



REPLACE
TRANS FAT



REPLACE ACTION PACKAGE

MODULE 3: **LEGISLATE OR** **REGULATE**

How-to guide for trans fat policy action



**World Health
Organization**

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CONTENTS

Acknowledgements	3
REPLACE action package	4
1. Background	6
2. Policy landscape assessment	6
3. Drafting laws and regulations	10
4. Key provisions for improving implementation	13
5. Other complementary measures	15
References	17
ANNEX 1. Decision guide for selecting a policy to eliminate industrially produced TFA	18
ANNEX 2. Example of a nutrition label	20
ANNEX 3. Good-practice examples of legislation and regulation	21

WEB RESOURCES

- › Elements of economic analysis of removing industrially produced trans fat from the food supply

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REPLACE ACTION PACKAGE

Elimination of industrially produced *trans*-fatty acids (TFA) from the global food supply by 2023 is a priority target of the World Health Organization (WHO). The REPLACE action package provides a strategic approach to eliminating industrially produced TFA from national food supplies, with the goal of global elimination by 2023. The package comprises:

- › an overarching technical document that provides a rationale and framework for this integrated approach to TFA elimination;
- › six modules; and
- › additional web resources to facilitate implementation.

The REPLACE modules provide practical, step-by-step implementation information to support governments to eliminate industrially produced TFA from their national food supplies. To achieve successful elimination, governments should implement best-practice legal measures (outlined in modules 3 and 6). Strategic actions outlined in the other modules are designed to support this goal, but it may not be necessary to implement each module.

The modules will be most useful to national governments, including policy-makers, food control or safety authorities, and subnational government bodies that advocate for, and enforce, policies relating to nutrition or food safety. Other audiences that may find these modules and accompanying web resources useful include civil society organizations, academic and research institutions, nutrition scientists and laboratories, and food industry associations and food companies.

MODULES OF THE REPLACE ACTION PACKAGE

SIX STRATEGIC ACTION AREAS	OBJECTIVE
<p>RE</p> <p>REVIEW dietary sources of industrially produced TFA and the landscape for required policy change</p>	<p>Introduce the REPLACE action package, and provide guidance on initial scoping activities and drafting of a country roadmap for TFA elimination. Initial scoping activities rely on information that is already known, or can be obtained through desk review or discussions with key stakeholders, with reference to other modules as needed</p>
<p>P</p> <p>PROMOTE the replacement of industrially produced TFA with healthier oils and fats</p>	<p>Describe oil and fatty acid profiles, and available replacement oils and fats, including feasibility considerations and possible interventions to promote healthier replacements</p>
<p>L</p> <p>LEGISLATE or enact regulatory actions to eliminate industrially produced TFA</p>	<p>Describe policy options and the current regulatory framework to eliminate industrially produced TFA. Provide guidance on assessment steps to guide policy design, and development of regulations suitable to the country context or updating of the existing legal framework to match the approach recommended by the World Health Organization</p>
<p>A</p> <p>ASSESS and monitor TFA content in the food supply and changes in TFA consumption in the population</p>	<p>Describe the goals and methods for TFA assessment. Provide guidance on designing and carrying out a study of TFA in food and human samples</p>
<p>C</p> <p>CREATE awareness of the negative health impact of TFA among policy-makers, producers, suppliers and the public</p>	<p>Describe approaches to advocacy and communications campaigns to support policy action. Provide guidance on key steps to design and implement effective advocacy and communications campaigns, and evaluate progress</p>
<p>E</p> <p>ENFORCE compliance with policies and regulations</p>	<p>Describe TFA policy enforcement approaches, offences and roles. Provide guidance on mapping existing and creating new enforcement powers and mechanisms, public communications, penalties, funding and timelines</p>

1. BACKGROUND

The most effective and consistent way to eliminate industrially produced TFA from the global food supply is by implementing legislative or regulatory actions to prohibit or strictly limit their use in any food. This module provides guidance on policy options and steps to design, enact and implement legislative and regulatory actions suitable to the country context, or to update the existing legal framework to reduce industrially produced TFA in the food supply.

Box 1 describes types of TFA and why actions are proposed to regulate industrially produced TFA.

BOX 1. WHY REGULATE ONLY INDUSTRIALLY PRODUCED TFA?

There are two main types of TFA:

- › industrially produced TFA, which are primarily found in partially hydrogenated oils (PHO), vegetable oils or fish oils converted from a liquid state into a solid state through the addition of hydrogen; and
- › naturally occurring TFA, which are found in meat and dairy products from ruminant animals, such as cattle, sheep, goats and camels.

In addition, industrially produced TFA can be inadvertently created during industrial refinement of vegetable oils, and when oils and fats are heated and reheated, such as during frying and baking at high temperatures. The percentage of TFA is much higher in PHO (25–45% of total fat) than in fat from ruminant sources (3–6%), refined oils (<2%) and oils subjected to cooking/heating (<3%). Therefore, PHO are often the major target of regulatory and legislative action. PHO are the predominant source of dietary TFA in most populations, particularly in countries that have not yet acted to remove industrially produced TFA from the food supply.

2. POLICY LANDSCAPE ASSESSMENT

Understanding TFA sources, the supply chain, stakeholders, regulatory agencies and legal processes will help inform which policy intervention will be most effective and practical. A range of policy options will help to reduce consumption of industrially produced TFA. These include the two recommended options: mandatory limits on the amount of industrially produced TFA, and a ban on PHO. These options are described in section 3. The feasibility of each option depends on the legal structure and environment of each jurisdiction, as well as political support.

This preliminary analysis should have a legal focus and build on the initial scoping completed as part of module 1.

The policy landscape assessment includes the following steps.

1. Refer to the evidence base collected as part of modules 1 and 5 to support legislative or regulatory actions to eliminate industrially produced TFA.
2. Map which government bodies are responsible for implementing, and have authority to implement, policy and legislative actions relating to food and nutrition, including food safety.
3. Collect and analyse existing laws and regulations that address food and nutrition issues.
4. Chart the government procedures and requirements to enact TFA restrictions.

2.1 STEP 1: REFER TO THE EVIDENCE BASE TO SUPPORT LEGISLATIVE OR REGULATORY ACTIONS TO ELIMINATE INDUSTRIALLY PRODUCED TFA

A strong evidence base for law and regulation leads to more effective public health policies that are also less vulnerable to legal challenge. Although scientific information on the negative health impact of TFA is well documented and uncontroversial, policy-makers can benefit from incorporating any available evidence – quantitative or qualitative – from their local context, including the impact of a specific product or the burden on a subpopulation. If the law or regulation is challenged, an official record of the evidence can help establish that the measure is based on the evidence, and no more restrictive than necessary to achieve its objective – these criteria are often helpful or necessary to withstand legal challenge.

Any proposed law or regulation should clearly articulate the objectives of the measure and link the measure to a specific public health goal, such as reducing the incidence of heart disease and stroke. It should explain the relationship between specific health problems and the consumption of products containing industrially produced TFA, as well as how the intervention will reduce these health problems. In some jurisdictions, this language appears within a preamble or in an attached policy statement. It often reflects the historical context and circumstances of the adoption of the law or regulation, identifies its goals, and declares relevant key principles and values. Policy-makers use this language to communicate the intention of the law to future readers, such as administrative implementers, judicial bodies, the public or other policy-makers.

Policy-makers should also note the sources and prevalence of TFA in the food supply, and their distinct paths through the supply chain – from manufacture, distribution, marketing and supply to consumer. Identifying the path and the distinct stakeholders along the way will help identify opportunities and possible challenges for the law or regulation – for example, which policy option is most suitable for the national context, and the relative ease of replacing TFA with healthier oils and fats at each stage.

If local evidence is not already available, policy-makers should look to other information or seek assistance from appropriate technical experts to develop the evidence base. This will include information on the amount of industrially produced TFA in the national food supply and the estimated population intake of TFA. Other evidence may include information on PHO production in the country – for example, market data showing that PHO production is high. Because TFA are harmful products, every country will benefit from eliminating them from the food supply, regardless of the sources or level of use.

Guidance on how to assess TFA in the food supply or TFA intake in populations is provided in the module 4. Guidance on issues relating to availability, costs and health benefits of healthier oils and fats is provided in module 2. Guidance on conducting an economic analysis of removing industrially produced TFA from the food supply is available in the web resources.

2.2 STEP 2: MAP WHICH GOVERNMENT BODIES ARE RESPONSIBLE FOR IMPLEMENTING, AND HAVE AUTHORITY TO IMPLEMENT, LEGISLATIVE OR REGULATORY ACTIONS RELATING TO FOOD AND NUTRITION

Each country allocates regulatory responsibility for food and nutrition in accordance with its own legal system and traditions. For example, one country's national constitution might divide regulatory powers across national, subnational and local authorities. Another country might

have existing legislation that establishes a national interagency food commission with authority to implement unified government policies.

Many governments have a single food regulator (such as a national food and drug control agency) with authority to limit TFA. However, multiple government bodies might also share regulatory responsibility for different phases of the supply chain. By confirming the scope of legal authority, roles and responsibilities of each agency, policy-makers can identify the most effective and legally sound home for the planned legislative or regulatory actions. Even if one agency has clear authority, this preliminary analysis can help identify government bodies with overlapping jurisdiction and minimize interagency conflicts, especially if all concerned agencies are involved, consulted and given an opportunity to comment.

Determining where regulatory authority lies can simply be a question of identifying whether any national ministry or agency has existing authority to regulate, monitor and enforce TFA elimination. This may include the authority to set permissible limits, test products for compliance, inspect facilities, issue administrative sanctions, if necessary, or respond to consumer complaints. Depending on the results of this analysis, broader mapping may be necessary to analyse the jurisdiction and authority of governmental or quasi-governmental bodies – national, subnational or local – to regulate any aspect of food and nutrition, including food safety. To complete the mapping, it may be helpful to match the phases of the food supply chain with the corresponding government body.

2.3 STEP 3: COLLECT AND ANALYSE EXISTING LAWS AND REGULATIONS THAT ADDRESS FOOD AND NUTRITION ISSUES

The next step is to analyse existing laws and regulations that might relate to TFA. A comprehensive review will evaluate all legal measures relating to food and nutrition, including constitutional provisions, laws, regulations, executive decrees and judicial rulings. Legal obligations under international or regional trade agreements, including investment treaties, should also be included in the analysis. For example, the Gulf Cooperation Council and the Eurasian Economic Union have enacted TFA restrictions that apply to their respective Member States. Voluntary measures, such as nonbinding industry advertising standards, should also be collected and analysed for completeness, although they are not a replacement for enforceable legal measures.

TFA-related provisions may be found in legal measures relating to:

- › public health
- › noncommunicable diseases
- › health promotion
- › food safety, including additives and toxins
- › nutrition
- › oils and fats
- › nutrition labelling
- › children’s health
- › food marketing
- › consumer protection
- › customs and border control.

2.4 STEP 4: CHART THE GOVERNMENT PROCEDURES AND REQUIREMENTS TO ENACT TFA RESTRICTIONS

The next step is to chart government processes and procedures for enacting legal measures. For example, certain legal measures may require an impact assessment that includes a formal economic analysis of the policy, and an explanation of which policy alternatives were

rejected and why. (See ‘Elements of economic analysis of removing industrially produced trans fat from the food supply’ in the web resources for more information.) There may also be a legal requirement to solicit feedback from stakeholders, including the public, industry, nongovernmental organizations and relevant government agencies, such as those responsible for foreign affairs, trade, industry and finance.

Industry involvement in policy-making should be avoided to protect against conflicts of interest in the policy-making process. However, if industry needs to be involved in some process, there should be clear rules to ensure transparency and otherwise prevent and manage any real or perceived conflict of interest.

Some countries publish draft regulations for a certain period (for example, 90 days), during which the public and other stakeholders are encouraged to submit comments. Regulators may be required to review and address each comment before the final regulation is implemented.

Governments may also need to provide a notification of new policies or legislation with a potential impact on trade under relevant regional trade agreements or World Trade Organization (WTO) agreements. For example, they may need to notify the WTO Committee on Technical Barriers to Trade (TBT) or regional intergovernmental bodies. These notifications give other Member States the opportunity to raise trade concerns before the policy is enacted. Specifically, the TBT Agreement aims to ensure that technical regulations, standards and conformity assessment procedures are nondiscriminatory and do not cause unnecessary obstacles to trade. Failure to follow the WTO rules can make a policy vulnerable to legal challenge. If trade rules are followed, governments have the right to implement measures to achieve legitimate policy objectives, such as the protection of public health through TFA restrictions (see Box 2).

BOX 2. INTERNATIONAL TRADE AND INVESTMENT AGREEMENTS

International trade and investment law must be taken into consideration when developing a TFA policy. If concerns remain, policy-makers should consult with attorneys with appropriate expertise.

Countries may be bound by a number of different international commitments. The multilateral trade agreements of the WTO regulate trade in goods, services and intellectual property, and are binding on the 157 WTO Members. Regional and bilateral trade or investment agreements between governments may separately define trade relations among parties to the agreement. Although each of these international instruments has unique requirements, most reserve a government’s sovereign authority to adopt laws and regulations that are necessary to protect public health.

Countries can strengthen their position under international trade law by:

- › collecting and documenting all supporting evidence and rationale related to the policy’s public health purposes, including citing the WHO guidance and other international standards that the policy is aiming to implement;
- › following and documenting government processes and procedural requirements for policy action and stakeholder consultation;
- › avoiding discrimination between domestic and imported foreign products, as far as possible; and
- › notifying the Committee on Technical Barriers to Trade of the relevant draft technical regulations.

3. DRAFTING LAWS AND REGULATIONS

Either strict limits that cap the percentage of industrially produced TFA across all foods or bans of PHO will significantly reduce consumption of TFA. These two options both have advantages; in some cases, a combination of the two may be desirable. For example, Peru has regulations that combine both policy options. The most feasible policy option will depend on country-specific situations. Certain legal and political considerations need to be weighed – for example, whether existing authority, complementary measures, trade mechanisms or a supportive political environment make implementation of one policy option more feasible. Additionally, technical considerations for enforcing policies must be considered at the outset, such as identifying the major source of TFA, existing compliance mechanisms and current testing capacity. The decision guide in Annex 1 can help policy-makers select the policy option that works best for the country context.

Depending on the legal framework in each country, restrictions may be enacted through a new or amended law, regulation, subdecree or other legal measure. If legislation is already in place that clearly authorizes a government body to regulate unsafe ingredients in food, that legislation is likely to include rules or other guidance about the type of legal measure and process that will be required to limit unsafe ingredients such as TFA. If no such legislation is in place or authority is unclear, new or amended legislation may be required, although this is uncommon.

Mandatory nutrition labelling is a recommended approach to any policy option to promote healthy diets. Although labelling alone is unlikely to eliminate industrially produced TFA, it does increase consumer knowledge and thereby encourages producers to reformulate their products. Labelling also allows monitoring of industry compliance with legally binding TFA limits, as well as tracking of TFA levels before and after regulations are implemented.

3.1 POLICY OPTION 1: SET A MANDATORY LIMIT ON THE AMOUNT OF INDUSTRIALLY PRODUCED TFA IN ALL FOOD

To be in line with the WHO guidance, the limit should be set as no more than 2 g of industrially produced TFA per 100 g of total fat in all foods.

Restrictions such as these have been highly effective in decreasing consumption of TFA and reducing mortality rates from cardiovascular disease. For example, Denmark was the first country in the world to regulate the content of TFA in food products, and nearly eliminated industrially produced TFA from the Danish food supply (see Box 3). In the three years following the policy's implementation, mortality attributable to cardiovascular disease decreased on average by approximately 14.2 deaths per 100 000 people per year (Restrepo & Rieger, 2016).

An advantage of this approach is that it has an effect on all refined oils, which can be useful in regions where levels of TFA in refined oils are higher than in other regions as a result of increased processing. Another advantage of this policy option is that it enables monitoring of TFA levels in food. Laboratory analysis methods exist for testing levels of TFA in food samples.

One challenge for setting a mandatory limit on TFA could be that small- and medium-scale producers, restaurants and other vendors may not be able to measure the amount of industrially produced TFA in the food they sell or serve. This challenge can be eliminated if all oils and fats sold to both consumers and businesses, along with any oils that are imported, are required to meet the threshold. Mandatory labelling will also mitigate this challenge. A 2% limit on industrially produced TFA should essentially eliminate the use of PHO as a primary ingredient in foods.¹

Key elements of an effective TFA restriction include the following.

- › **Mandatory nutrition labelling requirement:** An effective label should include a consistent and understandable statement of the amount of TFA in line with Codex Alimentarius (Codex) guidelines – that is, immediately following the declaration of the total fat, an amount expressed as grams per 100 grams or per 100 millilitres or per package.² See Annex 2 for a sample annotated label.
- › **Definition of the restricted substance:** “Trans-fatty acids (TFA)” must be defined in a clear and scientifically sound manner. WHO defines TFA as all fatty acids with a double bond in the trans configuration, regardless of whether they are produced industrially or come from ruminant sources, including conjugated linoleic acid.
- › **Specific threshold limits for industrially produced TFA in oils and fats in all foods:** 2 g of industrially produced TFA or less per 100 g of total fat in all foods is recommended.

BOX 3. CASE STUDY: SAMPLE LEGISLATION, DENMARK

In Denmark, the Ministry of Environment and Food issued an Executive Order (Order No. 161 of 11 March 2003) that prohibits the sale of oils and fats and any other food to consumers if they have a content of industrially produced TFA higher than 2 g per 100 g of oil or fat.

The most important aspects of the legislation are that:

- › the content of TFA in oils, fats and food products must not exceed 2 g per 100 g of oil or fat;
- › it applies to industrially produced oils and fats in the Danish market that are intended for, or likely to be consumed by, humans, either alone or as part of food products; and
- › the rule exempts animal fats with a natural content of TFA.

Control of any legislative infringements is under the jurisdiction of local authorities via the Danish Veterinary and Food Administration. Subsequent analysis and data on TFA in food are documented in the report “Danish data on trans-fatty acids in foods” (2014) from the Ministry of Food, Agriculture and Fisheries, and the National Food Institute at the Technical University of Denmark. See Annex 3 for sample legislation.

¹ Certain products used in cooking, such as pan release agents and emulsifiers, may still contain PHO. However, the TFA levels in the final cooked product are still required to be below 2% of the total fat.

² In countries where serving sizes are normally used, this information may be given per serving only, as quantified on the label, or per portion, provided that the number of portions contained in the package is stated.

3.2 POLICY OPTION 2: BAN PRODUCTION OR USE OF PHO AS AN INGREDIENT IN ALL FOODS

An alternative effective approach is to prohibit PHO by classifying them as unsafe for human consumption, in the same manner that additives or harmful compounds are prohibited. By banning PHO, the primary dietary source of industrially produced TFA is eliminated from the food supply. This regulatory approach has similar effects to eliminating industrially produced TFA from the food supply. Government efforts to eliminate PHO from packaged foods will substantially reduce exposure of consumers to a known risk factor for cardiovascular disease (Clapp et al., 2014).

A major advantage to this approach is that it focuses further upstream on the process that creates industrially produced TFA. By focusing on process rather than on the resulting product, the production of PHO is limited at processing plants so that PHO is eliminated from all downstream points of the supply chain. This can be particularly advantageous for countries that have a limited number of processing plants, by making implementation and enforcement of the ban more manageable and highly cost-effective. Another advantage is that a PHO ban does not apply restrictions to trace levels of TFA created during refinement processing, which can help to avoid opposition from industry relating to these minor TFA sources.

In countries where the food regulator actively maintains a list of prohibited substances (see Box 4 for an example), the infrastructure for regulating such substances is already in place and likely to be well understood by other government bodies, food producers and the public. PHO can be treated like any other prohibited harmful compound in food. The food regulator should regulate PHO in accordance with the established legal standard for unsafe compounds in food.

A PHO ban can create challenges for monitoring compliance. First, laboratory testing methods exist for TFA but not for PHO. Reconciling a ban on PHO with compliance testing methods for TFA can add complexity. A possible solution is to set TFA thresholds for products to estimate presence of PHO. Countries with mandatory and reliable labelling of TFA levels avoid this concern. Second, for countries that mostly import foods, it is difficult to regulate processes of partial hydrogenation that occur outside the country. Partnering with border agencies can help address this challenge. If PHO-containing products are mostly domestic in origin, the process of partial hydrogenation can probably be easily identified and regulated by designated inspectors at processing plants.

Key elements of an effective PHO ban include the following.

- › **Required ingredients list:** An ingredients list on pre-packaged food must disclose the presence of industrially produced TFA as well as each other ingredient present in the food product. Technical regulations for product disclosure should ensure that industrially produced TFA are easily identifiable and consistent with the definition of the restricted substance.
- › **Definition of the restricted substance:** “Partially hydrogenated oil” must be defined in a clear and scientifically sound manner. For example, the United States Food and Drug Administration defines PHO as “those oils and fats that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4”.

BOX 4. CASE STUDY: SAMPLE REGULATION, CANADA

Canada implemented its prohibition on the use of PHO in foods by adding PHO to Part 1 of its List of Contaminants and Other Adulterating Substances in Foods, which is incorporated by reference into its Food and Drug Regulations. The Regulations are divided into two parts: Part 1 sets out substances that, if present in food at any level, result in the food being declared as “adulterated”; Part 2 sets out the maximum levels for specific substances in certain foods that, if exceeded, result in a declaration of adulteration. By adding PHO to Part 1 of the List, any food containing PHO would be declared adulterated, and its sale in Canada would be prohibited in accordance with the Food and Drugs Act.

Part 1

ITEM NO.	SUBSTANCE	FOOD
18	Partially hydrogenated oils (PHO)	All foods

The prohibition applies to PHO, defined as oils and fats that:

- › have been hydrogenated; and
- › have an iodine value of greater than 4 (which indicates partial rather than full hydrogenation).

Ingredients that do not satisfy both these conditions are excluded from the definition of a PHO. See Annex 3 for sample legislation.

4. KEY PROVISIONS FOR IMPROVING IMPLEMENTATION

Restrictions alone may not always be sufficient to achieve high compliance. Policy-makers should consider whether any of the following provisions would improve implementation in the local context and under the local legal system.

- › **Mandatory nutrition labelling requirement:** As discussed above, labelling is important for monitoring compliance. Mandatory TFA labelling can also lead industry to reformulate its products. An effective label should include a consistent and understandable statement of the amount of TFA, in line with Codex guidelines. See Annex 2 for a labelling example.
- › **Effective date and implementation schedule:** Legal measures to eliminate TFA should be implemented as early as possible. Nevertheless, food producers need time to test and reformulate products, acquire new supply lines and renegotiate contracts, redesign and produce new labels, and exhaust existing stock. These potential challenges can be addressed with a reasonable transition schedule, accompanied by education for producers and consumers. An effective date of 6–18 months after the final legal measure is approved is a reasonable transition period. Alternatively, the rules can provide for a structured transition schedule for implementation by reducing the maximum threshold limit for TFA according to a specific timeline. For example, an initial limit for industrially produced TFA of less than 10 g per 100 g of total fat could begin 6 months after enactment; after 12 months, the threshold could be reduced to less than 5 g per 100 g; after 18 months, it could be reduced to less than 2 g per 100 g. Specific food categories, such as fried foods, bakery products or margarines, might have different implementation schedules, depending on the complexities of reformulation. In any case, the enacted legal

measures should be fully implemented for all products as soon as possible to achieve WHO's TFA elimination target for 2023. See module 6 for more information.

- › **Charging and sanctioning of violators:** A range of enforcement mechanisms and sanctions should be in place to deter violations. Existing administrative, civil and criminal procedures can be used to enforce TFA limits, or new procedures can be created. Any enforcement should correct violations quickly, while ensuring due process for all parties. Sanctions should be severe enough to deter violations, while remaining proportionate to the offence. See module 6 for more information.
- › **Consultations with stakeholders and comment periods:** The law may require consultation and coordination among government agencies and stakeholders. For example, the United States and Canada engaged in comment and petition periods before enacting their respective PHO bans. Regulatory agencies should provide key stakeholders – particularly industry stakeholders, the media and the public – with information about the health evidence, the legal requirements and techniques for replacing TFA with healthier alternatives. Although industry stakeholders should be consulted during the legislative process, mechanisms must be in place to ensure that the process is free from any conflict of interest. The regulatory process and its integrity should remain government led.
- › **Monitoring and evaluation requirements:** An appropriate regulatory body should be authorized, required and empowered to monitor and evaluate the effectiveness of the restrictions. The monitoring body should, at a minimum, measure reductions of TFA in the food supply. If resources are available, it should also measure changes in TFA population intake and the resulting health impact, which can be measured by testing or modelling health outcomes in the population. Additionally, the monitoring agency should determine whether the restriction is achieving its objective, sanctions are serving as a deterrent, and food producers are complying with the letter and spirit of the rules; it should also examine whether other obstacles are preventing full implementation of the legislation. The monitoring agency should determine whether new evidence supports a revision to the restrictions, such as revising the definition of TFA or lowering the threshold. The findings and conclusions should be published in a report that should be distributed to policy-makers, experts and the public. See module 4 for more information.
- › **Delegation of authority:** To implement all the provisions of TFA restrictions, a regulatory agency may need to delegate certain responsibilities to other government agencies. For example, a national food and drug authority may not have sufficient staff to fulfil its statutory obligation to inspect all food establishments across the country, so it might assign this responsibility to subnational and local sanitation inspectors. The legislation should specify which responsibilities are delegable or not, to whom and under what conditions. See module 6 for more information.
- › **Education and outreach:** Compliance with the restrictions will be higher if regulated entities receive advance notice of the legislation, are allowed sufficient time to reformulate products and recipes, and are provided with resources to encourage compliance, such as a list of compliant products and vendors. Before enforcement, regulated entities should have a clear understanding of the need for the restriction, their legal obligations and techniques for replacing TFA with healthier alternatives. Regulatory agencies should provide information about the restriction and the health evidence to key stakeholders, the media and the public. Industry stakeholders may also share technical knowledge and express concerns during this process. Recommendations on a public media campaign are in module 5. Recommendations on providing support on healthier replacement oils and fats are in module 2.
- › **Resource allocation:** Effective implementation of TFA restrictions – including education, inspection, testing, monitoring, evaluation and enforcement – requires human and financial resources. Over time, this work may be incorporated into existing sanitation inspections at minimal cost, but there may be some additional expenses during launch that should be budgeted for. Budgeting rules and procedures will be jurisdiction specific,

but the legislation should ensure that the government allocates sufficient resources to the appropriate government agencies and activities. Some jurisdictions allow licensing fees and financial penalties to be used to fund ongoing implementation.

- › **TFA-free claims:** Legislation should restrict the ability of food producers and vendors to make TFA-free claims, whether on the front of the package, at the point of sale, in ingredients lists or in other marketing materials. In certain cases – for example, if TFA reduction was accompanied by an increase in saturated fat – such claims can mislead consumers to believe that a product is a healthier option. If claims are allowed, the legislation should require a clear threshold (for example, less than 0.1 g of TFA per 100 g of food or serving) so that such claims are valid. Because a TFA-free claim implies a nutritional endorsement, any product that does qualify for TFA-free claims should also be required to meet other nutrition standards, including limits on saturated fat.

5. OTHER COMPLEMENTARY MEASURES

If political or technical barriers currently prevent the enactment of a comprehensive national ban or strict limit on TFA, local and subnational governments should enact other complementary measures to reduce consumption of TFA to the greatest extent possible. These measures, along with education campaigns and other communications, can help prepare consumers and manufacturers to eliminate industrially produced TFA by 2023. Each measure should be evaluated on the basis of its ability to reduce consumption of industrially produced TFA, its ease of enactment and implementation, and its potential to lay the groundwork for a national ban on industrially produced TFA.

Box 5 gives an example of a staged introduction of restrictions.

BOX 5. CASE STUDY: NEW YORK CITY

New York City (NYC) took the lead on restricting industrially produced TFA in the United States. The NYC Department of Health and Mental Hygiene (DOHMH) amended the NYC Health Code to restrict industrially produced TFA in any food service establishment that is required to hold a NYC DOHMH permit, including restaurants, caterers, mobile food-vending units and mobile food commissaries.

From 1 July 2007, food service establishments in NYC were not allowed to use PHO, shortenings or margarines for frying, pan-frying (sautéing), grilling or as a spread unless these ingredients contained less than 0.5 g of TFA per serving. Food establishments could continue temporarily using oils and shortenings containing industrially produced TFA for deep-frying cake batter and yeast dough.

From 1 July 2008, no food containing PHO, shortenings or margarines with 0.5 g or more of TFA per serving could be stored, used or served by food service establishments. To enforce the ban, DOHMH food inspectors checked the packaging of food used in restaurant kitchens for the presence of 'PHO' in ingredients lists or for the amount of TFA on nutrition facts panels, to ensure that the food contained less than 0.5 g of TFA per serving. Violators faced fines of at least \$200, and received a follow-up inspection to determine compliance.

A national ban on PHO followed; the United States Food and Drug Administration regulations become effective between 18 June 2018 and 1 January 2021, depending on the product.

Possible other complementary measures may include the following.

- › **Local restrictions:** If localities have authority to regulate restaurants and other food service establishments within their jurisdiction, local TFA restrictions may be possible. In the absence of national actions, local governments should consider implementing TFA restrictions to the full extent of their authority, but this may depend on disclosure of TFA on nutrient declaration which is often called back-of-the-pack labels.
- › **Sale and service restrictions in government facilities:** Strict facility-based restrictions can be implemented in any government-funded facility, including educational, health, social services, sport and recreation, military or prison facilities (see example in Box 6). Such restrictions are often incorporated into broader nutritional guidelines and standards that are relevant to the public setting and require nutrition labelling that includes TFA. Authority for such restrictions may derive from a local or national government's unique position as a property owner and a purchaser of food. Although the restriction would apply only to certain facilities or institutions, it should include the same elements as a national ban or limit (for example, definition, scope, inspection, sanctions).

BOX 6. CASE STUDY: SALE AND SERVICE RESTRICTIONS IN GOVERNMENT FACILITIES, URUGUAY

In September 2013, the government of Uruguay adopted Law No. 19.140 on “healthy eating in schools”. It mandated the Ministry of Health to develop standards for food available in canteens and kiosks in schools, prohibited advertising for these food items, and restricted the availability of salt shakers. The school food standards were elaborated in March 2014 in two further documents: Regulatory Decree 60/014 and the National Plan of Health Promoting Schools.

The standards aimed to promote food with “natural nutritional value” and a “minimum degree of processing”, and to limit the intake of free sugars, saturated fat, TFA and sodium. Limits are set per 100 g of food, per 100 mL of drink and per 50 g portion. Prohibited food includes sugary beverages and energy drinks, confectionery, salty snacks, cakes and chocolate. Implementation of the school food standards and restrictions on advertising began in public schools in 2015, and compliance is being monitored.

- › **Required ingredients lists:** Ingredients lists on pre-packaged foods are required and should disclose the presence of industrially produced TFA. Pre-packaged food labels usually include a list of each ingredient in descending order of predominance.³ In other words, the list contains every ingredient present in the food product, in order from greatest to least by weight. Technical regulations usually create the rules that govern this list and affect how products are disclosed. Depending on the rules, the same ingredient might appear as “partially hydrogenated vegetable oil”, “shortening”, “vegetable oil” or “oil”. Policy-makers should review and modify these rules to ensure that industrially produced TFA are easily identifiable. This might include rules regarding the use of common terms (such as “margarine” or “shortening”), the grouping of similar ingredients (such as combining all vegetable oils into a single entry), and whether the function of an ingredient must be disclosed (such as “partially hydrogenated (vegetable) oil, used as a preservative”). The ingredients list should not imply nutrient content characteristics of an ingredient, so terms such as “nonhydrogenated” or “unhydrogenated” that imply that the product is free from TFA should be prohibited.

³ Under Codex, all ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food (CXS 1-1985: Codex General Standard for the Labelling of Prepackaged Foods).

- › **Front-of-pack labelling:** Labels on the front of packaged foods can inform consumers about the level of TFA in the products. This may help consumers make healthier choices and encourage producers to reformulate their products.
- › **Fiscal measures:** Industrially produced TFA can be less expensive than healthier alternative oils and fats. Governments can use taxes and other fiscal measures to increase the relative price of TFA. Increases in the relative price would decrease demand and raise additional revenue. See module 2 for more information.
- › **Marketing restrictions:**⁴ Governments may restrict marketing of products that contain industrially produced TFA. A strong restriction would limit marketing of products containing TFA through any marketing technique or medium. Including amounts of TFA in nutrient declaration (such as back-of-the pack labels or nutrition facts panels) will make it easier to implement these marketing restrictions.
- › **Voluntary measures:** If no legally enforceable measures are currently possible, governments might accept voluntary measures to reduce TFA. However, although these programmes may achieve some reductions in TFA levels and prompt a wider conversation about feasibility, voluntary measures are not as effective as legally enforceable measures and can undermine the political will to pursue mandatory measures. One way to make these measures more effective would be to request industry to include the amount of TFA in nutrient declaration (such as back-of-the pack labels or nutrition facts panels).

REFERENCES

Clapp J, Curtis CJ, Middleton AE, Goldstein GP. (2014). Prevalence of partially hydrogenated oils in US packaged foods, 2012. *Prev Chronic Dis.*, 11:E145.

Restrepo BJ, Rieger M. (2016). Denmark's policy on artificial trans fat and cardiovascular disease. *Am J Prev Med.*, 50(1):69–76.

⁴ “Marketing” refers to any form of commercial communication or message that is designed to increase, or has the effect of increasing, the recognition, appeal and/or consumption of particular products and services. It comprises anything that acts to advertise or otherwise promote a product or service.

ANNEX 1. DECISION GUIDE FOR SELECTING A POLICY TO ELIMINATE INDUSTRIALLY PRODUCED TFA

The recommended policy options in the REPLACE action package – limiting TFA to 2% of total fat in all foods, and banning the production or use of PHO – are designed to eliminate TFA from national food supplies. Both policies make it impossible to use PHO on a large scale, but do allow for small amounts of TFA from animal fats, refined oils and fully hydrogenated oils.

Deciding between the two policy options will depend on country-specific factors. In some cases, a combination of both policies may be appropriate. This annex outlines some key considerations to guide policy-makers in selecting a TFA policy that is most suitable for their country context (see Tables 1 and 2).

Table 1. Important legal and political considerations

CONSIDERATIONS	TFA LIMIT SHOULD BE CONSIDERED IF:	PHO BAN SHOULD BE CONSIDERED IF:
Existing authority	Existing food and nutrition laws allow for the inclusion of a 2% limit	Existing food and nutrition laws cover harmful compounds in foods AND there is a maintained list of prohibited substances in food
Complementary measures already in place	Complementary measures require TFA assessment, such as for labelling – particularly if the policy is effective and being enforced	Narrowly applied PHO ban is in place – such as for infant formula – particularly if the policy is effective and being enforced
Trade	Neighbouring countries or countries within an economic union have similar policies	Neighbouring countries or countries within an economic union have similar policies
Political support	Influential support is likely	Influential support is likely

Table 2. Important technical considerations for enforcing TFA policies

CONSIDERATIONS	TFA LIMIT SHOULD BE CONSIDERED IF:	PHO BAN SHOULD BE CONSIDERED IF:
Major source of TFA	The major source of TFA consumption is imported products, especially if ports of entry can require TFA content to be labelled on imported products	The major source of TFA consumption is PHO manufactured domestically, especially if a limited number of PHO manufacturers exist in the country
Existing compliance mechanisms	A functioning administrative structure allows easy enforcement of a 2% limit with modest investment of financial and human resources	A functioning administrative structure allows easy enforcement of a PHO ban with modest investment of financial and human resources
Capacity for testing	<p>The country can test foods for TFA levels</p> <p>OR</p> <p>The country has access to a regional laboratory that can support testing</p> <p>OR</p> <p>The country has mandatory and reliable labels with understandable statements of the amount of TFA in nutrient declaration (such as back-of-the pack labels or the nutrition facts panels)</p>	<p>The country does not have capacity to test foods for TFA levels</p> <p>OR</p> <p>The country has mandatory and reliable labels that require PHO (or equivalent⁵) to be listed as an ingredient</p>

⁵ Depending on the country, “partially hydrogenated vegetable oil” may appear as “shortening”, “vegetable oil” or “oil”. To ensure that industrially produced TFA are easily identifiable, policy-makers should be aware of all possible list forms of PHO that would be covered by a ban.

ANNEX 2. EXAMPLE OF A NUTRITION LABEL

WHY IS TRANS FAT STILL ON THE LABEL IF THE FOOD AND DRUG ADMINISTRATION (FDA) IS PHASING IT OUT?

TFA will be reduced but not eliminated from foods, so the FDA will continue to require this information on the label. In 2015, the FDA published a final determination that PHO, the source of industrially produced TFA, are not generally recognized as safe, but this determination would not affect naturally occurring TFA, which would still exist in the food supply. TFA are present naturally in food from some animals, mainly ruminants such as cows and goats. Also, industry can currently use some oils that are approved as food additives and can still petition the FDA for certain uses of PHO.

In the United States, *trans*-fatty acids should be listed as “*Trans* fat” or “*Trans*” on a separate line under the listing of saturated fat in the nutrition label. *Trans* fat content must be expressed as grams per serving to the nearest 0.5-g increment below 5 g and to the nearest gram above 5 g. If a serving contains less than 0.5 g, the content, when declared, must be expressed as “0 g”.

Nutrition Facts			
Serving Size 2/3 cup (55g)			
Servings Per Container About 8			
Amount Per Serving			
Calories 230	Calories from Fat 40		
			% Daily Value*
Total Fat 8g			12%
Saturated Fat 1g			5%
<i>Trans</i> Fat 0g			
Cholesterol 0mg			0%
Sodium 160mg			7%
Total Carbohydrate 37g			12%
Dietary Fiber 4g			16%
Sugars 1g			
Protein 3g			
Vitamin A			10%
Vitamin C			8%
Calcium			20%
Iron			45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

ANNEX 3. GOOD-PRACTICE EXAMPLES OF LEGISLATION AND REGULATION

REGULATORY OPTION 1: SET A MANDATORY LIMIT ON THE AMOUNT OF INDUSTRIALLY PRODUCED TFA IN ALL FOOD – SAMPLE LEGISLATION FROM DENMARK.

Other examples of similar legislation or regulations are available on the WHO Global database on the Implementation of Nutrition Action (GINA).⁶

1. -----IND- 2002 0216 DK- EN- ----- 20020619 --- --- PROJET

2003

Order No. 160 of 11 March

Courtesy translation Order on the content of *trans* fatty acids in oils and fats etc.

The following is laid down pursuant to Section 13, Section 55, subsection 2 and Section 78 subsection 3 of Act No 471 of 1 July 1998 on foodstuffs etc. (Foodstuffs Act):

Chapter 1

Scope

Section 1. This Order applies to oils and fats, including emulsions with fat as the continuous phase which, either alone or as part of processed foodstuffs, are intended, or are likely, to be consumed by humans.

Subsection 2. The Order does not apply to the naturally occurring content of trans fatty acids in animal fats or products governed under other legislation.

Subsection 3. The Order only applies to products sold to the final consumer.

Section 2. It is prohibited to sell the oils and fats covered by the Order to consumers if they contain a higher level of the trans fatty acids defined in the Annex than that stated in Section 3.

Section 3. As from 1 June 2003, the content of trans fatty acids in the oils and fats covered by this Order must not exceed 2 grams per 100 grams of oil or fat, cf. however subsection 2.

Subsection 2. From 1 June 2003 until 31 December 2003 the oils and fats covered by this Order and included in processed foodstuffs which also contain ingredients other than oils and fats and which are produced by the foodstuffs industry, in retail outlets, catering establishments, restaurants, institutions, bakeries etc. may, however, contain up to 5 grams of trans fatty acids per 100 grams of oil or fat.

Section 4. In products which are claimed to be “free from trans fatty acids”, the content of trans fatty acids in the finished product shall be less than 1 gram per 100 grams of the individual oil or fat.

⁶ See <https://extranet.who.int/nutrition/gina/en>

Chapter 2

Penalty provisions etc.

Section 5. A fine shall be imposed on anyone who contravenes Section 2 or Section 4 of this Order.

Subsection 2. The penalty may increase to imprisonment for up to two years if the contravention was committed wilfully or through gross negligence, and the contravention

- 1) caused damage to health or led to the risk thereof, or
- 2) resulted in, or was intended to result in, financial gain for the perpetrator themselves or for others, including as a result of savings made.

Subsection 3. Criminal liability may be incurred by companies etc. (legal entities) in accordance with the rules of Chapter 5 of the Penal Code.

Section 6. This Order shall enter into force on 31 March 2003.

Subsection 2. Products manufactured before this Order has entered into force, as well as products manufactured within the periods stated in Section 3(2), may be sold until expiry of the best before date.

Definition of trans fatty acids

For the purposes of this Order, trans fatty acids are defined as the sum of all fatty acid isomers with 14, 16, 18, 20 or 22 carbon atoms and one or more trans double bonds, i.e. C14:1, C16:1, C18:1, C18:2, C18:3, C20:1, C20:2, C22:1, C22:2 fatty acid trans isomers, but only polyunsaturated fatty acids with methylene interrupted double bonds.

REGULATORY OPTION 2: BAN PRODUCTION OR USE OF PHO AS AN INGREDIENT IN ALL FOODS – SAMPLE REGULATION FROM CANADA

Other examples of similar legislation or regulations are available on GINA⁷.

Foods (continued)

DIVISION 15 Adulteration of Food

- B.15.001 (1)** A food referred to in column 2 of Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods* is adulterated if the corresponding substance referred to, by name or class, in column 1 is present in or on the food.
- (2)** A food referred to in column 2 of Part 2 of the *List of Contaminants and Other Adulterating Substances in Foods* is adulterated if the corresponding substance referred to, by name or class, in column 1 is present in or on the food in an amount that exceeds the maximum level set out in column 3.
- (3)** If a substance referred to, by name or class, in column 1 in Part 2 the *List of Contaminants and Other Adulterating Substances in Foods* is present in or on the corresponding food referred to in column 2, the food is, in respect of the presence of the substance, exempt from the application of paragraph 4(1)(a) of the Act if the amount of the substance does not exceed the maximum level set out in column 3.
- (4)** Subsections (1) to (3) do not apply to a substance that is present in or on a food as
- (a)** a food additive;
 - (b)** a pest control product as defined in subsection 2(1) of the *Pest Control Products Act* or its components or derivatives; or
 - (c)** a veterinary drug or its metabolites.

⁷ See <https://extranet.who.int/nutrition/gina/en>

List of Contaminants and Other Adulterating Substances in Foods

Part 1

Item No.	Column 1 Substance	Column 2 Food
1	Mineral oil	All foods, except foods requiring the use of mineral oil as part of good manufacturing practice ¹
2	Paraffin wax	All foods, except chewing gum with a paraffin wax base
3	Petrolatum	All foods
4	Coumarin, an extract of tonka beans, the seed of <i>Dipteryx odorata</i> Willd. or <i>Dipteryx oppositifolia</i> Willd.	All foods
5	Fatty acids and their salts containing chick-edema factor or other toxic factors	All foods
18	Partially hydrogenated oils	All foods

Combination of both policy options—sample regulation, Peru.

Reglamento que establece el proceso de reducción gradual hasta la eliminación de las grasas trans en los alimentos y bebidas no alcohólicas procesados industrialmente

SUPREME DECREE N° 033-2016-SA

6.1.- En un plazo de hasta 18 meses contados a partir de la vigencia del Reglamento, el uso y/o contenido de grasas trans no será mayor de:

PRODUCTO	GRASAS TRANS LIMITE
a) Grasas, aceites vegetales y margarinas	2 g de Ácidos grasos trans por 100 g ó 100 ml de materia grasa
b) Resto de alimentos y bebidas no alcohólicas procesadas industrialmente	5 g de Ácidos grasos trans por 100 g ó 100 ml de materia grasa

6.2.- Para efectos de la eliminación del uso y/o contenido de grasa trans, se establece que en un plazo de 54 meses, contados a partir de la vigencia del presente Reglamento se eliminará el uso y contenido de grasas trans que provienen de la hidrogenación parcial en cualquier alimento y bebida no alcohólica procesada.

(Unofficial translation)

Regulation that establishes the process of gradual reduction until the elimination of trans fats in industrially processed foods and non-alcoholic beverages

6.1. In a period of up to 18 months counted from the effective date of the Regulation, the use and/or trans fat content will not be greater than:

PRODUCT	TRANS FAT LIMIT
a) Fats, vegetable oils and Margarines	2 g of trans fatty acids by 100 g or 100 ml of fat
b) Other foods and processed non-alcoholic beverages	5 g of trans fatty acids by 100 g or 100 ml of fat

6.2 For purposes of eliminating the use and/or content of trans fat, it is established that within a period of 54 months, counted from the effective date of this Regulation, the use and content of trans fats that comes from partial hydrogenation in any food and processed non-alcoholic beverage will be eliminated.



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REPLACE
TRANS FAT