REPLACE
TRANS FAT

REPLACE TRANS FAT: AN ACTION PACKAGE TO ELIMINATE INDUSTRIALLY PRODUCED TRANS-FATTY ACIDS

MODULE 3: LEGISLATE OR REGULATE

How-to guide for trans fat policy action

World Health Organization

REPLACE trans fat: an action package to eliminate industrially produced trans-fatty acids.
Module 3: Legislate or regulate. How-to guide for trans fat policy action

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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
RE	**REVIEW** dietary sources of industrially produced TFA and the landscape for required policy change	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	**PROMOTE** the replacement of industrially produced TFA with healthier oils and fats	Describe oil and fatty acid profiles, and available replacement oils and fats, including feasibility considerations and possible interventions to promote healthier replacements
L	**LEGISLATE** or enact regulatory actions to eliminate industrially produced TFA	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
A	**ASSESS** and monitor TFA content in the food supply and changes in TFA consumption in the population	Describe the goals and methods for TFA assessment. Provide guidance on designing and carrying out a study of TFA in food and human samples
C	**CREATE** awareness of the negative health impact of TFA among policy-makers, producers, suppliers and the public	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
E	**ENFORCE** compliance with policies and regulations	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

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.