

Elimination of Industrially Produced *Trans*-fatty Acids

A Regulatory Drafting Tool



PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas

Elimination of Industrially Produced *Trans*-fatty Acids

A Regulatory Drafting Tool

Washington, D.C., 2021



Elimination of Industrially Produced Trans-fatty Acids: A Regulatory Drafting Tool

© Pan American Health Organization, 2021

PAHO/NMH/RF/21-0031

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO license (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).



Under the terms of this license, this work may be copied, redistributed, and adapted for non-commercial purposes, provided the new work is issued using the same or equivalent Creative Commons license and it is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that the Pan American Health Organization (PAHO) endorses any specific organization, product, or service. Use of the PAHO logo is not permitted.

Adaptations: If this work is adapted, the following disclaimer should be added along with the suggested citation: “This is an adaptation of an original work by the Pan American Health Organization (PAHO). Views and opinions expressed in the adaptation are the sole responsibility of the author(s) of the adaptation and are not endorsed by PAHO.”

Translation: If this work is translated, the following disclaimer should be added along with the suggested citation: “This translation was not created by the Pan American Health Organization (PAHO). PAHO is not responsible for the content or accuracy of this translation.”

Suggested citation. Elimination of Industrially Produced Trans-fatty Acids: A Regulatory Drafting Tool. Washington, D.C.: Pan American Health Organization; 2021. License: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://iris.paho.org>.

Sales, rights, and licensing. To purchase PAHO publications, contact sales@paho.org. To submit requests for commercial use and queries on rights and licensing, visit <http://www.paho.org/permissions>.

Third-party materials. If material that is attributed to a third party, such as tables, figures, or images, is reused from this work, it is the user’s responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned material or component from this work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of PAHO concerning the legal status of any country, territory, city, or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers’ products does not imply that they are endorsed or recommended by PAHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by PAHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall PAHO be liable for damages arising from its use.

Contents

Abbreviations and Acronyms	v
Presentation	vi
Acknowledgments:	vii
Introduction	1
About the Regulatory Drafting Tool	1
About Trans Fats	2
What Are Trans Fats?	2
Health Harms of Trans Fats	2
World Health Organization Recommendations	2
Trans Fat Regulations Globally	3
Model Regulation for the Elimination of Industrially Produced <i>Trans</i>-fatty Acids	4
1.1 General	4
Article 1 – Objective	4
Article 2 – Definitions	4
1.2 Authority	5
Article 3 – Powers and Duties of the [Agency]	5
1.3 Scope	5
Article 4 – Restrictions on <i>Trans</i> -fatty Acids	5
1.4 Labeling	7
Article 5 – List of Ingredients	7
Article 6 – Nutrient Declaration	7
Article 7 – <i>Trans</i> fat-free Claim	8
1.5 Implementation and Enforcement	8
Article 8 – Inspections	8
Article 9 – Declaration of Conformity	9
Article 10 – Penalties	9
Article 11 – Complaint Mechanism	11
1.6 Effective Date	11
Article 12 – Effective Date	11
1.7 Miscellaneous Provisions	12
Article 13 – Monitoring and Evaluation	12
Article 14 – Multi-agency Coordination Group	13
Conducting an Inventory of Current Policies	14
2.1 Policy Inventory	14
2.1.1 Authority to Regulate <i>Trans</i> -fatty Acids	14
2.1.2 Scope of Regulation	14
2.1.3 Labeling	15
2.1.4 Implementation and Enforcement	15
2.1.5 Effective Date	15
2.1.6 Other Provisions	15

Explanations on Model Regulations for the Elimination of Industrially Produced <i>Trans</i>-fatty Acids	16
3.1 Objectives	16
3.2 Authority to Regulate <i>Trans</i> -fatty Acids	17
3.2.1 Authority for Regulation and Enforcement	18
3.2.2 Authority for Monitoring and Evaluation	20
3.3 Scope of the Regulation on <i>Trans</i> -fatty Acids	22
3.3.1 Best-practice Approaches	22
3.3.2 Decision Guide	24
3.3.3 The Easiest Approach to a Best-practice Policy	25
3.3.4 Ban on Partially Hydrogenated Oils	26
3.3.5 Limit of Two Percent for Industrially Produced <i>Trans</i> -fatty Acids	27
3.3.6 Combination of a Ban on Partially Hydrogenated Oils and a Limit of Two Percent for Industrially Produced <i>Trans</i> -fatty Acids	28
3.4 Labeling	29
3.4.1 Mandatory Ingredient List with Partially Hydrogenated Oils Clearly Identifiable	30
3.4.2 Mandatory Inclusion of <i>Trans</i> -fatty Acids in Nutrient Declaration	32
3.4.3 <i>Trans</i> Fat-free Claim	34
3.5 Implementation and Enforcement	36
3.5.1 Inspection of Critical Control Points	37
3.5.2 Declaration of Conformity	39
3.5.3 Liability, Offences, and Penalties	42
3.5.4 Complaints and Reporting Mechanism	44
3.6 Effective Date	45
3.7 Miscellaneous Provisions	48
3.7.1 Definitions	48
3.7.2 Multi-agency Coordination Group	51
3.7.3 Replacement of Oils and Fats	53
3.7.4 Other Provisions	54
References	55
Annex: Key Activities to Support Drafting Regulations on <i>Trans</i>-fatty Acids	56
1. Policy Landscape Assessment	56
2. Political Support	59
3. Replacement of Oils and Fats	61
4. Ongoing Monitoring and Surveillance	61
5. Notification to the World Trade Organization	61

Abbreviations and Acronyms

CLA _____ conjugated linoleic acid

iTFA _____ industrially produced *trans*-fatty acid

NCD _____ noncommunicable disease

PHO _____ partially hydrogenated oil

TFA _____ *trans*-fatty acid

WHO _____ World Health Organization

WTO _____ World Trade Organization

Presentation

Consumption of *trans*-fatty acids (TFAs) is a major cause of global morbidity and mortality. To effectively reduce global consumption of TFAs, the Pan American Health Organization (PAHO) / World Health Organization (WHO) recommends that all countries eliminate industrially produced *trans*-fatty acids (iTFA), the main source of TFAs in the human diet, from their national food supply.

The purpose of this regulatory drafting tool is to assist government agencies and ministries in developing or reforming national legislation or regulation aiming to eliminate iTFAs from their food supply.

Countries' approaches to mandatory iTFA elimination will vary based on their legal framework, existing authorities and capacities, political will, and food supply. However, any country can enact best-practice TFA regulation. This publication is intended to help countries to develop the best regulatory language and approach given their local context.

This regulatory drafting tool was designed for policymakers and civil servants tasked with implementing and/or strengthening national food and nutrition programs. While useful for legally trained readers, this publication is also intended for a nonlegal audience wanting to advance iTFA elimination through regulation.

This publication provides a practical overview of key legal aspects of iTFA elimination, focusing on evidence-based, effective, and tested approaches. As such, this tool limits itself to providing guidance on how to develop and implement the PAHO/WHO-recommended policies, as well as supplementary provisions shown to be effective at supporting their effectiveness.

Acknowledgments:

The Pan American Health Organization (PAHO) gratefully acknowledges the following contributions: Simone Bosch (SICABO Consulting) prepared the first draft of the tool, and contributed to the conception, design and critical revision of the work. and, to the critical revision for important intellectual content. Aaron Schwid (Vital Strategies), Lindsay Steele (Resolve To Save Lives, an initiative of Vital Strategies) and Fabio da Silva Gomes (PAHO/WHO) contributed to the conception, and design, drafting, and critical revision of the tool, and to the drafting of the work and critical revision for important intellectual content. Aaron Schwid (Vital Strategies), Lindsay Steele (Resolve To Save Lives, an initiative of Vital Strategies) and Fabio da Silva Gomes (PAHO/WHO) contributed to the conception and design of the work, and to the drafting of the work and critical revision for important intellectual content. Ignacio Ibarra (PAHO/WHO), Chizuru Nishida and Rain Yamamoto (WHO), contributed to the critical revision of the work for important intellectual content.

PAHO also acknowledges the support from Resolve To Save Lives, an initiative of Vital Strategies.

Introduction

About the Regulatory Drafting Tool

The proposed legal language is intended as a starting point in the development of a legal approach to the elimination of industrially produced *trans*-fatty acids (iTFA) and should be adapted to reflect a country's legal system and policy needs. Therefore, the proposed legal language might not be adopted through a new regulation for *trans*-fatty acids (TFAs) but might instead be used to guide the amendment of existing legal instruments to ensure implementation and enforcement of provisions on iTFA elimination.

With dozens of successfully adopted and implemented national TFA regulations to date, the proposed legal language is mainly based on country experiences, guidance from the World Health Organization (WHO), and Codex Alimentarius standards.

The effectiveness of regulation significantly improves with effective implementation and enforcement which, to a large extent, are dependent on local context. Therefore, implementation and enforcement are only discussed to the extent where they can be strengthened through appropriate wording in legal instruments.

This tool uses decision-tree questions to help users populate a context-specific, iTFA elimination policy that aligns with global best practices. Any TFA regulation should include important provisions, such as those granting legal authority to adopt a TFA regulation, defining the scope of the regulation, creating an inspection and enforcement framework, and setting an effective date. For each discussed aspect, suggested legal wording is provided.

This tool uses “regulation” in a general sense to include laws, acts, regulations, decrees, or other similar terms used in national legal systems that are compulsory for affected parties. It uses “food law” to refer to legal provisions governing food and nutrition, including language in acts, regulations, ministerial or executive decrees, and other legal instruments requiring the government, food industry, or civil society to ensure the safety and healthfulness of food. This definition takes into account the various possible approaches to regulate food and nutrition legally and the necessity to adapt any approach to the country context.

“Agency” (or “agencies”) is used to refer to the relevant government body (or bodies) that will be responsible for adopting, implementing, and enforcing a TFA regulation. This might include one or several ministries, departments, agencies, divisions, or differently named entities that deal with health, food and nutrition, customs, or even the environment. Each country has its own governmental structure; consequently, the responsible government bodies differ accordingly. Where different entities are responsible, it is important that they collaborate from the outset, and that responsibilities be clearly defined.

About Trans Fats

What Are Trans Fats?

Trans-fatty acids (TFAs), or trans fats, are a type of fat of natural or artificial origin. Naturally occurring trans fat is produced by bacteria in the gut of ruminants (e.g., cattle, goats, and sheep). Dairy and meat products derived from these animals contain small amounts of *trans* fat. Industrially produced *trans*-fatty acids (iTFA) are created by adding hydrogen to oils and fats (so-called hydrogenation) to produce partially hydrogenated oils (PHOs), which are solid or semi-solid fats. They can also be unintentionally created during industrial refinement of oils and fats, and when oils and fats are heated and reheated (e.g., during frying or baking at high temperatures).

PHOs are common in baked goods, prepackaged foods, margarines, spreads, and some cooking oils. They are the main source of TFAs in the human diet. The food industry uses PHOs because they have desirable commercial properties: they are cheap and have a long shelf life; they can withstand repeated heating and do not easily become rancid; and they are easy to use in baked goods due to being semi-solid at room temperature.

Health Harms of Trans Fats

TFAs have no known health benefits and are a major contributor to heart disease worldwide. It is estimated that they cause about 260,000 deaths every year (1).

High TFA intake increases the risk of death from coronary heart disease by 28% (2). For every 1% increase in daily energy obtained from TFAs, coronary heart disease mortality rises by 12% (3). In addition, studies have associated the consumption of TFAs with an increased risk for other noncommunicable diseases (NCDs) and related conditions such as ovarian cancer (4), infertility, endometriosis, Alzheimer's disease, diabetes, and obesity (5, 6).

World Health Organization Recommendations

WHO published six REPLACE modules recommends reducing TFA intake in adults and children whose TFA intake is greater than 1% of total energy intake (7). The intake of total TFAs (from both ruminant and industrial sources) of less than 1% of total energy intake translates to less than 2.2 g per day for a 2,000-calorie diet.

Elimination of iTFAs from the global food supply by 2023 is a key target of the WHO's 13th General Programme of Work (2019–2023). In 2018, WHO launched the REPLACE action framework, and in 2019, WHO published the six-modules REPLACE package to support governments with evidence-based tools to implement an iTFA limit and/or a PHO ban (both considered best-practice policies, see [3.3.1 Best-practice Approaches](#) for more information).

R E P L A C E

REVIEW	PROMOTE	LEGISLATE	ASSESS	CREATE	ENFORCE
dietary sources of industrially produced TFA and the landscape for required policy change	the replacement of industrially produced TFA with healthier oils and fats	or enact regulatory actions to eliminate industrially produced TFA	and monitor TFA content in the food supply and changes in TFA 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

Source: World Health Organization. Replace trans fat: an action package to eliminate industrially produced trans-fatty acids [Internet]. Geneva: WHO; 2019 [cited 21 Oct 202]. Available from: <https://www.who.int/teams/nutrition-and-food-safety/replace-trans-fat>

Trans Fat Regulations Globally

By November 2021, 63 countries had adopted iTFA regulations, of which 46 are best-practice policies.¹This number shows that the elimination of iTFAs is economically, politically, and technically feasible.

1 WHO TFA Country Score Card, with a live map, is available on the WHO Global database on the Implementation of Nutrition Action (GINA). Available from: <https://extranet.who.int/nutrition/gina/en/scorecard/TFA>

1. Model Regulation for the Elimination of Industrially Produced *Trans*-fatty Acids



1.1 General

Article 1 – Objective

The objective of this Regulation is to eliminate industrially produced *trans*-fatty acids from the national food supply to protect the public from this harmful substance causing cardiovascular diseases and other noncommunicable diseases. Restricting the use of industrially produced *trans*-fatty acids in foods, including fats and oils, and requiring adequate labeling informing consumers of the presence of *trans*-fatty acids aims to reduce the incidence of diseases related to the consumption of *trans*-fatty acids and decrease associated health care and indirect costs.

Article 2 – Definitions²

- “*Trans*-fatty acids” means all fatty acids with at least one carbon-carbon double bond in the trans configuration, regardless of whether they are produced industrially or are derived from ruminant sources.
- “Industrially produced *trans*-fatty acids” means all fatty acids with at least one carbon-carbon double bond in the trans configuration, and which are produced by industrial processes, including partial hydrogenation and heat treatment of oils and fats.
- “Partially hydrogenated oils” means oils and fats that have been hydrogenated, but not to complete or near complete saturation, and that have an iodine value of greater than four (4).

² Refer to [Section 3.7.1](#) Definitions for guidance on additional definitions that might be required.

1.2 Authority

Article 3 – Powers and Duties of the [Agency]³

Option 1: delegation of authority to single agency

The [agency] shall have the responsibility to:

- a oversee and monitor the implementation of this Regulation;
- b adopt and implement additional [policies, standards, decrees, orders, and guidelines] to implement and enforce this Regulation;⁴
- c inspect and investigate facilities and products for compliance with this Regulation;
- d initiate lawsuits⁵ and seek appropriate penalties⁶ for violations of this Regulation;
- e initiate an amendment of this Regulation if new scientific and independent evidence and international nutrition guidance changes on recommended limits of industrially produced *trans*-fatty acids in food products;
- f [establish, convene, and chair a multi-agency coordination group for the implementation and enforcement of this Regulation].⁷

Option 2: delegation of authority to multiple agencies

The [agency A] shall have the responsibility to:

- a [task];
- b [task].

The [agency B] shall have the responsibility to:

- a [task];
- b [task].

The [agency C] shall have the responsibility to:

- a [task];
- b [task].

1.3 Scope

Article 4 – Restrictions on *Trans*-fatty Acids

Option 1: ban of partially hydrogenated oils

Recommended: ban without exceptions

The production, import, [export], use, sale, and supply of any food, including fats and oils, that contain partially hydrogenated oil are prohibited.

Alternative: ban with limited exceptions

1. The production, import, [export], use, sale, and supply of any food, including fats and oils, that contain partially hydrogenated oil are prohibited.
2. The [agency] may exempt products manufactured using partially hydrogenated oils from this restriction if such partially hydrogenated oils are not intended for human consumption.

3 Wherever you see “agency” in angular brackets, insert the name of the appropriate regulatory authority.

4 Refer to [Section 3.5.1](#) Inspection of Critical Control Points for guidance.

5 Refer to [Section 3.5.4](#) Complaints and Reporting Mechanism for guidance on establishing a complaints mechanism for the public.

6 Refer to [Section 3.5.3](#) Liability, Offences, and Penalties for more information.

7 Only insert if a multi-agency coordination group is to be established. Refer to [Section 3.7.2](#) Multi-agency Coordination Group for guidance.

Option 2: limit on *trans*-fatty acids

*Option 2.A: limit using industrially produced *trans*-fatty acids definition (no exceptions)*

The production, import, [export], use, sale, and supply of oils, fats, or foods that contain more than 2 g of industrially produced *trans*-fatty acids per 100 g of total fat are prohibited.

*Option 2.B: limit using *trans*-fatty acids definition (no exceptions)*

1. The production, import, [export], use, sale, and supply of oils, fats, or foods that contain more than 2 g *trans*-fatty acids per 100 g of total fat are prohibited.
2. This article does not apply to naturally occurring *trans*-fatty acids.

*Option 2.A: limit using industrially produced *trans*-fatty acids definition (with exceptions)*

1. The production, import, [export], use, sale, and supply of oils, fats, or foods that contain more than 2 g of industrially produced *trans*-fatty acids per 100 g of total fat are prohibited.
2. The [agency] may exempt defined food products from the limit on *trans*-fatty acids if such products are not intended for human consumption.

*Option 2.B: limit using *trans*-fatty acids definition (with exceptions)*

1. The production, import, [export], use, sale, and supply of oils, fats, or foods that contain more than 2 g *trans*-fatty acids per 100 g of total fat are prohibited.
2. This article does not apply to naturally occurring *trans*-fatty acids.
3. The [agency] may exempt defined food products from the limit on *trans*-fatty acids if such products are not intended for human consumption.

Optional paragraph: shifting burden of proof of compliance to manufacturers/importers

Any product that contains any partially hydrogenated oils shall be determined to exceed the limit on *trans*-fatty acids in Subarticle 1 unless the manufacturer or importer provides the [agency] with sufficient evidence to establish that the product does not exceed the limit. [A declaration of conformity according to [Article 9 / (name of law where such declarations are regulated)] suffices as evidence.]⁸

Option 3: ban of partially hydrogenated oils and limit on *trans*-fatty acids

*Option 3.A: limit using industrially produced *trans*-fatty acids definition (no exception)*

The production, import, [export], use, sale, and supply of oils, fats, or foods that contain partially hydrogenated oil or that contain more than 2 g of industrially produced *trans*-fatty acids per 100 g of total fat are prohibited.

*Option 3.B: limit using *trans*-fatty acids definition (no exceptions)*

1. The production, import, [export], use, sale, and supply of oils, fats, or foods that contain partially hydrogenated oil or that contain more than 2 g of *trans*-fatty acids per 100 g of total fat are prohibited.
2. This article does not apply to naturally occurring *trans*-fatty acids.

⁸ Reference to a declaration of conformity if it forms part of the TFA regulation. Refer to [Article 9](#).

Option 3: ban of partially hydrogenated oils and limit on *trans*-fatty acids

Option 3.A: limit using industrially produced *trans*-fatty acids definition (with exceptions)

1. The production, import, [export], use, sale, and supply of oils, fats, or foods that contain partially hydrogenated oil or that contain more than 2 g of industrially produced *trans*-fatty acids per 100 g of total fat are prohibited.
2. The [agency] may exempt defined products from the restrictions in Subarticle 1 if such products are not intended for human consumption.

Option 3.B: limit using *trans*-fatty acids definition (with exceptions)

1. The production, import, [export], use, sale, and supply of oils, fats, or foods that contain partially hydrogenated oil or that contain more than 2 g of *trans*-fatty acids per 100 g of total fat are prohibited.
2. The [agency] may exempt defined products from the restrictions in Subarticle 1 if such products are same comment on industrial processing not intended for human consumption.
3. This article does not apply to naturally occurring *trans*-fatty acids.

Optional paragraph: shifting burden of proof of compliance to manufacturers/importers

Any product that contains any partially hydrogenated oils shall be determined to exceed the limit on *trans*-fatty acids in Subarticle 1 unless the manufacturer or importer provides the [agency] with sufficient evidence to establish that the product does not exceed the limit. [A declaration of conformity according to [Article 9 / (name of law where such declarations are regulated)] suffices as evidence.]⁹

1.4 Labeling

Article 5 – List of Ingredients

1. In the list of ingredients, refined oils shall be stated as “oil”¹⁰ together with either the term “vegetable” or “animal”.
2. Where an oil has undergone hydrogenation, the list of ingredients shall qualify whether “fully hydrogenated” or “partially hydrogenated”.
3. The use of the terms “unhydrogenated”, “nonhydrogenated” or similar terms, implying that oils and fats have not been partially or fully hydrogenated, is prohibited.

Article 6 – Nutrient Declaration

1. The amount of *trans*-fatty acids shall be stated in the nutrient declaration as “*trans* fat”,¹¹ immediately following the declaration of the total fat content on a separate line.
2. The amount of *trans*-fatty acids shall be expressed in grams [milligrams] per 100 g or 100 ml¹² of product, rounded to the nearest tenth of a gram.

⁹ Reference to a declaration of conformity if it forms part of the TFA regulation. Refer to [Article 9](#).

¹⁰ Codex General Standard for Labelling of Prepackaged Foods excludes olive oil from the category of refined oils covered by this provision.

¹¹ Each jurisdiction should select a stated term that is most likely to be understood by the population whether “*trans*”, “*trans* fat” or “*trans*-fatty acids” or a local equivalent. The Codex Guidelines on Nutrition Labelling CAC/GL 2-1985 proposes the use of “*trans* fatty acids”. Canada uses “*trans*”. The United States of America uses “*trans* fat”.

¹² Choose the one that fits your national labeling regulations requirements. You may also choose to require stating the amount of TFAs both per 100g/ml and per serving, provided the number of servings per package is stated.

Article 7 – *Trans* fat-free Claim

Recommended: ban of *trans*-fat free claim

1. Claims that a product is free from, or low in, *trans*-fatty acids (“TFA-free claim”) are prohibited.
2. This article is applicable to claims appearing on the product packaging and off the product packaging, including, but not limited to, marketing materials, advertisements, and at the point of sale.

Alternative: *trans* fat-free claim with restrictions

1. Claims that a product is free from *trans*-fatty acids (“TFA-free claim”) are permitted if:
 - a. the content of *trans*-fatty acids in the finished product is not higher than 0 g [mg]¹³ per 100 g / ml of product; and
 - b. no more than 10% of energy of the finished product derives from saturated fat; and
 - c. [no more than 10% of energy of the finished product derives from free sugars]; and
 - d. [no more than 30% of energy of the finished product derives from total fat]; and
 - e. [the content of sodium in the finished product is less than 1 mg/kcal].
2. This article is applicable to claims appearing on the product packaging and off the product packaging, including, but not limited to, marketing materials, advertisements, and at the point of sale.

1.5 Implementation and Enforcement

Article 8 – Inspections

Inspectors of the [agency] shall have the power and duties to:

- a. Inspect facilities where oils, fats, and other food products are processed, refined, manufactured, prepared, packaged, labeled, or served, with or without advance notice;
- b. Search premises where violations of this Regulation are suspected;
- c. Review and request documents and records on products and the supply chain from natural persons or legal entities engaged in the import, export, manufacture, storage, distribution, sale, or use of oils, fats, or other food products;
- d. Collect and analyze food samples;
- e. Train regulated entities;
- f. Seize food products;
- g. Report violations;
- h. Investigate complaints;
- i. Issue warnings or other penalties pursuant to [regulations];¹⁴
- j. Suspend licenses to operate food businesses on a temporary basis.

¹³ Please note that the limit and precision of TFA detection may vary by country.

¹⁴ Insert the name(s) of regulation(s) containing the penalties and measures inspectors can issue/take.

Article 9 – Declaration of Conformity

1. Before placing on the market or importing for consumption any vegetable oil or fat or prepackaged food, any legal entity importing or manufacturing domestically such products shall issue a declaration of conformity including:
 - a. Identification of the food product covered by the declaration;
 - b. Identification of the manufacturer or importer;
 - c. A declaration¹⁵ signed by an authorized representative of the manufacturer or importer stating that the food product complies with the [ban of partially hydrogenated oils / limit on *trans*-fatty acids] in Article 4 of this Regulation.
2. Legal entities importing or domestically producing vegetable oils and fats containing more than one gram of industrially produced *trans*-fatty acids per 100 g of fat/oil shall:
 - a. Submit samples of such products to a third-party laboratory to be tested for compliance with the [ban of partially hydrogenated oils / limit on *trans*-fatty acids] in Article 4; and
 - b. Based on such testing, issue a declaration of conformity that certifies that such products comply with the [ban of partially hydrogenated oils / limit on *trans*-fatty acids] in Article 4; and
 - c. Maintain records of declarations of conformity and laboratory test results and attestations supporting such declarations of conformity for a period of at least five years.
3. The [agency] shall establish guidelines on the testing requirements of Subarticle 2.
4. The declaration of conformity shall be provided by:
 - a. Food manufacturers, producers of vegetable oils and fats, and importers to wholesalers, retailers, repackaging facilities, and the [agency];
 - b. Food manufacturers and producers of oils and fats to exporters upon request.
5. The [agency] shall establish rules under which importers of prepackaged food and vegetable oils and fats may rely on foreign manufacturers' laboratory test results and declarations of conformity.
6. The [agency] may issue a [directive / administrative order] defining additional requirements of the declaration of conformity.

Article 10 – Penalties

1. A fine of at least [currency] [amount] but not exceeding [currency] [amount] shall be imposed on any natural person contravening Article 4 regarding the [ban of partially hydrogenated oils / maximum limit of industrially produced *trans*-fatty acids] or Articles 5, 6 and 7 regarding labeling.

¹⁵ The signed declaration can be replaced with a sworn affidavit or a notarized declaration if they form part of the legal tradition of the country. They carry more legal weight than a signed declaration, but the administrative burden on manufacturers and importers to obtain them is higher.

2. A fine of [five to ten percent of the annual revenue based on the latest available audited yearly accounts, or, in the absence of audited accounts, the latest available yearly accounts / at least [currency] [amount] but not exceeding [currency] [amount]] shall be imposed on any legal entity contravening Article 4 regarding the [ban of partially hydrogenated oils / maximum limit of industrially produced *trans*-fatty acids], Article 9 regarding the declaration of conformity, or Articles 5, 6 and 7 regarding labeling.
3. A natural person or small legal entity that commits an offence for the first time may be issued a warning instead of a fine pursuant to Subarticles 1 and 2 of this article with [number] months to correct the offending circumstances contravening this Regulation. If, after the expiration of [number] months, the offending circumstances have not been remedied, a fine pursuant to Subarticles 1 and 2 shall be imposed.
4. When an offence defined under this article is committed for a second time, the fines pursuant to Subarticles 1 and 2 of this article may be doubled. If an offence is committed a third time and for any subsequent time, the fine may be tripled.
5. In addition to imposing a fine pursuant to Subarticles 1, 2, and 4 of this article, any administrative license held by a natural person or legal entity may be revoked, suspended, or its issuance or renewal denied. In grave or repeat cases, the closure, suspension, or dissolution of the legal entity may be ordered.
6. The [agency] may mandate the recall or seizure and destruction, with costs borne by the manufacturer or importer,¹⁶ of any food:
 - a. That contains [partially hydrogenated oils / industrially produced *trans*-fatty acids above the established limit] contravening Article 4; or
 - b. That does not comply with the labeling requirements of Articles 5, 6 and 7; or
 - c. For which a declaration of conformity pursuant to Article [number] has not, or has fraudulently, been issued.
7. The penalties and sanctions of this article may be reduced or waived if a natural person or legal entity commits an offence defined in Subarticles 1 and 2 relying in good faith on a declaration of conformity pursuant to Article [number].
8. [Falsifying documents such as declarations of conformity or import documents, removing or hiding evidence, or hindering inspections shall incur criminal liability in accordance with [Chapter/Section] [number] of the Penal Code.]
9. [Violations of this Regulation resulting in grave harm to the health or physical integrity of a person may incur criminal liability in accordance with [Chapter/Section] [number] of the Penal Code if such violations are committed with willful intent or gross negligence.]

¹⁶ The national regulation may provide for enforcement actions such as seizures and injunctions applicable to food products violating food regulations to stop the continued production, distribution, and sale of such noncompliant food products. A reference to such provisions can be an alternative to including them in the TFA regulation.

Article 11 – Complaint Mechanism

The [agency] shall establish a reporting and complaint mechanism through a hotline or website, and shall investigate all credible reports of violations.

1.6 Effective Date

Article 12 – Effective Date

Option 1: single effective date

This Regulation shall enter into force [number] [days/months] after its publication in the Official Gazette.¹⁷

Option 2: structured transition period based on type of food industry actor

1. This Regulation shall enter into force [number] [days/months] after its publication in the Official Gazette.
2. Notwithstanding Subarticle 1 of this article, large-scale food enterprises shall comply with this Regulation as from [date (for short-term rollout period)].
3. Notwithstanding Subarticle 1 of this article, small- and medium-scale food enterprises, restaurants, and vendors shall comply with this Regulation as from [date (for medium-term rollout period)].

Option 3: structured transition period based on type of product

1. This Regulation shall enter into force [number] [days/months] after its publication in the Official Gazette.¹⁷
2. Notwithstanding Subarticle 1 of this article, all oils and fats covered by this Regulation shall comply with this Regulation as from [date].
3. Notwithstanding Subarticle 1 of this article, all other foods covered by this Regulation shall comply with this Regulation as from [date].

Option 4: structured transition period: incremental reduction of industrially produced *trans*-fatty acids content¹⁸

1. This Regulation shall enter into force [number] [days/months] after its publication in the Official Gazette.¹⁷
2. Notwithstanding Subarticle 1 of this article, the content of industrially produced *trans*-fatty acids in all oils, fats, and foods shall not exceed 5 g per 100 g of total fat as from [date].
3. Notwithstanding Subarticle 1 of this article, the content of industrially produced *trans*-fatty acids in all oils, fats, and foods shall not exceed 2 g per 100 g of total fat as from [date].

Option 5: process-based timeline based on the stages of the supply chain

1. This Regulation shall enter into force [number] [days/months] after its publication in the Official Gazette.¹⁷
2. Notwithstanding Subarticle 1 of this article,
 - a. Oils, fats, and foods imported or manufactured after [date] shall comply with Article 4 regarding [maximum levels of industrially produced *trans*-fatty acids / the ban of partially hydrogenated oils];
 - b. Oils, fats, and foods shall be labeled in compliance with Articles [numbers] from [date];
 - c. Oils, fats, and foods not in compliance with this Regulation may continue to be sold until [date].

17 Countries have different legal requirements and customs for when newly passed laws or regulations go into effect. The effective date should align with the standard practice of that country.

18 This approach is only possible if an iTFA limit is being implemented (not applicable to regulations implementing a PHO ban).

1.7 Miscellaneous Provisions

Article 13 – Monitoring and Evaluation

1. The [agency] shall be responsible for monitoring the implementation and enforcement of this Regulation and for evaluating its impact.
2. The [agency] shall establish a sampling plan and adopt a strategy to monitor the following indicators at a minimum:
 - a. Content of industrially produced *trans*-fatty acids in oils, fats, and other food products;
 - b. Oils and fats used to replace industrially produced *trans*-fatty acids in food products;
 - c. Compliance with this Regulation;
 - d. Emerging scientific and independent evidence on the health harms of industrially produced *trans*-fatty acids and international nutrition guidance on recommended limits of industrially produced *trans*-fatty acids in food products;
 - e. [Population intake of *trans*-fatty acids];
 - f. [Health impact of this Regulation].
3. The [agency] shall make a monitoring and evaluation report publicly available every 12 months, adhering to applicable data privacy laws.

Article 14 – Multi-agency Coordination Group

Option 1: establish multi-agency coordination group

1. A multi-agency coordination group shall be established to [coordinate/support and advise on] the implementation and enforcement of this Regulation.
2. The multi-agency coordination group shall have the following responsibilities:
 - a. Advise on new laws, regulations, and other policies in respect to *trans*-fatty acids;
 - b. Provide guidance on appeals against enforcement measures;
 - c. Make recommendations on the issuance, renewal, suspension, or revocation of licenses;
 - d. Make suggestions on how to improve enforcement;
 - e. Serve as focal point for issues on *trans*-fatty acids for national, subnational, and local agencies, and other countries;
 - f. Assist and contribute public information activities on *trans*-fatty acids.
3. The multi-agency coordination group shall comprise representatives from all relevant enforcement authorities, including [names of authorities]. The group may invite academics and other experts, but not food industry representatives and their agents, to participate or observe, as appropriate.
4. The multi-agency coordination group shall develop terms of reference. Roles and responsibilities shall be determined [include process]¹⁹ for the implementation of this Regulation.

Option 2: mandate an existing multi-agency coordination group

1. The [name of existing multi-agency coordination group on food/nutrition] shall be responsible for coordinating the implementation and enforcement of this Regulation and for advising and supporting competent enforcement authorities.
2. The [name of the existing multi-agency coordination group] shall have the following responsibilities:
 - a. Advise on new laws, regulations, and other policies in respect to *trans*-fatty acids;
 - b. Provide guidance on appeals against enforcement measures;
 - c. Make recommendations on the issuance, renewal, suspension, or revocation of licenses;
 - d. Make suggestions on how to improve enforcement;
 - e. Serve as focal point for issues on *trans*-fatty acids for national, subnational, and local agencies, and other countries;
 - f. Assist and contribute public information activities on *trans*-fatty acids.

¹⁹ Depending on the legal system, the roles and responsibilities might be determined in the terms of reference or by a directive or notification issued by the government organ responsible for the adoption of the TFA regulation.

2. Conducting an Inventory of Current Policies



The policy inventory provides an overview of provisions that should be in place for an effective TFA regulation. The policy inventory can be used as a checklist to determine whether the existing regulatory framework already includes relevant provisions on TFA elimination. The policy inventory can also be used to compare the final draft of the TFA regulation against the checklist to ensure it is a strong and comprehensive regulation.

2.1 Policy Inventory

2.1.1 Authority to Regulate *Trans*-fatty Acids

- Authorizes appropriate agencies:²⁰
 - To set mandatory limits on harmful compounds in food; AND
 - To inspect facilities; AND
 - To inspect products; AND
 - To hold violators accountable (i.e., to impose and collect fees and impose sanctions).

2.1.2 Scope of Regulation

- Sets mandatory limits as:
 - PHO ban; OR
 - iTFA limit at 2%; OR
 - PHO ban and iTFA limit at 2%.
- Defines PHOs or iTFAs with:
 - No exceptions; OR
 - Limited evidence-based exceptions.

²⁰ The authority to regulate *trans*-fatty acids might not be specific to this harmful compound but a broader authority to regulate food and/or nutrition.

- Includes all food product categories and facilities with:
 - No exceptions; OR
 - Limited exceptions that pose no health risk (such as use in research).

2.1.3 Labeling

- Requires labeling on prepackaged food to support inspections:
 - Ingredients list with PHOs clearly identifiable; AND
 - Nutrient declaration with TFA levels clearly indicated; AND
 - Imposes appropriate conditions on TFA-free claims.

2.1.4 Implementation and Enforcement

- Allows for inspection and enforcement of:
 - Critical control points; AND
 - All other relevant points of supply chain.
- Defines liability and offences:
 - Civil; AND/OR
 - Criminal; AND/OR
 - Administrative.
- Sets proportionate and deterrent penalties.
- Establishes a complaints mechanism.

2.1.5 Effective Date

- Sets effective date of 6–18 months following publication.
- Implemented fully by 2023.

2.1.6 Other Provisions

- Defines key terms.
- Establishes objectives for regulation.
- Requires regular monitoring and evaluation.
- Encourages cooperation within government through multi-agency coordination group.
- Includes miscellaneous provisions required under national law.

3. Explanations on Model Regulations for the Elimination of Industrially Produced *Trans*-fatty Acids



3.1 Objectives

Defining the regulatory objective(s) is important in order to think through the legislative project from the outset, identify challenges and barriers to achieve the regulatory objective(s), and set parameters and define mechanisms to achieve the objective(s). A clear definition of the objective(s) also enables monitoring and evaluation to determine whether the TFA regulation was successful, thus improving accountability. By linking the TFA regulation via the objective to a clear public health goal and explaining how the measure will support achievement of this goal, this section can help mitigate any potential legal challenges.

Public health goals of iTFA elimination are:

- Protection of the population / lives saved from these harmful substances;
- Prevention and reduction of cardiovascular diseases, type 2 diabetes, and other noncommunicable diseases caused by TFAs;
- Savings in healthcare costs with respect to the treatment of TFA-related diseases;
- Savings in indirect costs through a reduction in absenteeism and lost productivity.

The protection of domestic manufacturers and products is not a valid reason to adopt and implement regulation on iTFA elimination. The focus should be on health benefits and secondary benefits such as the economic benefits²¹ of a healthier population.

21 Local estimates show that iTFA elimination is cost-effective, see:

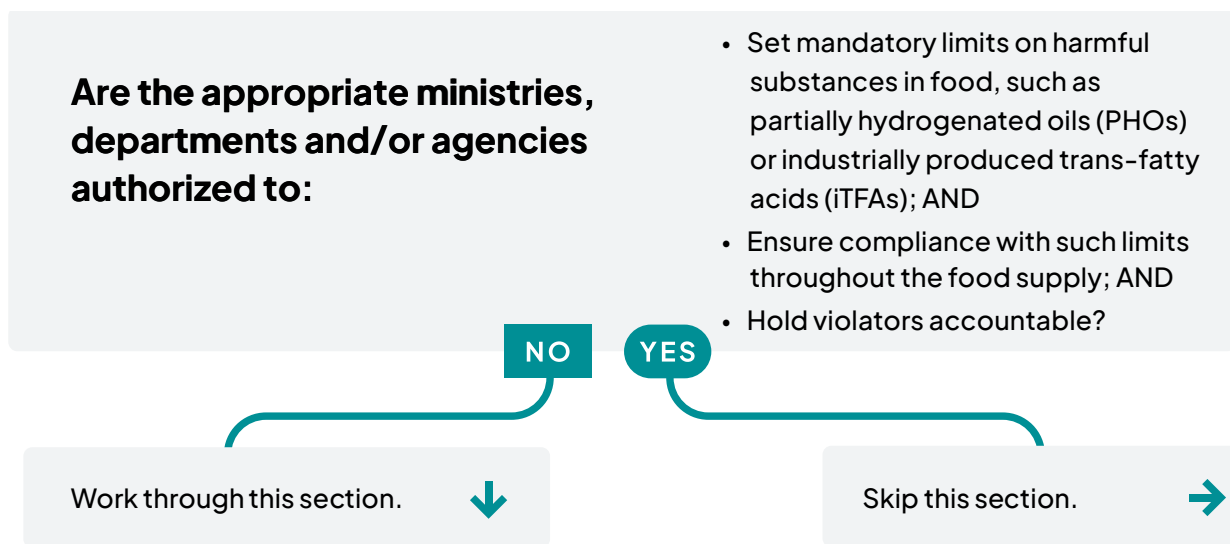
- Rubinstein A et al. Eliminating artificial trans fatty acids in Argentina: estimated effects on the burden of coronary heart disease and costs. *Bull World Health Organ.* 2015;93:614–622. doi: 10.2471/BLT.14.150516
- Pearson-Stuttard J et al. Cost-effectiveness analysis of eliminating industrial and all trans fats in England and Wales: modelling study. *J Pub Health.* 2017;39(3):574-582. doi: 10.1093/pubmed/fdw095

Depending on the legal system, the objectives might be expressed in a preamble or as an objective clause to the TFA regulation itself, or it might form part of a policy document and/or communication strategy of the authority in charge of drafting the TFA regulation.

SUGGESTED LEGAL LANGUAGE²²

The objective of this [regulation/order/notification] is to eliminate industrially produced *trans*-fatty acids from the national food supply by replacing them with healthier alternatives high in unsaturated fatty acids to protect the public from these harmful substances causing cardiovascular diseases and other noncommunicable diseases. Restricting the use of industrially produced *trans*-fatty acids in foods, including fats and oils, and requiring adequate labeling informing consumers of the presence of *trans*-fatty acids aims to reduce the incidence of diseases related to the consumption of *trans*-fatty acids and decrease associated health care and indirect costs.

3.2 Authority to Regulate *Trans*-fatty Acids



- Allen K et al. Potential of trans fats policies to reduce socioeconomic inequalities in mortality from coronary heart disease in England: cost effectiveness modelling study. *BMJ*. 2015;351:h4583. doi: 10.1136/bmj.h4583
- Commission staff working document. Impact assessment accompanying the document Commission Regulation (EU) amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in animal fat, in foods intended for the final consumer. European Commission, Brussels: 2019. Available from: https://ec.europa.eu/food/sites/food/files/safety/docs/fs_labelling-nutrition_transfats_swd_ia-pt01.pdf
- Burns, R. Estimate of Costs and Benefits of Removing Partially Hydrogenated Oils (PHOs) from the US Food Supply. Memorandum from the Office of the Commissioner to the Office of Food Additive Safety. Department of Health and Human Services, Food and Drug Administration, Washington D.C.: 2015. Available from: <https://www.who.int/docs/default-source/documents/replace-transfats/l-elements-of-economic-analysis.pdf>

²² Unless specified otherwise, the sections on suggested legal language are based on country experience.

3.2.1 Authority for Regulation and Enforcement

One or several government agencies should already have the legal authority, and might be required, to implement and enforce regulations on food hazards.²³ For example, sanitary inspectors and customs authorities might already by law be authorized and empowered to implement and enforce existing food and nutrition regulations on harmful substances as part of their mandate. Similarly, a food regulator might be authorized and empowered to issue administrative penalties when such regulations are infringed upon.

If the authority for implementation and enforcement activities is not clear or has not been delegated, it is essential to make it clear or delegate it; otherwise, the TFA regulation will never be properly implemented.²⁴ During the policy landscape assessment (refer to the Annex), it should have become evident which agency (or agencies) could fulfill the implementation and enforcement functions.

Integration with permit or licensing schemes

Many countries already have permit or licensing schemes in place that require businesses that manufacture, process, pack, import, or sell food to register and maintain a valid permit or license to operate within the country. It is probable that the regulations underpinning such schemes already contain provisions on authority to regulate and enforce food law. If this is the case, check the legal language carefully. It might be possible to amend the existing provisions to add the necessary authority to regulate industrially produced trans-fatty acids (iTFA) and incorporate a ban on partially hydrogenated oil (PHOs) and/or 2% iTFA limit in the existing schemes.

Granting such authority allows the regulatory agency to make the issuance and renewal of licenses and permits conditional upon compliance with a trans-fatty acid (TFA) regulation. Businesses are dependent on maintaining valid permits and licenses to operate; therefore, complying with a TFA regulation and other food law requirements is a business imperative. Consequently, such schemes are a very effective enforcement measure, in addition to not requiring excessive additional capacity or costs.

23 It is assumed that one or several government authorities already exist that can regulate, implement, and enforce regulations governing food and nutrition. If this is not the case, such an authority must first be established. It goes beyond the scope of this document to provide guidance on how to establish such an authority. If there are no appropriate legal instruments governing food products that could be amended, or the executive bodies do not have the authority to adopt or amend regulations, parliament (or its equivalent depending on national circumstances) must either authorize an executive body to adopt regulation or pass a law mandating iTFA elimination. The food control system assessment tool designed by the Food and Agriculture Organization of the United Nations and the World Health Organization can be used to analyze the performance of the national food control system and to identify priority areas of improvement. See: Food and Agriculture Organization (FAO) and World Health Organization (WHO). Food control system assessment tool. Food safety and quality series No. 7/1 to 7/5. Rome; 2019. Available from: <http://www.fao.org/documents/card/en/c/ca5334en>

24 For example, it might be more appropriate to delegate authority and describe responsibilities in other laws, regulations, or rules governing enforcement mechanisms for overall food and nutrition than the TFA regulation by adding provisions there. Depending on the legal system, it might be necessary to issue an administrative order rather than amending existing laws and regulations. Whichever approach is most appropriate, it should legally define which responsibilities are delegated, to whom, and under what conditions.

Regularly, permit and licensing schemes require businesses to pay fees to obtain and renew permits and licenses. It might be possible to increase fees to account for necessary TFA enforcement measures such as inspections and other compliance checks. Alternatively, it might be possible to charge for compliance checks, such as laboratory tests of food products.

Where permit and licensing schemes for the food industry do not exist, a limited system could be established as an interim measure for those businesses that contribute most to the TFA burden, such as importers of food that tend to be high in iTFAs, or manufacturers of PHOs, while the country establishes a more comprehensive scheme that covers food hazards in general.

SUGGESTED LEGAL LANGUAGE

OPTION 1: DELEGATION OF AUTHORITY (SINGLE AGENCY)

The [agency]* shall have the responsibility to:

- a. oversee and monitor the implementation of this [regulation/order/decree];
- b. adopt and implement additional [policies, standards, decrees, orders, and guidelines] to implement and enforce this [regulation/order/decree];
- c. inspect and investigate facilities and products for compliance with this [regulation/order/decree];²⁵
- d. initiate complaints²⁶ and seek appropriate penalties²⁷ for violations of this [regulation/order/decree];
- e. initiate an amendment of this [regulation] if new scientific and independent evidence emerges and/or international nutrition guidance changes on recommended limits of industrially produced *trans*-fatty acids in food products;
- f. issue recommendations or [directives]²⁸ on healthy replacement options for industrially produced *trans*-fatty acids;
- g. [establish, convene, and chair a multi-agency coordination group for the implementation and enforcement of this [regulation/order/decree]]²⁹.

OPTION 2: DELEGATION OF AUTHORITY (MULTIPLE AGENCIES)

The [agency A]* shall have the responsibility to:

- a. [task]
- b. [task]

The [agency B]* shall have the responsibility to:

- a. [task]
- b. [task]

The [agency C]* shall have the responsibility to:

- a. [task]
- b. [task]

25 Refer to [Section 3.5.1](#) Inspection of Critical Control Points for guidance.

26 Refer to [Section 3.5.4](#) Complaints and Reporting Mechanism for guidance on establishing a complaints mechanism for the public.

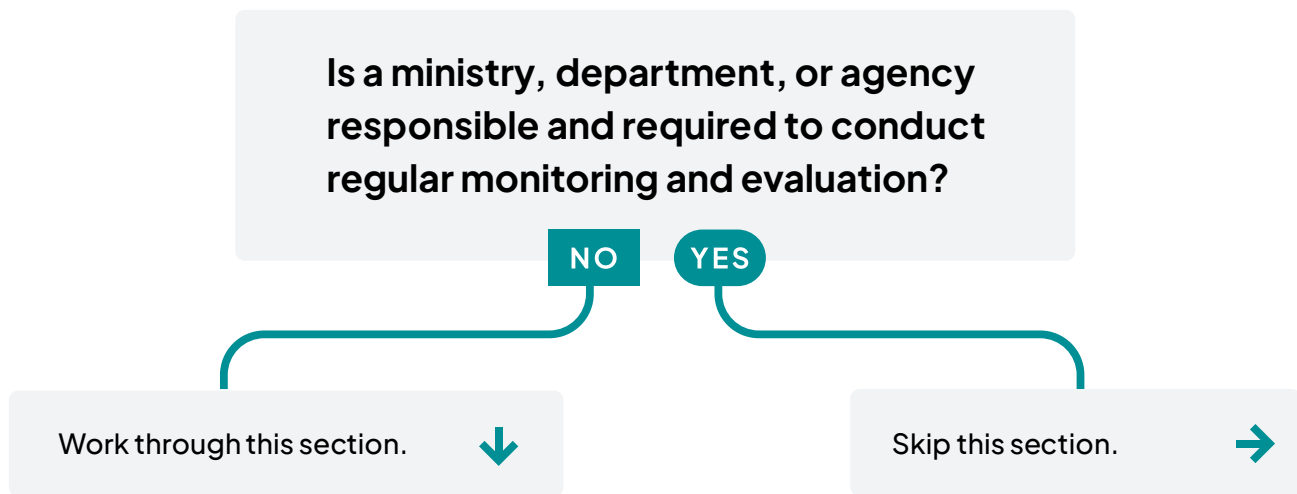
27 Refer to [Section 3.5.3](#) Liability, Offences, and Penalties for more information.

28 Insert the name of the appropriate legal instrument – it should be lower in the legal hierarchy than the TFA regulation.

29 Only insert if a multi-agency coordination group is to be established. Refer to [Section 3.7.2](#) Multi-agency Coordination Group for guidance.

* Insert the name of the appropriate regulatory authority.

3.2.2 Authority for Monitoring and Evaluation



A regulatory body or independent institution should already have the authority, and might be required, to monitor and evaluate the effectiveness of TFA regulation.³⁰ For example, a food regulator might already by law be authorized, required, and empowered to monitor and evaluate regulations on food hazards as part of its mandate; as such, a newly introduced PHO ban, for example, would not require authorizing an agency for monitoring and evaluation.

If the responsibility for monitoring and evaluation is not clear or has not been delegated, it is important to make it clear or delegate it. During the policy landscape assessment (refer to the Annex), it should have become clear which agency (or agencies) could fulfill this function. In some countries, an academic or other independent organization (without ties to industry) can be charged with monitoring and evaluating government policies.

At a minimum, the monitoring and evaluation activities should encompass monitoring the TFA content in the food supply, replacement oils and fats used, compliance with the TFA regulation, and assessing emerging evidence to decide whether the TFA regulation needs revising (e.g., if new evidence were to suggest a lower TFA limit to be more effective).

³⁰ It is assumed that one or several government authorities already exist that are able to monitor and evaluate the implementation of a TFA regulation as part of an overarching monitoring scheme for food additives, harmful substances, etc. If this is not the case, such an authority must first be established. It goes beyond the scope of this document to provide guidance on how to establish such an authority.

If the requisite capacity and resources are available, it would be beneficial to monitor changes in consumption patterns of TFAs and the health impact of the TFA regulation.

The agency should be required to publish the findings and conclusions of its activities regularly and publicly in accordance with data privacy and other laws.

Refer to Module 4: Assess of WHO's REPLACE action package for information on how to conduct monitoring for TFA elimination.³¹

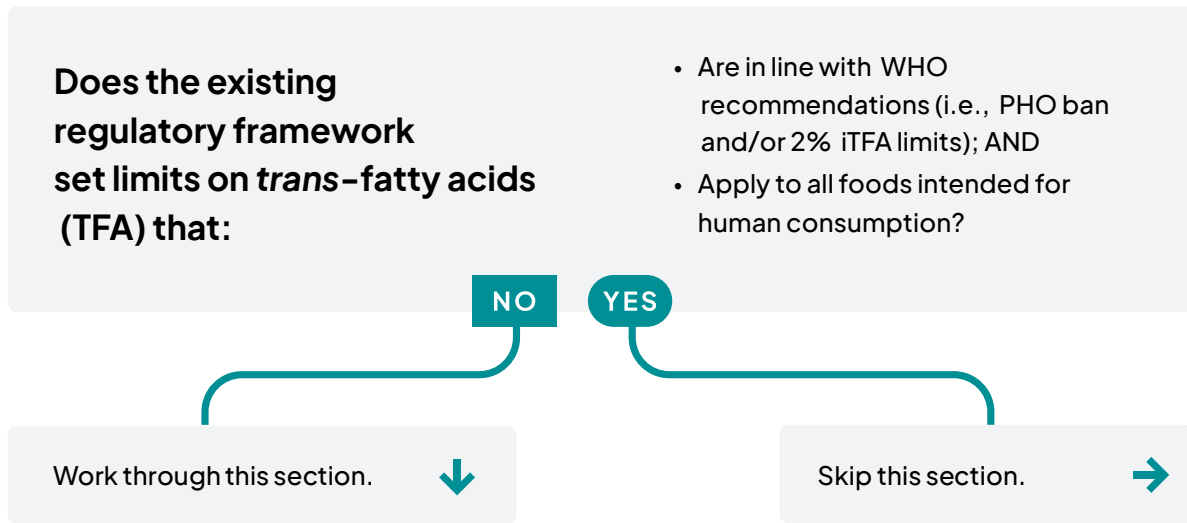
SUGGESTED LEGAL LANGUAGE

1. The [agency]* shall be responsible for monitoring the implementation and enforcement of this [regulation/order/notification] and for evaluating its impact.
2. The [agency]* shall establish a sampling plan and adopt a strategy to monitor the following indicators at a minimum:
 - a. Content of industrially produced *trans*-fatty acids in oils, fats, and other food products;
 - b. Oils and fats used to replace industrially produced *trans*-fatty acids in food products;
 - c. Compliance with this [regulation/order/notification];
 - d. Emerging scientific and independent evidence on the health harms of industrially produced *trans*-fatty acids and international nutrition guidance on recommended limits of industrially produced *trans*-fatty acids in food products;
 - e. [Population intake of *trans*-fatty acids];
 - f. Health impact of this [regulation/order/notification];
 - g. [Health impact of the oils and fats used to replace industrially produced *trans*-fatty acids in food products].
3. The [agency]* shall make a monitoring and evaluation report publicly available every 12 months, adhering to applicable data privacy laws.

* Insert the name of the appropriate regulatory authority.

31 REPLACE action package. Module 4: Assess. How-to guide for trans fat surveillance. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324823/WHO-NMH-NHD19.15-eng.pdf>

3.3 Scope of the Regulation on *Trans*-fatty Acids



3.3.1 Best-practice Approaches

PHOs are the main source of iTFAs and, thus, a direct target for elimination. Alternatively, setting an appropriate cap on the amount of iTFAs in foods ensures total TFA levels remain low. The recommended best-practice approaches to eliminate iTFAs are:

1. PHO ban;
2. 2% iTFA limit: limiting iTFAs to 2 g per 100 g of total fat in all foods;
3. Combination of the two policies: PHO ban and 2% iTFA limit.

Any of these three best-practice options will eliminate the vast majority of products that contain TFAs. Nevertheless, on the margins, there may be slight advantages or disadvantages for choosing one option over the other.

The focus of elimination are iTFAs because ruminant TFAs are not the main source of TFAs in the human diet, and limiting ruminant TFAs can be achieved by implementing recommendations on saturated fats (the source of naturally occurring TFAs are ruminant-derived food products that are high in saturated fats).

	Advantages	Disadvantages
PHO ban	<ul style="list-style-type: none"> • The focus is on upstream factors of iTFA elimination, i.e., PHO processing rather than food products manufactured using PHOs. • Countries that maintain lists of prohibited substances in food already have the regulatory framework and implementation mechanism in place to simply add PHOs to the other banned substances. • Countries with a limited number of domestic PHO manufacturers can achieve iTFA elimination in a manageable and cost-effective way by implementing a PHO ban. • A PHO ban avoids regulatory issues with trace amounts of iTFAs created in refinement and heating processing. 	<ul style="list-style-type: none"> • A laboratory method to specifically measure PHOs is not available. • Monitoring and enforcement of a PHO ban is difficult if most TFA-containing food is imported (i.e., partial hydrogenation happens outside the country), unless the imported products' labeling (ingredient list) is reliable.
2% iTFA limit	<ul style="list-style-type: none"> • Monitoring is possible as TFA content can be tested in laboratories (however, note that a universally recognized method to distinguish between ruminant and industrially produced TFAs does not exist). • A 2% iTFA limit covers all processed and refined oils, independent of the industrial process used. 	<ul style="list-style-type: none"> • The implementation of a 2% iTFA limit can be a challenge for small and medium-sized producers, restaurants, and vendors who may not be able to measure the TFA content in their food.
Combination of PHO ban and 2% iTFA limit	<ul style="list-style-type: none"> • Combines advantages of the PHO ban and 2% iTFA limit (see rows above). • Targets iTFAs from PHOs and refined oils, in situations where both are sources of TFA intake. 	<ul style="list-style-type: none"> • Small and medium-sized producers, restaurants, and vendors might find the implementation of combined restrictions burdensome or difficult. • If the provisions restricting PHOs and iTFAs are phrased incoherently, it might create confusion, for example, when enforcing the regulation. This issue can be avoided by proper regulatory drafting.

3.3.2 Decision Guide

The following decision guide³² helps determine whether a PHO ban, a 2% iTFA limit, or a combination of both are most appropriate for a country's context. The results of the policy landscape assessment will be helpful when working through the decision guide.

Important legal and political considerations

CONSIDERATIONS	TRANS-FATTY ACIDS (TFA) LIMIT SHOULD BE CONSIDERED IF:	PARTIALLY HYDROGENATED OILS (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 labeling – 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	Neighboring countries or countries within an economic union have similar policies	Neighboring countries or countries within an economic union have similar policies
Political support	Influential support is likely	Influential support is likely

32 Source: REPLACE action package. Module 3: Legislate or regulate. How-to guide for trans fat policy action. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324822/WHO-NMH-NHD-19.14-eng.pdf>

Important technical considerations for enforcing policies on TFAs

CONSIDERATIONS	TRANS-FATTY ACIDS (TFA) LIMIT SHOULD BE CONSIDERED IF:	PARTIALLY HYDROGENATED OILS (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 labeled 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-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 equivalent) to be listed as an ingredient</p>

3.3.3 The Easiest Approach to a Best-practice Policy

From a regulatory drafting perspective, the easiest way to eliminate iTFAs is by adding PHOs to a list of prohibited substances deemed unsafe for human consumption (e.g., arsenic, lead, and certain artificial colorings and preservatives) or removing them from a list of substances deemed safe for human consumption. Alternatively, the list of substances could be amended to prohibit more than 2 g of iTFAs per 100 g of total fat. Inclusion on this list should trigger automatic restriction across the food supply and grant the government key powers to implement the restriction. However, this approach works only in very specific circumstances set out below.

First, this approach only works if food law already covers harmful compounds and a list of prohibited (or permitted) substances is maintained. If this is given, PHOs or excessive iTFAs can be treated like any other harmful substance by being added to the list. The existing implementation and enforcement structure for the list will automatically cover PHO or excessive iTFAs.

Second, including PHOs or excessive iTFAs in a list of prohibited substances (or removing them from a list of approved substances) requires a functioning regulatory framework and enforcement system governing food and nutrition. In other words, it necessitates that most supplementary measures already be in place, such as government agencies authorized to regulate, implement, and enforce prohibited, or permitted, substances and labeling provisions.

Country examples

Canada maintains a List of Contaminants and Other Adulterating Substances in Foods, which is incorporated by reference into its Food and Drug Regulations. Partially hydrogenated oils (PHOs) were added to this list, applicable to “all foods”.

In the United States of America, any substance intentionally added to food is considered an additive and, as such, is governed by the Federal Food, Drug, and Cosmetic Act. Additives require approval by the United States Food and Drug Administration, and lists of approved substances are kept.

Additives that are Generally Recognized As Safe (GRAS) do not need this specific approval. The United States Food and Drug Administration removed PHOs’ GRAS status in 2015, which resulted in a de facto PHO ban over the next few years.

3.3.4 Ban on Partially Hydrogenated Oils

Approach

The percentage of iTFAs in PHOs averages 25–45% of total fat (but can be as high as 60%), much higher than the TFA content in ruminant sources, which is about 3–6%; refined oils contain generally less than 2% of iTFAs, and cooking or heating creates below 3% of iTFAs in the oils used (8). Because of this high content of iTFAs in PHOs, PHOs are an effective target for regulatory action.

Banning PHOs, ultimately, classifies them as unsafe for human consumption, similar to prohibiting certain additives or compounds harmful to human health. Banning PHOs significantly lowers exposure of consumers to iTFAs.

Definition of PHOs

PHOs should be defined in a scientifically appropriate manner. Refer to [Section 3.7.1](#) Definitions for guidance on the definition of PHOs as well as other potentially necessary definitions.

Definition of Applicable Food Categories

The best practice is to ban PHOs for all foods to ensure iTFAs are eliminated. If exceptions are allowed, they should be very limited and restricted to PHO use for technical reasons that do not pose a risk to health. Examples of such acceptable exemptions are pan release agents or emulsifiers. However, excluding entire food categories from the PHO ban, such as dairy, would not count as exemption and is strongly discouraged as it would compromise the public health effect of the policy.

SUGGESTED LEGAL LANGUAGE

COMPLETE BAN

The production, import, [export], use, sale, and supply of any food, including fats and oils, that contain partially hydrogenated oil are prohibited.

OPTIONAL LIMITED EXCEPTION

The [agency]* may exempt products manufactured using partially hydrogenated oils from this restriction if such partially hydrogenated oils are used solely for industrial processing or are otherwise not intended for human consumption.

* Insert the name of the appropriate regulatory authority.

3.3.5 Limit of Two Percent for Industrially Produced *Trans*-fatty Acids

Limiting iTFAs to no more than 2 g per 100 g of total fat in all foods is also a best-practice policy and an equally good policy option as a PHO ban. It also results in a virtual elimination of iTFAs from the food supply.

Definition of the Limit for iTFAs, and Exceptions

It is recommended that a threshold limit be set of 2 g of iTFAs per 100 g of total fat in all foods (so-called “2% iTFA limit”). This threshold has been shown to be effective in significantly reducing iTFA intake and related mortality due to heart disease (6).

It is essential to extend the limit to all foods, not just oils and fats, as otherwise the iTFA content in food products can exceed 2%.

Exceptions to the 2% iTFA limit are not recommended. The 2% limit already gives producers some leeway for trace amounts of iTFAs that may occur inadvertently during production.

Notably, food products containing both naturally occurring and industrially produced TFAs are subject to the TFA regulation, such as dairy products containing PHOs. Equally, applying different limits to different categories (e.g., a 5% iTFA limit to foods and a 2% limit to oils and fats) is not an acceptable exemption and should be avoided. Both “exemptions” would significantly compromise the public health effect of the TFA regulation.

Importantly, the 2% iTFA limit should not be limited to foods sold to the final consumer, as this creates implementation issues. In other words, exemptions for foods sold to food industry actors (e.g., restaurants, vendors, and small-scale producers) should generally not be permitted; this to ensure all actors only work with oils, fats, and foods that adhere to the threshold limit. If exceptions are allowed, they should be very limited and based on evidence. For example, some emulsifiers or

pan release agents might contain excessive levels of iTFAs but applications for an exemption may be allowed provided that the final product does not exceed the 2% limit and no reasonable alternative replacements exist.

Definition of TFAs

TFAs should be defined in a scientifically appropriate manner. Whether iTFAs need to be defined depends on how the TFA regulation is structured. If ruminant (naturally occurring) TFAs are excluded from the scope of the TFA regulation, it might not be necessary. If ruminant TFAs are not excluded, iTFAs must be defined. Refer to [Section 3.7.1](#) Definitions for guidance on the definition of TFAs as well as other potentially necessary definitions.

SUGGESTED LEGAL LANGUAGE

LIMIT USING iTFA DEFINITION

The production, import, [export], use, sale and supply of oils, fats, or foods that contain more than 2 g of industrially produced *trans*-fatty acids per 100 g of total fat are prohibited.

ALTERNATIVE APPROACH: LIMIT USING TFA DEFINITION

1. The production, import, [export], use, sale and supply of oils, fats, or foods that contain more than 2 g of *trans*-fatty acids per 100 g of total fat are prohibited.
2. This article does not apply to naturally occurring *trans*-fatty acids.

OPTIONAL LIMITED EXCEPTION

The [agency]* may exempt defined food products from the limit on *trans*-fatty acids in [Article/Subarticle] [number] if such products are used solely for industrial processing or are otherwise not intended for human consumption.

* Insert the name of the appropriate regulatory authority.

3.3.6 Combination of a Ban on Partially Hydrogenated Oils and a Limit of Two Percent for Industrially Produced *Trans*-fatty Acids

Depending on the country context, a combination of the two best-practice policies can adequately address the particular circumstances and needs of the country. If drafted properly, this combination approach can provide all the advantages of both policies with fewer disadvantages.

For example, a PHO ban might address domestic PHO production, but the population may continue to be exposed to iTFAs produced through poor refining processes. In this case, combining the 2% iTFA limit with the PHO ban would help protect the population against such dangerous levels of iTFAs from sources other than PHOs.

Please refer to [Section 3.3.4](#) Ban on Partially Hydrogenated Oils, and [Section 3.3.5](#) Limit of Two Percent for Industrially Produced *Trans*-fatty Acids for a detailed discussion of the rationale for the suggested legal language.

SUGGESTED LEGAL LANGUAGE

MANDATORY LIMIT USING iTFA DEFINITION

The production, import, [export], use, sale and supply of oils, fats, or foods that contain partially hydrogenated oil or that contain more than 2 g of industrially produced *trans*-fatty acids per 100 g of total fat are prohibited.

ALTERNATIVE OPTION: LIMIT USING TFA DEFINITION WITH EXCLUSION FOR NATURALLY OCCURRING TFAs

1. The production, import, [export], use, sale and supply of oils, fats, or foods that contain partially hydrogenated oil or that contain more than 2 g of *trans*-fatty acids per 100 g of total fat are prohibited.
2. This article does not apply to naturally occurring *trans*-fatty acids.

OPTIONAL LIMITED EXCEPTION

The [agency]* may exempt defined products from the restrictions in [Article/Subarticle] [number] if such products are not intended for human consumption.

* Insert the name of the appropriate regulatory authority.

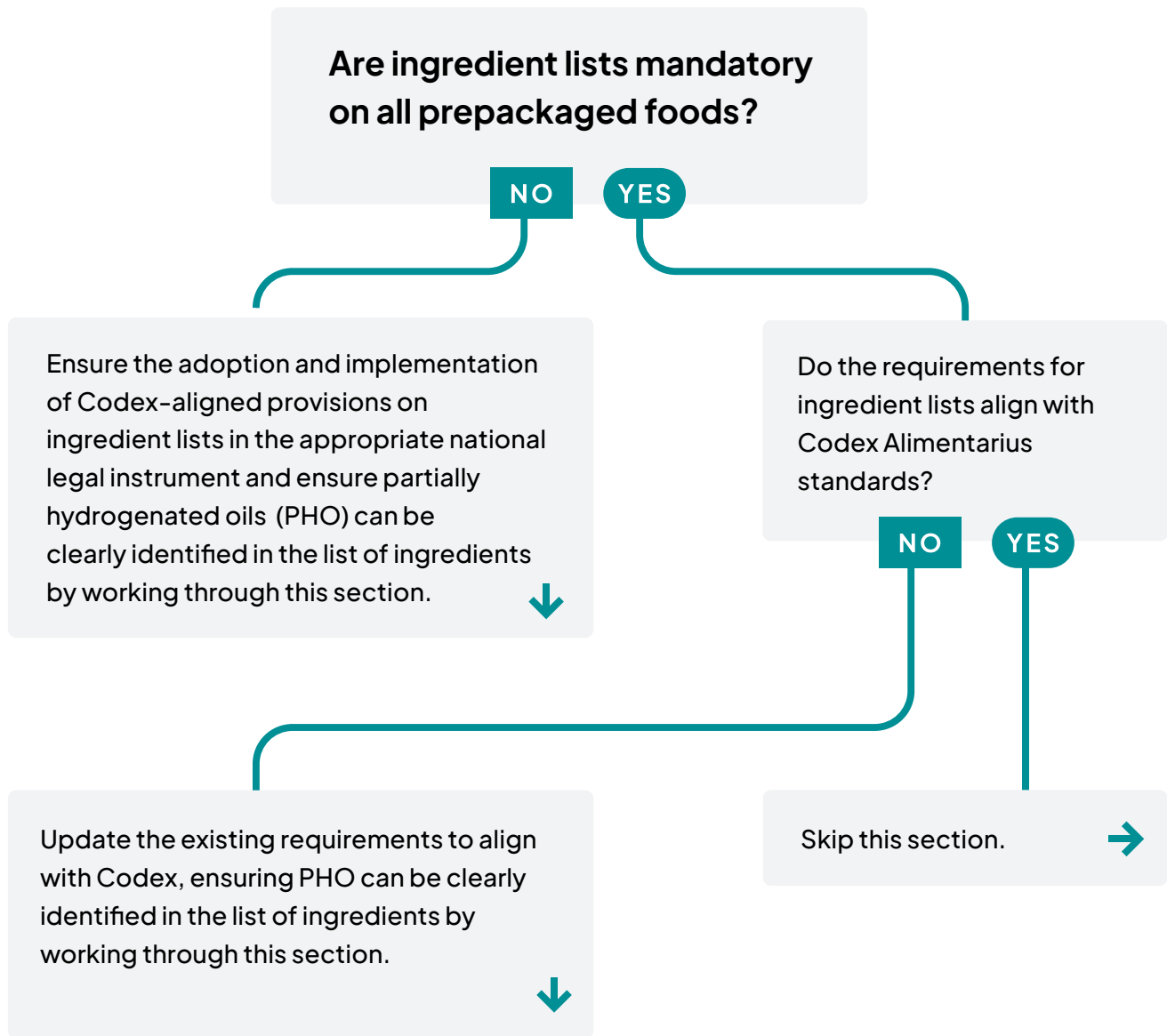
3.4 Labeling

Mandatory nutrition labeling is a recommended policy to promote healthy diets in general. Specifically for iTFA elimination policies, labeling can greatly facilitate inspection of products, which supports implementation, enforcement, and monitoring. In addition, nutrition labeling facilitates and increases consumer knowledge, and incentivizes food manufacturers to reformulate their products.

Note, however, that unpackaged food products do not bear nutrition labels, for example, unpackaged baked goods or street food. Raw ingredients are also often not labelled.

Countries should plan for additional enforcement and monitoring activities to ensure labels are accurate and legible.

3.4.1 Mandatory Ingredient List with Partially Hydrogenated Oils Clearly Identifiable



Most countries have laws that require ingredients lists on foods in line with Codex standards.³³ *The Codex General Standard for the Labelling of Prepackaged Foods*³⁴ contains the international standard for the labeling of prepackaged foods offered to consumers or used in catering, including on how to declare a list of ingredients and provisions on the listing of oils and fats. Given its universal acceptance, it is important that legal language not deviate from the General Standard. The suggested legal language below follows the provisions of the General Standard.

Mandatory ingredient lists should state all ingredients in descending order of their weight. The lists not only help consumers understand the contents of the food but also support monitoring and enforcement by enabling easy detection of PHOs as ingredients. However, this is only possible if PHOs are described consistently. For example, if the term “hydrogenated oil” is used, it is not clear whether partially or fully hydrogenated oil was used (fully hydrogenated oils do not contain iTFAs and are not within the scope of a TFA regulation). Similarly, “vegetable oil” might indicate PHOs, but this is not certain. Therefore, in order to make PHOs easily identifiable, it is important that labeling regulations require food manufacturers disclose whether oils are partially hydrogenated.

Note that margarine and vegetable shortening can be potential sources of PHOs in food products. They are often listed in the ingredient list without specifying their ingredients in parentheses immediately following their common name, “margarine” or “shortening”. Their presence might indicate that the product contains PHOs, which should alert inspectors to the need to obtain more information on the product (for example, by sending samples to a laboratory for testing, asking for documentation on the product, or carefully checking a declaration of conformity).

The ingredient list should not be used to imply that a product is TFA-free by using terms such as “unhydrogenated” or “nonhydrogenated” as this would constitute marketing.

As a reminder, a standard laboratory test for PHOs does not (yet) exist, which is why mandatory ingredient lists requiring the disclosure of PHOs are so important.

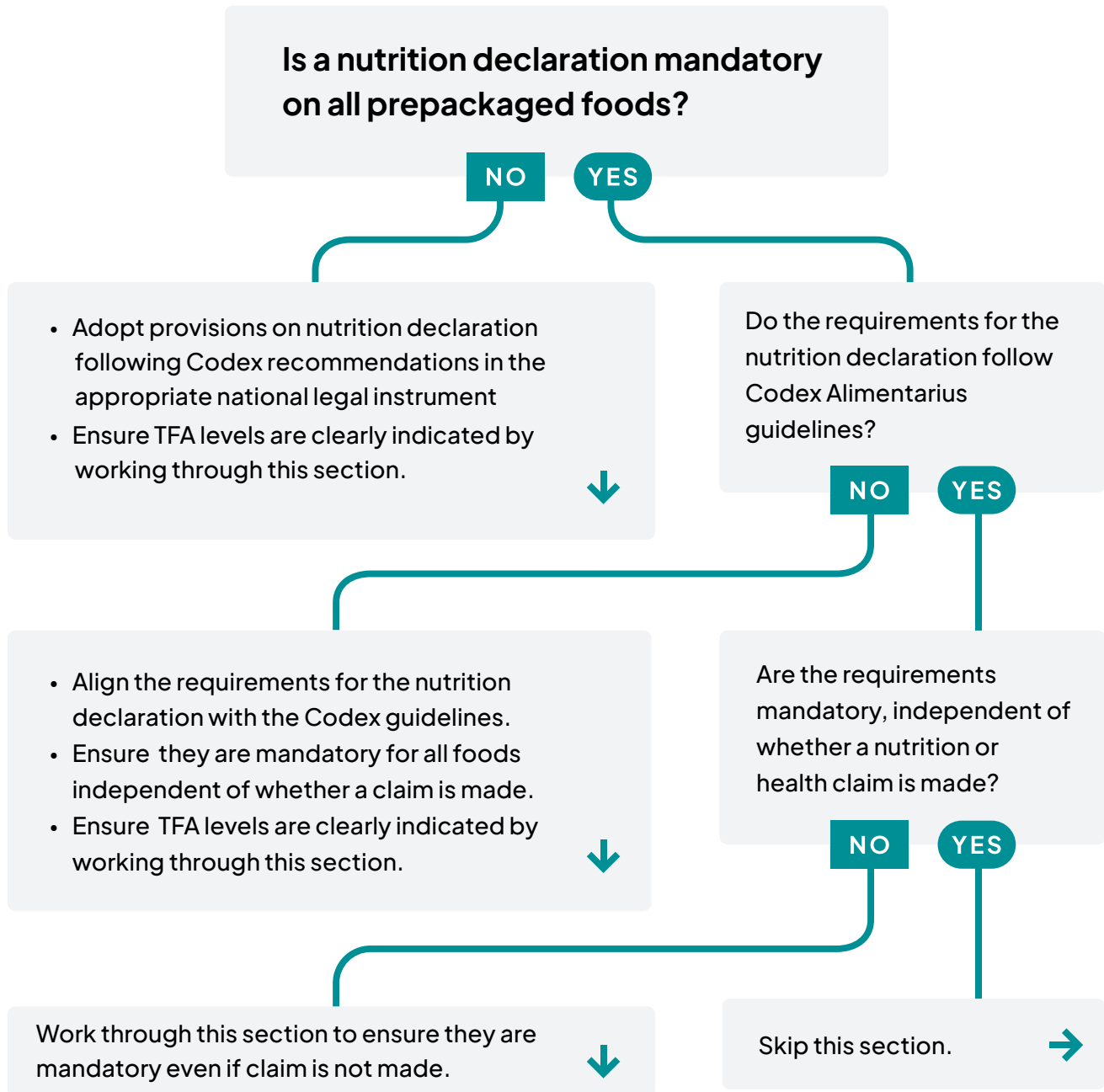
SUGGESTED LEGAL LANGUAGE

1. In the list of ingredients, refined oils shall be stated as “oil” together with either the term “vegetable” or “animal”.
2. Where an oil has undergone hydrogenation, the list of ingredients shall qualify whether “fully hydrogenated” or “partially hydrogenated”.
3. The use of the terms “unhydrogenated”, “nonhydrogenated”, or similar terms, implying that oils and fats have not been partially or fully hydrogenated, is prohibited.

33 If existing regulations on food labeling do not require lists of ingredients, respective provisions should be included in the existing regulations. Alternatively, it may make sense to adopt a new legal instrument on food labeling in general, including provisions on lists of ingredients. If neither is possible, it should be considered whether language on ingredient lists, as proposed in this section, could be included in the TFA regulation.

34 Codex General Standard for the Labelling of Prepackaged Foods, CXS 1-1985.
Available from: <http://www.fao.org/3/Y2770E/y2770e02.htm>

3.4.2 Mandatory Inclusion of *Trans*-fatty Acids in Nutrient Declaration



The Codex Guidelines on Nutrition Labelling³⁵ contain recommendations on how nutrient declarations should be structured and states mandatory nutrients to be declared in nutrient declarations. They recommend that “Countries where the level of intake of *trans*-fatty acids is a public health concern should consider the declaration of *trans*-fatty acids in nutrition labelling.”

35 Codex Guidelines on Nutrition Labelling CAC/GL 2-1985.
Available from: <http://www.fao.org/fao-who-codexalimentarius/thematic-areas/nutrition-labelling/en/>

Furthermore, the Codex Guidelines for Use of Nutrition and Health Claims provide guidance on the conditions when making a nutrition or health claim.

A nutrient declaration contains information on the amount of each nutrient contained in the product, expressed per 100 g or 100 ml of food product, or stated per package or serving. As with the ingredient list, it provides important nutritional information to consumers, but it also helps monitor and enforce a 2% iTFA limit. High levels of TFAs can also indicate possible presence of PHOs. Where labeling is reliable, inspectors can check TFA content without having to have access to laboratories able to measure TFA content; vendors, restaurants, and smaller producers benefit from knowing the TFA content of the raw ingredients and food products they use when producing the food served and sold to consumers.

Labeling can also be used to create a baseline data on the TFA burden to evaluate the effectiveness of the TFA regulation.

The TFA content should be disclosed in a consistent and understandable statement following the Codex Alimentarius recommendations.

Where existing regulations on food labeling do not require a nutrient declaration,³⁶ or where they are required only when health and nutrition claims are made, respective mandatory provisions should be included in the existing regulations. Alternatively, it may make sense to adopt a new legal instrument on food labeling in general, including mandatory provisions regarding nutrient declaration. If neither is possible, consideration should be given as to whether language on nutrient declaration, as proposed below, could be included in the TFA regulation.

Note that the disclosure of the TFA content in a nutrient declaration includes TFAs from all sources, including industrial and natural sources. Consumers should be encouraged to reduce consumption of TFAs regardless of source, which is why the label discloses total TFAs. If inspectors review a label and find that total TFAs are less than 2% of all fat, then there is no need to test whether the amount of iTFAs exceeds the limit. On the other hand, if total TFAs exceed 2% of total fat, then inspectors may need to investigate further to determine whether the amount of iTFA exceeds the limit.

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%
Trans 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

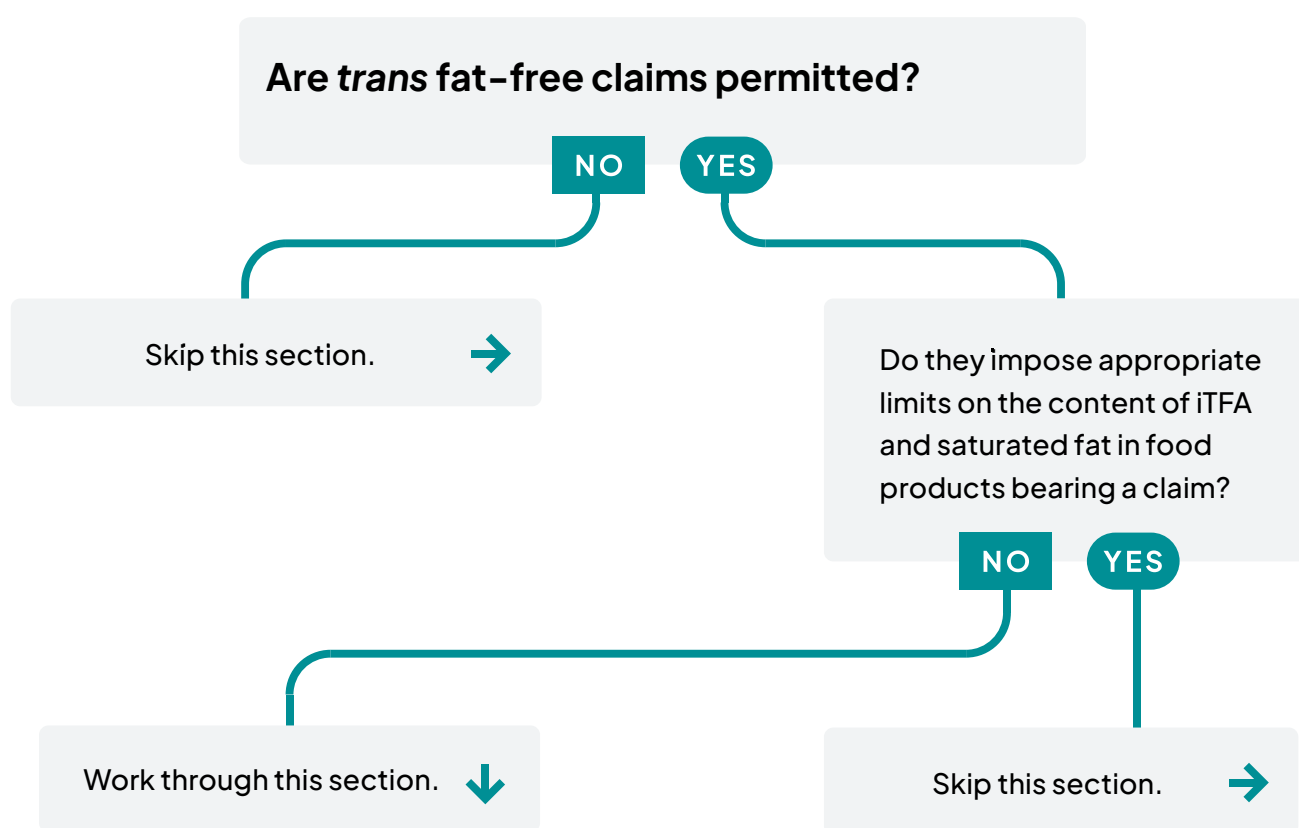
Example of a nutrient declaration

36 If "nutrient declaration" is not defined in a national food law, a definition is necessary (refer to [Section 3.7.1](#) Definitions for a proposed definition).

SUGGESTED LEGAL LANGUAGE³⁷

1. The amount of *trans*-fatty acids shall be stated in the nutrient declaration as “trans fat”³⁸, immediately following the declaration of the total fat content on a separate line.
2. The amount of *trans*-fatty acids shall be expressed in grams [milligrams] per 100 g or 100 ml [an in addition, it may also be presented per serving, provided the number of servings per package is stated]³⁹ of product.
3. [The amount of *trans*-fatty acids may be expressed as 0 g if the content of *trans*-fatty acids is not higher than 0 g [mg] per 100 g / ml of food product.]⁴⁰

3.4.3 *Trans* Fat-free Claim



37 The first two subarticles of the suggested legal language follow the Guidelines; the third subarticle is based on country experience.

38 Each jurisdiction should select a stated term that is most likely to be understood by the population whether “trans”, “trans fat” or “*trans*-fatty acids” or a local equivalent. The Codex Guidelines on Nutrition Labelling CAC/GL 2-1985 proposes the use of “trans fatty acids”. Canada uses “trans”. The United States of America uses “trans fat”.

39 Choose the one that fits your national labeling regulations requirements. You may also choose to require stating the TFA amount both per serving and per 100 g/ml.

40 Include this subarticle if you permit TFA-free claims and align the amount below which TFAs may be expressed as 0 g with the threshold for the TFA-free claim. If TFA-free claims are prohibited, this subarticle is not necessary. Refer to [Section 3.4.3 *Trans* fat-free Claim](#) for guidance.

Regulation should restrict the ability to use claims⁴¹ that a food product is free from, or low in, TFAs (TFA-free claim), be it on the food package, at the point of sale, or through marketing materials and activities. Using a TFA-free claim may create the impression that a product is a healthy or healthier choice when often such products are high in other unhealthy fats (often as replacement for TFAs) or nutrients. A TFA-free claim would single out products in an unwarranted way and constitute a form of misleading marketing communication by creating a “health halo”. In addition, any product should be free of iTFAs once a PHO ban and/or 2% iTFA limit has been implemented; therefore, using a TFA-free claim would be misleading for consumers. For these reasons, it is strongly recommended that TFA-free claims be prohibited.

If TFA-free claims are to be permitted, regulation should set clear requirements to justify such claims. Additionally, regulation should also set a threshold for saturated fat⁴² for products qualifying for a TFA-free claim to disincentivize food manufacturers from replacing iTFAs with saturated fat. Similar limits should be considered for sodium, sugars, and other targeted substances of concern. Consumers often view health and nutrition claims as nutritional endorsement; therefore, it is important to minimize the content of unhealthy substances in the food product.

SUGGESTED LEGAL LANGUAGE⁴³

RECOMMENDED: PROHIBITION OF TFA-FREE CLAIM

1. Claims that a product is free from, or low in, *trans*-fatty acids (“TFA-free claim”) are prohibited.
2. This article is applicable to claims appearing on the product packaging and off the product packaging, including, but not limited to, marketing materials, advertisements, and at the point of sale.

ALTERNATIVE OPTION: TFA-FREE CLAIM

1. Claims that a product is free from *trans*-fatty acids (“TFA-free claim”) are permitted if:
 - a. The content of *trans*-fatty acids in the finished product is not higher than 0 g [mg]⁴⁴ per 100g /ml of product; and
 - b. No more than 10% of energy of the finished product derives from saturated fat; and
 - c. [The content of sodium in the finished product is less than 1 mg per kcal]; and
 - d. [No more than 10% of energy of the finished product derives from free sugars]; and
 - e. [No more than 30% of energy of the finished product derives from total fat].
2. This article is applicable to claims appearing on the product packaging and off the product packaging, including, but not limited to, marketing materials, advertisements, and at the point of sale.

41 If “claim” is not defined in national law, such as a food law or marketing regulation, a definition is necessary (refer to [Section 3.7.1](#) Definitions for a proposed definition).

42 If “saturated fat” is not defined in the national food law, a definition is necessary (refer to [Section 3.7.1](#) Definitions for a proposed definition).

43 The suggested legal language is based on country experience and draft language on TFA-free claims by Codex (Codex work on TFA-free claims was discontinued). A Codex discussion paper of 2017 is available from: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-39%252Fnf39_09e.pdf

44 Please note that the limit and precision of TFA detection may vary by country.

3.5 Implementation and Enforcement

The effectiveness of a TFA regulation improves significantly with effective implementation and enforcement.⁴⁵ The goal is a system that grants the government broad authority to inspect products and facilities, and hold any violators accountable, while trusting officials with discretion to focus their limited resources on high-impact targets. Therefore, before embarking on the development and adoption of legislation or regulation, it is essential to also consider the country and local context, capacity, and challenges with respect to implementation and enforcement, and to account for them in the drafting stage. Work on an implementation plan should start early. Implementing a regulation can be challenging if it is not well considered during the development and analysis of policy options. The analysis of the country and local context will determine which of the suggestions in this toolkit take priority.

It is necessary to consider how compliance with the proposed TFA regulation will be ensured and whether the existing compliance and enforcement system for food law can accommodate the new regulation. If it cannot, provisions to provide for the authority and measures to implement and enforce the TFA regulation will need to be drafted, and their implementation planned for (for example, by setting aside funds for an increase in inspection officers or increasing laboratory capacity).

The most efficient and cost-effective way to implement and enforce a TFA regulation is by incorporating it into the existing implementation and enforcement structures of regulation governing sanitation, food, and nutrition. That way, existing financial and human resources can be leveraged. For example, inspections of PHO producers could be incorporated into existing food inspections for sanitation and hygiene, or compliance with the TFA regulation made a requirement to obtain, or maintain, permits and licenses.

While conflicts of interest and undue influence of the food industry must be managed, it is important to understand reasonable challenges to implementing a TFA regulation to ensure the TFA regulation and its implementation plan mitigate such challenges appropriately, such as through technical assistance or adequate transition periods.

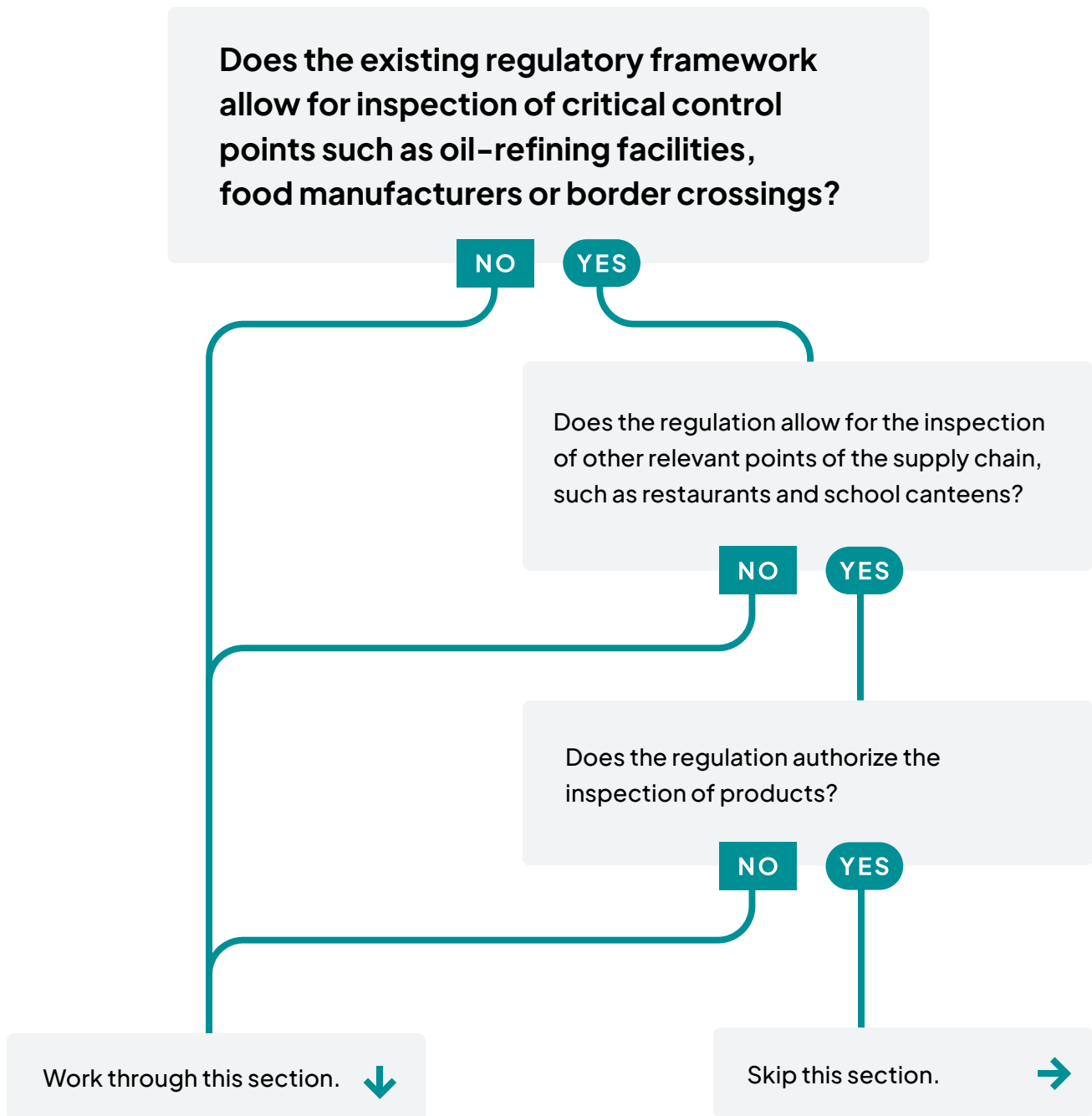
Refer to [Module 6: Enforce of WHO's REPLACE](#) action package for more general information on how to develop, launch and implement an enforcement plan.⁴⁶ In addition, FAO and WHO's food control system assessment tool can be used to analyze the performance of the national food control system and to identify priority areas of improvement.⁴⁷

45 It goes beyond the scope of this regulatory drafting toolkit to address all necessary aspects if a country does not yet have functioning implementation and enforcement mechanisms for food and nutrition regulation. This section limits itself to the most essential aspects of provisions necessary to ensure that a TFA regulation can be successfully implemented and enforced. Also refer to Section 3.4 Labeling, as labeling is an effective tool to support implementation and enforcement.

46 REPLACE action package. Module 6: Enforce. How-to guide for trans fat policies and enforcement of regulations. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324826/WHO-NMH-NHD-19.17-eng.pdf>

47 Food and Agriculture Organization (FAO) and World Health Organization (WHO). Food control system assessment tool. Food safety and quality series No. 7/1 to 7/5. Rome; 2019. Available from: <http://www.fao.org/documents/card/en/c/ca5334en>

3.5.1 Inspection of Critical Control Points



Targeted inspection of critical control points is an effective and cost-efficient enforcement approach. To determine the critical control points that require inspection, it is necessary to identify actors, places, and circumstances along the supply chain where noncompliance is most likely to occur. This might include oil-refining facilities, border crossings or ports of entry where most of a country's food imports enter the territory, food establishments with vulnerable populations such as cafeterias of health and child facilities, or food products likely to contain PHO and/or high levels of iTFAs such as margarines or fried and baked goods.

The responsibilities for implementation and enforcement that might need to be defined and delegated depend on the country context and the chosen TFA elimination policy. For example, if a PHO ban is implemented because the TFA burden stems from a few domestic PHO producers, subnational sanitary inspectors might be able to inspect facilities. However, if most iTFAs are consumed in imported, prepackaged food, a 2% iTFA limit or PHO ban would need to be implemented by the authorities responsible for customs clearance.

The following proposed legal language is intended to illustrate the necessary responsibilities of inspectors to effectively implement and enforce a TFA regulation. It is not meant to replace overarching regulation establishing inspection systems for food and sanitation or the respective agency (or agencies) responsible for such inspections.⁴⁸

SUGGESTED LEGAL LANGUAGE⁴⁹

INSPECTORS OF THE [AGENCY]* SHALL HAVE THE POWER AND DUTIES TO

- a. Inspect facilities where oils, fats and other food products are processed, refined, manufactured, prepared, packaged, labeled, or served, with or without advance notice;
- b. Search premises where violations of this [regulation/order/notification] are suspected;
- c. Review and request documents and records on products and the supply chain from natural persons or legal entities engaged in the import, export, manufacturing, storing, distributing, selling, or using of oils, fats, or other food products;
- d. Collect and analyze food samples;
- e. Train regulated entities;
- f. Seize food products;
- g. Report violations;
- h. Investigate complaints;
- i. Issue warnings or other penalties pursuant to [regulations];⁵⁰
- j. Suspend licenses to operate food businesses on a temporary basis.

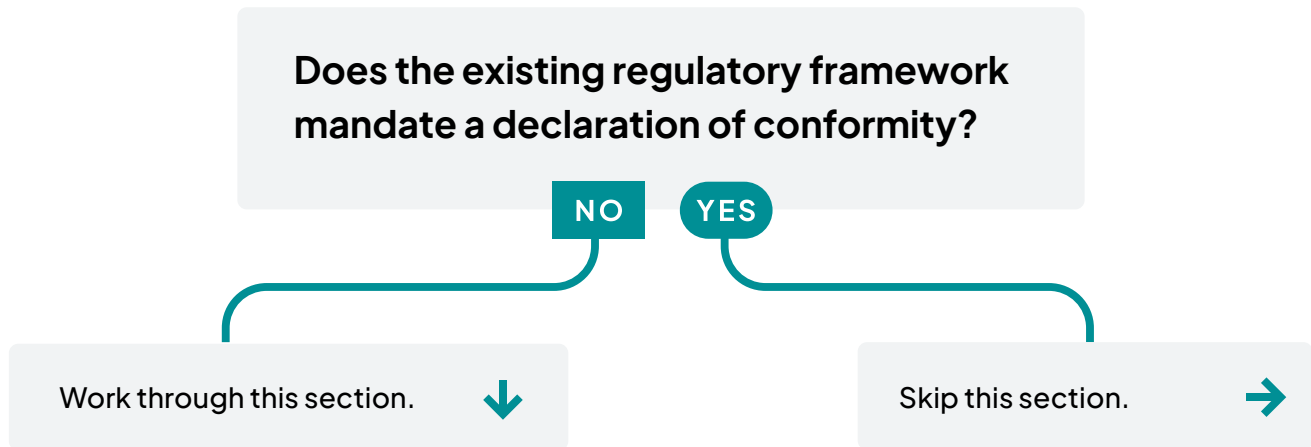
* Insert the name of the appropriate regulatory authority.

48 It is assumed that one or several government authorities already exist that have the authority to inspect critical control points in relation to food products, as well as a functioning inspection system (which would also include existing regulations or guidelines defining the qualifications, training, and certifications necessary for inspectors as well as their responsibilities). If this is not the case, such an authority and/or inspection system must first be established. It goes beyond the scope of this document to provide guidance on how establish an inspection authority and system.

49 Based on: REPLACE action package. Module 6: Enforce. How-to guide for trans fat policies and enforcement of regulations. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324826/WHO-NMH-NHD-19.17-eng.pdf>

50 Insert the name(s) of regulation(s) containing the penalties and measures inspectors can issue/take.

3.5.2 Declaration of Conformity



Depending on country capacity for testing and enforcement, it might make sense to put the burden to prove compliance onto manufacturers and importers of oils, fats, and food products. One way of doing this is by mandating declarations of conformity.

Declarations of conformity are an enforcement mechanism whereby food industry actors are required to sign an affidavit or declaration stating that their products comply with the TFA regulation's limit on PHOs and/or iTFAs. It is an approach that puts the obligation for compliance on food industry actors rather than government agencies.⁵¹

The TFA regulation should define who must provide declarations of conformity to which government agency, and what content the declaration of conformity should contain. To facilitate trade, a country should consider accepting declarations of conformity of importers and/or foreign manufacturers.

In some cases, the industry may be required to submit additional evidence to support the declaration of conformity, such as recent laboratory test results confirming the TFA and other fat levels. For example, additional testing requirements may be required for any product that contains PHOs, products that contain more than 1 g TFAs per 100 g of total fat, or for any oil refiner that hydrogenates oils or fats.

⁵¹ Conformity assessment may also require a certification of conformity. A certification is generally conducted by a third party and includes some type of surveillance by the third party to ensure ongoing compliance. Often, certification schemes include an on-product mark or symbol indicating the conformity of a certified product. While certification schemes are a valid and effective enforcement tool, they do require the establishment and participation of a third-party certifying body. This makes them more complex than relying on declarations of conformity, which are the proposed mechanism in this toolkit.

To ensure reliability of test results, it is important that accredited laboratories follow recognized testing methods to determine whether food products adhere to the TFA regulation's iTFA limit and/or PHO ban. WHO developed the Global Protocol for Measuring Fatty Acid Profiles of Foods, which provides a globally harmonized method to measure TFAs in foods.⁵²

Where a food product undergoes substantial change (for example, change in ingredients or altered manufacturing process), it must be tested again, and a new declaration of conformity issued.

In many countries, manufacturers and importers are already required to submit records and documents on the ingredients and processes used for their food products. The competent authority has the responsibility to inspect documents and facilities for various hazards and confirm the accuracy of the industry disclosures. For example, the law might require disclosure of pesticides, food additives, veterinary drugs, contaminants, microbiological hazards, and more. Where such disclosure requirements already exist, policymakers should consider integrating the TFA disclosure requirements into the existing disclosure system, rather than creating a parallel process for TFAs.

52 World Health Organization (WHO). Global protocol for measuring fatty acid profiles of foods, with emphasis on monitoring *trans*-fatty acids originating from partially hydrogenated oils. Geneva; 2020. Available from: <https://apps.who.int/iris/handle/10665/338049>

SUGGESTED LEGAL LANGUAGE

1. Before placing on the market or importing for consumption any vegetable oil or fat or prepackaged food, any legal entity importing or manufacturing domestically such products shall issue a declaration of conformity including:
 - a. Identification of the food product covered by the declaration;
 - b. Identification of the manufacturer or importer;
 - c. A declaration⁵³ signed by an authorized representative of the manufacturer or importer stating that the food product is in compliance with the [ban of partially hydrogenated oils / limit on *trans*-fatty acids] in Article [number] of this [regulation/order/notification].
2. Legal entities importing or domestically producing vegetable oils and fats containing more than 1 g of industrially produced *trans*-fatty acids per 100 g of fat/oil shall:
 - a. Submit samples of such products to a third-party laboratory to be tested for compliance with the [ban of partially hydrogenated oils / limit on *trans*-fatty acids] in Article [number]; and
 - b. Based on such testing, issue a declaration of conformity that certifies that such products comply with the [ban of partially hydrogenated oils / limit on *trans*-fatty acids] in Article [number]; and
 - c. Maintain records of declarations of conformity and laboratory test results and attestations supporting such declarations of conformity for a period of at least [five] years.
3. The [agency]* shall establish guidelines on the testing requirements of Subarticle 2.
4. The declaration of conformity shall be provided by:
 - a. Food manufacturers, producers of vegetable oils and fats, and importers to wholesalers, retailers, repackaging facilities, and the [agency]*;
 - b. Food manufacturers and producers of oils and fats to exporters upon request.
5. The [agency]* shall establish rules under which importers of prepackaged food and vegetable oils and fats may rely on a foreign manufacturers' laboratory test results and declarations of conformity.
6. The [agency]* may issue a [directive / administrative order] defining additional requirements of the declaration of conformity.

* Insert the name of the appropriate regulatory authority.

In addition, or as an alternative, to a declaration of conformity, the burden of proof for compliance of food products can be shifted to economic operators, such as food manufacturers or importers, by declaring any product containing PHOs noncompliant unless proved otherwise.

SUGGESTED LEGAL LANGUAGE

Any product that contains any partially hydrogenated oils shall be determined to exceed the limit on *trans*-fatty acids in [Article/Subarticle] [number], unless the manufacturer or importer provides the [agency]* with sufficient evidence to establish that the product does not exceed the limit. [A declaration of conformity according to [Article (number) / (name of law where such declarations are regulated)] suffices as evidence.]⁵⁴

* Insert the name of the appropriate regulatory authority.

53 The signed declaration can be replaced with a sworn affidavit or a notarized declaration if they form part of the legal tradition of the country. They carry more legal weight than a signed declaration, but the administrative burden on manufacturers and importers to obtain them is higher.

54 Optional reference to a declaration of conformity if it forms part of the TFA regulation.

3.5.3 Liability, Offences, and Penalties



TFA restrictions should be designed and implemented to encourage broad compliance. Most companies will follow the law without threat of sanctions. However, the threat of sanctions can be a powerful motivator for certain players. To enable effective enforcement of the TFA regulation, a range of penalties, sanctions, and administrative measures should be in place to deter noncompliance and hold offenders accountable. It is possible that the existing administrative, civil, and criminal procedures in place are sufficient to enforce the TFA regulation; it may be necessary to reference these existing provisions in the TFA regulation. If none exist, or the procedures are inadequate, new procedures must be developed, defining what constitutes an offence and what penalties, sanctions, and administrative measures are applicable. During the policy landscape assessment (refer to the Annex), it should have become clear whether existing procedures suffice.

Penalties, sanctions, and administrative measures should deter offences. However, if the penalty for noncompliance is negligible compared to operational costs, they will not dissuade offenders. At the same time, penalties, sanctions, and administrative measures should be proportionate to the committed violation. They should also be nuanced enough to adequately respond to the type of offender (e.g., small restaurant vs. large food manufacturer), the harm caused, and whether it is the first or a repeat offence. To achieve this, a range of penalties might be considered: warnings, license suspensions or revocations, product recalls, fines, additional testing or disclosure requirements, and imprisonment (for extreme cases only).

Some countries allow administrative fines to be earmarked for a specific government agency or activity. If this is the case in your country, you might want to consider including a respective provision in the TFA regulation, dedicating paid fines to implementation activities on TFAs or broader nutrition regulations.

In countries with a large informal food sector contributing to the TFA burden, penalties need to be commensurate with the offender's ability to pay. Agencies might choose to focus on collaboration, education, and community engagement as an implementation mechanism for this sector rather than relying too heavily on sanctions.

SUGGESTED LEGAL LANGUAGE

1. A fine of at least [currency] [amount] but not exceeding [currency] [amount] shall be imposed on any natural person contravening Article [number] regarding the [ban of partially hydrogenated oils / maximum limit of industrially produced *trans*-fatty acids] or Articles [numbers] regarding labeling.
2. A fine of five to ten percent of the annual revenue based on the latest available audited yearly accounts, or, in the absence of audited accounts, the latest available yearly accounts / at least [currency] [amount] but not exceeding [currency] [amount]] shall be imposed on any legal entity contravening Article [number] regarding the [ban of partially hydrogenated oils / maximum limit of industrially produced *trans*-fatty acids], Article [number] regarding the declaration of conformity, or Articles [numbers] regarding labeling.
3. A natural person or small legal entity that commits an offence for the first time may be issued with a warning instead of a fine pursuant to Subarticles 1 and 2 of this article with [number] months to correct the offending circumstances contravening this [regulation/order/notification]. If, after the expiration of [number] months, the offending circumstances have not been remedied, a fine pursuant to Subarticles 1 and 2 shall be imposed.
4. When an offence defined under this article is committed for a second time, the fines pursuant to Subarticles 1 and 2 of this article may be doubled. If an offence is committed a third time and for any subsequent time, the fine may be tripled.
5. In addition to imposing a fine pursuant to Subarticles 1, 2, and 4 of this article, any administrative license held by a natural person or legal entity may be revoked or suspended, or its issuance or renewal denied. In grave or repeat cases, the closure, suspension, or dissolution of the legal entity may be ordered.
6. The [agency]* may mandate the recall or seizure and destruction, with costs borne by the manufacturer or importer,⁵⁵ of any food:
 - a. That contains [partially hydrogenated oils / industrially produced *trans*-fatty acids above the established limit] contravening Article [number]; or
 - b. That does not comply with the labeling requirements of Articles [numbers]; or
 - c. For which a declaration of conformity pursuant to Article [number] has not, or has fraudulently, been issued.
7. The penalties and sanctions of this article may be reduced or waived if a natural person or legal entity commits an offence defined in Subarticles 1 and 2 relying in good faith on a declaration of conformity pursuant to Article [number].
8. [Falsifying documents such as declarations of conformity or import documents, removing or hiding evidence, or hindering inspections may incur criminal liability in accordance with [Chapter/Section] [number] of the Penal Code.]
9. [Violations of this [regulation/order/notification] resulting in grave harm to the health or physical integrity of a person may incur criminal liability in accordance with [Chapter/Section] [number] of the Penal Code if such violations are committed with willful intent or gross negligence.]

* Insert the name of the appropriate regulatory authority.

⁵⁵ The national regulation may provide for enforcement actions such as seizures and injunctions applicable to food products violating food regulations to stop the continued production, distribution, and sale of such noncompliant food products. A reference to such provisions can be an alternative to including them in the TFA regulation.

3.5.4 Complaints and Reporting Mechanism



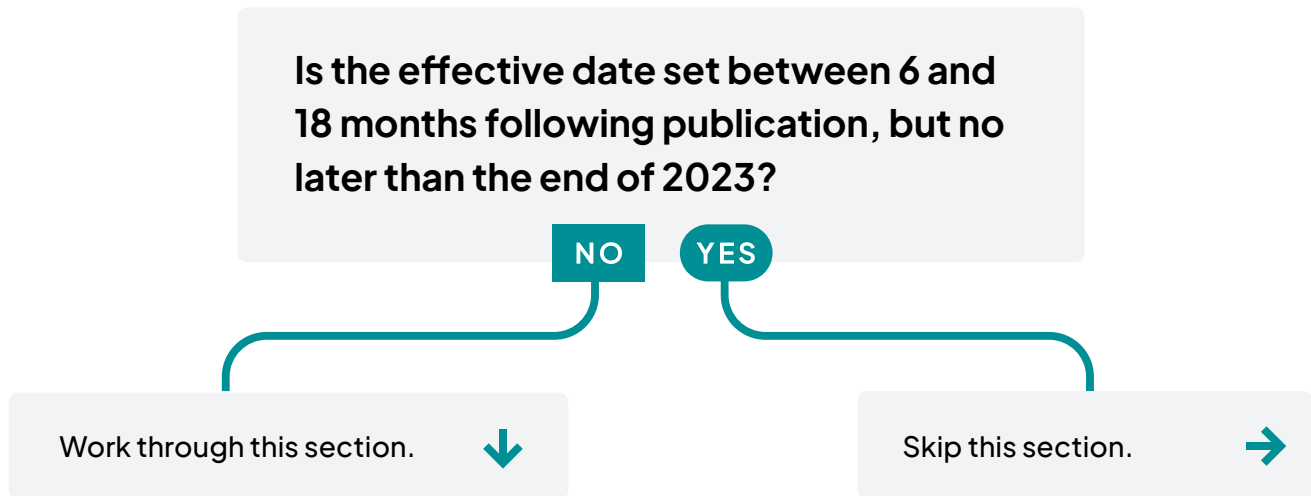
Enforcement agencies are not able to check every product, facility, or food company for compliance with the TFA regulation. They will need to focus their efforts on those products, facilities, and companies that are most likely to be noncompliant or whose noncompliance is most damaging. However, members of the public, academic institutions, nongovernmental organizations, and competitors might detect potential violations enforcement agencies are not aware of. Such information can be vital for enforcement agencies. A reporting and complaints mechanism allows members of the public to report potential violations easily to enforcement agencies, and enforcement agencies to obtain and investigate such critical information.

SUGGESTED LEGAL LANGUAGE

The [agency]* shall establish a reporting and complaint mechanism through a hotline or website and shall investigate all credible reports of violations.

* Insert the name of the appropriate regulatory authority.

3.6 Effective Date



Generally speaking, a regulation goes into effect upon its publication in the Official Gazette (or equivalent public notification). For some regulations, it makes sense to provide for a reasonable transition period to allow all affected stakeholders to adjust to new requirements.

In the case of iTFA elimination, the food industry needs to be given time to adapt its procurement and manufacturing processes to phase out iTFAs, adjust product labeling, and use up existing stock. Government might need time to build implementation and enforcement capacity. Experience has shown that a transition period of 6–18 months after the TFA regulation’s effective date is reasonable and feasible for the food industry. The transition period can be coupled with implementation measures such as technical assistance to small and medium-sized producers or consumer education.

Alternatively, instead of a single effective date when the regulation goes fully into effect for all products, the regulations could establish a step-wise transition. Examples of such step-wise transition periods are:

1. A tiered system based on the type of regulated actor needing to comply, for example, small and medium-sized producers, vendors, and restaurants are given a longer transition period than are large producers. Note that this type of transition period requires definitions for each of the different, named regulated actors;
2. A structured transition schedule incrementally reducing iTFA content over a defined timeline, for example, a reduction of iTFA content to 5% within 12 months and to 2% within 18 months. Note that this approach only works for a 2% iTFA limit (not a PHO ban). It should be checked with local industry whether such an incremental approach facilitates implementation (depending on the type of industry actors);

3. A tiered system based on the type of product, for example, products that are more difficult to reformulate are granted a longer transition period than those that can be more easily reformulated to comply with the new TFA regulation. Alternatively, oils and fats as basic ingredients for other food products need to comply, for example, within 12 months, while all other food products need to comply within 18 months;
4. A process-based timeline based on the stages of the supply chain, for example, different timelines for product reformulation, adjustments to manufacturing processes, labeling redesign, and removal of noncompliant products by retailers.

The type of transition period depends on the country context, its food system, and the type of iTFA elimination policy chosen. Whichever approach is used, full implementation of the TFA regulation should happen as quickly as possible, taking no longer than 18 months, and ideally be completed by the WHO's and PAHO's iTFA elimination target of 2023.

Refer to [Module 6: Enforce of WHO's REPLACE](#) action package for information on how to create an implementation plan.⁵⁶

56 REPLACE action package. Module 6: Enforce. How-to guide for trans fat policies and enforcement of regulations. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324826/WHO-NMH-NHD-19.17-eng.pdf>

SUGGESTED LEGAL LANGUAGE

SIMPLE TRANSITION PERIOD (SINGLE EFFECTIVE DATE, APPLICABLE TO PHO BAN AND 2% iTFA LIMIT)

This [regulation/order/notification] shall enter into force [number] [days/months] after its publication in the Official Gazette.

Example 1 of a structured transition period: based on type of food industry actor (applicable to PHO ban and 2% iTFA limit)

1. This [regulation/order/notification] shall enter into force [number] [days/months] after its publication in the Official Gazette.
2. Notwithstanding Subarticle 1 of this article, large-scale food enterprises shall comply with this [regulation/order/notification] as from [date].
3. Notwithstanding Subarticle 1 of this article, small and medium-scale food enterprises, restaurants, and vendors shall comply with this [regulation/order/notification] as from [date].

Example 2 of a structured transition period: based on type of product (applicable to PHO ban and 2% iTFA limit)

1. This [regulation/order/notification] shall enter into force [number] [days/months] after its publication in the Official Gazette.
2. Notwithstanding Subarticle 1 of this article, all oils and fats covered by this [regulation/order/notification] shall comply with this [regulation/order/notification] as from [date].
3. Notwithstanding Subarticle 1 of this article, all other foods covered by this [regulation/order/notification] shall comply with this [regulation/order/notification] as from [date].

Example 3 of a structured transition period: incremental reduction of iTFA content (only applicable to 2% iTFA limit)

1. This [regulation/order/notification] shall enter into force [number] [days/months] after its publication in the Official Gazette.
2. Notwithstanding Subarticle 1 of this article, the content of industrially produced *trans*-fatty acids in all oils, fats, and foods shall not exceed 5 g per 100 g of total fat as from [date].
3. Notwithstanding Subarticle 1 of this article, the content of industrially produced *trans*-fatty acids in all oils, fats, and foods shall not exceed 2 g per 100 g of total fat as from [date].

Example 4 of a structured transition period: process-based timeline based on the stages of the supply chain (applicable to PHO ban and 2% iTFA limit)

1. This [regulation/order/notification] shall enter into force [number] [days/months] after its publication in the Official Gazette.
2. Notwithstanding Subarticle 1 of this article,
 - a. Oils, fats, and foods imported or manufactured after [date] shall comply with Article [number] regarding [maximum levels of industrially produced *trans*-fatty acids / the ban of partially hydrogenated oils];
 - b. Oils, fats, and foods shall be labeled in compliance with Articles [numbers] from [date];
 - c. Oils, fats, and foods not in compliance with this [regulation/order/notification] may continue to be sold until [date].

3.7 Miscellaneous Provisions

3.7.1 Definitions

Definition of *Trans*-fatty Acids

TFAs must be defined in a clear and scientifically sound way to avoid implementation issues due to confusion as to which fatty acids are included in the definition.

SUGGESTED LEGAL LANGUAGE⁵⁷

DEFINITION OF TFA

“*Trans*-fatty acids” means all fatty acids with at least one carbon-carbon double bond in the trans configuration, regardless of whether they are produced industrially or are derived from ruminant sources.

Some countries have opted to exclude naturally occurring TFAs from their regulations, in which case iTFAs do not need to be defined as it is implicitly the focus of the regulation. Other countries do define iTFAs, which is particularly important if the TFA regulation also contains labeling provisions. It can also make sense if a 2% iTFA limit is being adopted. In other words, a definition of iTFAs is optional, based on how the TFA regulation is crafted.

SUGGESTED LEGAL LANGUAGE⁵⁷

DEFINITION OF iTFA

“Industrially produced *trans*-fatty acids” means all fatty acids with at least one carbon-carbon double bond in the trans configuration, and which are produced by industrial processes, including partial hydrogenation and heat treatment of oils and fats.

Definition of Partially Hydrogenated Oils

PHOs contain high amounts of iTFAs, and are often the primary source of iTFAs, especially where PHOs are allowed. If PHOs are prohibited, they must be defined in a clear and scientifically sound way to avoid implementation issues due to confusion as to which oils and fats are included in the definition. In particular, it is necessary to ensure that fully hydrogenated oils, which do not contain iTFAs, are not included in the definition.

57 Based on WHO definitions. World Health Organization (WHO). Guidelines: Saturated fatty acid and trans-fatty acid intake for adults and children. Geneva: WHO; 2018 (Draft issued for public consultation in May 2018). Available from: [https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)

While most PHOs are made from vegetable oils, animal-derived oils can also be partially hydrogenated (e.g., partially hydrogenated fish oils). Therefore, the definition of PHOs should not be limited to vegetable oils but include all oils and fats, especially where partially hydrogenated fish oils are commonly used or available in the country.

Oils and fats that have been fully or completely hydrogenated are saturated fats and do not fall within the scope of these restrictions. Iodine value can be used to distinguish full from partial hydrogenation. An iodine value greater than four indicates partial rather than full hydrogenation.

SUGGESTED LEGAL LANGUAGE⁵⁸

“Partially hydrogenated oils” means oils and fats that have been hydrogenated, but not to complete or near complete saturation, and that have an iodine value of greater than four (4).

Other definitions

Depending on the legal framework, additional definitions might be required. These include:

- Conjugated linoleic acids (CLAs): Where CLAs are an issue given the country context, it makes sense to include their ban in the TFA regulation. If included, CLAs must be defined.
- Saturated fat: Where saturated fat is not defined by the national food law, it is necessary to define it if a TFA-free claim is permitted where saturated fat content remains below a certain level (refer to Section 3.4.3 *Trans* fat-free claim).
- Unsaturated fat: Where unsaturated fat is not defined by the national food law, it is necessary to define it if the objective contains the legal language as recommended (refer to [Section 3.1 Objectives](#)).
- sugars: where free sugars are not defined by the national food law, it is necessary to do so if the TFA-free claim is only permitted if free sugars do not exceed a defined threshold (refer to [Section 3.4.3 Trans fat-free Claim](#)).
- Agency: Where the legal tradition requires defining the responsible regulatory authority rather than naming it throughout the regulation, it must be defined.
- Labeling: Where the national food law does not contain definitions on labeling, relevant ones must be included in the TFA regulation if it contains labeling provisions (refer to [Section 3.4 Labeling](#)).
- Types of food industry actors: Where national regulation governing business or industry does not define the different food industry actors, they must be defined in the TFA regulation.

⁵⁸ Based on PAHO/WHO definitions.

- World Health Organization (WHO). 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. Geneva: World Health Organization; 2020.
- Pan American Health Organization. Plan of Action for the Elimination of Industrially Produced Trans-Fatty Acids 2020-2025. (Document CD57/8). Washington DC: Pan American Health Organization; 2020.

SUGGESTED LEGAL LANGUAGE

DEFINITION OF SYNTHETIC CONJUGATED LINOLEIC ACIDS⁵⁹

“Synthetic conjugated linoleic acids” means all geometric and positional isomers of conjugated linoleic acid obtained by the alkaline isomerization of oils and fats.

DEFINITION OF SATURATED FAT⁶⁰

“Saturated fatty acids” means fatty acids containing only, or predominantly, single carbon-carbon bonds.

DEFINITION OF UNSATURATED FAT⁶⁰

“Unsaturated fatty acids” means fatty acids with one or more double bonds in the fatty acid chain. A fat molecule is monounsaturated if it contains one double bond, and polyunsaturated if it contains more than one double bond.

DEFINITION OF FREE SUGARS⁶¹

“Free sugars” means all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus the sugars that are naturally present in honey, syrups, fruit juices and fruit juice concentrates.

DEFINITION OF THE AGENCY

The “agency” means the [national/federal] government authority responsible for regulating [food and nutrition / health / health-related products] and implementing respective regulations.

LABELING DEFINITIONS

“Claim” means any representation that states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition, or any other quality.⁶² A claim can occur in any marketing, including on the package, in advertisements, or at point of sale.

“Nutrient declaration” means a standardized statement or listing of the nutrient content of a food.⁶³

59 Based on Brazil’s Resolution RDC 332 of 23 December 2019 defining the requirements for use of industrial trans fats in food. Available from: <https://extranet.who.int/nutrition/gina/en/node/39071>

60 Based on WHO definitions. World Health Organization (WHO). Guidelines: Saturated fatty acid and trans-fatty acid intake for adults and children. Geneva: WHO; 2018 (Draft issued for public consultation in May 2018). Available from: [https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation\(1\).pdf](https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WHO%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf)

61 Based on WHO definition. World Health Organization (WHO). Guideline: sugars intake for adults and children. Geneva: WHO; 2015.

62 Definition from Codex General Standard for the Labelling of Prepackaged Foods, Codex Stan 1-1985.

Available from: <http://www.fao.org/3/Y2770E/y2770e02.htm>

63 Definition from Codex Guidelines on Nutrition Labelling, CAC/GL 2-1985. Available from: <http://www.fao.org/3/y2770e/y2770e06.htm>

DEFINITION OF FOOD INDUSTRY ACTORS

“Small-scale food enterprise” means a legal entity involved in the manufacture, export, import, wholesale, retail sale, or repackaging of food for profit with a paid-up capital not exceeding [currency] [number].

“Medium-scale food enterprise” means a legal entity involved in the manufacture, export, import, wholesale, retail sale, or repackaging of food for profit with a paid-up capital of above [currency] [number] and not exceeding [currency] [number].

“Large-scale food enterprise” means a legal entity involved in the manufacture, export, import, wholesale, retail sale, or repackaging of food for profit with a paid-up capital of above [currency] [number].

“Restaurant” means a commercial or not-for-profit institution providing prepared food for public consumption on a regular or seasonal basis directly to consumers and includes both eat-in and take-away establishments.

“Vendor” means a natural person selling foods for profit for public consumption directly to consumers on a regular or seasonal basis, with or without facilities.

3.7.2 Multi-agency Coordination Group



Given the different enforcement activities, it is possible that one agency might act as the lead enforcement agency while other agencies have supplementary enforcement responsibilities. If several agencies are responsible for enforcement, a multi-agency coordination group could be used to coordinate the implementation and enforcement activities relevant to the TFA regulation. Either a pre-existing coordination group on food and nutrition could be tasked with this, or a new group established.

SUGGESTED LEGAL LANGUAGE

MULTI-AGENCY COORDINATION GROUP: EXISTING GROUP

1. The [name of existing multi-agency coordination group on food/nutrition] shall be responsible for coordinating the implementation and enforcement of this [regulation/order/notification] and for advising and supporting competent enforcement authorities.
2. The [name of the existing multi-agency coordination group] shall have the following responsibilities:
 - a. Advise on new laws and regulations in respect to *trans*-fatty acids;
 - b. Provide guidance on appeals against enforcement measures;
 - c. Make recommendations on the issuance, renewal, suspension, or revocation of licenses;
 - d. Make suggestions on how to improve enforcement;
 - e. Serve as focal point for issues on *trans*-fatty acids for national, subnational, and local agencies, and other countries;
 - f. Assist and contribute public information activities on *trans*-fatty acids.

MULTI-AGENCY COORDINATION GROUP: TO BE ESTABLISHED

1. A multi-agency coordination group shall be established to [coordinate / support and advise on] the implementation and enforcement of this [regulation/order/notification].
2. The multi-agency coordination group shall have the following responsibilities:
 - a. Advise on new laws and regulations in respect to *trans*-fatty acids;
 - b. Provide guidance on appeals against enforcement measures;
 - c. Make recommendations on the issuance, renewal, suspension, or revocation of licenses;
 - d. Make suggestions on how to improve enforcement;
 - e. Serve as focal point for issues on *trans*-fatty acids for national, subnational, and local agencies, and other countries;
 - f. Assist and contribute public information activities on *trans*-fatty acids.
3. The multi-agency coordination group shall comprise representatives from all relevant enforcement authorities, including [names of authorities]. The group may invite academics and other experts, but not food industry representatives and their agents, to participate or observe, as appropriate.
4. The multi-agency coordination group shall develop terms of reference. Roles and responsibilities shall be determined [include process]⁶⁴ for the implementation of this [regulation/order/notification].

64 Depending on the legal system, the roles and responsibilities might be determined in the terms of reference or by a directive or notification issued by the government organ responsible for the adoption of the TFA regulation.

3.7.3 Replacement of Oils and Fats

To maximize the public health impact of the TFA regulation, iTFAs should be replaced with healthier fats and oils (monounsaturated and polyunsaturated fatty acids) and as little saturated fat as possible. To achieve this aim, various oils, fats, and blends as well as technologies such as interesterification and fractionation can be used.⁶⁵

It would be impractical to legally define which oils, fats, blends, and technologies may be used as healthier replacement alternatives given the many available options. Suitable replacement alternatives also depend heavily on the country context (for example, availability of oil seeds, technical expertise of manufacturers, existing agriculture and fiscal policy framework impacting the availability of healthier alternatives, and main products that need to be reformulated), making a universally applicable legal provision on replacement options impossible.

In addition, the science and technology on healthy replacement options is evolving, contributing to the impracticability of legally defining which oils, fats, and technologies must be used to replace iTFAs.

Last, legally prescribing which oils to use (e.g., canola oil or olive oil) or prohibiting the use of certain oils (e.g., palm oil) is problematic from a trade law perspective. It might be challenged as a discriminatory measure if it affects domestic and foreign products differently. It might also be challenged on the grounds that it is an unnecessary measure because oils high in saturated fatty acids can be blended or interesterified with oils high in polyunsaturated fatty acids to create healthier formulations.

While a normative provision on iTFA replacement is not recommended for the above-mentioned reasons, it is possible to include the replacement of iTFAs with healthier oils and fats in the objectives provision (refer to [Section 3.1](#) Objectives). One of the public health goals of iTFA elimination is the prevention and reduction of cardiovascular diseases, which is shared with measures to reduce saturated fat consumption. Aiming to replace iTFAs with healthier oils and fats strengthens the health benefits of the regulation and contributes to policy measures and interventions taken to curb saturated fat intake.

Additionally, labeling measures can be used to minimize the replacement of iTFAs with oils and fats high in saturated fat. For example, a TFA-free claim may only be permitted if both the TFA and saturated fat content of a product are within strict limits. For more information, refer to [Section 3.4](#) Labeling.

65 For more information and guidance on replacement options, refer to the Annex (3. Replacement of Oils and Fats) and: REPLACE action package. Module 2: Promote. How-to guide for determining the best replacement oils and interventions to promote their use. Geneva: World Health Organization; 2019. Available from: https://cdn.who.int/media/docs/default-source/nutritionlibrary/replace-transfat/replace-module-2-p.pdf?sfvrsn=e9f83030_4

Governments can also support a move toward healthier replacement options using tools other than regulation:

- Provide guidance, information, recommendations, and support to the food industry on healthier and environmentally friendly alternatives for iTFAs based on food supply and evidence;
- Strengthen and mandate monitoring, evaluation, and reporting of reformulation and its health effects (refer to [Section 3.2.2](#) Authority for Monitoring and Evaluation);
- Create a supportive policy framework incentivizing healthier replacement options.

Refer to [Section 3 of the Annex](#) for more information on practical steps governments can take alongside the drafting of TFA regulation to support healthy reformulation.

3.7.4 Other Provisions

This toolkit is focused on provisions that are essential to a TFA regulation. However, in some legal traditions, it might be customary to include other provisions. Where this is the case, they should be included as per the legal tradition to ensure the TFA regulation complies with national regulatory conventions. Such standard provisions might include:

- Repeal clause;
- Severability clause;
- Subnational authority/preemption.

References

1. Afshin A et al. Health effects of dietary risks in 195 countries, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. Supplementary appendix. *The Lancet* 2019;393(10184):1958-1972. doi: 10.1016/S0140-6736(19)30041-8.
2. De Souza RJ et al. Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. *BMJ* 2015;351:h3978. doi: 10.1136/bmj.h3978.
3. Pearson-Stuttard J et al. Cost-effectiveness analysis of eliminating industrial and all trans fats in England and Wales: modelling study. *J Pub Health* 2017;39(3):574-582. doi: 10.1093/pubmed/fdw095.
4. Yammine S et al. Dietary and circulating fatty acids and ovarian cancer risk in the European Prospective Investigation into Cancer and Nutrition. *Cancer Epidemiol Biomarkers Prev* 2020;29:1739-49. doi: 10.1158/1055-9965.EPI-19-1477.
5. Micha R, Mozaffarian D. Trans Fatty Acids: Effects on Cardiometabolic Health and Implications for Policy. *Prostag Leukotr Ess* 2008;79(3-5):147-152. doi: 10.1016/j.plefa.2008.09.008.
6. Downs SM, Bloem MZ, Zheng M, et al. The Impact of Policies to Reduce trans Fat Consumption: A Systematic Review of the Evidence. *Curr Dev Nutr*. 2017;1(12):cdn.117.000778. Published 2017 Nov 13. doi:10.3945/cdn.117.000778.
7. World Health Organization (WHO). Guidelines: Saturated fatty acid and trans-fatty acid intake for adults and children. Geneva; 2018 (Draft issued for public consultation in May 2018).
8. World Health Organization (WHO). REPLACE action package. Module 3: Legislate or regulate. How-to guide for trans fat policy action. Geneva; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324822/WHO-NMH-NHD-19.14-eng.pdf>
9. World Health Organization (WHO). WHO announces certification programme for trans fat elimination. 17 November 2020. Available from: <https://www.who.int/news/item/17-11-2020-who-announces-certification-programme-for-trans-fat-elimination>
10. Kontis V et al. Three Public Health Interventions Could Save 94 Million Lives in 25 Years. *Circulation* 2019;140(9):715-25. doi: 10.1161/CIRCULATIONAHA.118.038160.

Annex: Key Activities to Support Drafting Regulations on *Trans*-fatty Acids

Ideally, the following activities should be completed in tandem with the drafting of regulations on *trans*-fatty acids (TFAs) to aid in the development of a finely tuned policy. However, any country can still enact a best-practice policy without completing all of these steps, and inability to complete these activities should not prevent or stall progress. These supporting activities include:

1. Conducting a policy landscape assessment;
2. Building political support;
3. Replacing unhealthy fats and oils;
4. Monitoring the effect of the regulation;
5. Notifying the final draft of the TFA regulation to the World Trade Organization (WTO).

1. Policy Landscape Assessment

It is advisable to conduct a policy landscape assessment prior to drafting the TFA regulation because the findings of the assessment will influence what approach to TFA elimination is taken. The key steps of the policy landscape assessment are:

1. Generate the evidence base;
2. Map governmental authority;
3. Collect and analyze existing laws;
4. Chart procedural requirements.

The following sections give a brief overview of the four steps. For more detailed guidance, refer to [Module 3: Legislate](#)¹ and [Module 1: Review](#)² of WHO's REPLACE action package.

1 REPLACE action package. Module 3: Legislate or regulate. How-to guide for trans fat policy action. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324822/WHO-NMH-NHD-19.14-eng.pdf>

2 REPLACE action package. Module 1: Review. How-to guide for landscape assessment and roadmap development for elimination of trans fats. Geneva: World Health Organization; 2019. Available from: https://cdn.who.int/media/docs/default-source/nutritionlibrary/replace-transfat/replace-module-1-re.pdf?sfvrsn=1885eaed_2

Step 1: Generate the Evidence Base

It is important to generate evidence to understand the local context regarding TFAs. Findings not only influence the provisions of the TFA regulation but are also helpful for substantiating and defending a TFA regulation against legal challenges. The following evidence should be generated:

1. TFA sources, their prevalence in the food supply; and traceability through the supply chain;
2. In-country production of PHOs and PHO imports;
3. Estimated intake of TFAs in the population;
4. Disparities of TFA intake among different population subgroups;
5. Cost of removing TFAs from the food supply:
 - Costs to agencies, particularly enforcement costs (e.g., inspections and laboratory tests) whereby the expected costs depend on what implementation and enforcement infrastructure already exists for food law;
 - Costs to food industry to change manufacturing processes, labeling, and procurement.

Not all information will already be available, and local evidence needs to be built. Where capacity does not allow for local evidence to be built up, international evidence might be used. For example, if evidence from a neighboring country with similar food habits exists, it could be used as a proxy. Alternatively, country-specific estimates on the disease burden resulting from TFAs generated by the Institute for Health Metrics and Evaluation could be used.³

Step 2: Map Government Authority

There might be several ways a TFA policy could be enacted, for example, via a regulation adopted by the ministry of health or a bill adopted by parliament. To understand the existing options, map the government bodies with authority and responsibility to regulate food and nutrition.

1. Is there one food regulator or are there several?
2. Is authority for food law dispersed on the national, subnational and/or local level?
3. Does a national authority have the authority to regulate, monitor, and enforce iTFA elimination?
4. Are there other national ministries or agencies of relevance that have authority to set standards and enforce them (for example, test food products for compliance, inspect facilities, issue administrative sanctions, and respond to consumer complaints)?

It is necessary to clearly map whether there are multiple responsible authorities, and/or authorities at different governmental levels, and/or different authorities in charge of adopting a regulation vs. enforcing it. Existing government authority needs to be considered when drafting the regulation and

3 The Global Burden of Disease (GBD) 2019 can be accessed at: <http://www.healthdata.org/gbd/2019>

deciding which regulatory route to choose. It also needs to be taken into account when building the case for iTFA elimination – all relevant agencies should be included in the process.

An analysis of existing authorities helps ensure that existing authorities and newly granted or delegated authorities do not conflict or overlap, which would create issues when implementing and enforcing TFA regulation.

Step 3: Collect and Analyze Existing Laws

It is important to understand whether any regulation exists at the national level that already regulates TFAs or PHOs in any way, including regional and bilateral agreements that the country is bound by. For example, a regulation might prohibit the use of PHOs in baby food, or require food products to state the TFA content on the back-of-pack nutrient panel.

Having clarity on existing measures helps inform which TFA policy will fit the country context best, given the existing regulatory framework. It also helps to design an effective policy and supports the development of advocacy arguments for a TFA regulation. For example, where existing labeling regulations help implement and monitor a TFA regulation, one step toward effective policy is already done.

At times, there is a tendency to add to the regulatory framework without evaluating existing regulations and their suitability for addressing a problem. Assessing existing regulations helps determine whether a new law or regulation, or new provisions, are necessary or whether the existing regulatory framework on food and nutrition already encompasses many of the necessary measures for effective iTFA elimination. Analyzing the existing legal framework also supports consistency between the new regulation (or provisions) and the existing ones, avoiding regulatory conflicts or overlaps.

Existing TFA-related provisions may be found in the different legal measures related to public health, NCDs, health promotion, nutrition, fats and oils, nutrition labeling, children's health, food marketing, food safety (including additives and compounds harmful to human health), consumer protection, or customs and border control.

Step 4: Chart Procedural Requirements

The last step of the policy landscape assessment is charting any procedural requirements that need to be followed in the adoption and implementation of a TFA regulation. For example, it might be the case that an impact analysis or formal economic analysis is required, that there are notification requirements, or that a formal public consultation is necessary.

If the procedural requirements mandate inclusion of the food industry in the development of the TFA regulation, clear rules must be established on how policymakers and the food industry engage in order to ensure transparency, manage conflicts of interest, and otherwise reduce potential interference in the regulatory process.

2. Political Support

Depending on the legal framework of the country and the prescribed process to adopt TFA regulation, political support needs to be built with the ministries concerned or the legislative power (parliament, congress, or another representative body). If an executive body (e.g., the ministry of health) needs to be authorized to regulate TFAs, or if primary legislation on iTFA elimination needs to be adopted, support of the legislative branch of government for iTFA elimination is crucial. If a ministry normally not concerned with health has the authority to regulate TFAs (e.g., the ministry of agriculture), it might be necessary for the ministry of health to work with the ministry responsible to build support for a TFA regulation.

The successful adoption of a TFA regulation or other legal instrument to strengthen TFA regulation (e.g., labeling regulations) will probably require cooperation among different political actors; this should be included in regulatory planning from the start.

Stakeholders / Stakeholder Analysis

Various actors within the regulatory process are influential in setting the food and nutrition agenda, including parliamentary leaders, standing and ad hoc committees relevant to food and nutrition, relevant ministries/ministers, influential members of parliament (both “champions” for public health policy and members who might be against TFA regulation), and secretariat staff who brief parliamentarians. Civil society organizations have a role to play and should be included in advocacy efforts, as appropriate. A stakeholder analysis can help gain clarity on which main actors are crucial to help build political support.

Situational Analysis

The process for proposing, drafting, and passing regulations with respect to food and nutrition varies from country to country. So do the overall legal framework, food system, historic context of food law and cultural, religious, and social norms around food and nutrition. Proponents should familiarize themselves with the context they operate in in order to determine the best approach to advocate and legislate for iTFA elimination.

Engagement of Policymakers

It is advisable to have current and reliable evidence on the health impacts of TFAs available when engaging with policymakers in order to enable them to make evidence-based arguments. It is also necessary that proponents familiarize themselves with the country context regarding TFA sources, TFA burden, existing measures on TFAs, TFA policies of neighboring countries and important trade partners/blocks, potential replacement options, and existing implementation and enforcement mechanisms.

Proponents may also want to point out the historic role that ministries and parliamentarians would play in participating in the elimination of the first risk factor for NCDs and achieving WHO certification for iTFA elimination (9).

ARGUMENTS FOR RELEVANT POLITICAL ACTORS FOR THE ELIMINATION OF INDUSTRIALLY PRODUCED *TRANS*-FATTY ACIDS

1. Industrially produced *trans*-fatty acids (iTFA) are industrially produced, toxic fats with no known health benefits.
2. iTFAs cause about 260,000 deaths and over 6 million disability-adjusted life years each year.
3. iTFAs can be replaced with healthier fats and oils in foods without impacting the taste and consistency of products.
4. Worldwide, iTFA elimination could save 17 million lives by 2040 (10), and countries that have eliminated iTFAs from their food supply have seen substantial health benefits.
5. iTFA elimination is a cost-effective policy that can save millions in health care costs and indirect costs such as absenteeism.⁴
6. The elimination of iTFAs from the food supply is a comparatively easy policy to implement as compared to other policies that address modifiable risk factors for NCDs.

For more detailed information, refer to [Module 6: Create](#) of WHO's REPLACE action package.⁵

4 The economic value of investing in global iTFA elimination has not been calculated but local estimates demonstrate the intervention's cost-effectiveness. For examples on cost-effectiveness, see Bösch et al. Trans Fat Free by 2023—A Building Block of the COVID-19 Response. *Front Nutr.* 2021;8:645750. doi: 10.3389/fnut.2021.645750.

5 REPLACE action package. Module 6: Create. How-to guide for creating trans fat awareness. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324826/WHO-NMH-NHD-19.17-eng.pdf>

3. Replacement of Oils and Fats

To maximize the impact of the TFA regulation, iTFAs should be replaced with healthier oils and fats. TFA regulations do not usually define which oils and fats should be used as healthier replacement alternatives. Nevertheless, it is advisable to address replacement options and promote healthy options tailored to the country context in parallel to drafting the regulation. Replacement options should take into account existing technological and financial capacity, current agriculture and fiscal policy frameworks impacting replacement options, available replacement oils and fats, and environmental and economic impact. Support for food companies, in particular small and medium-sized companies, can take the form of guidance documents, helplines, websites, and training. Promoting healthier and environmentally friendly replacements for iTFAs might also require adoption of agriculture policies to support the production of oilseeds and incentives for food industry to prioritize healthier replacement options. It may also be necessary to prepare for opposition from edible-oil producers and/or their associations to the TFA regulation and the accompanying proposed, healthier replacement options.

[Module 2: Promote](#) of WHO's REPLACE action package⁶ provides an overview of oils and fats, replacement options, and how to support food industry. It also contains information on supporting policies, such as agriculture and import policies, and tax incentives.

4. Ongoing Monitoring and Surveillance

Measuring TFA levels in food is important in order to monitor the effect of, and assess compliance with, the TFA regulation. Ideally, a baseline of TFA levels in the national food supply should be established before the TFA regulation takes effect, in order to measure the impact of the regulation. Additionally, TFA surveillance can help raise awareness on the issue by providing local data on the TFA burden.

[Module 4: Assess of WHO's REPLACE action package](#)⁷ provides guidance on how to conduct TFA surveillance, and supplementary web resources⁸ contain laboratory and survey protocols. WHO's new laboratory protocol entitled Global Protocol for Measuring Fatty Acid Profiles of Foods, with Emphasis on Monitoring *Trans*-Fatty Acids Originating from Partially Hydrogenated Oils⁹ provides a globally harmonized method to measure TFAs in foods.

5. Notification to the World Trade Organization

6 [REPLACE action package. Module 2: Promote](#). How-to guide for determining the best replacement oils and interventions to promote their use. Geneva: World Health Organization; 2019. Available from: https://cdn.who.int/media/docs/default-source/nutritionlibrary/replace-transfat/replace-module-2-p.pdf?sfvrsn=e9f83030_4

7 [REPLACE action package. Module 4: Assess](#). How-to guide for trans fat surveillance. Geneva: World Health Organization; 2019. Available from: <https://apps.who.int/iris/bitstream/handle/10665/324823/WHO-NMH-NHD-19.15-eng.pdf>

8 Available from: <https://www.who.int/teams/nutrition-and-food-safety/replace-transfat>

9 Available from: https://www.who.int/publications/i/item/9789240018044?searchresult=true&query=partially+hydrogenated+oils&scope=&rpp=10&sort_by=score&order=desc

This section provides a brief overview of the notification of the final draft of the TFA regulation to the WTO, but it is important to check whether it must be notified to other trade bodies as well (e.g., regional economic unions).

The General Agreement on Tariffs and Trade permits governments to take measures impacting trade to protect human, animal, or plant life and health if such measures are not implemented to discriminate against certain (foreign) products or protect domestic products. The Agreement on Technical Barriers to Trade (TBT Agreement)¹⁰ and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)¹¹ are two additional WTO agreements that lay out rules on how to balance governments' legitimate interests to implement standards while avoiding protectionism in disguise.

Under the TBT Agreement and the SPS Agreement, national legislation and regulations at draft stage must be submitted to members of the Agreements for them to assess whether the draft legal text breaches the Agreements and might impact their exports. The goal is to increase transparency, encourage global harmonization, and prevent the adoption of measures that impede trade by protecting domestic over foreign products.

The TBT Agreement's objectives are to ensure that technical regulations, standards, and conformity assessment procedures are nondiscriminatory (that is, do not favor domestic products by discriminating against foreign ones, or differential treatment of foreign products), and to avoid the creation of unnecessary trade obstacles. Signatories of the TBT Agreement are permitted to adopt measures they deem necessary to achieve legitimate policy objectives, for example, the protection of human health and safety. In most cases countries should use international standards, such as those issued by Codex, but their use is not required where it would be ineffective or inappropriate (for example, a country may have climatic or geographical factors, or technological problems that prevent it from achieving its legitimate objective with the international standard).¹² The TBT Agreement is applicable to all products, industrial and agricultural.

10 Available from: https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

11 Available from: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

12 WTO TBT Agreement, Article 2.4: "Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

The SPS Agreement deals with food safety and animal and plant health standards. As with the TBT Agreement, signatories may adopt measures to achieve legitimate policy objectives, but they must be: (i) based on science; (ii) only applied to the degree necessary to protect human, animal, or plant life and health; and (iii) nondiscriminatory. Deviation from international standards is only permitted where there are scientific reasons for it based on an assessment of the potential health risks.

New legislation and regulations, as well as changes to existing ones, must be notified under both the TBT and SPS Agreements to ensure transparency and enable other Member States and economic actors' knowledge of the latest standards. Depending on the content of the TFA regulation, a notification under the TBT Agreement and/or SPS Agreement may be necessary. For example, labeling provisions would fall under the TBT Agreement, while a PHO ban or a 2% iTFA limit would be matter for the SPS Agreement.

Under the TBT Agreement, a new regulation (or the amendment of an existing one unless the amendment does not differ substantially from an already notified regulation) introducing new standards, conformity assessment procedures, or technical regulations must be notified to the WTO Secretariat. The WTO Secretariat then circulates the notification to other Member States and publishes it on its website. During the 60-day period for commenting, the draft regulation may not be adopted.

Under the SPS Agreement, a new law or regulation (or an amendment of an existing one) must be notified to the WTO Secretariat if an international standard does not exist, or if the regulation deviates from an international standard, and it might affect trade. The WTO Secretariat then circulates the notification to other Member States and publishes it on its website. It is recommended that at least a 60-day period be granted for comments, and that requests for an extension of the comment period should normally provided for a 30-day period.

If comments are received, they may trigger bilateral or multilateral discussions in the TBT Committee and SPS Committee. Comments may result in the notifying country changing the content of its proposed law or regulation, postponing its adoption or entry into force, or withdrawing it entirely. Both notifications under the TBT Agreement and the SPS Agreement can be submitted online using the Notification Submission System.¹³

13 Available from: https://hss.wto.org/Index_en.htm, with information on the system at https://www.wto.org/english/tratop_e/sps_e/sps_e.htm#notifications

Consumption of *trans*-fatty acids (TFAs) is a major cause of global morbidity and mortality. TFAs have no known health benefits and are a major contributor to heart disease worldwide. It is estimated that TFAs cause about 260,000 deaths every year.

To effectively reduce the consumption of TFAs, the Pan American Health Organization (PAHO) / World Health Organization (WHO) recommend that all countries eliminate industrially produced *trans*-fatty acids (iTFA), the main source of TFAs in the human diet, from their national food supply.

This publication has been designed to assist government agencies and ministries in developing or reforming national legislation or regulation aiming to eliminate iTFAs from the food supply in their countries. While useful for legally trained readers, this publication is also intended for a nonlegal audience wanting to advance iTFA elimination through regulation.

Decision-tree questions are used to help users of this tool populate a context-specific iTFA elimination regulation that aligns with PAHO/WHO best practices. It covers the important provisions to be considered in the text of the regulation, such as those granting legal authority to adopt a TFA regulation, defining the scope of the regulation, creating an inspection and enforcement framework, and setting an effective date.

The publication includes a model regulation and provides a practical overview of key legal aspects of iTFA elimination, focusing on evidence-based, effective, and tested approaches. It guides readers on how to draft regulations to implement the PAHO/WHO-recommended iTFA elimination policies, as well as supplementary provisions shown to support their effectiveness.

PAHO



Pan American
Health
Organization



World Health
Organization
REGIONAL OFFICE FOR THE
Americas