats	and monitor trans fat content in the food supply and changes in trans fat consumption in the population	awareness of the negative health impact of TFA among policy-makers, producers, suppliers, and the public	compliance with policies and regulations

## BACKGROUND

### WHAT ARE TRANS-FATTY ACIDS?

Trans-fatty acids (TFA) are fatty acids with at least one double carbon-carbon bond in the trans configuration. TFA can be produced industrially by the partial hydrogenation of vegetable and fish oils, but also occur at lower levels naturally in meat and dairy products from ruminant animals, such as cattle, sheep, goats, and camels. Industrially-produced TFA are the predominant source of dietary TFA in many populations,<sup>1</sup> particularly in countries which have not taken action to remove industrially produced TFA from the food supply.

Industrially produced TFA were first introduced into the food supply in the late 19th and early 20th centuries with the invention of partially hydrogenated oils. These oils are most frequently found in baked and fried foods, prepared or pre-packaged snacks and food, and cooking oils and spreads. They were developed as a replacement for animal fats such as butter, but are also used to increase the shelf life of foods and oils by lowering their oxidation potential as well as to alter the texture and because their cost is lower than that of animal fats. Partially hydrogenated oils became more popular in the 1950s-1970s with the discovery of the negative health impacts of saturated fatty acids (SFA).<sup>2</sup> However, by the late 20th century, an extensive body of evidence had accumulated from various studies on the negative metabolic effects of TFA as well as on the relationship between TFA intake and coronary heart disease (CHD).<sup>3, 4</sup>

### DETRIMENTAL HEALTH EFFECTS OF TFA CONSUMPTION

Consumption of TFA is strongly associated with increased risk of CHD and related mortality.<sup>5</sup> Globally, increased TFA intake is estimated to be responsible for more than 500,000 deaths per year.<sup>6</sup> TFA increases levels of LDL (unhealthy) cholesterol and decreases levels of HDL (healthy) cholesterol.<sup>2, 7, 8</sup> Replacement of TFA with unsaturated fatty acids decreases the risk of CHD,<sup>7</sup> in part, by ameliorating the negative effects of TFA on blood lipids. In addition, there are indications that TFA may increase inflammation and endothelial dysfunction.<sup>4</sup>

### TFA CONSUMPTION AND THE GLOBAL PUBLIC HEALTH AGENDA

WHO recommends that total TFA intake be limited to less than 1% of total energy intake,<sup>9</sup> which translates to less than 2.2 g/day in a 2,000-calorie diet. This recommendation has been achieved in a growing number of countries and should be achievable globally. Elimination of industrially-produced TFA from the food supply is critical to achieving this aim. By decreasing the risk of CHD events and mortality, it will help reduce premature death from noncommunicable diseases, one of the health targets (Goal 3.4) of the United Nations Sustainable Development Goals. Elimination of industrially-produced TFA will also contribute to the creation of an enabling food environment which promotes healthy diets and help achieve the global nutrition and diet-related noncommunicable disease targets endorsed by the World Health Assembly and committed to at the 2nd International Conference on Nutrition and the Decade of Action on Nutrition (2016 - 2025).<sup>10, 11</sup>

### MONITORING TFA INTAKE AND CONTENT IN THE FOOD SUPPLY

Current knowledge about TFA intake in many countries is generally not adequate. In many European countries where data exist, TFA intake has declined during the past decade and the average intake of TFA is now relatively low, although inequalities in intake across different socioeconomic groups may persist.<sup>1, 12</sup> However, TFA intake data are limited or not available for many countries, in particular in Asia, Africa, Eastern Europe, and the Eastern Mediterranean. Where available, the heterogeneity of TFA intake data due to different sampling and assessment methods also makes data comparisons between and across countries and regions challenging.

Where there are existing data, they indicate a wide range of TFA intakes in different countries, from 0.3% of total energy intake in China to 4.2% in Iran.<sup>1</sup> The Global Burden of Disease Study estimated that global TFA intake ranges from 0.2 to 6.5% of total energy intake.<sup>13</sup>

The limited availability of reliable and current data on the TFA content of foods also adds to the challenge of assessing and monitoring changes in the TFA content of the food supply as well as changes in estimated population intake. The few existing studies show high levels of TFA in both street food and packaged food. Analyses of foods sold by street vendors in Kyrgyzstan and Tajikistan found that the TFA content of pre-packaged wafers was more than 100% of the recommended limit for daily TFA intake (3.8 and 2.5g TFA per serving, respectively); some freshly prepared foods had levels almost as high.<sup>14, 15</sup> A survey of street food in India (Delhi and Haryana) found that 25% of snack foods had levels of TFA exceeding the legal limit set by Denmark.<sup>16</sup> In six Eastern European countries, hundreds of products containing high levels of TFA were found in grocery stores in 2014, almost double the number found in 2012.<sup>17</sup>

Monitoring is necessary, not only for the purpose of assessing content in the food supply and changes in TFA consumption, but, importantly, also to assess which fatty acids are being used to replace TFA, as this has health implications.

### REDUCING TFA IN THE FOOD SUPPLY

Various actions have been initiated by governmental and public health organizations in different countries and regions to reduce TFA intake.

#### Legislation of TFA content of food products

Overall, the most effective and consistent way to reduce TFA in the food supply has been through implementing legislative or regulatory actions to limit or prohibit industrially-produced TFA.<sup>18</sup> Denmark was the first country to mandate limits on industrially-produced TFA, implementing legislation in 2003 that limited industrially-produced TFA to 2% of total fat content in all foods in the marketplace, including imported and restaurant foods. This dramatically reduced levels of industrially-

produced TFA in their food supply.<sup>19</sup> Since then similar legislative or regulatory actions have been taken to limit industrially-produced TFA in European countries including Austria, Hungary, Iceland, and Norway, in a few countries in the Americas and Asia, and in one African country. A different approach was recently adopted by Canada and the United States, both of which took advantage of existing regulations to essentially ban partially hydrogenated oils, the source of industrially-produced TFA.

#### **Coordinated, voluntary reductions of TFA in food products**

In some countries, notably Canada, the Netherlands and the UK, voluntary measures to limit TFA content of food products led to major reductions in the food supply.<sup>12, 20, 21</sup> In 2006, the Canadian Trans Fat Task Force recommended that industrially-produced TFA should not exceed 2% of total fat content for vegetable oils and soft spreadable margarines, and total TFA should not exceed more than 5% of fat content for all other foods. Canada then undertook a structured voluntary approach to achieve these recommended limits which included a robust monitoring system, public announcements about progress, and the option to regulate to reduce TFA if targets were not met.<sup>20</sup> This approach led to major reductions in TFA intake over five years.<sup>22</sup> Despite the progress, however, Canada enacted a regulation to ban partially hydrogenated oils by September 2018.<sup>23</sup> Other voluntary initiatives, such as New York City's request to food service establishments to replace partially hydrogenated oils with oils without TFA, were notably unsuccessful, spurring the city to regulate food establishments.<sup>18, 24</sup>

#### **Other policies to reduce TFA**

When regulatory or legislated limits are not possible, there are other interim policy actions that countries or jurisdictions can take. One strategy is to ban the use of industrially-produced TFA in school food, such as in Lithuania.<sup>25</sup> In the United States and Canada, prior to the recent regulations to fully restrict TFA, some local jurisdictions implemented restrictions in restaurant and food service settings, taking advantage of their authority over restaurant foods through food safety inspection systems.<sup>18</sup>

#### **Labelling for TFA and SFA together**

Requiring that both the TFA and SFA content of foods be listed as part of the nutrient declaration also has potential to reduce TFA intake. Canada was first country to implement this in 2005 and it has since been implemented in approximately 15 countries, predominantly in the Americas. Although labelling is intended to allow consumers to choose products without TFA, it requires that consumers are aware of the health effects of TFA, are able to interpret nutrition labels accurately, and are motivated to do so. To help facilitate the consumers' understanding, an increasing number of countries are implementing front-of-pack labelling, in addition to the nutrient declaration. It has been noted that health claims such as "trans-fat free" can be problematic if single nutrient claims are used to increase the market appeal of unhealthy foods high in sugar, salt or SFA.<sup>26</sup>

More importantly, mandatory TFA labelling can lead industry to reformulate products. In the United States, mandatory labelling coupled with consumer education and media campaigns that created high levels of consumer awareness led manufacturers to reformulate food products to reduce TFA content.<sup>27</sup> However, even in the United States, reductions in TFA after labelling varied by brand and slowed over time.<sup>28</sup>

Another limitation of labelling is that it often applies only to packaged foods and not to foods purchased at restaurants and fast-food outlets. In many low- and middle-income countries, the main source of TFA is often food purchased from the informal food sector, such as street vendors, rather than commercially pre-packaged food.

While unlikely to lead to TFA elimination on its own, as part of comprehensive regulatory measures, such as mandatory limits on TFA,<sup>18</sup> labelling can be important. Labelling both the TFA and SFA content allows monitoring of industry compliance with mandatory TFA limits and concomitant changes in SFA. It also allows monitoring of TFA levels prior to initiation of a regulatory limit or to monitor the effectiveness of voluntary actions if enacting regulations is not possible.

#### **Agricultural policies to support TFA elimination**

Agricultural policies can also promote the supply and use of healthier oils. For example, in conjunction with its voluntary TFA limits, Canada provided research and development support to Canadian oil producers to produce high oleic oils. These oils have been used successfully to replace oils rich in TFA used for deep frying foods in the United States and Canada.<sup>29</sup> Similarly, in Argentina, a cooperative agreement was put into place to improve the availability of healthy fats and oils to replace fats high in TFA; this proved instrumental in driving reformulation of Argentinian packaged foods.<sup>20, 29</sup>

#### **Regional strategies**

In 2007, a Pan American Health Organization (PAHO) Task Force was set up to achieve the vision of Trans Fat Free Americas through implementing legislative action similar to the proposal by the Canadian Trans Fat Task Force. Various actions were taken by countries in the American Region. For instance, Argentina implemented several policies to reduce industrially-produced TFAs, including the enforcement of mandatory labelling of TFA in food in 2006 and the amendment of the food code in 2014 to limit industrially-produced TFA to 2% of total fats in vegetable oils and margarines and below 5% of total fats in other foods).<sup>30</sup>

These examples of policy actions implemented by various countries demonstrate that implementation of a suite of strategic actions is required to effectively eliminate industrially-produced TFA in countries.

# THE REPLACE ACTION PACKAGE

The REPLACE action package serves as a roadmap for countries to implement actions towards elimination of industrially-produced TFA. The following six strategic action areas ensure the prompt, complete, and sustained elimination of industrially-produced

TFA from the food supply. These strategic action areas are not necessarily listed in a stepwise order, but rather provide recommended actions to achieve the elimination of industrially produced TFA.

## RE

**REVIEW** dietary sources of industrially-produced trans fats and the landscape for required policy change

A landscape review is a crucial first step in implementing the REPLACE package, and includes mapping and assessment of:

### DIETARY SOURCES OF INDUSTRIALLY-PRODUCED TFA:

- › This includes identification of major sources of TFA in the diet, both in terms of food sector (e.g. packaged food, street food) and food category (e.g. confectioneries such as cookies and cakes, fried snacks), as well as identification of products or product types with high TFA content and those with lower TFA content but consumed in large quantities

### THE EXISTING POLICY ENVIRONMENT, INCLUDING IDENTIFICATION OF:

- › Government bodies with jurisdiction over reducing and eliminating industrially-produced TFA in foods at the national and local levels, as well as implementing nutrition labelling
- › Existing government policies that favour particular types of oils over others

### KEY STAKEHOLDERS, INCLUDING:

- › Government bodies with a role in either writing or enforcing TFA regulations
- › Industry groups and associations as well as the industry context that may be impacted by TFA regulations, i.e.:
  - Supply and cost of healthier alternatives to TFA
  - The ability of small and medium producers to use those alternatives
  - The major drivers of the oil supply
- › Health professionals, civil society and consumer groups interested in TFA elimination

### COSTS AND AVAILABILITY OF FATS AND OILS

## P

**PROMOTE** the replacement of industrially-produced trans fats with healthier fats and oils

TFA regulations generally do not specify what types of fats or oils should replace industrially-produced TFA. The draft WHO guidelines on SFA and TFA intake for adults and children suggest using polyunsaturated fatty acids (preferred) or monounsaturated fatty acids as a replacement for TFA.<sup>9</sup> Agriculture and trade policies can play a role by helping expand market share for healthier fats and oils and reducing/eliminating subsidies, if present, for fats and oils high in SFA.

- › Provide recommendations for replacement of common fats and oils that contain TFA with healthier fats and oils
- › Assess opportunities and barriers to TFA elimination and replacement with healthier fats and oils, including through engagement of the food and agricultural industry
- › Provide technical assistance to small- and medium-sized enterprises, if necessary, to overcome barriers to successfully implement TFA regulations
- › Enlist existing government structures that support agricultural businesses to provide strategic support (e.g. innovation research, small grants) to the food industry to replace TFA with healthy alternatives
- › Remove subsidies, where existing, on partially hydrogenated vegetable oils and tropical oils high in SFA
- › Ensure the implementation of nutrition labelling including mandatory nutrient declaration as well as front-of-pack labelling, if relevant
- › Purchase and use only products containing healthy fats and oils in public institutions (e.g. schools, hospitals, government offices, etc.) and in government programmes, including those that provide supplemental nutrition to women and children, school nutrition programmes, and any other programmes supported by public funds
- › Increase consumer awareness on how to choose products containing healthier oils and fats (see section C below)

## L

**LEGISLATE** or enact regulatory actions to eliminate industrially-produced trans fats

Comprehensive regulatory actions toward the elimination of industrially-produced TFA include either those that prohibit partially hydrogenated oils or those that limit industrially-produced TFA content to no more than 2g/100g of total fat or oil in all foods. In many countries, this has been accomplished through amending existing policies or regulations (e.g. United States, Canada, Argentina), while in other countries, TFA elimination has been accomplished through new legislation (e.g. Denmark).

**EXPLORE POSSIBLE WAYS TO ENACT THE FOLLOWING REGULATORY ACTIONS:**

**MANDATORY LIMITS**

- › Limit industrially-produced TFA to a percentage of total fats, such as less than 2 g/100g of total fat or oil in all foods (e.g. Denmark)

**BAN ON PARTIALLY HYDROGENATED OILS**

- › If possible within existing food regulations, amend them so that partially hydrogenated oil are classified as unsafe (e.g. Canada where partially hydrogenated oil were banned by adding them to the list of contaminants and other adulterating substances in food).

In the case of mandatory limits, enacting mandatory labelling of both the TFA and SFA content of foods can improve monitoring.

## A

**ASSESS** and monitor trans fat content in the food supply and changes in trans fat consumption in the population

Assessment of the levels of TFA in the food supply and which fatty acids are being used to replace TFA can help to establish the baseline and assess changes over time. Results should be reported regularly, particularly change in TFA and SFA content by food category and compliance with regulations. A baseline should be conducted, with yearly updates after regulations go into effect; in the absence of regulation, updating the data every 5 years is reasonable to track change over time.

If possible, assessment of TFA intake allows evaluation of whether regulatory actions to eliminate TFA are reaching the ultimate goal of reducing total TFA intake in all population sub-groups to <2.2 g/day.

**ASSESSMENT OF TFA CONTENT OF FOOD**

- › This includes identification of major sources of TFA in the diet, both in terms of food sector (e.g. packaged food, street food) and food category (e.g. confectioneries such as cookies and cakes, fried snacks), as well as identification of products or product types with high TFA content and those with lower TFA content but consumed in large quantities
- › Develop a monitoring system for TFA and SFA in key food categories (e.g. cooking fats, fry oils, packaged baked goods) using labels (if TFA and SFA contents are available and are reliable) and food analyses. A publicly accessible database of both TFA and SFA nutrient label data and sampled/laboratory analysed TFA and SFA content could be established.
- › Ideally, data would include three types of foods: fats and oils available to both consumers and commercial producers, packaged foods, and street or restaurant foods. If resources are limited, an initial assessment could focus on fats and oils, adding key packaged food categories the following year (if relevant to a country's intake profile), and finally include food from the restaurant or informal sector, such as street vendors.

**ASSESSMENT OF TFA INTAKE**

- › Population-level food consumption surveys can be used to estimate TFA intake of the population or population sub-groups. Availability of updated food composition data is important to accurately assess TFA intake through food consumption surveys.
- › A recently developed plasma assay allows for the use of biomarkers rather than dietary surveys to determine total TFA intake levels.<sup>31†</sup> If resources allow, the TFA plasma assay can be used as part of ongoing population-based surveys in a selected set of target groups likely to have high exposure to TFA (i.e. urban residents, younger adults). This can be used to determine the baseline TFA intake and then track changes over time in response to regulatory actions.<sup>‡</sup>
- › Breast milk samples have also been used to monitor changes in population TFA intakes, as breast milk levels can be used to estimate TFA intake.<sup>32</sup>

† A detailed draft protocol for TFA plasma assay is available to help facilitate implementation of TFA intake assessment.

‡ In the United States, this method was used on a sub-sample of National Health and Nutrition Examination Survey (NHANES) participants in both 2000 and 2010 to determine that TFA intake declined significantly over the decade.

## C

**CREATE** awareness of the negative health impact of TFA among policy-makers, producers, suppliers, and the public

Increasing awareness of the health impacts of TFA and levels of exposure to TFA in the population can be key to motivating policy change and spurring and supporting sustainable implementation of regulatory actions as well as required industry actions to reformulate food products.

- Increase the awareness and knowledge of policy-makers in order to gain support for the development and implementation of legislative and regulatory actions and for enforcement of compliance.

- Publicly commit to TFA elimination, highlighting current TFA intake level and the negative health effects of TFA.

The government or key civil society stakeholders can take the lead in educating the public, including how to identify TFA on labels.

- Support and highlight research on the health and economic benefits of eliminating TFA, on TFA levels in food, and TFA intake; develop and implement an earned media strategy to amplify these issues and findings.

- Advocate for TFA elimination and replacement with healthier oils.

Assessments of TFA content in foods or TFA intake can be used as part of an earned media strategy to encourage rapid actions by government and industry.

Highlighting food products containing high levels of industrially-produced TFA can help increase the consumer awareness of food products to avoid.

Advocacy by consumer groups can be important to promote reformulation of packaged foods.<sup>28, 33</sup>

- Conduct targeted food/oil manufacturer and/or restaurant education campaigns on ways to reduce TFA without increasing SFA, health benefits of TFA elimination, and on how to comply with current regulations where applicable.

## E

**ENFORCE** compliance with policies and regulations

Enforcement is key to the effective and sustained implementation and compliance of policies and regulations. Regulations on limiting or labelling TFA should include clearly defined penalties for non-compliance. The monitoring system described above can be used as the basis for monitoring compliance.

- Clearly define and enforce penalties for products that do not comply with regulations.

- Develop a compliance monitoring system (*linked to A and L above*).

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