REPLACE
TRANS FAT

REPLACE ACTION PACKAGE

MODULE 6: ENFORCE

How-to guide for trans fat policies and enforcement of regulations

World Health Organization

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REPLACE ACTION PACKAGE

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

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

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

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

MODULES OF THE REPLACE ACTION PACKAGE

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

1. BACKGROUND

Countries can effectively achieve the target of eliminating industrially produced TFA from their food supplies by implementing and enforcing policies, laws and regulations relating to industrially-produced TFA. Importantly, TFA laws and regulations are relatively easy to implement, and countries can achieve high rates of compliance within a short time frame. Implementation and enforcement of TFA laws and regulations involve a range of activities, such as disseminating information about the new legislation to stakeholders, collecting complaints from the public, inspecting and testing products and facilities, checking nutrition labels for prohibited ingredients, and warning and sanctioning violators to improve compliance. A well-tailored enforcement strategy can ensure high levels of compliance across all stakeholders with only modest investments of financial and human resources, especially when it is integrated into existing structures and considered throughout the policy-making process.

This module describes key steps, strategies and other considerations for countries when designing and implementing an enforcement system.

As best practice, countries should either set a mandatory limit on the amount of industrially produced TFA in all food or ban the production and use of partially hydrogenated oils (PHO) as an ingredient in all foods. (See module 3 for more information.) Because both policies significantly reduce consumption of TFA, the general enforcement strategy for both policies will be similar, with minor differences. With either policy option, countries can tailor the enforcement strategy to the local context by following these steps throughout the development, launch and implementation of an enforcement strategy.

- Development phase
  - **Step 1:** Analyse the regulatory authority to enforce TFA policy.
  - **Step 2:** Make an inventory of available enforcement resources.
  - **Step 3:** Design an appropriate inspection strategy to assess compliance.
- Launch phase
  - **Step 4:** Set a clear timeline for implementation.
  - **Step 5:** Inform stakeholders about the legal requirements.
  - **Step 6:** Mobilize resources for enforcement activities.
- Implementation phase
  - **Step 7:** Monitor legal compliance across the supply chain and identify violations.
  - **Step 8:** Hold violators accountable through legal systems.
  - **Step 9:** Share enforcement results with policy-makers and the public.

The most effective way to implement and enforce TFA policy is to embed TFA-focused provisions into existing functioning administrative structures. By doing so, countries can avoid producing legislation that is impractical to implement, even if it is technically well drafted. Countries may be able to integrate TFA-focused implementation and enforcement mechanisms into their current food and nutrition regulatory systems. Countries that do not already have functioning mechanisms to enforce food and nutrition policies should address this serious gap more broadly.

As governments create enforcement strategies, they should address the phases and steps in an iterative and holistic manner; each step does not need to be completed before moving on to the next. The topics described in this module should be considered early in the legislative drafting process as policy-makers anticipate enforcement authority, rule-making and other mechanisms for TFA control. As ongoing enforcement uncovers new challenges, governments should revise policies and procedures as appropriate.

2. DEVELOP ENFORCEMENT STRATEGY

Enforcement strategies for TFA should be part of the overall government-led regulatory activities to guarantee the safety, quality and integrity of foods. Such enforcement strategy should fit the specific TFA legal measures that are in effect, the country's implementation capacity and the local context.

To design an enforcement strategy best suited for the local context, the following steps need to be taken.

1. Analyse the regulatory authority to enforce TFA policy.
2. Make an inventory of available enforcement resources.
3. Design an appropriate inspection strategy to assess compliance.

2.1 STEP 1: ANALYSE THE REGULATORY AUTHORITY TO ENFORCE TFA POLICY

Where there are already TFA restrictions, the existing legislation should clearly define which administrative authorities[1] have the power to enforce the legislation. Laws usually outline the enforcement powers of the relevant administrative authorities and other institutions. The roles and responsibilities of individual officials (such as a sanitary inspector or laboratory technician) may be elaborated in more detail in the rules or regulations that relate to implementation of laws.

Although one agency may have primary implementation and enforcement authority, other agencies may have responsibility for enforcement within the jurisdiction. For example, a local health department might conduct restaurant inspections, whereas the ministry of commerce inspects refineries and the customs authority inspects imported products. In this instance, the ministry of health has principal responsibility, but other ministries have concurrent or delegable enforcement authority.

If the legislation does not clearly establish enforcement authority, policy-makers should look to related laws for guidance on enforcement mechanisms. These provisions may be found in a general law on food and nutrition, laws that created the respective institutions, constitutional provisions or other government decrees. An administrative order may be needed to enable effective enforcement.

[1] Administrative authorities are responsible for implementing and enforcing law. Depending on the country and jurisdiction, administrative authorities can take the form of government agencies (such as a food and drug control agency), ministries, departments, divisions, organizations, commissions, units or even specific offices. These terms may be used interchangeably to capture the wide variety of governmental bodies that enforce law throughout the world, but all uses mean administrative authority generally.

KEY ENFORCEMENT STRATEGY: EMPOWER A MULTI-AGENCY WORKING GROUP

When multiple agencies are involved in enforcement, countries can establish a working group to guide implementation and coordinate activities relating to TFA. If there is already a multi-agency working group responsible for coordinating implementation of food and nutrition issues, that group may be empowered to manage TFA issues. The working group should be responsible for advising and supporting the competent authorities in enforcement. Other possible functions may include:

- proposing or advising on new laws and regulations;
- making recommendations on the issuance or revocation of licences;
- providing guidance on appeals against enforcement measures;
- suggesting additional efficiencies to improve enforcement;
- serving as a point of contact for other countries and agencies working on TFA issues; and
- supporting and contributing to public information activities to educate the population on TFA.

The working group should include representatives from each government body involved in TFA control, such as agriculture, health, customs, standards, justice, trade and industry, as well as municipal and provincial officials, as appropriate. The working group may also include academics and other experts, especially food scientists and legal experts who can supplement government capacities. Unless required by law, representatives of the food industry or their agents should not be part of such working group.

2.2 STEP 2: MAKE AN INVENTORY OF AVAILABLE ENFORCEMENT RESOURCES

TFA laws and regulations can be implemented with minimal additional expense and effort, especially if countries take advantage of existing resources. Before developing an enforcement strategy, countries should take stock of their current enforcement resources, including all human, equipment and financial resources. A realistic inventory can help countries to identify the best enforcement approach by highlighting strengths and shortcomings in their current mechanisms. This inventory should build on the scoping and mapping exercises from modules 1, 3 and 4.

The inventory should include an assessment of the human resources available, including the number of qualified inspectors and enforcement officers, such as health and sanitation inspection officers, and food laboratory technicians. The assessment should consider the geographic location of these officers in relation to centres of food production and service. It should document and quantify the current inspection, outreach and education, and enforcement activity already occurring within facilities that produce TFA to determine whether there will be opportunities to efficiently add to existing inspection schemes, rather than develop new ones. If facilities require inspectors with different qualifications, the assessment should account for this need. The inventory should determine whether others can be easily trained to undertake the required roles.

With only moderate improvements, existing facilities and equipment may be available to support enforcement. The inventory should include a list of facilities, including laboratories, and other equipment available to support TFA collection and analysis. These may be owned by the government or may be available for government use at a reasonable price. For example, a

university may already run a laboratory that is equipped to test TFA levels in foods. Laboratories with certain equipment, or that employ relevant methods, may be equipped to rapidly adopt TFA assessment methods. These include infrared spectroscopy, gas chromatography, Fourier-transform infrared spectroscopy, reverse-phase silver ion high-performance liquid chromatography, and silver nitrate thin-layer chromatography. The assessment should consider the quality of the facilities and their equipment, and the cost of any upgrades that might be necessary. In addition to the core equipment and facilities needed, governments should consider whether there are enough resources to support ongoing maintenance, as well as office supplies, transportation and other costs. For more on assessment techniques, see module 4.

KEY ENFORCEMENT STRATEGY: USE REGIONALLY ACCREDITED LABORATORIES

For countries that do not have the capacity to test food samples for TFA, it may be possible to consider using regionally accredited laboratories for these tests. Governments may have different processes for accrediting laboratories or approving the test results of nongovernmental laboratories. For governments that have no capacity or insufficient capacity to test for TFA, it may be important to research the accreditation or approval processes for laboratories early in the process of developing policy and enforcement strategies, especially if these processes are likely to be time-consuming. Also, accreditation information may provide a more comprehensive understanding of a country's potential testing capacity, which may inform the decision of which inspection strategy is most appropriate.

Agency budgets should include support for implementation and enforcement of new policies; however, budgets generally are already set when new legislation is put in place, so agencies may initially need to reallocate existing resources. The inventory should consider whether the current budget has room to support additional costs for new staff and facilities. If not, policy-makers should consider whether it is likely that additional funds will be granted during the next budget cycle. In regulatory environments where fee- or fine-based revenue generation is administratively possible, these resources should be considered, if necessary and appropriate.

After the inventory of enforcement resources is complete, governments should assess strengths and challenges in monitoring and evaluation requirements to implement TFA laws and regulations. For example, if in-country laboratory capacity is limited but budget analysis shows available resources for procuring equipment, policy-makers would need to decide whether there are enough human resources to use and maintain any new equipment that is bought, or whether there is capacity to train current staff in its use. If so, these decisions would need to be reflected in the budget allocation process.

2.3 STEP 3: DESIGN AN APPROPRIATE INSPECTION STRATEGY TO ASSESS COMPLIANCE

Based on the assessment of the government's authorities and resources, countries should design a strategy to inspect products and facilities to determine whether they comply with TFA laws and regulations. The strategy should consider various inspection techniques, such as laboratory testing, label analysis and facility investigation. Inspection strategies may differ, depending on how the legal measures regulate TFA, such as whether they ban all PHO or impose a limit on the percentage of TFA allowed.

Inspection techniques to assess compliance include the following.

- **Laboratory testing:** A certified laboratory conducts scientific tests on samples of foods to determine the precise levels of TFA. Laboratory testing allows inspectors to accurately assess TFA levels in foods and ensure that these levels do not exceed the legal limit. Laboratory analysis may include the need for specialized equipment and testing facilities,

as well as significant expertise and training to perform the testing appropriately. This is often challenging for low-resource countries with limited or no laboratory facilities. Furthermore, laboratory tests cannot reliably identify PHO (as distinct from other TFA), so this option should not be used to enforce a PHO ban without additional validation. Excess levels of TFA usually indicate the presence of PHO (although this is not conclusive), because PHO are the primary source of TFA and tend to significantly raise the level of TFA in all foods. See module 4 for further explanation of assessment methods and criteria for laboratory selection.

- **Label analysis:** Inspectors can review labels on packaged foods to determine whether the product complies with limits. There should be a requirement to disclose TFA quantities on nutrition labels and to list PHO (or equivalents) with other ingredients. This inspection tactic can be used to quickly enforce either a TFA limit or a PHO ban, especially when scientific testing is not widely available. However, there are limitations to this approach: some countries have not required disclosure of TFA in nutrient declaration, such as back-of-the-pack labels or nutrition facts panels, or PHO in ingredients lists; labels are rarely available on bulk or prepared foods; and inspectors must rely on the truth of the label without additional validation, which may require scientific testing. Additionally, PHO may appear on the ingredient list in different forms – for example, "partially hydrogenated vegetable oil", "shortening" or "margarine" – so inspectors must be aware of the common terms for PHO.
- **Facility investigation:** Inspectors can investigate whether factories, processing plants, and other oil and fat refineries are engaging in the process of partial hydrogenation – a major source of TFA. Legislation should provide inspectors with the power to inspect establishments where partial hydrogenation might occur, and to search industrial premises if violations are suspected. This tactic is especially efficient when a large amount of TFA in the food supply can be traced to a handful of domestic producers, thereby reducing the need for extensive testing further downstream. In most cases, inspectors will already be monitoring these facilities, so existing inspection sites and protocols need only be updated to include TFA-specific compliance requirements.
- **Review of documents and records:** Government inspectors can review customer and shipping records, supply contracts, bills of lading and other documents that enable characterization of the full supply chain. Legislation should provide inspectors with the power to request relevant documents, especially if there is a reasonable suspicion that a violation of law has occurred. The documents can reveal important information about the various companies throughout the supply chain.

See Annex 1 for solutions-oriented approaches for inspections.

KEY ENFORCEMENT STRATEGY: CONSIDER INCORPORATING A LICENCE, REGISTRATION OR PERMIT SCHEME

Licensing, registration and permitting schemes can be an efficient and powerful anchor for TFA enforcement measures. Many countries already require businesses that manufacture, process, pack or hold food to register and maintain a licence to operate within the jurisdiction. Similar requirements may be in place for importers. Because suspension or termination of a licence can be financially devastating, businesses are highly motivated to fulfil all licensing requirements. For example, a licensed oil refiner might be asked to declare that no vegetable oils are partially hydrogenated on the premises. If the refiner falsely reports the absence of PHO, they would be in violation of the law and risk losing their licence. Similarly, a restaurant might be required to declare that no menu items contain more than the permissible threshold of industrially produced TFA to maintain their operating permit.

By incorporating TFA restrictions into existing pre-market registration or licensing schemes, governments can communicate new standards to a wide range of stakeholders and hold them to those standards with minimal additional effort or cost. If no current pre-market registration or licensing schemes exist, countries might consider establishing a limited registration or licensing scheme for stakeholders who are most likely to handle TFA, such as producers and importers of hydrogenated oils.

3. LAUNCH ENFORCEMENT STRATEGY

After designing an enforcement strategy in accordance with a national context, countries should take all the steps needed to ensure that the law can be enforced on its date of effect. Structured and thoughtful preparation will ease adoption of the TFA policy across the affected sectors. This preparation should be done in consultation with relevant stakeholders to ensure effective dissemination of information and resources. To launch an enforcement strategy, the following general steps may be implemented.

4. Set a clear timeline for implementation.
5. Inform stakeholders about the legal requirements.
6. Mobilize resources for enforcement activities.

3.1 STEP 4: SET A CLEAR TIMELINE FOR IMPLEMENTATION

Legal measures should include a reasonable implementation period for phasing out the use of industrially produced TFA. This rollout period gives stakeholders adequate time to reformulate products and dispose of current supplies. It also gives government officials time to design an enforcement strategy, train their officials and procure equipment. Eighteen months may be enough time for stakeholders to fully comply with the laws and regulations. No matter how the implementation schedule is designed, all timelines should ensure that the legal measures are fully implemented for all products before the WHO target of 2023.

There are different ways to design a rollout period, such as prescribing:

- a single effective date, commonly 6–18 months after publication of the law;
- a structured transition schedule by incrementally reducing the maximum threshold limit for TFA across all foods over a specified time – for example, setting an initial 5% TFA limit for the first six months after enactment, then further reducing the maximum limit to 2% after 12 months;
- different schedules for specific food categories (for example, fried foods, baked goods, margarines), with timelines dependent on the complexity of reformulation; or
- process-based timelines directed at the stages of the supply chain – for example, reformulating recipes, adjusting manufacturing processes, redesigning labels and marketing materials, and removing noncompliant products from retail locations.

See Annex 2 for example timelines for compliance, as well as examples of TFA-specific penalties.

3.2 STEP 5: INFORM STAKEHOLDERS ABOUT THE LEGAL REQUIREMENTS

To ensure compliance, the government should inform stakeholders about any new legal requirements. Ideally, all relevant stakeholders would be notified about the legislation before its enforcement.

Simply publishing new legal measures via official outlets (or providing a link on an agency website) is rarely enough to ensure that all stakeholders understand and comply with the new requirements. Instead, a comprehensive communications strategy is needed.

A comprehensive communications strategy frames the law as a necessary public health measure that will save lives. (See module 5 for more information.) This can increase awareness of, and support for, the law and greatly reduce the burden on enforcement agencies. As part of comprehensive outreach and communication, governments should:

- provide opportunities for stakeholders to review and comment on draft laws and/or regulations before their enactment; there should be clear rules to ensure transparency and otherwise reduce industry interference in the policy-making process;
- publish and distribute the final legal requirements widely;
- provide detailed, tailored guidance about the legal obligations to all affected stakeholders;
- suggest techniques to help buyers conduct due diligence of their suppliers;
- train inspectors and other officials;
- enlist media and civil society to help mobilize public support for the law, and industry compliance with the law;
- provide advance notice about enforcement as the deadline for compliance approaches; and
- notify offenders of noncompliance and take appropriate regulatory action (for example, fines, closure).

Before and during the policy implementation process, governments should also communicate with companies and provide them with technical support to help ensure compliance and ease the transition to healthier replacement oils. (See module 2 for details.)

3.3 STEP 6: MOBILIZE RESOURCES FOR ENFORCEMENT ACTIVITIES

Countries are encouraged to allocate the minimal resources needed to effectively enforce TFA legislation. Governments should take steps to ensure that necessary funds can be used to launch and sustain enforcement activities over the long term. This can be done efficiently and inexpensively by employing the following strategies.

- **Allocate a sustainable budget for implementation and enforcement activities:** Administrative agencies should dedicate existing funds to support enforcement activities, as permitted by law. These agencies should also request funds – through budgets, other appropriations or revenue-generation procedures – to support the additional activities required to implement new government policies.
- **Incorporate TFA enforcement into existing systems:** To reduce costs, enforcement agencies should enlist human resources and equipment that are already dedicated to food and nutrition (inventoried in Step 2, above). TFA inspections can be incorporated into existing food inspection processes, such as those used for sanitation and hygiene. By empowering and educating existing food inspectors to enforce TFA provisions, countries can avoid the need to create a new unit or dedicate staff solely to enforce TFA laws and regulations. Agencies can pool additional resources, so that each agency can collaborate and cooperate with the primary authority to share the necessary equipment (for example, laboratory supplies, office space, vehicles) and human resources (for example, inspectors, employees) to comply with the law. Although specific tests may be different, the same inspectors and equipment can be used to collect, seal and transport food samples for analysis and other testing. See the case study in Box 1 for more information.
- **Consider charging businesses for inspections, if feasible:** Licensing and permitting schemes often involve a fee for initial issuance and renewal of the licence or permit. Consider modifying this fee to accommodate additional anticipated expenses for TFA compliance checks. In some jurisdictions, agencies can charge businesses a fee for each inspection and/or laboratory analysis that is required by law. These fees can be cycled back into the system to fund implementation and enforcement activities. Even in countries where government-acquired fees are consolidated into a general fund, the awareness that these fees will increase may help to make the case that additional inspection resources are warranted at the agency level.
- **Apply financial sanctions to fund enforcement:** In some countries, administrative fines paid by violators can be dedicated to a specific government body or activity. Businesses that fail to comply with legal requirements can, if allowable, be fined to fund future enforcement. In jurisdictions where defendants have the right to defend themselves in court, some governments offer a lower fee if the defendant agrees to plead guilty to the offence and waive a trial. In some cases, these fees can be dedicated to ongoing enforcement of food and nutrition (such as TFA) provisions, or their collection can be used to justify supplementing an agency's budget.

BOX 1. CASE STUDY: NEW YORK CITY'S LIMIT ON TFA IN RESTAURANTS, USING AN EXISTING LICENSING (PERMIT) SYSTEM

New York City (NYC) led the United States in limiting TFA in restaurants in 2007. An amendment to NYC's Health Code phased out the use of industrially produced TFA in all food service establishments that required a NYC Health Department permit, including restaurants, caterers, mobile food-vending units and mobile food-vending commissaries. In September 2006, the Board of Health published a notice of intention to ban TFA; the Board held a public hearing in October 2006. Support for the ban was overwhelmingly positive, and the Board of Health adopted a resolution to eliminate industrially produced TFA. The regulation was implemented in two stages.

- On 1 July 2007 (six months from passage of the regulation, after a draft regulation had been published and comments from affected industries received and addressed), food service establishments in NYC were not allowed to use PHO, shortenings or margarines for frying, pan-frying (sautéing) or grilling, or as a spread, unless their product labels or other documents from the manufacturer showed that these ingredients contained less than 0.5 g of TFA per serving. Food establishments could continue using TFA-containing oils and shortenings for deep-frying cake batter and yeast dough until the regulation took full effect on 1 July 2008.
- On 1 July 2008, no food containing PHO, shortenings or margarines with 0.5 g or more of TFA per serving could be stored, used or served by food service establishments.

To enforce these new rules, after substantial media coverage and clear regulatory information had been sent to every licensed establishment, NYC Health Department inspectors incorporated the TFA regulation into their routine restaurant health inspections. According to United States labelling regulations, foods with more than 0.5 g of TFA per serving must list the amount of TFA in the product. During their regularly scheduled inspections, restaurant inspectors examined the ingredients statements of packaged foods stored by the restaurant. If PHO were listed, they referred to the nutrition facts panel to determine whether the level of TFA present in the food was above the permitted threshold. Additionally, NYC's Board of Health reserved the right to perform laboratory testing to ensure compliance. Finally, NYC used Administrative Tribunal hearing officers to assess fines amounting to between $200 and $2000 for each violation, with penalty increases for repeat violations. The NYC Health Department routinely analysed violations and repeat violators, using these data to meet with the restaurant industry to help drive compliance. It also periodically reported publicly its inspection findings and violation rates.

4. IMPLEMENT ENFORCEMENT STRATEGY

Once a TFA law comes into effect, the government should identify and deter violations, and provide public feedback on the status of implementation. To ensure that the objectives of the TFA policy are maintained permanently, the following general steps may be implemented.

7. Monitor legal compliance across the supply chain and identify violations.
8. Hold violators accountable through legal systems.
9. Share enforcement results with policy-makers and the public.

4.1 STEP 7: MONITOR LEGAL COMPLIANCE ACROSS THE SUPPLY CHAIN AND IDENTIFY VIOLATIONS

Successful enforcement requires monitoring of compliance across the supply chain – importing, exporting, manufacturing, storing, distributing, selling and using products with TFA – and identifying the gamut of violations that may occur. Governments should observe the following principles.

- **Identify the most critical control points:** This requires identifying actors, places and instances along the supply chain where violations are most likely to occur, including facilities that are especially likely to handle TFA (for example, oil refiners with partial hydrogenation facilities), food categories and products that are likely to contain high TFA levels (for example, fried and baked goods, margarine, shortening), and facilities with particularly vulnerable populations (for example, school cafeterias). See the case study in Box 2 for further discussion.
- **Establish monitoring procedures that target critical control points:** Particularly in the early stages of TFA enforcement, governments should conduct spot inspections at targeted critical control points. Inspectors should aim to target the main sources of TFA supplied to the population, whether high consumption is due to the level of TFA per serving or the product's popularity. Inspectors should prioritize the largest manufacturers, which are the easiest and least costly to inspect, while being the most vulnerable to public scrutiny. Targeted inspections will send an immediate message to businesses that the government intends to strictly enforce the laws and regulations.
- **Include TFA checks with general health and safety inspections:** Following the initial rollout and enforcement effort, most countries should have high levels of compliance throughout the supply chain, including critical control points. TFA inspections can then be incorporated into general health and safety inspections. By continuing to regularly check for TFA after the initial enforcement push slows, governments discourage businesses from reintroducing TFA. These monitoring and investigative processes may be integrated into a broader surveillance strategy to assess any remaining TFA in the food supply. (See module 4 for further discussion.)
- **Share monitoring responsibility across agencies:** Monitoring compliance across the supply chain requires collaboration and shared responsibility between agencies. For example, health officials should collaborate with customs officers at border points to help identify violators outside the scope of typical health inspections, especially if imported food products are a significant source of TFA.
- **Focus monitoring on "bad actors":** Inspectors, particularly in countries with limited resources, may consider focusing monitoring on businesses that have committed repeated or especially egregious violations in the past. These might include businesses

that deliberately misled inspectors, fraudulently mislabelled products, or committed other serious violations of food and nutrition laws. Although inspectors should avoid discriminating against, or harassing, any individual or business, it may be appropriate to focus inspections on businesses that have previously defied food and nutrition laws.

- **Institute effective record-keeping and documentation of violations:** Governments should take steps to ensure that all inspections – whether or not they detect violations – are properly recorded. Procedures should ensure proper documentation of all relevant details of the inspection, including date and time, location and description of the facility, the inspector's details, samples collected, documents compiled, tests performed, whether notice was given and chains of custody. Additional steps should be taken to guarantee the integrity of any samples, packaging, test results and other collected evidence.
- **Create and track indicators of enforcement activities and compliance results:** Each agency involved in enforcement activities should determine how it will evaluate its own activities for meeting targets, efficiency and anticorruption practice. Trends in compliance should be calculated at the facility, industry sector, supply chain and geographic levels. These should be routinely calculated and reviewed by senior personnel. Findings should inform future activities.
- **Design testing protocols with the proper technical expertise:** Inspection protocols should acknowledge that current tests for TFA, although scientifically valid, may have certain limitations. TFA levels vary across products and product lines, so a single test of one sample may not provide representative results. Trace amounts of TFA can inadvertently form through processing of other edible oils, so oils that are repeatedly reheated (such as French fry or doughnut oil) may have higher levels of TFA than fresh oil. Available testing methods also have a standard margin of error. The inspection protocol should include quality assurance and quality control measures to account for these uncertainties – for example, testing multiple products over time and providing an allowance for TFA levels within a reasonable margin of error. (See the protocol for measuring TFA in foods in module 4 for more details.)
- **Establish a complaints line:** Consumers, consumer organizations, academic institutions, whistle-blowers and competitor food companies may have additional information and resources on TFA levels in food. The government should establish a hotline or website where the public can report possible violations. This intelligence can guide inspectors in conducting follow-up investigations.

BOX 2. CASE STUDY: THAILAND'S EXPERIENCE ENFORCING ITS BAN ON PHO

Thailand completed an in-country assessment of TFA consumption and production. The assessment confirmed that products made via partial hydrogenation (doughnut frying fat, shortening, margarine, fried donuts, pies, puffs and pastries) contained the highest percentage of TFA in Thailand's food supply. The assessment also found that western-style foods, not local foods, used the most PHO. The government undertook a 12-month situational analysis that included a food survey and focus groups with stakeholders (including oil and fat producers and importers, food producers and importers, regulators, laboratory experts and consumer protection organizations). Following this, the government issued a Draft of Notification at the end of 2017 that was open to a six-month public hearing.

On 13 July 2018, the Ministry of Public Health published Notification No. 388 that:

- prohibits the production, importation and distribution of PHO and its products in Thailand;
- establishes that noncompliance with the law will subject offenders to imprisonment for 6–24 months, along with fines of 5000–20 000 baht (US$ 150–600); and
- entered into force on 9 January 2019, 180 days after publication, to allow for an orderly transition.

To enforce the new rules, Thailand identified a critical control point in the supply chain: three in-country processing plants capable of partially hydrogenating oil. Thailand regulates all upstream production of PHO by monitoring these sites. Downstream, Thailand's Food and Drug Administration (FDA) established monitoring procedures that target critical control points for post-marketing TFA compliance by testing food samples that are the main sources of TFA. Targeted testing saves costs because widespread testing is expensive. It also ensures that money is not wasted on testing foods that are not likely to have high levels of TFA. Food surveys used for surveillance and monitoring will be done in partnership with the FDA, Thai Health and local universities, which makes continued enforcement sustainable and affordable.

Importers of food products must ensure that imported products do not contain PHO or use ingredients that contain PHO. Thai FDA inspectors at the port may request evidence that products do not contain PHO in margarine, shortening, creamer, whipping cream or bakery products (for example, biscuits, cakes, pastries, cookies). Finally, the Agriculture Research and Development Agency has committed to providing full support for situational analyses and product development as needed under the ban.

4.2 STEP 8: HOLD VIOLATORS ACCOUNTABLE THROUGH LEGAL SYSTEMS

Once a violation has occurred, the government should ensure that the violator is held accountable. This requires defining what constitutes an offence under TFA law and pursuing a deterrent penalty through the appropriate legal system.

Typically, each element of an offence will be defined directly in the relevant law and/or regulation. Each element of the offence must be proven to satisfy the legal requirements. See Annex 3 for example legislation and further explanation on establishing elements of an offence. Penalties should be strong enough to deter violations, while remaining proportionate to the offence. There is no "one size fits all" type of penalty, but penalties are most effective as a deterrent when people believe that their noncompliance will be detected and quickly punished, and when the cost of noncompliance is substantial relative to other operational expenses.

Rather than providing a single penalty for any violation, penalties should increase as the behaviour becomes more egregious or harmful. The range of penalties might include:

- warnings
- additional testing or disclosure requirements
- recall of products
- fines that rise with repetition and severity of offending
- licence suspension or revocation
- imprisonment (in extreme circumstances).

See Annex 2 for more examples of TFA-specific penalties and accompanying example legislation. Box 3 discusses enforcement of TFA legislation in the informal food sector.

KEY ENFORCEMENT STRATEGY: MONITOR LEGAL COMPLIANCE AT THE BORDER THROUGH IMPORT CONTROLS

In the United States, the Food and Drug Administration (FDA) regulates the level of colour additives in food. Colour additives are another industrially produced substance that are considered dangerous in excessive levels when added to food; successful techniques to enforce restrictions on colour additives provide lessons for TFA enforcement. To monitor compliance at the border, the FDA uses import alerts as one enforcement strategy.

Normally, inspectors at the border must physically inspect each product to determine whether it complies with the law. When inspectors notice a pattern of violations, they can issue an import alert that gives them authority to detain products without physical examination. For example, the FDA issued an import alert that identified more than 450 manufacturers and products from 35 countries using illegal or undeclared colour additives. This alert places the responsibility back on the importer to ensure that the imported product complies with the laws and regulations. These import alerts stop products in violation with the law from being distributed, provide uniform coverage across the country, and free agency resources to examine other shipments.

Applying a similar system to TFA restrictions may increase countries' capacity to monitor compliance at their borders, especially for countries with robust nutrition labelling laws. For example, import alerts could be sent out for products when customs officials see PHO listed as an ingredient or TFA levels exceed legal limits on nutrition facts panels, or when customs officials receive alerts from other countries that a manufacturer of an imported good has been cited for a violation. Additionally, some countries use databases of products that commonly contain TFA to enable customs officials to screen and test for these products at the border.

BOX 3. ENFORCEMENT IN THE INFORMAL FOOD SECTOR

In many low- and middle- income countries, TFA-containing foods are prevalent in the informal food sector – for example, street vendors and secondary markets. Governments will need innovative enforcement strategies to reach this informal sector because testing every product is not feasible, and vendors are not in a position to test and label their own foods.

Enforcement approaches in the informal food sector should focus on education and collaboration. For example, inspectors can issue warnings aimed at educating vendors on changing oils to healthier options. Additionally, partnership with, and outreach to, informal food sector associations can help disseminate key messages. These techniques represent an opportunity for community engagement rather than merely imposing penalties. This approach has the added benefit of curtailing the potential for, and perception of, corruption by lower-level food inspectors.

Although there may be sanctions for violations, these should be aligned with a vendor's ability to pay, especially in the informal market. The fine for a violation by an individual street vendor should be proportionately smaller than the fine for a corporate food manufacturer; equivalent fines would not be appropriate. These sanctions might be part of an existing pre-market registration or licensing scheme.

Governments can also incentivize vendors to share information about their oil suppliers, so that enforcement agencies can identify critical control points upstream. For example, a vendor's penalty might be waived if the vendor discloses specific information on their suppliers.

Some countries hold wrongdoers accountable for a civil wrong consisting of an intentional or negligent breach of a duty of care that inflicts loss or harm. The goal of civil law is usually to provide restitution to a harmed person, not necessarily to punish the offender, but the threat of civil penalties can be a strong incentive to comply with the law. These types of cases fall under tort or delict law, depending on the legal tradition. Different legal theories can support a civil claim for a TFA violation – for example, violation of a statutory duty created by a consumer protection or food safety law, or violation of a general duty of care owed to customers. Civil claims can usually be brought by anyone who is harmed by the defendant's breach, including individuals, groups, organizations and even government agencies. Civil procedure rules will set out standards that courts and parties must follow when adjudicating cases brought by either government agencies or the general public.

Some countries allow more punitive measures for TFA violations through criminal or penal law, especially for egregious or deliberate violations. In most criminal cases, the government agency or harmed individual files a complaint with a government prosecutor, who decides whether to pursue a criminal case against the defendant in accordance with the law. A prosecutor may be able to initiate a case without a formal complaint by a victim. Many of the same sanctions available in civil court may be available in criminal cases, although these sanctions are usually defined precisely in a penal code or similar statutes. In certain extreme cases, imprisonment may be a possible punishment. The threat of these punishments incentivizes compliance, even if they are rarely or never employed.

Refer to Annexes 2 and 3 for example legislation that incorporates the penal code within enforcement procedures.

4.3 STEP 9: SHARE ENFORCEMENT RESULTS WITH POLICY-MAKERS AND THE PUBLIC

Enforcement agencies should share the results of enforcement activities with policy-makers and the public. The following practices in good governance and information-sharing will improve overall implementation and enforcement.

- **Use the media to shame violators:** Food manufacturers are deeply concerned about their reputation around safety issues. Governments can develop press and campaign materials to notify the public that certain foods or products continue to have TFA above legal limits.
- **Publish enforcement reports:** Governments should require public reporting of the results of enforcement actions. Reports should include the number and location of inspections conducted, a summary of the results, any removal or correction made to marketed products, a breakdown of any violations based on severity and other factors, measures taken to ameliorate violations, and other relevant observations. Regular reporting of enforcement results allows policy-makers and the public to stay informed on the general levels of compliance and identify specific bad actors. See Annex 4 for examples of regularly reported publications on compliance and enforcement from the United States Food and Drug Administration and Health Canada.
- **Ensure transparency:** Enforcement agencies should also consider reporting on the strengths and weaknesses of their enforcement efforts – for example, whether allocated resources are enough to meet needs, or whether any legal or procedural obstacles are hindering effective implementation. Reporting challenges and opportunities directly to policy-makers should contribute to improved enforcement over time.
- **Encourage intergovernmental cooperation:** Enforcement agencies should consider sharing the results of investigations with their counterparts in other jurisdictions. Because a violator that is caught in one jurisdiction may try to unload the same products in another jurisdiction, this information exchange can greatly aid in the identification of noncompliant products or companies that are chronic violators. The terms of this mutual exchange may require a memorandum of understanding or another formal agreement. Beyond sharing information on specific violations, the information exchange may include sharing of general information on enforcement techniques. Examples of this approach exist for regulation of food dyes. For example, whenever a food product that poses a threat to human health is detected in a European Union Member State, the European Union distributes an alert across its members to allow appropriate authorities in other Member States to react.
- **Include civil society:** Although enforcement of laws is a fundamental responsibility of government, civil society also plays an important role in monitoring and accountability. Even in the absence of sophisticated government enforcement mechanisms, civil society can help identify bad actors and pressure the industry to voluntarily recall noncompliant products and reformulate product lines to avoid use of TFA. Governments should empower and encourage civil society to support enforcement.

REFERENCE

World Bank. (2005). Good practices for regulatory inspections: guidelines for reformers. Washington, DC: World Bank.

ANNEX 1. SUGGESTED INSPECTION PRACTICES

Table 1. Designing an appropriate inspection strategy to assess compliance: laboratory testing

MINIMUM PRACTICE	BASIC PRACTICE	IDEAL PRACTICE
Governments rely on label analysis of TFA levels in foods or PHO listed as an ingredient, but reserve the right to test samples for compliance if a violation is suspected	Use regionally accredited laboratories to test food samples, prioritizing products likely to have high levels of TFA	Adopt laboratory standards with specific rules to ensure that test results are trustworthy, including minimum qualifications of technicians, quality of equipment, schedule of calibrating equipment and procedures to maintain chain of custody

RESOURCES

Source: Adapted from World Bank (2005).

Table 2. Designing an appropriate inspection strategy to assess compliance: facility investigation

MINIMUM PRACTICE	BASIC PRACTICE	IDEAL PRACTICE
Inspectors make unannounced visits to designated sites on a schedule (e.g. once a quarter, once a year), focusing enforcement on targeted food products that are most likely to have large amounts of TFA and facilities that are most likely to produce large amounts of TFA	Inspectors track repeat offenders and high-risk sites (e.g. facilities with ability for partial hydrogenation), and allocate the major share of resources for inspections in these areas	Inspectors maintain databases to track offences by sector and business, and target inspections to these sites' activities

RESOURCES

Source: Adapted from World Bank (2005).

STEPS TOWARDS GOOD PRACTICE ACROSS ALL CAPACITY LEVELS

- Determine appropriate standards for laboratories to accurately test TFA levels in products
- Determine the number of in-country laboratories available, including universities and private laboratories, and certify those that meet minimum standards
- Resolve conflict of interest issues if laboratories are owned (or heavily used and/or funded) by food companies
- Train and quality assure laboratory technicians in basic procedures for accurately testing for TFA in food

STEPS TOWARDS GOOD PRACTICE ACROSS ALL CAPACITY LEVELS

- Set up information systems that identify high-risk sectors and businesses within these sectors
- Develop and track indicators to monitor activities and progress towards inspection goals
- Use data to calculate trends and patterns in compliance and noncompliance by sector, region, etc.
- Track repeat offenders and potential “usual suspects”, based on trends and sector-wide patterns
- Focus on the most egregious violators, to reduce the number of inspections needed, and save time and money
- Shift inspection resources towards the highest-risk sectors and businesses

Table 3. Designing an appropriate inspection strategy to assess compliance: inspection procedures

MINIMUM PRACTICE	BASIC PRACTICE	IDEAL PRACTICE
Inspectors follow basic inspection procedures developed by the regulatory body in charge of enforcement of TFA policy	Inspectors follow published guidance, in consultation with the business community, on inspection procedures, including monitoring of inspector actions	Inspectors publish detailed, transparent and consistent procedures covering every step of the inspection process through to resolution of problems. Procedures are backed by legal requirements, providing due process

RESOURCES

Source: Adapted from World Bank (2005).

Table 4. Inspectors and inspection powers

People or entities importing, exporting, manufacturing, storing, distributing, selling and using products with TFA should be subject to inspection and required to provide records to inspectors so that inspectors can track noncompliant products.

INSPECTORS ARE GENERALLY GIVEN THE POWER TO:	INSPECTORS SHOULD ALSO BE REQUIRED TO:
› Inspect facilities with or without advance notice › Search premises where they suspect that a law is being violated › Enter premises where food is being manufactured, packed, labelled, served, etc. › Complete spot checks › Train business personnel › Ask for information or documentation from food businesses › Collect and analyse food samples › Issue warnings or other penalties › Seize products › Suspend licences to operate food businesses on a temporary basis › Report violations › Investigate complaints	› Follow detailed, transparent and consistent procedures covering every step of the inspection process, through to final resolution of problems › Provide guidance, in consultation with the business community, on TFA inspection procedures › Discuss how procedures can be organized to best support appeals with due process › Provide testimony when needed during adminstrative or court proceedings › Be properly trained to enforce TFA law, which may require new technical expertise

Source: Adapted from World Bank (2005).

STEPS TOWARDS GOOD PRACTICE ACROSS ALL CAPACITY LEVELS

- Draft a procedures manual for review by appropriate stakeholders
- Consult with the business community on the manual so that they understand how to comply with the legislation
- Discuss how procedures can be organized for any appeals process, with consideration given to due process
- Train inspectors on detailed elements of the inspection process
- Do not give inspectors authority to close businesses; this decision should be made by appropriate legal authorities

ANNEX 2. EXAMPLES OF TIMELINES FOR COMPLIANCE AND TFA-SPECIFIC PENALTIES

As more and more countries have implemented TFA laws and regulations, different approaches for timelines for compliance have emerged. Table 1 provides the effective date and implementation schedules used by selected countries to enforce their TFA laws.

Table 1. Example timelines for compliance

COUNTRY	TYPE OF POLICY	EFFECTIVE DATE AND IMPLEMENTATION SCHEDULE
Argentina (MERCOSUR Common Market Group)	Mandatory limit on the amount of industrially produced TFA of 2% of total fat in vegetable oils and margarines, and 5% of total fat in all other food products	In 2010, Argentina enacted regulatory maximum limits of 2% of industrially produced TFA per total fat in margarines and vegetable oils, and 5% per total fat in other foods. The compliance period for manufacturers to achieve these limits was two years for margarines and vegetable oils (2012), and four years for other foods (2014)
Canada	Ban on production or use of PHO as an ingredient in all food	On 15 September 2017, Health Canada published a Notice of Modification[2] that forbids the use of PHO in foods. PHO was added to Part 1 (column 1) of Health Canada's List of Contaminants and Other Adulterating Substances in Foods[3] Enforcement of the new requirement by the Canadian Food Inspection Agency includes a two-year phase-in period, during which foods containing PHO that were manufactured before 17 September 2018 can continue to be sold. This period will be allowed, to exhaust existing stock and avoid unnecessary food waste. However, manufacturers will not be permitted to add PHO to foods produced on or after 17 September 2018

[2] See https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/modification-prohibiting-use-partially-hydrogenated-oils-in-foods/information-document.html

[3] See https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/contaminants-adulterating-substances-foods.html

EXAMPLE LEGISLATION

(Unofficial translation)

MERCOSUR Common Market Group – Technical Subgroup No. 3 "Technical Regulations and Conformity Assessment"

"Article 2° – Allow a maximum period of eighteen (18) months for the food industry to reduce the trans fats of industrial production, establishing that the content may not be greater than 2% of the total content of fats in vegetable oils and margarines intended for direct consumption and greater than 5% of total fats in the rest of the food. These limits will not apply to fats from ruminants, including the milk fat of the product.

Article 3° – Give yourself a maximum term of four (4) years to the food industry so that the content of trans fats is not greater than 2% of total fat, both in foods of direct consumption as in ingredients for industrial use. It will not apply to fats from ruminants, including milk fat from the product."

"Food and Drug Regulations

C.R.C., c. 870

DIVISION 15 (TITRE 15)

Adulteration of Food (Falsification des produits alimentaires)

B.15.001 (1) A food referred to in column 2 of Part 1 of the List of Contaminants and Other Adulterating Substances in Foods is adulterated if the corresponding substance referred to, by name or class, in column 1 is present in or on the food."

COUNTRY	TYPE OF POLICY	EFFECTIVE DATE AND IMPLEMENTATION SCHEDULE
Denmark	Mandatory limit on the amount of industrially produced TFA in all foods to no more than 2 g per 100 g of total fat	In 2003, Denmark introduced a law limiting the amount of TFA to 2 g per 100 g of oil or fat. Oils labelled “trans fat free” could not contain more than 1 g of TFA per 100 g of fat. Multi-ingredient food could contain up to 5 g of TFA for every 100 g of oil or fat, but only until December 2003. The law entered into force on 31 March 2003, with a six-month grace period for food to be phased out of the market
Thailand	Ban on production or use of PHO as an ingredient in all foods	On 13 July 2018, the Ministry of Public Health Notification No. 388 Re: Prescribed Prohibited Food to be Produced, Imported, or Sold was published in the Royal Gazette. To allow for an orderly transition in the marketplace, the Thai Food and Drug Administration has given a 180-day grace period, with the official enforcement date of 9 January 2019

EXAMPLE LEGISLATION

(Unofficial translation)

"Order on the content of trans-fatty acids in oils and fats etc.

Section 13, Section 55, subsection 2 and Section 78, subsection 3 of Act No. 471 of 1 July 1998 on foodstuffs etc. (Foodstuffs Act):

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

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

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

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

(Unofficial translation)

"Notification of the Ministry of Public Health

No. 388 B.E.2561 (2018)

RE: Prescribed Prohibited Food to be Produced, Imported, or Sold

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Based on obvious scientific evidence, it is indicated that *trans*-fatty acids derived from partially hydrogenated oils have an effect on increasing the risk of coronary heart disease.

By virtue of the provisions of section 5 and 6(8) of the Food Act B.E.2522 (1979), the Minister of Public Health hereby issues the Notification as follows:

Clause 1 – Partially hydrogenated oil and food products containing partially hydrogenated oil are prohibited to be produced, imported or sold.

Clause 2 – This notification shall come into effect after 180 days from the day following date of its publication in the Government Gazette."

Notified on 13th June B.E.2561 (2018)
Signed Piyasakol Sakolsatayadorn
(Mr. Piyasakol Sakolsatayadorn)
Minister of Public Health

(Published in the Government Gazette Vol. 135, Special Part 166 (Ngor), dated 13 July 2018)

COUNTRY	TYPE OF POLICY	EFFECTIVE DATE AND IMPLEMENTATION SCHEDULE
United States of America	Ban on production or use of PHO as an ingredient in all foods	On 16 June 2015, the Food and Drug Administration (FDA) made its final determination (preliminary determination in November 2013) that PHO are not "generally recognized as safe" (GRAS) for use in food. The law expressly includes an effective date of enforcement and implementation schedule, and has been adjusted since its entry into force (18 June 2018). Despite extending the compliance date for certain uses of PHO, 18 June 2018 remains the date after which manufacturers cannot add PHO to food. The extended compliance date for products produced before 18 June is 1 January 2020.[4] To allow time for reformulation, the FDA is extending the compliance period to stop manufacturing foods with specific, limited petitioned uses to 18 June 2019 until 1 January 2021, to allow these products to work their way through distribution

[4] The FDA states that this action balances the health benefits of removing PHO from the food supply with the need to provide an orderly "transition to the market place".

EXAMPLE LEGISLATION

80 FR 34650

Docket No. FDA-2013-N-1317

"Final Determination Regarding Partially Hydrogenated Oils

A Notice by the Food and Drug Administration on 06/17/2015

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notice; declaratory order.

SUMMARY:
Based on the available scientific evidence and the findings of expert scientific panels, the Food and Drug Administration (FDA or we) has made a final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced *trans* fatty acids (IP-TFA) are generally recognized as safe (GRAS) for any use in human food. This action responds, in part, to citizen petitions we received, and we base our determination on available scientific evidence and the findings of expert scientific panels establishing the health risks associated with the consumption of *trans* fat.

DATES:
Compliance date: Affected persons must comply no later than June 18, 2018."

Table 2. Examples of TFA-specific penalties

COUNTRY	TYPE OF POLICY	TYPE OF PENALTY
India	Mandatory limit on the amount of TFA of 5% in fats, oils and emulsions	License suspension and/or revocation
Norway	Mandatory limit on the amount of industrially produced TFA in all food of 2 g per 100 g of total fat	Fines that rise with repetition and severity; imprisonment
Singapore	Mandatory limit on the amount of industrially produced TFA in all food of 2 g per 100 g of total fat	Fines that rise with repetition and severity
Thailand	Ban on production or use of PHO as an ingredient in all food	Fines that rise with repetition and severity; imprisonment

EXAMPLE LEGISLATION

"India, Food Safety and Standards (Food Products Standards and Food Additives) and Regulations/Food Safety Standards (Licensing and Registration of Food Businesses) Regulation

Provided that wherever the standards given in these regulations are at variance with any of the provisions of the licenses already granted, Food Business Operator shall comply with the provisions of these regulations within six months from the date of commencement of the regulations.

2.1.8 Suspension or cancellation of Registration Certificate or license

(1) The Registering or Licensing Authority in accordance with the provisions of section 32 of the Act may, after giving the concerned Food Business Operator a reasonable opportunity of being heard, suspend any registration or license in respect of all or any of the activities for which the registration/license has been granted under these Regulations after recording a brief statement of the reasons for such suspension, if there is reason to believe that the Food Business Operator has failed to comply with the conditions within the period mentioned in any Improvement Notice served under Section 32 of the Act. A copy of such statement shall be furnished to the concerned Food Business Operator whose Registration or license has been suspended."

"Act relating to food production and food safety, etc. (Food Act)

6 Penalty
Any infringement of the provisions laid down in these Regulations or individual decisions given pursuant to these Regulations is a criminal offence according to section 28 of the Food Act.

§ 28. *Penal measures*
Any person who wilfully or through gross negligence contravenes provisions or decisions laid down in or pursuant to this Act, or decisions taken pursuant to the Act, is liable to fines or to a term of imprisonment not exceeding one year or both, unless more severe penal provisions apply. Complicity or an attempt is liable to the same penalties. If there are particularly aggravating circumstances, a term of imprisonment not exceeding two years may be imposed."

"Sale of Food Act [Chapter 283, Section 56(1)],

PART V PENALTY

Penalty

261. Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $1,000 and in the case of a second or subsequent conviction to a fine not exceeding $2,000."

"Notification of the Ministry of Public Health No. 388 B.E.2561 (2018)

Partially hydrogenated oil and food products containing partially hydrogenated oil are prohibited to be produced, imported, or sold.

Violators will be fined 5,000 baht to 20,000 baht and can be detained for 6 months to 2 years."

ANNEX 3. ELEMENTS OF AN OFFENCE

EXAMPLE: DENMARK LEGISLATION

"Chapter 2
Penalty provisions etc.

Section 2. It is prohibited to sell the oils and fats covered by the Order to consumers if … [the content of trans fatty acids in the oils and fats … exceed[s] 2 grams per 100 grams of oil or fat].

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

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

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

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

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

In this case, Danish law spells out various types of offences, depending on relevant sections of the law, that constitute a contravention of its TFA restrictions. For example, elements for an offence under Section 2 include:

1. selling oil and fats that contain
2. TFA that exceeds 2 grams per 100 grams of oil or fat
3. in accordance with the definition of TFA provided in the law.

An offence under Section 4 constitutes:

1. a finished product with the "free from TFA" claim that
2. contains TFA greater than 1 gram per 100 grams of the individual oil or
3. contains TFA greater than 1 gram per 100 grams of the individual fat or
4. both in accordance with the definition of TFA provided in the law.

The prescribed punishment for either is a fine; however, the law also provides for greater consequences (imprisonment) if the offence was committed "willfully" or "through gross negligence". To prove this, the offence must either have:

1. caused damage to health or
2. led to the risk of damage to health or
3. resulted in or
4. intention to result in
5. financial gain for the perpetrator or
6. for others and
7. savings made are included as financial gain.

Further, criminal liability is prescribed to companies (and other legal entities) in accordance with the Danish Penal Code.

ANNEX 4. EXAMPLES OF REGULARLY REPORTED PUBLICATIONS ON COMPLIANCE AND ENFORCEMENT

CANADA

General compliance and enforcement information can be found on Health Canada's website: http://www.inspection.gc.ca/about-the-cfia/accountability/compliance-and-enforcement/eng/1299846323019/1299846384123. Health Canada publishes enforcement data relating to suspensions and cancellations, notification of charges and prosecution bulletins. It also publishes quarterly reports of noncompliant and disposed-of food products (categorized by domestic food and imported food), refused shipments, administrative monetary penalties, cancelled certifications, and suspended and/or cancelled accreditation of certification bodies. An example is shown below of publication of a noncompliant and disposed-of domestic food product (quarter July–September 2018).

Canada publishes Annual Inspection Summary Reports that outline inspection activities conducted by the Canadian Food Inspection Agency, which provides all federal inspection services related to food, and enforces food safety and nutritional quality standards.

Ontario

Regulated Party's Name	Location	Authority	Product Description	Reason for Seizure and Detention	Date of Final Product Disposition
732840 Ontario Limited (#409)	Toronto, Ont.	MIR	frozen ready to eat Jamaican-style beef patties	other non - compliance - other	2018-08-31
1376357 Ontario Ltd. (#743)	Toronto, Ont.	MIA	refrigerated, spicy and mild cooked beef filling for Jamaican patty	other non - compliance - other	2018-08-20
Black River Juice Company Ltd. (N/A)	Mississauga, Ont.	CAPA	Black River brand Bartlett pear juice	other non - compliance - other	2018-08-02

UNITED STATES

General compliance and enforcement can be found on the webpage of the United States Food and Drug Administration: https://www.fda.gov/Food/ComplianceEnforcement/default.htm. The FDA also previously published “The enforcement story”, a publication documenting all enforcement-related activities in all product areas over which the FDA has jurisdiction, including enforcement statistics, and documentation of egregious violations and their ensuing penalties.

The FDA publishes weekly Enforcement Reports that track and display updates on all the recalls it monitors, organized by classification, reasoning, code information and product description. An example is shown below for a product containing a restricted substance.

Product Details

Product Description:
SleepWorks Liquid Vitamin & Mineral Herbal Supplement 12 single serving bottles - 2 Fl Oz (60 mL) Net 24 Fl Oz (720 mL), product code W3721
Reason for Recall:
Product contains beta phenyl gamma aminobutyric acid HCl.

Product Quantity:
53,205 cartons
Recall Number:
F-0843-2019

Code Information:
Lots 1711010, 1711018, 1801168, 1801180, 1802108, 1802123, 1802136, 1803198, 1806019, 1806141, 1806159, 1807068, 1808061, 1809089
Classification:
Class II

Event Details

Event ID:
81764
Voluntary / Mandated:
Voluntary: Firm Initiated

Product Type:
Food
Initial Firm Notification of Consignee or Public:
E-Mail

Status:
Terminated
Distribution Pattern:
United States

Recalling Firm:
AdvoCare International, LP
2801 Summit Ave Plano,
TX 75074-7453 United
States

Recall Initiation Date:
11/12/2018

Center Classification Date:
2/7/2019

Date Terminated:
4/17/2019

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REPLACE
TRANS FAT