CARDIOVASCULAR HEALTH

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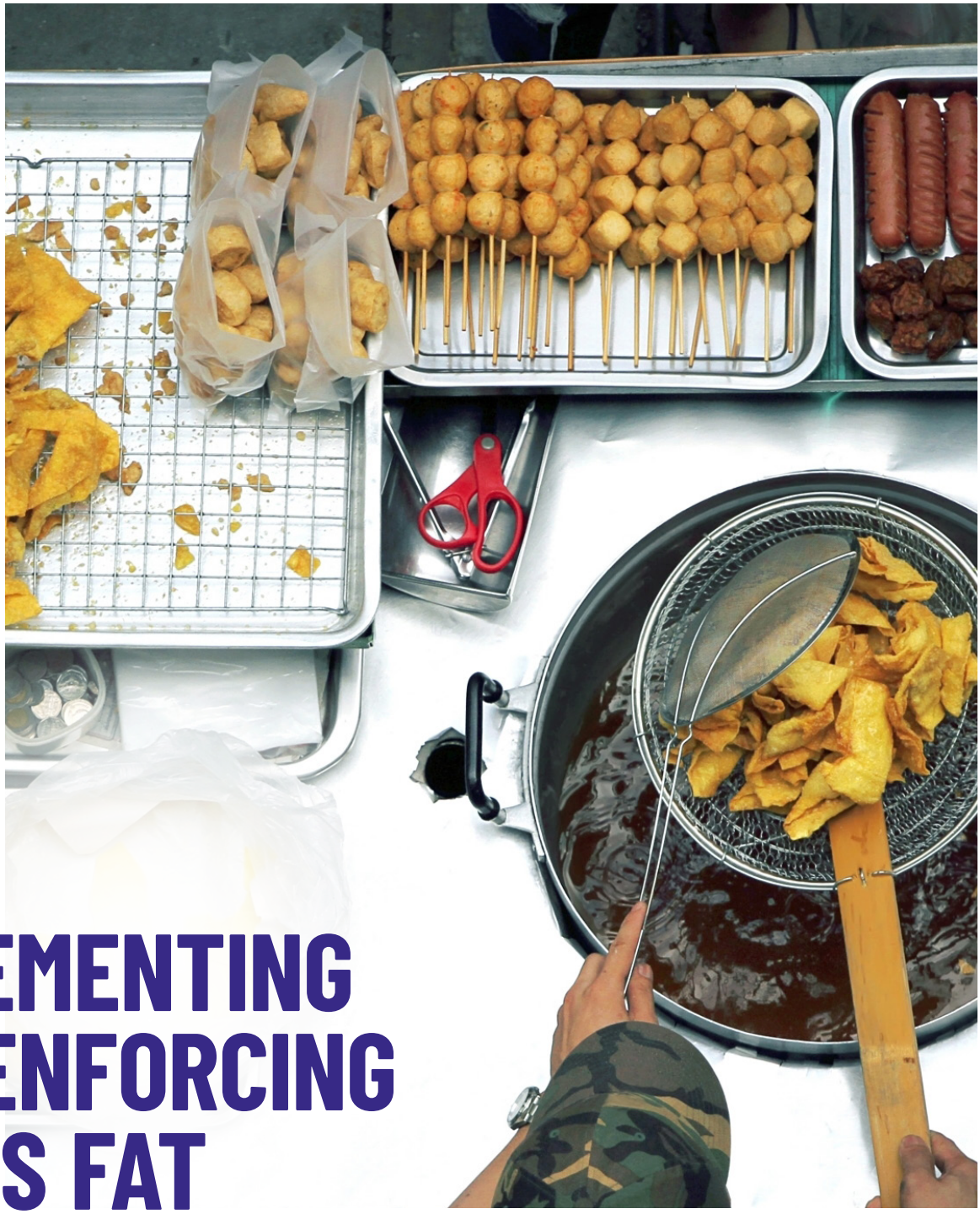

IMPLEMENTING AND ENFORCING TRANS FAT ELIMINATION POLICIES

Case Studies

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ABBREVIATIONS & ACRONYMS

AOAC	Association of Official Analytical Chemists
CVD	cardiovascular disease
DG SANTE	Directorate-General for Health and Food Safety (EU)
DTU	Technical University of Denmark
DVFA	Danish Veterinary and Food Administration
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
GCC	Gulf Cooperation Council
GINA	Global Database on the Implementation of Nutrition Action
IFBA	International Food & Beverage Alliance
ISO	International Organization for Standardization
iTFA	industrially produced *trans* fatty acids
JRC	Joint Research Centre
NCD	non-communicable disease
ODECU	Organization of Consumers and Users (Organización de Consumidores y Usuarios) (Chile)
PAHO	Pan American Health Organization
PHO	partially hydrogenated oils
RDA	recommended dietary allowance
SFDA	Saudi Food & Drug Authority
SMEs	small-and medium-sized enterprises
TFA	*trans* fatty acids
WHO	World Health Organization
WHO EMRO	WHO Regional Office for the Eastern Mediterranean

INTRODUCTION

Background

For the past 30 years, cardiovascular disease (CVD) has been the leading cause of death globally, with coronary heart disease alone responsible for 16% of the world's total deaths (WHO, 2021a). Between 2000 and 2019, deaths from ischaemic heart disease rose faster than deaths from any other disease, increasing from over two million in 2000 to nearly nine million in 2019 (WHO, 2020a). Heart disease and other non-communicable diseases (NCDs) lead to increased risk of serious illness and death from COVID-19 (WHO, 2021a; Bösch et al., 2021); addressing the underlying causes of severe COVID-19 outcomes is a global priority today. Consequently, preventing CVD and other NCDs continues to be an urgent matter not only to save lives, but to support the recovery of economies and health systems following the COVID-19 pandemic.

Best-practice policies are:

1. A mandatory national limit of 2 grams iTFA per 100 grams of total fat in all foods ("2% iTFA limit"), or
2. A mandatory national ban on the production or use of partially hydrogenated oils (PHO) as an ingredient in all foods ("PHO ban") (WHO, 2021a).

A policy package aimed at preventing CVD should include policies focusing on the improvement of the food environment and population diet. One of the recommended nutrition policies to address CVD is the elimination of industrially produced *trans* fatty acids (iTFA), a heart-damaging compound that can be replaced in foods without impacting their consistency, taste or cost.

The elimination of iTFA from the global food supply is a priority target of the World Health Organization's current strategic plan (13th General Program of Work, 2019–2023) as an effective and cost-effective policy measure to save lives. In 2018, WHO called for the complete removal of iTFA from the global food supply by 2023 with the launch of the REPLACE action framework (WHO, 2021a). REPLACE provides governments with a roadmap to eliminating iTFA from the food supply, including six modules guiding the development, implementation, enforcement, monitoring and evaluation of best-practice iTFA policies (WHO, 2021b).

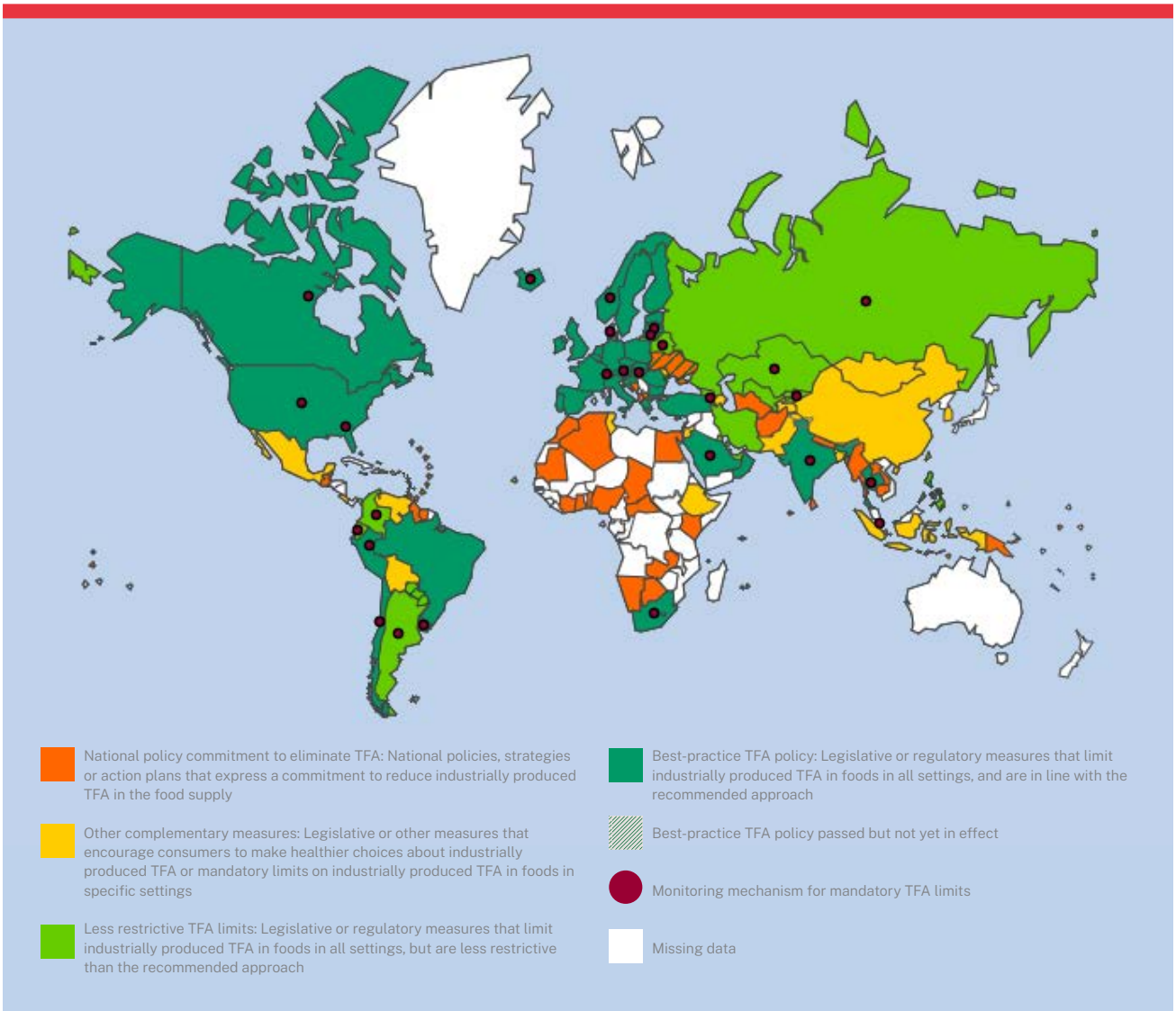
WHAT ARE TRANS FATS?

***Trans* fatty acids (TFA), or trans fats, are unsaturated fatty acids of natural or industrial origin. Naturally occurring TFA is produced in the gut of ruminants; products made from ruminants (dairy and meat from animals such as cows and sheep) contain small amounts of TFA. Industrially produced TFA (iTFA) are created in a process called hydrogenation to produce partially hydrogenated oils (PHO), which are solid or semi-solid fats. Globally, most iTFA is consumed through PHO, which are commonly found in baked goods, pre-packaged foods and some cooking oils.**

iTFA have no known health benefits and are a significant contributor to CVD worldwide, causing an estimated 260,000 deaths annually (Afshin et al., 2016). iTFA intake has also been associated with an increased risk for other NCDs and related conditions such as ovarian cancer, infertility, endometriosis, Alzheimer's disease, diabetes and obesity (Bösch et al., 2021).

Currently, mandatory best-practice policies are in effect in 45 countries, covering around 2.8 billion people (35.5% of the global population) (WHO, 2022). In 2020 and 2021 alone, 27 countries implemented best-practice policies, demonstrating the feasibility of enacting mandatory iTFA regulations. However, most policies to date have been implemented in high-income countries in the Americas and Europe. Only four lower-middle-income countries (Bangladesh, India, Philippines, Ukraine)[1] and eight upper-middle-income-countries (Brazil, Bulgaria, Paraguay, Peru, Romania, South Africa, Thailand, Turkey) have passed a best-practice policy; no low-income country has adopted one (WHO, 2022). Since low-and middle-income countries (LMICs) bear up to 90% of the global CVD burden (Owolabi et al., 2016), it is imperative to extend the protection of best-practice policies globally.

By the end of 2022, WHO plans to open applications for its Validation Programme for Trans Fat Elimination. Eligible countries must demonstrate that they have not only adopted a best-practice policy, but also implemented it with effective monitoring and enforcement systems (WHO, 2021a). It is the first-ever program to recognize country efforts to eliminate an NCD risk factor.



1 India's 2% iTFA limit has been in effect since January 2022 (WHO, 2021a). Bangladesh's 2% iTFA limit is expected to go into effect in December 2022 (WHO, 2021c). The Philippine's combined PHO ban and 2% iTFA limit is expected to go into effect in July 2023 (WHO, 2021d). Ukraine's 2% iTFA limit is expected to go into effect in 2023. (WHO, n.d.).

Aim of the report

This report presents six case studies from five countries and one economic union in different parts of the world that have enacted a best-practice policy to eliminate iTFA from their food supply. The case studies focus on the implementation, enforcement, monitoring and evaluation of iTFA regulations rather than their development and adoption . Numerous publications exist on the development of iTFA policies, and the sheer number of adopted regulations shows the feasibility of passing mandatory iTFA regulations. However, little is known about how countries implement iTFA regulations – a problem because many countries interested in iTFA elimination are discouraged by uncertainties around the practicalities of policy implementation.

This report aims to address this gap by providing information on how governments have tackled implementation and enforcement questions. Its intent is to encourage policymakers to adopt iTFA regulations by showing that enforcement is feasible.[2] Because this report provides examples of practical implementation and enforcement strategies, it may also be useful for civil society organizations advocating for iTFA elimination.

These case studies were chosen to be representative in policy choice, implementation strategy, geography and political system. Countries with a fully implemented best-practice policy in October 2021 were considered. Countries were only included if interviews could be obtained.

The report is based on desk research and nine interviews with 12 interviewees, most of whom wanted to remain anonymous.[3] Annex 1 details the methodology, case selection process and resources used.

2 For guidance on how to include implementation and enforcement considerations at the drafting stage of an iTFA policy, refer to PAHO's *Elimination of Industrially Produced Trans-fatty Acids: A Regulatory Drafting Tool*, available at https://iris.paho.org/handle/10665.2/55242.

3 Chile: Undersecretariat of Public Health, Ministry of Health. Denmark: Danish Veterinary and Food Administration (DVFA) and National Food Institute at the Technical University of Denmark. European Union: Directorate-General for Health and Food Safety (DG SANTE). Saudi Arabia: Saudi Food & Drug Authority (SFDA). Singapore: Health Promotion Board. Thailand: Foundation for Consumers and Thai Food and Drug Administration (Thai FDA).

Overview of case studies

DENMARK

In March 2003, **Denmark** enacted a 2% iTFA limit for all food products that took effect in January 2004.

Early outreach to and collaboration with food manufacturers by the Danish Veterinary and Food Administration, and the National Food Institute's expertise on fats and industrial processes, supported successful implementation of the iTFA limit. The National Food Institute's expertise on fats and industrial processes was important for successful implementation, and its laboratory expertise essential to successfully sampling and testing food products to ensure compliance. Due to high compliance, inspections have decreased since 2013. In April 2021, Denmark's national iTFA limit was replaced by the European Union's 2% iTFA limit.

CHILE

Chile passed a 2% iTFA limit for all food products in April 2009, which took effect after a two-year transition period.

iTFA is completely prohibited in baby and toddler formula and may only contain a maximum of 3 grams natural TFA per 100 grams of fat. Compliance monitoring is linked with surveillance for labeling requirements under the Sanitary Food Regulations and the Food Labeling and Advertising Law, making efficient use of limited enforcement resources. Compliance with the iTFA limit is high, and serious sanctions have not been necessary.

SINGAPORE

Singapore also took a step-wise approach. In May 2012, a 2% iTFA limit on fats and oils was introduced, taking effect one year later.

It was replaced with a ban on the use and importation of PHO in June 2021, taking effect after a one-year transition period. The implementation and enforcement of the iTFA limit was the responsibility of the Singapore Food Agency (SFA) while the Ministry of Health is responsible for the PHO ban. The SFA performed pre-marketing checks, while the Ministry of Health only conducts post-marketing surveillance. Domestic companies could access grants from Enterprise Singapore and technical support from the Health Promotion Board to help with reformulation to phase out PHO.

SAUDI ARABIA

Saudi Arabia took a step-wise approach to iTFA elimination in November 2015.

First, in November 2015, a 2% iTFA limit for fats and oils and a 5% iTFA limit for all other foods was enacted; it took, effect two years later. Then, in December 2018, a PHO ban was adopted; after a two-year transition period this ban replaced the earlier iTFA limits in January 2020. In September 2021, Saudi Arabia introduced limits on total TFA content (artificial and natural) for ruminant products, refined oils, fully hydrogenated oils and baby formula. The Saudi Food & Drug Authority (SFDA) conducted several workshops with and for the food industry to address potential issues ahead of implementation and to provide an opportunity for smaller companies to learn from multinationals. The SFDA sought advice from countries with experience testing for iTFA to overcome challenges with their laboratory methodology.

THAILAND

Thailand passed a ban on the production, importation and sale of PHO in July 2018, which went into effect in January 2019.

Key to successful implementation and enforcement were the availability of a database on TFA levels in products informing the implementation and enforcement strategy; collaboration and communication between stakeholders; existing laboratory capacity; the availability of replacement oils; capable oil and fat manufacturers; and iTFA policies implemented in key export markets.

EUROPEAN UNION

In April 2019, the **European Union (EU)** adopted a 2% iTFA limit in foods intended for the final consumer and for supply to retail.

The limit came into effect in April 2021 and is enforced by national authorities, while the EU's Directorate for Health and Food Audits and Analysis is responsible for confirming effective control systems at the member state level. The EU's iTFA limit will have significant spill-over effects since companies exporting to the EU must also comply with the iTFA limit.

Conclusions

Each of the six case studies highlights a slightly different strategy for implementation, enforcement and monitoring and evaluation of an iTFA regulation, but common themes, success factors and challenges emerge. Below are the key insights for countries considering the implementation of an iTFA policy.

Lessons learned

- The adoption, implementation and enforcement of a mandatory iTFA policy is **politically, technologically and practically feasible**.
- iTFA regulations have the potential to produce significant **spill-over effects benefitting populations** beyond the jurisdiction where the regulations are implemented.
- **Laboratory capacity is the main challenge** of enforcing an iTFA regulation. Scientific support to advise on testing methodology, sampling strategy and staff training is essential.
- The availability of affordable and culturally acceptable **replacement oils and fats** to manufacturers significantly facilitates implementation.
- Food industry actors are technologically and financially able to reformulate products. Nevertheless, government authorities must ensure transition periods are adequate and provide industry with information on the policy changes and support where needed, particularly to smaller operators.
- Most **enforcement costs** come from sampling and testing food products for compliance. Enforcement activities must be budgeted appropriately to ensure adequate sampling and testing. Linking monitoring activities for related food policies, such as food labeling, can be a more effective use of a limited enforcement budget.
- **Monitoring for compliance** ideally includes pre-and post-marketing surveillance and laboratory testing of food samples. Using food labels for compliance controls is cheaper, but less reliable; they should be used as a complement to testing, and as a tool to identify high-risk food products.
- Adequate **penalties, sanctions and administrative measures** must be put in place to enable effective enforcement of iTFA regulations.
- The evaluation of iTFA policies by governments is generally weak and mostly focuses on iTFA levels. Greater **investment in monitoring and evaluation** would help contribute to a better understanding of replacement oils and fats, iTFA intake and the health impact of iTFA regulations.

Feasibility

All interviewees (see Annex 1 for details) agreed that a mandatory approach to iTFA elimination covering all food products is politically and technologically feasible, effective and a good use of limited government resources. It was highlighted that unlike other food policies, such as labeling, implementing an iTFA policy does not require consumer education; it may, however, be valuable (see the case study for Saudi Arabia).

While implementation and enforcement will vary from country to country, the iTFA policy itself is transferable to any context. None of the interviewees could envision a barrier that would make implementation and enforcement of a mandatory best-practice policy impossible.

Spill-over effects

While iTFA regulations are only applicable in the jurisdictions where they were enacted, they can have significant spill-over effects in other markets. For example, all foods imported into the EU must comply with the EU's 2% iTFA limit. Therefore, trading partners who export to the EU must ensure that their products are compliant. This has the potential to also benefit the populations where these non-EU manufacturers are located if they reformulate food produced for the domestic market.

While supra-national regulations such as the EU's iTFA limit can significantly expand the benefits of iTFA elimination to populations further afield, national policies can also have positive impacts on other jurisdictions. For example, some of Thailand's key export markets had implemented a mandatory best-practice policy, which supported the decision to implement a PHO ban nationally. Conversely, a large percentage of imported food products in Saudi Arabia originate from the USA, where PHO is banned. The knowledge that these foods were already PHO-free encouraged Saudi Arabia to introduce its own PHO ban.

Laboratory capacity

The main challenge of enforcing an iTFA regulation is laboratory capacity. In all the cases studied for this report, laboratory methodologies had to be developed to test for iTFA and staff trained on sampling and testing. The scientific support of academics was crucial in Thailand (Mahidol University) and Denmark (Technical University of Denmark). The EU could rely on the Joint Research Centre, the EU's science and knowledge service, for laboratory support, while Saudi Arabia reached out to

health and research agencies of other countries for advice (Health Canada, U.S. Centers for Disease Control and Prevention).

All case study countries and EU member states had existing laboratory infrastructure in place to support enforcement of food legislation; none had to build laboratory capacity from the ground up. Where laboratory capacity does not exist, use of a regional laboratory or contracting a private laboratory could be considered until a national reference laboratory is made operational.

Availability of replacement oils and fats

Implementation is significantly facilitated if affordable and culturally acceptable replacement oils and fats are available to manufacturers. In Thailand and Singapore, palm and coconut oils fit these criteria; however, it would be preferable to replace iTFA with healthier unsaturated fats. In Chile, the staggered implementation timeline ensured that food manufacturers had access to reformulated oils and fats that were free of, or only contained very low amounts of, PHO.[4] In Singapore and Saudi Arabia, the step-wise policy approach also led to the availability of iTFA-free oils and fats for domestic food manufacturers prior to best-practice policies taking effect. In Saudi Arabia, PHO is mostly replaced with palm oil high in saturated fat which the SFDA would like to address in future.

Support for food industry actors

Some food industry actors claim that reformulation to phase out PHO is impossible or too expensive. However, the food industry was able to comply in the numerous countries that have implemented iTFA regulations, including the cases studied in this report. A study conducted for the EU estimated that implementation costs to businesses equaled 0.0066% of the output value of the sector (European Commission, 2019b), demonstrating that replacing iTFA with healthier fats and oils is technologically and economically feasible.

4 Note that a transition period of five years is considered long and is not recommended. Chile was an early adopter and as such needed a longer lead time than countries adopting iTFA regulations now. Experience has shown that six to eighteen months are feasible for industry to take the necessary steps to comply with an iTFA regulation (adapt procurement and manufacturing processes, adjust product labeling, use up existing stock).

All profiled iTFA regulations set a transition period of between six months and five years to allow sufficient time for reformulation; most used a duration of one to three years.

Nevertheless, the responsible government authorities must work with food industry actors (as the regulated entities) to ensure that transition periods are adequately set, provide information on the policy changes and offer help where needed. The approach to industry support will depend on their existing capability, capacity and know-how, and should be tailored to the national industry's needs. If industry challenges are not adequately addressed, timely implementation of an iTFA regulation will be difficult.

All profiled iTFA regulations set a transition period of between six months and five years to allow sufficient time for reformulation; most used a duration of one to three years. At five years, Chile had the longest transition period; this reflects Chile's staggered implementation approach, with a two-year transition period for fats and oils and an additional three years for all foods to ensure appropriate replacement oils were available to food manufacturers and operators.

In all countries and EU member states except for Denmark, effective dates were met. In Denmark, a few smaller companies found it challenging to adapt some baking applications and production processes; they were granted a short extension of the transition period. However, Denmark was the first country to implement an iTFA limit in 2004 and since then, know-how and technology have significantly advanced.

All included countries provided information and support to food industry to some extent. For example, Singaporean companies could access grants and technical support to help with reformulation. Saudi Arabia organized industry workshops and facilitated knowledge transfer from multinational companies to small-and medium-sized enterprises (SMEs). Thailand issued guidelines on how to comply with the PHO ban. In Denmark, the Technical University of Denmark, a close collaborator of the Danish Veterinary and Food Administration provided technical support. Such help was particularly important for SMEs who tend to struggle more to comply with food legislation than large and multinational companies.

Enforcement costs

While none of the countries has evaluated the enforcement costs incurred, all interviewees agreed that sampling and testing food products for compliance account for most of the enforcement costs. None of the countries chose to rely solely on food labels to check for compliance, which is cheaper than laboratory testing but less reliable. Because of limited enforcement budgets, all countries had to either limit the frequency of enforcement monitoring or sample sizes. It is crucial to budget for enforcement activities appropriately to ensure that adequate sampling and testing is possible.

Only Chile opted to link compliance monitoring of the iTFA limit with compliance monitoring of food labeling requirements. Combining monitoring efforts for multiple regulations allowed Chile to use the available enforcement budget more effectively and strengthen overall surveillance of critical nutrients.

It must be noted that at the time of implementation, all case study countries and EU member states had an existing, functional national health governance structure capable of implementing and enforcing mandatory food legislation. This is key to the successful implementation and enforcement of food legislation such as an iTFA elimination regulation. None of the countries had to build a new or strengthen an existing enforcement system and infrastructure. Consequently, enforcement costs were limited to sampling and testing of food products; additional costs, beyond the usual running of existing agencies, were not incurred.

Compliance monitoring

Monitoring for compliance ideally includes pre-and post-marketing surveillance.[5] While Singapore, Saudi Arabia and Chile's Ministries of Health only conduct post-marketing surveillance, Denmark, EU countries and local health authorities in Chile also perform pre-marketing surveillance; Thailand will do so in its next monitoring campaign.

Independent of surveillance approach, all profiled countries opted to focus on the recommended method of laboratory testing of food samples. While food labels are used to identify food products at risk of non-compliance, none of the countries relied on food labels alone for enforcement purposes. Despite investments in laboratory capacity, most profiled countries had limited enforcement budgets which restricted the way compliance monitoring could be conducted. Saudi Arabia is the only country which set regular compliance monitoring as a key performance indicator for the SFDA, and Denmark alone conducted monitoring campaigns every two years for a prolonged period.

Functional national health governance structures capable of implementing and enforcing mandatory food legislation is essential to successful iTFA elimination.

Budget constraints were addressed by establishing a consumer complaints line where suspected violations can be reported (Saudi Arabia), linking monitoring activities for related food policies (Chile), and setting compliance thresholds at which compliance monitoring is reduced (Denmark, Thailand).

Compliance reports were difficult to find online. To promote accountability, it is recommended to make them publicly available.

Adequate sanctions for non-compliance

To enable effective enforcement of their iTFA regulations, all case study countries, the EU and EU Member States have put in place a range of penalties, sanctions and administrative measures to deter non-compliance and hold violators accountable. While some countries include sanctions in the iTFA regulation, others refer to existing legal instruments, such as a penal code. Simultaneously, measures set out in administrative laws or regulations are applicable.

5 Pre-marketing surveillance includes checks of critical control points such oil refining facilities, border crossings or ports of entry where most of a country's food imports enter the territory. Post-marketing surveillance focuses on food products already placed on the market, sampling in supermarkets, shops and other food vendors.

A wide range of sanctions and measures exist in the profiled countries, from warnings and fines to food recalls, food destruction, withdrawal of business or product licenses, and business closure. Only Denmark and Thailand allow for imprisonment in severe cases, though neither country has ever resorted to it for any food law violation .

It was only possible to ascertain the fine amount for Singapore and Thailand. In both cases, fines are negligible and therefore unlikely to deter food industry actors from non-compliance. Measures such as withdrawal of licenses (Thailand) or food recalls (Thailand and Singapore) are more effective, particularly in the absence of adequate fines.

Evaluation

The evaluation of iTFA policies by governments is generally weak and mostly focuses on the iTFA content in the food supply . All profiled countries and the EU conduct compliance monitoring showing iTFA levels after policy implementation, but only Denmark, Singapore and Thailand conducted baseline assessments of iTFA levels. Accurate baseline data on iTFA levels helps not only policy evaluation but helps inform implementation and enforcement. It is recommended that baseline data on iTFA content in food products be collected prior to the implementation of an iTFA regulation.

Knowledge of iTFA levels in the food supply does not permit conclusions on population iTFA intake. Therefore, it is recommended to evaluate the policy's impact both on iTFA levels and on iTFA intake, if resources allow. Only Denmark and Singapore conducted baseline assessments on iTFA intake prior to policy implementation. In Thailand, an innovative pilot project using blood plasma to establish iTFA intake levels is under way. It will provide baseline data and information on the PHO ban's impact on population intake of iTFA.

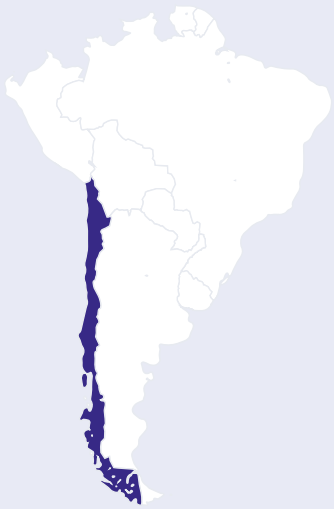
It is important to evaluate if iTFA is replaced with fats and oils high in saturated fats or, preferably, healthier unsaturated fats. If iTFA is mostly replaced with saturated fats, it weakens the potential health benefits of an iTFA policy and further policy action may be required. Only Denmark and Singapore track replacement oils and fats as part of their monitoring efforts. However, despite both countries finding frequent replacement with saturated fats, policy action does not seem to have been taken to date to promote healthier substitutions.

Evaluating the health impact of iTFA policies is more difficult. In some cases, it is too early to establish any health benefits (e.g., Thailand and the EU). Only Denmark is in the process of studying the health impact of their iTFA limit; Saudi Arabia plans to evaluate health outcomes in future.

Countries are encouraged to plan and budget for evaluations of their iTFA policies to contribute to a better understanding of replacement oils/fats, iTFA intake and health impacts. At a minimum, the change in iTFA levels in products contributing significantly to the iTFA burden should be evaluated. It is recommended to also assess replacement oils. Resources permitting, an ideal evaluation will analyze the impact of the regulation on TFA intake and health outcomes.

CHILE

AT A GLANCE



- In 2009, Chile adopted a limit of 2 grams iTFA per 100 grams of fats in all food products. The limit took effect in 2011 for margarines and fats for domestic use, and in April 2014 for all other food products.
- iTFA is prohibited in baby and toddler formula and may only contain a maximum of 3 grams natural TFA per 100 grams of fat.
- The enforcement of Chile's Food Labeling and Advertising Law, in effect since 2016, resulted in stronger monitoring for critical nutrients, including testing more products for iTFA.
- Compliance with the iTFA limit is high, and serious sanctions have not been issued. The Ministry of Health assumes the high compliance is due to the availability of replacement oils and fats with low or no iTFA content.

Overview of Chile's limit on industrially produced trans fats

On April 23, 2009, the Chilean Ministry of Health published Decree 106, introducing a limit of 2 grams iTFA per 100 grams of fats in all food products.[6] The limit took effect two years after publication for margarines and fats for domestic use, and five years after publication for all other food products. The Ministry of Health would like to eventually extend the regulation on iTFA to eliminate fully hydrogenated oils, but there are currently no concrete plans for this.[7]

Decree 106 also established a limit of 3 grams total TFA per 100 grams of fats for baby formula and follow-on milks. In 2019, this was modified to specify that baby formula and follow-on milks may not contain any iTFA, and the 3% limit applies to ruminant TFA derived from dairy.

If a food product contains more than 3 grams of total fat per serving, fat types, including TFA, must be declared separately on the nutrient panel; if the TFA content is 0.5 grams or less per serving, the label may state 0 grams (Sanitary Food Regulation, Art. 115). TFA-free claims are permitted as long as the food product contains less than 0.5 grams of saturated fat and a maximum of 0.2 grams TFA per serving (Sanitary Food Regulations, Art. 120).[8], [9]

6 Decree 106 modified Art. 248 of the Sanitary Food Regulations (Decree No. 977/96) by adding the iTFA limit. To learn more about the development and adoption of Chile's iTFA limit, refer to the case study on Chile by NCD Alliance (2019).

7 Unless indicated otherwise, all information contained in this case study on the Chilean iTFA limit was obtained through an interview and email exchange with an official of the Ministry of Health (Ministry of Health, 2021).

8 Permitted terms are: *libre* (free of), *no contiene* (doesn't contain), *exento* (free of), *sin* (without), *no tiene* (doesn't have), *cero* (zero), *0* and *0%*.

9 Claims of low, reduced or no cholesterol are only permitted if one serving does not contain more than 0.2 grams TFA and 2 grams saturated fat; claims that a product is free from saturated fat are only allowed if one serving does not contain more than 0.2 grams TFA and 0.5 grams saturated fat (Sanitary Food Regulations, Art. 120).

Implementation

The Ministry of Health is responsible for implementation of the iTFA limit, with support from the Chilean Public Health Institute (*Instituto de Salud Pública de Chile*). The Public Health Institute houses Chile's ISO 17025:2017 certified national reference laboratory (ISP, 2021).

The transition period of two years for oils and fats was shorter than for other food products to ensure that all food manufacturers had access to reformulated oils and fats with no or low iTFA content while adjusting recipes to comply with the iTFA limit. This phased approach addressed the challenge of insufficient technology and raw materials to support reformulation at the time of enactment, taking into account that fats and oils are more likely to contain iTFA than other foods, and considering the technological feasibility of phasing out iTFA. Additionally, focusing on domestic margarine and oil producers during the first phase seemed to be the most straightforward approach given that only a few operated in Chile, facilitating enforcement. Lastly, the staggered transition period addressed an administrative request by trade associations to allow additional time for bakery and pastry products, which were the most difficult to reformulate.

After enactment of the iTFA limit, an implementation plan was developed. The plan's activities did not distinguish between large companies and SMEs. It did not include any specific educational activities such as public campaigns on TFA, as the iTFA limit was largely invisible to consumers and thus did not require them to understand what iTFA is (PAHO, 2022). The staff of the reference laboratory was trained before and after enactment of the iTFA limit on product sampling and laboratory methodology to measure TFA.

Implementation costs

There are no publicly available studies on the implementation costs to industry, and implementation costs incurred by government have not been evaluated. Nevertheless , the Ministry of Health deemed the iTFA limit cost-effective because Chile did not run public education campaigns as part of its implementation.

The phased approach in Chile helped address/ease reformulation and administrative challenges.

Chile has a system for tracking enforcement actions, and compliance is monitored according to the available budget.

Enforcement

The Ministry of Health and the Regional Ministerial Secretariates for Health, collectively referred to as the Health Authority, are responsible for enforcing the iTFA limit. The Chilean Public Health Institute supports enforcement by performing laboratory analysis at the request of, and with financing from, the Ministry of Health.

Chile has a system for tracking enforcement actions, and compliance is monitored according to the available budget. The number of products included in the surveillance plan and the number of surveillance activities carried out depend on the budget allocation. Independent of budget, compliance is regarded as the primary responsibility of manufacturers (PAHO, 2022).

The Health Authority can require certificates of analysis from manufacturers and importers to show compliance with food or sanitary laws including the iTFA limit as needed, based on the risk that the products contain iTFA or do not comply with the limit. The Health Authority may also inspect production facilities or conduct inspections for cause; according to the Ministry of Health, neither of these actions have been taken to date.

Unlike other Latin American countries, Chile does not require pre-market food registration (PAHO, 2022).

Import control

The Health Authority is responsible for import control. Three types of import controls exist: 1) no inspection, 2) inspection without sampling and 3) inspection with sampling (with sampling costs borne by the importer). Which control is applied depends on the food product's composition, its epidemiological risk, whether it is being imported for the first time and prior violations.

"Control sampling" is conducted for foods entering Chile for the first time and those with a history of rejection due to non-compliance with microbiological, physical-chemical or other requirements. Every consignment is sampled, and only when three successive samples show compliance with current sanitary regulations does control of the product switch from "control sampling" to "monitoring sampling." (Ministry of Health, 2015)

In "monitoring sampling," sampling frequency is based on the importation history and the level of risk of the product.[10] High-risk products are sampled once every three consignments, medium-risk products once every five consignments and low-risk products once every eight consignments. However, the Regional Ministerial Secretaries for Health are authorized to deviate from the sampling frequency based on epidemiological precedents, their surveillance plan or other reasons. If products are found to be non-compliant more than twice during the last three evaluated imports, subsequent imports will be subject to the more stringent "control monitoring." (Ministry of Health, 2015)

Linking compliance monitoring: food labeling and iTFA limit

Pre-packaged foods are required to bear standardized nutrition labels pursuant to Art. 115 of the Sanitary Food Regulations (Decree 977/96). Calories, total fat, saturated and trans fat, cholesterol, carbohydrates, sugars and sodium may exceed the declared value up to 20%. Pre-packaged foods must also bear warning labels for calories, sugar, salt and saturated fat if they exceed defined threshold based on the Food Labeling and Advertising Law.

To enforce the Food Labeling and Advertising Law and to obtain up-to-date information on the nutritional content of foods, the Ministry of Health's Department of Food and Nutrition developed the National Surveillance Plan for Food Labeling and Nutritional Quality (*Plan Nacional*

10 For example, oils and fats are considered medium risk, baby foods and prepared foods ready for consumption are high risk, and farinaceous snacks low risk.

de Vigilancia de Etiquetado Nutricional y Calidad Nutricional), which includes sugar, saturated fat, sodium and iTFA as critical nutrients as well as calories (Ministry of Health, 2012, 2021). The surveillance plan focuses on high-risk foods, based on the likelihood of exceeding thresholds for calories and/or critical nutrients due to their characteristic food composition and previous monitoring results; frequent consumption by the population; or consumption by children.

Enforcement of the Food Labeling and Advertising Law resulted in strengthened monitoring of the iTFA limit.

High compliance with the iTFA limit

Compliance with the iTFA limit in Chile is high, exceeding 90% in each of the three surveillance campaigns (see Monitoring and evaluation, below) conducted by the Ministry of Health between 2018 and 2021.

ODECU, a consumer organization, found 100% compliance in 2015 based on laboratory analyses of 49 products, including margarines (12 brands), *alfajores*[11] and biscuits (six brands), cookies (15 brands), fried potato snacks and corn tortillas (10 brands) and cereal bars (six brands) (ODECU, 2015).

Compliance with food labeling requirements has also been consistently high since 2013 — approximately 90% according to the three surveillance campaigns conducted between 2018 and 2021.

The Ministry of Health assumes the high rate of compliance with the iTFA limit is due to the availability of oils and fats that contain low or no iTFA. However, variability in food production and technology limitations have prevented 100% compliance (NCD Alliance, 2019).

The Ministry of Health does not publish compliance reports specific to the iTFA limit, instead including monitoring results of iTFA levels in surveillance reports for critical nutrients overall.

Sanctions for violations

A wide range of possible sanctions exist in Chile, from warnings to fines, food recalls, closure of businesses and the prohibition to operate the business. However, serious sanctions have not been issued to date.

If imported food is in breach of applicable food regulations, the Health Authority can order it be destroyed (with costs borne by the importer), used for purposes other than human consumption, or exported. Importers can appeal these decisions. (Ministry of Health, 2015)

Enforcement costs

The main enforcement cost was designating resources for laboratory analysis, but the exact amount is not known.

Compliance in Chile is high, exceeding 90%

Monitoring and evaluation

Surveillance campaigns to check compliance with the iTFA limit and labeling requirements (nutrition labeling and warning labels) were carried out under the Ministry of Health's leadership in 2018, 2019 and 2020/21.[12] The Health Authority of the Metropolitan Area (Santiago de Chile) sampled

11 An *alfajor* (singular, plural: *alfajores*) is a traditional Argentine pastry: a sandwich cookie with a filling of *dulce de leche* (caramel).

12 Publication of the monitoring reports is expected in 2022.

products included in the plan, taking multiple samples per product, and the reference laboratory at the Public Health Institute tested samples.

The monitoring campaigns did not analyze each sample for calories and all other critical nutrients (sugar, sodium, saturated fat and TFA) but instead prioritized analysis of the most harmful nutrient(s) per food category.

In 2018, 45 out of 135 samples (33%) were tested for iTFA; in 2019, 71 of 121 samples (59%); and in 2020-2021, 144 of 219 samples (66%). Product groups sampled for iTFA included cereal bars, breakfast cereals, cookies, sweet and savoury snacks, crackers, margarine, light mayonnaise and tin loafs. Samples for all product categories except light mayonnaise were 100% compliant. All six samples of light mayonnaise analyzed in 2019 exceeded the iTFA limit, which improved to one out of six samples being non-compliant in 2020/2021.The Ministry of Health does not monitor with which oils and fats iTFA is replaced nor does it evaluate the iTFA limit's effect on population TFA intake[13] or health outcomes. At the time of writing, there were no academic evaluations of Chile's iTFA limit available.

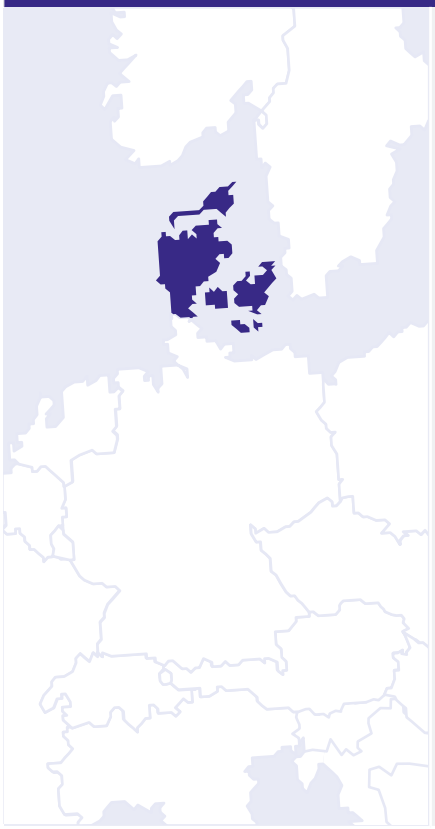
Lessons learned

- Implementing an iTFA limit does not require investment in consumer education because people do not need to understand what iTFA is or know the composition of a food product to be protected from iTFA. Because Chile's policy did not require public education campaigns, the Ministry of Health deemed it cost-effective and a good use of government resources to reduce population exposure to iTFA .
- Linking surveillance activities for the iTFA limit with monitoring efforts for other food policies, such as labeling, is an effective way to strengthen monitoring and maximize the use of limited government resources.
- Ideally, countries should try to collect data on the iTFA content in food products prior to enacting TFA regulations (based on labeling or, preferably, through laboratory analysis). However, as the Chilean case shows, it is not necessary to have a detailed national baseline study on iTFA sources and burden prior to developing or implementing a TFA regulation. Chile became a front-runner on iTFA elimination with the support of academic and industry experts, political will, and using international evidence extrapolated to the national context (see NCD Alliance, 2019).
- It is feasible for the food industry to comply with a TFA regulation. The necessary technology and validated laboratory protocols exist.
- An efficient national health governance structure capable of implementing mandatory public policies is key to successful implementation and enforcement of a TFA elimination regulation.

13 The last national food consumption survey, conducted in 2010, did not include TFA intake (University of Chile, n.d.). Therefore, a baseline for TFA intake does not exist should the Ministry of Health evaluate TFA intake in future.

DENMARK

AT A GLANCE



- In 2004, Denmark implemented a national 2% iTFA limit for foods intended for human consumption.
- Early outreach to and collaboration with food manufacturers by the Danish Veterinary and Food Administration (DVFA) and the National Food Institute's expertise in fats and industrial processes supported successful implementation.
- Scientific support by the National Food Institute was essential to successfully sampling and testing food products to verify compliance.
- From 2004–2013, control campaigns were conducted every two years by DVFA with a focus on sampling and laboratory analysis. Due to widespread compliance, the rate of inspection has been reduced to intermittent controls since 2013.
- In 2021, Denmark's regulation was replaced by the European Union's 2% iTFA limit.

Overview of Denmark's iTFA limit

On March 11, 2003, the Ministry of Environment and Food issued Executive Order No. 160, introducing a limit of 2 grams of iTFA per 100 grams of oil and fats; the limit applied to both domestic and imported foods intended for, or likely to be consumed by, humans, either alone or as part of food products. After a transitional limit of 5 grams iTFA per 100 grams of oil and fats was instated for the latter half of 2003, the limit came into full effect on January 1, 2004. Products manufactured before the effective date of the Order could be placed on the market and sold until the expiry of their shelf life.

Until May 1, 2010, the claim "free of *trans* fatty acids" was permitted if the food product contained less than 1 gram iTFA per 100 grams of oils or fats (Executive Order No. 312/2010). The TFA-free claim was repealed to comply with new EU regulations on nutrition and health claims (Regulation (EC) No 1924/2006).

On April 24, 2019, the European Union (EU) adopted an iTFA limit of 2% in all foods intended for the final consumer and for supply to retail (Regulation (EU) 2019/649). The EU iTFA limit came into effect on April 1, 2021,[14] replacing the Danish limit.

14 For information on the *development* of the EU's TFA limit, refer to the respective case study in WHO's Progress Report on Trans Fat Elimination 2021 (WHO, 2021, p. 24 f.). For information on the *implementation and enforcement* of the EU's TFA limit, see the case study below.

Implementation

The Danish Veterinary and Food Administration (DVFA) is the government authority responsible for implementation of the iTFA limit.

Between 1994 and 2003, the Danish Nutrition Council published reports on the harmfulness of iTFA reached out to food manufacturers and chain restaurants demanding reformulation and actively engaged with the press to increase pressure on the food industry and politicians to act. The DVFA started a dialogue with the food industry as part of its preparatory work to ensure smooth implementation of the iTFA limit. Because of these efforts, the food industry had already begun reformulation prior to the enactment of the iTFA limit and achieved a certain degree of compliance by the time the limit was adopted. By 1999, all of Denmark's margarine producers had already eliminated iTFA in a competition to launch iTFA-free margarines and increase their market share (Astrup, 2006; DVFA, 2014).

In addition to the Danish Nutrition Council's and DVFA's activities, there was pressure from scientists and media on industry to phase out iTFA. The press gave extensive positive coverage to the iTFA limit, including interviews with leading TFA scientists in Denmark, Professors Steen Stender and Arne Astrup. As a result, the DVFA did not have to do any media outreach or conduct a public campaign because the attention and awareness the press coverage garnered were sufficient to help the DFVA push for industry change.

The DVFA did not issue any guidance or information for food industry and business operators. However, the National Food Institute at the Technical University of Denmark (DTU) contributed their expertise in fats and industrial processes such as esterification in discussions with food industry on technical implementation issues.

Transition period

The transition period was set at nine months; the government assumed both large corporations and small to mid-sized enterprises (SMEs) could meet the effective date based on preliminary dialogues with food industry actors. Most producers were able to comply by the effective date, but several small companies struggled to reformulate certain baking applications and some confectionery products such as glazing. To provide more time to comply, the DVFA granted them an implementation exemption which extended the transition period by around one year. The DVFA opted for this approach to avoid extending the transition period for all food producers and because the products in question accounted for only a small share of population iTFA intake.[15] Apart from this extension, implementation efforts did not differentiate between companies of different sizes.

15 From December 31, 2006, the Danish Veterinary and Food Administration (DVFA) was formally given the authority to grant dispensations from the iTFA limit in special circumstances, if warranted (Executive Order No. 1477/2006). This amendment aimed to increase legal certainty for what had been general practice of the DVFA: to grant exemptions for DVFA-issued executive orders in special circumstances. Besides Executive Order No. 160 (Trans Fatty Acid Order), numerous other executive orders were updated to expressly grant the DVFA's authority to exempt to formalise its general practice.

Implementation costs

There is no available information on DVFA's implementation costs. Because of the narrow scope of the policy, the DVFA assumes that the costs of implementing the iTFA limit would be similar to implementation costs for other food legislation.

Likewise, there are no publicly available studies on the implementation costs to industry or potential sales losses. The DVFA assumes that industry's costs were manageable because DVFA did not receive complaints from industry and prices of reformulated products did not increase.

Success factors and challenges

Early dialogue with industry ensured that there were no surprises for industry and that all practical and technical changes necessary for implementation were in place by the time the iTFA limit was enacted. This positive and cooperative process facilitated implementation, and since industry was able to reduce the iTFA content without too many difficulties, the TFA regulation was not perceived as burdensome.

Laboratory support from the National Food Institute at DTU was essential for the DVFA's success in enforcing the iTFA limit, and ongoing scientific research continued to generate convincing evidence on the harmfulness of iTFA. The opinion of the European Food Safety Authority (EFSA, 2010) provided further evidence on the risks of TFA consumption and support for iTFA limits. Both helped DVFA by demonstrating that the Danish decision to ban iTFA was the right approach.

The DVFA did not face significant challenges to implementation. However, some companies producing fats for deep-frying struggled to comply by the effective date, as did shortening producers, who found it challenging to identify useful replacements for iTFA providing the same elasticity. These producers still managed to comply by the effective date without support from the DVFA using their own experts and research.

Because the Danish iTFA limit was more stringent than the European Union's rules on TFA, the European Commission (EC) claimed in 2004 that the iTFA limit contravened EU free-trade agreements and commenced steps to sue the Danish Government. In 2007, the EC withdrew its case, recognizing the Danish claim that TFA's health risks justified the iTFA limit in the interest of public health. (WHO EURO, 2015; USTR, 2008)

The DVFA is the government authority responsible for implementing the iTFA limit.

Enforcement

The DVFA is also responsible for the enforcement of the iTFA limit. It receives support from the National Food Institute at DTU, which developed the methodology for distinguishing between iTFA and ruminant TFA (see Annex 1) used by the laboratory connected to the DVFA.[16] Prior to enactment, the laboratory introduced new analytical methods to ensure accurate testing based on DTU's work. The National Food Institute also advises the DVFA and its laboratory on questions about food composition (relevant foods to consider for sampling) and development of analytical methods.

Inspections are carried out by the DVFA's four food inspection units, each of which covers a different region of Denmark. The food inspection units check domestic food companies, oil and fats manufacturers and food importers for compliance with all applicable food legislation, not just the iTFA limit. Companies putting food on the market are responsible for ensuring that imported products comply with the iTFA limit. If there are any doubts regarding compliance, the inspection units are in dialogue with the DVFA.

Initially, control campaigns were conducted every two years to ensure that the DVFA could react to non-compliance with the iTFA limit. Since 2013, the inspection units conduct controls only intermittently since non-compliance had decreased over the years (for more information, see below under "Monitoring and Evaluation"). In the most recent inspection campaign in 2017, of the 50 products sampled, only one, an imported biscuit product, did not comply with the iTFA limit.

The focus of control campaigns was to sample and analyze food products. Inspectors received detailed instructions on products to be included in the campaign (e.g., fats and oils, bakery goods, snacks and deep fried foods) and were also instructed to look at labeling for information on partially hydrogenated oils to identify relevant products for sampling and laboratory analysis. The DVFA checked not only the

16 The National Food Institute did not use any standardised method (e.g., ISO) to develop the laboratory protocol to test for iTFA. For fat extraction, the protocol is based on the Nordic Committee on Food Analysis (NMKL) method, a Nordic-countries approach which they modified and validated. Both the laboratory at DTU and DVFA are ISO 17025 certified. (Bysted, 2021)

iTFA content in sampled products but also whether their labeling was compliant with current legislation (Bysted, 2021).

All food legislation, including the iTFA limit, is subject to ongoing control activities. However, to prioritize resources for use on different food legislation topics, inspection units conduct risk-based enforcement and monitoring. If the risk of non-compliance is high, enforcement and monitoring activities are increased; if the risk is low, controls are reduced. Because compliance with the iTFA limit has been high over many years and enforcement has never been an issue, it is considered a low-risk (but not a no-risk) piece of food legislation, and controls are minimal. This means that the inspection units do not sample food products on an ongoing or regular basis, but only at the DVFA's discretion, every few years. In the words of the interviewee from the DVFA, "don't shoot sparrows with cannons."

DTU supported the inspection units in identifying high-risk products requiring testing. At the time the iTFA limit was implemented, it was not known which products were high in iTFA. Over the years, the DVFA learned that certain products are consistently high-risk — margarine, frying fat and baked goods.

Sanctions for violations

Individuals violating the iTFA limit may be fined or imprisoned for up to two years if the violation is committed with intent or gross negligence and caused damage or danger to health, or was committed for financial gain (including through savings) (§4 of Executive Order No. 1427).

Companies are prosecuted according to Chapter 5 of the Danish Penal Code, which is applicable to any infringement of national or EU-harmonized food law. When an inspector finds that a company violates food law, they have the following enforcement actions at their disposal:

- Guidance (if the non-compliant action is so minor that sanctioning would not be proportionate)
- Warning
- Order to refrain from carrying out the non-compliant action
- Administrative fine
- Reporting to the police
- Withdrawal of licenses or registrations granted under the food law

Inspectors choose the sanction deemed necessary to ensure that the company corrects the non-compliance. If the company continues to fail to comply, the sanctioning is escalated.

Warnings are the most frequent sanctions when identifying products on the market that exceed the iTFA limit. The warned company is responsible for stopping the sale of the non-compliant products immediately. There have been no major problems when inspectors followed up on enforcement actions.

Enforcement costs

The DVFA has not evaluated enforcement costs. However, it notes that analytical controls (i.e., laboratory testing of food samples) are generally more expensive than control systems that do not require sampling and laboratory testing (e.g., which can rely on food labeling only).

Future enforcement actions

The EU's iTFA limit, which replaced the Danish iTFA limit, has a slightly different scope than the Danish limit. Enforcement mechanisms may therefore require adjustment, for example with additional focus on document checks as part of the EU self-control scheme, or possibly increased focus on business-to-business sales of food products potentially containing iTFA. How the EU iTFA limit will be controlled in practice in Denmark had not yet been decided at the time of writing this case study.

Furthermore, the EU methodology to determine iTFA content deviates slightly from the Danish approach (see Annex 1) which might necessitate adaptation by the Danish laboratories (Bysted, 2021).

Success factors

The main enabler of successful enforcement of the iTFA limit in Denmark was the cooperation between the DVFA and the National Food Institute at DTU, which devised the analytical approach and provided information on which products are high-risk and should be sampled.

Monitoring and Evaluation

iTFA content in food

The DVFA, in collaboration with the National Food Institute (DVFA, 2014), conducted surveys on the TFA content in food before and after implementation of the iTFA limit: 2002/3 (253 samples), 2004/5 (148 samples), 2006/7 (45 samples), 2010 (96 samples) and 2012/13 (95 samples). Products were sampled based on existing knowledge about products typically containing iTFA. Figure 1 shows the percentage of products exceeding 2 grams iTFA per 100 grams of fat. In 2002/03, 65 of 253 products analyzed contained more than 2 grams iTFA per 100 grams of fat. By 2004/05, most products (131 out of 148, or 89%) were compliant with the iTFA limit, increasing to 94% in 2012/13 (89 of 95). Other academic studies also confirmed that the iTFA content decreased because of the iTFA limit (see Annex 2).

In 2002/03, before implementation of the iTFA limit, the iTFA content in sampled products ranged from 3 grams to 54 grams iTFA per 100 grams of fat; 5% (14 of 253 samples) contained more than 20 grams iTFA per 100 grams of fat and 2.4% (6 of 253 samples) contained more than 40 grams iTFA per 100 grams of fat. After implementation of the iTFA limit, only few of the non-compliant products contained more than 20 grams iTFA per 100 grams of fat. Non-compliant products were generally cakes, biscuits, cookies, waffles, microwave popcorn, French fries, deep-fried potatoes and some types of candy, in particular caramel.

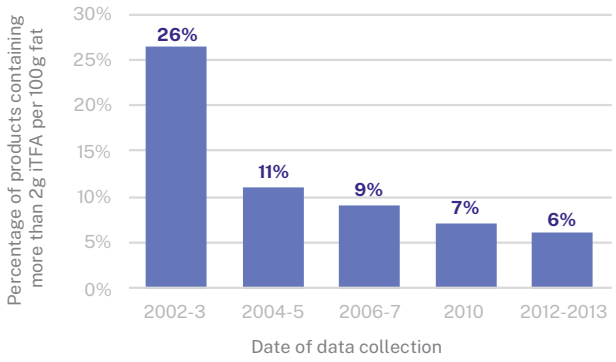


Fig. 1 Five surveys performed between 2002 (prior to the iTFA limit) and 2013 showed that the percentage of products containing more than 2 grams iTFA per 100 grams of fat dropped from 26% to 6%. *Source*: DVFA, 2014.

Replacement of iTFA

The study (DVFA, 2014) also evaluated the fats and oils used to replace iTFA. To establish what iTFA was replaced with, 61 paired samples[17] were analyzed to determine their fat profile. In more than two thirds of the products, iTFA was substituted with saturated fats (see Figure 2), which was expected; replacement fats were coconut fat and palm oil. iTFA content was generally reduced in margarines and shortenings without increasing the amount of saturated fats, but by increasing monounsaturated fats. Likewise, most French fries and frozen potato products had increased monounsaturated fat content, resulting in significantly healthier products.

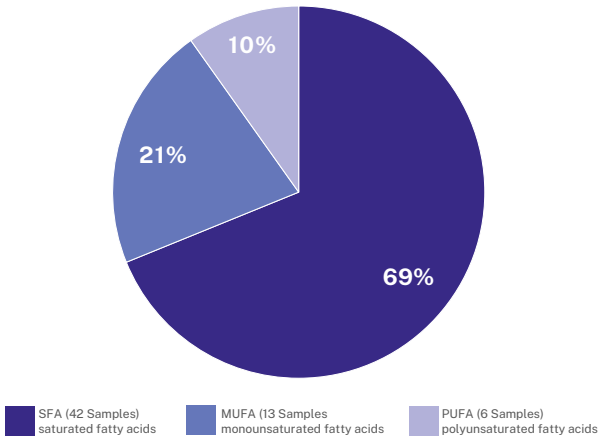


Fig. 2 Substitution of iTFA with other fats. *Source*: DVFA, 2014.

Bysted et al. (2009) looked at the substitution of iTFA between 2002/03 and 2006/07 and observed that iTFA in 60 paired samples was replaced with saturated fat in 68% of products, monounsaturated fat in 22% and polyunsaturated fat in 10% of products. The saturated fat stemmed mostly from coconut fat and palm oil. Importantly, in frying fats, iTFA was mostly replaced with monounsaturated fat. The overall fat content of samples remained unchanged by the reformulated fat profiles.

iTFA intake

The study (DVFA, 2014) calculated iTFA intake for 2002/02, 2003/04 and 2005/2008 using the Danish National Surveys of Diet and Physical Activity of the same years and product surveys of 1995, 1999, 2002/03, 2004/05, 2006/07, and 2010. To estimate iTFA intake, the General Intake Estimation System a proprietary software, was used to calculate nutrient intake based on dietary registration, recipes and nutrient content databases. Three intake levels were established: "average," "worst case" and "worst worst case."[18] From 2000 to 2008, the average iTFA intake decreased in all age groups for both genders. The average intake of iTFA did not constitute a health issue in the period 2005-08 because even in the "worst case" scenario, the average intake did not exceed 0.13 grams iTFA per day, and in the "worst worst case" scenario, it did not exceed 0.69 grams iTFA per day.

A study (Jakobsen et al., 2006) using consumption data from 1995 estimated that the median intake of ruminant TFA in the Danish population aged 1 to 80 years is 1.7 grams per day, corresponding to 0.7% of energy intake, with dairy products being the main source of ruminant TFA. Since ruminant TFA content in food products remains unchanged, Bysted (2021) assumes that this estimate is still

17 "Paired samples" were samples included in two of the five surveys and with higher levels of iTFA in the earlier survey. It is unclear if the samples were representative for the food market as a whole; however, the paired samples represented commodities commonly containing iTFA: margarines, shortenings, frying oils, chocolate, confectionary products, sweets, cakes, cookies, biscuits, fruit spread, microwave popcorn, French fries, frozen potato products, fast food (tortilla, taco pie, spring roll), ice cream, catering products.

18 In the "worst case" and "worst worst case," it is assumed that many people have significant brand loyalty, which these calculations can compensate for to some extent

somewhat applicable, assuming that consumption of dairy and meat products remained more or less stable over the years. Therefore, it can be assumed that the daily TFA intake in the Danish population is somewhere between 1.83 grams ("worst case") and 2.39 grams ("worst worst case") per day, which would suggest that most of the population ingests less than 2.2 grams of TFA per day, the maximum amount recommended by WHO based on a 2,000-calorie diet.

Currently, the National Food Institute at DTU is collaborating with partners on a study on total TFA intake (ruminant and industrial) in the Danish population over time, from the 1970s to today. The study, to be published in 2022, will also analyze potential correlations between TFA intake and different diseases over time (Bysted, 2021).

Health impact of the iTFA limit

Various studies on the Danish iTFA limit found that it was successful at lowering mortality attributable to cardiovascular diseases, despite around two thirds of iTFA being replaced by saturated fats (see Annex 2).

The DVFA has no plans to conduct future evaluations of the iTFA limit. However, DTU maintains a public food composition database[19] with a continuous view on food composition in general.

Lessons learned

- The Danish example shows that setting an iTFA limit of 2% is possible and effective at protecting consumers. The many other countries who have followed the Danish example, in addition to the EU's regional iTFA limit, demonstrate the feasibility and transferability of the policy.
- The most effective way of eliminating iTFA is by regulating the amount of iTFA permitted in food (through an iTFA limit or a PHO ban) as compared to other options like regulating TFA labeling or claims. This is supported not only by the Danish experience, but also by the impact assessment conducted by the EU.20
- Enforcement monitoring of an iTFA regulation is most important in the years immediately following its implementation when the risk of non-compliance is highest. Targeting foods likely to exceed the iTFA limit reduces monitoring costs by focusing on a narrower sample base of high-risk foods.
- A partnership between government and academia facilitates implementation and enforcement. In the Danish case, scientific support to establish laboratory methodologies to test for iTFA and to advise on sampling was essential for successful implementation and enforcement of the iTFA limit.
- Despite the many implemented TFA policies worldwide and overwhelming evidence on the harmfulness of TFA, countries should note that there is potential for trade complaints and should prepare accordingly.

19 Available at https://frida.fooddata.dk/.

20 The impact assessment, as well as other documents and information on the EU iTFA limit, can be found at https://ec.europa.eu/food/safety/labelling-and-nutrition/trans-fat-food_en#further-information. Also refer to the case study on the EU iTFA limit in this report.

EUROPEAN UNION

AT A GLANCE

- Since 2021, foods intended for the final consumer and for supply to retail in the European Union may not contain more than 2 grams iTFA per 100 grams of fat.
- All foods imported into the EU must comply with the iTFA limit, producing significant spill-over effects for trading partners for whom adhering to a 2% iTFA limit will consequently become common practice.
- The Directorate for Health and Food Audits and Analysis is responsible for confirming that effective control systems exist at the member state level. Member state authorities are responsible for the implementation, enforcement and monitoring of the iTFA limit at the national level. They must follow the applicable EU control framework and a harmonized laboratory methodology to test for iTFA.

Overview of the EU's limit on industrially produced trans fats

In April 2019, the European Commission (EC) adopted an iTFA limit of 2 grams iTFA per 100 grams of fat in all foods intended for the final consumer and for supply to retail (Regulation (EU) 2019/649 of 24 April 2019). The iTFA limit took effect on April 1, 2021. The limit may be exceeded by food business operators for food that is not intended for the final consumer nor intended for supply to retail (e.g., oil supplied to food manufacturers), as long as information on the amount of iTFA is provided.

Because the iTFA limit was introduced via regulation, it is directly applicable at the member state level (i.e., no need for transposition into national law). Member state authorities are responsible for the implementation of the iTFA limit at the national level.

Food products exceeding the iTFA limit were permitted to be placed on the market until April 1, 2021. Assuming a shelf life of six months to a year for products high in iTFA, iTFA should be eliminated from European supermarkets by April 2022 (Stender, 2019).

While the EU's iTFA limit is only applicable in EU jurisdictions, all foods imported into the EU must comply with it, and EU controls carried out in non-EU countries to check compliance with EU food law extend to checking compliance with the iTFA limit. Because trade partners that export to the EU must ensure their products are compliant, populations where these non-EU manufacturers are located may also benefit if food produced for the local market is also reformulated.

The iTFA limit was chosen over a PHO ban because it was considered the most effective measure in terms of public health, consumer protection and compatibility with the internal market (European Commission, 2015).[21] Labeling TFA content was ruled out because it was not considered cost-effective (Martin Saborido et al., 2016). Low consumer awareness and understanding of TFA in the EU would have necessitated extensive consumer education. The EC considered consumer decision-making on the healthfulness of food already complex with public health messaging on other harmful nutrients, such as sugar and saturated fat, and deemed it too confusing to add TFA to nutrition labeling without educating consumers. The public cost of consumer education in addition to industry's cost to change labeling was considered too high with respect to the expected health impact (European Commission, 2015).

EU food labeling does not permit "Free of *trans* fatty acids" claims (Regulation (EC) No 1924/2006).

Implementation

A transition period of two years was set to accommodate the needs of SMEs to reformulate their products and work through any technical challenges. The two-year period was established based on extensive information gathering, including stakeholder questionnaires, for the impact assessment (European Commission, 2019a).

The EC did not fund or provide specific technical assistance to manufacturers.[22] Fats and oils suppliers already had technical solutions for all their products and were able to offer their customers technical solutions and support to change product formulations. Bigger manufacturers with technical know-how committed to support SMEs through the process of becoming compliant with the iTFA limit.

Implementation costs

Prior to enactment of the regulation, a modelling study put the public administrative cost for implementation at €5 million (around US$4.97 million) (European Commission, 2019b).

Estimated business costs encompassed one-time product testing costs of €3.6 million (around US$3.58 million), one-time administrative costs of €18 million (around US$17.9 million), product reformulation costs of €9.8 million (around US$9.75 million), and additional ingredient costs of €44.5 million (around US$44.27 million) (European Commission, 2019a). Overall, the study estimated costs to businesses would represent 0.0066% of the annual output value of the 1.019 million businesses assumed to be affected (European Commission, 2019a, 2019b).

There are no studies to date assessing the actual implementation costs incurred. The Directorate-General for Health and Food Safety (DG SANTE) estimates that the EC and member states incurred no more than the typical costs associated with a new piece of food legislation.

21 For information on the *development* of the EU's iTFA limit, refer to the respective case study in WHO's Progress Report on Trans Fat Elimination 2021 (WHO, 2021, p. 24 f.)

22 Unless indicated otherwise, all information on the EU's iTFA limit was obtained through interviews with an official of DG SANTE (DG SANTE, 2021a).

160 employees conduct controls to verify that the responsible national authorities in member states are fulfilling their legal implementation and enforcement duties under EU law.

Enforcement

Responsibility at EU level

At the EU level, the Directorate for Health and Food Audits and Analysis (formerly known as the Food and Veterinary Office), a division of DG SANTE located in Ireland, is responsible for ensuring the existence of effective control systems for EU food law at the member state level. The Directorate has 160 employees who conduct controls to verify that the responsible national authorities in member states are fulfilling their legal implementation and enforcement duties under EU law. This is mostly done via audits of control systems (rather than individual premises). The Directorate also audits compliance with EU food standards in non-EU countries exporting food products to the EU. Audit reports are made public[23] (DG SANTE, n.d.).

DG SANTE develops five-year plans that set out the priorities for its control system. This prioritization considers legal requirements for EC controls, the risk of non-compliance in each policy area, as well as the EC's political priorities. Each year, based on the five-year plan, DG SANTE also publishes an annual work program[24] developed in consultation with other EC services (where relevant) and with EU member states. The program's audits include EU and non-EU countries (DG SANTE, n.d.).

23 Audit reports can be accessed at https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm, and an interactive audit map at https://ec.europa.eu/food/audits-analysis/audit_map/index.cfm.

24 Annual audit work programs are available at: https://ec.europa.eu/food/horizontal-topics/official-controls-and-enforcement/health-and-food-audits-and-analysis/work_en.

Controls of member state enforcement systems

The current five-year plan for 2021-2025 does not contain the iTFA limit as a priority audit topic (DG SANTE, 2021b). The following explains the general control process applicable to controls of member states' enforcement systems for the iTFA limit.

Audits are usually carried out by two auditors, often with the presence of a national expert from the member state. The audit program will typically include a pre-audit questionnaire, visits to the control authority, several regional and local authorities, laboratories and various accompanied site visits (e.g., farms, food processors, retailers). The findings of the audit are presented at a closing meeting and in a written report (DG SANTE, n.d.).

If deficiencies are identified, audit reports may make recommendations to assist the competent member state authorities in taking corrective measures. The actions taken are followed up either administratively, via general follow-up audits or by on-the-spot audits. If non-compliance is sufficiently serious, the EC, in agreement with member states, may take stronger actions which include legal action, restrictions or even bans on the movement of goods or animals (DG SANTE, n.d.).

When compliance with a food law is known to be high, the Directorate for Health and Food Audits and Analysis conducts fewer checks but does not stop them entirely. If there are indications that a food topic has become a problem, the frequency of controls is increased.

At member state level

The respective authorities of member states are responsible for enforcement of the iTFA limit at the national level. Member states must have an implementation and enforcement structure that enables enforcement of EU food law. If non-compliant entities are found, member states are responsible for sanctions and expected to ensure future compliance of violators. In general, enforcement of the iTFA limit follows the same rules and is done in the same way as any other EU food law enforcement (European Commission, n.d., a).

Member state control authorities must be equipped with an ISO 17025-accredited laboratory whose competence and associated quality control measures are regularly checked by national accreditation bodies (Chapter IV, Regulation (EU) 2017/625). When testing samples for iTFA, member states must follow the laboratory methodology developed by the Joint Research Centre (JRC), the EU's science and knowledge service. Member states can contact the JRC if they encounter technical issues with the methodology; JRC then coordinates

to ensure arising issues can be dealt with in a harmonized manner.

Member states are responsible for following the EU framework on the control of sanitary and phytosanitary requirements. Several legal texts regulate the controls to be done. The most relevant is the Official Controls Regulation (Regulation (EU) 2017/625), which contains rules on the competent member state authorities and delegation to other bodies; general requirements for controls; rules on sampling, analyses, tests and diagnoses; provisions on animals and goods entering the EU from non-EU countries; financing enforcement activities; rules on official certifications; reference laboratories; administrative assistance and cooperation; activities carried out by the EU; planning and reporting; and enforcement actions. It requires member states to establish multi-annual national control plans.

Member states submit annual reports on official controls conducted to the EC (European Commission, n.d., a).

Harmonized laboratory approach to iTFA testing

Without a consistent approach to laboratory testing, a product might be considered compliant in one EU member state and non-compliant in another based on different measurements. To avoid such inconsistencies, the JRC, with its years of experience at the member state level, was involved from early in the policy process to establish an EU laboratory methodology to test TFA levels in food. As a starting point, the JRC studied all existing methodologies in member states. The JRC then developed a methodology to determine TFA levels in foods with mixed sources of oils and fats, to be used across the EU to standardize TFA testing (Annex 4).

A few months before the iTFA limit went into effect, DG SANTE invited technical staff of all member state control authorities to a meeting to finalize the proposed methodology. The final protocol was shared with member states and is available online (Ulberth & Wenzl, 2021). It will ensure that products are assessed for compliance in the same way throughout the EU.

The JRC methodology is a work in progress; as the EC and member states gain more experience with TFA testing, they may modify and refine the approach. They may also update the methodology if an international consensus on how to test for TFA arises that deviates from the JRC protocol.[25]

JRC has a unit that deals with methodological issues of enforcement and coordinates and maintains a network with member state control authorities to discuss food-related topics. If issues arise, a group of member states can be convened to discuss whether action needs to be taken (e.g., writing and publishing a clarifying document) or if the problem can be resolved with internal discussion alone. Implementation and

25 For example, the EU might decide to align with the WHO protocol for measuring TFA (WHO, 2020) which was published after the JRC methodology was finalized.

Without a consistent approach to laboratory testing, products may be compliant in one EU country and non compliant in another.

enforcement issues requiring JRC to convene an expert working group are especially common with new legislation.

When the EU notified the WTO of their TFA regulation, the EC was contacted by various non-EU countries inquiring about methodology, which the EC shared with interested parties.

Enforcement costs

A modelling study conducted prior to the EU's adoption of the iTFA limit estimated the public administrative costs for monitoring and enforcement to be €6.1 million (around US$6.07 million) for the first two years after implementation, and €3.4 million (US$3.38 million) annually from the third year onward (European Commission, 2019b).

There are no studies to date assessing the actual enforcement costs incurred. DG SANTE estimates that the EC and member states incurred the normal costs associated with any new piece of food legislation. Regarding laboratory costs in particular, DG SANTE assumes member states did not incur additional costs since all had the requisite laboratory technology and know-how already.

Monitoring and evaluation

At EU level

It is part of the EU policy cycle to evaluate all regulations after several years on the following dimensions:

- Effectiveness: whether the policy reached its objectives;
- Efficiency: what are the costs and benefits;
- Relevance: whether it responds to stakeholders' needs;
- Coherence: how well it works with other actions; and
- EU added value: the benefits of acting at EU level (European Commission, n.d., b).

EU evaluations are publicly communicated via evaluation roadmaps and planned on a multi-annual basis. Completed evaluations are made public. Anyone can provide feedback on evaluation plans and participate in public consultations on ongoing evaluations. (European Commission, n.d., b).

At the time of writing, there was no timeline set for an evaluation of the iTFA limit as it had been in effect for less than a year.

Health impacts of the iTFA limit will be monitored by the regular reviews on the "State of Health in the EU[26] (European Commission, 2019a).

At member state level

Ongoing monitoring at member state level, including monitoring of iTFA content in food products, is the responsibility of the respective national authorities (European Commission, 2019a).

26 Information on the "State of Health in the EU" can be found at https://ec.europa.eu/health/state-health-eu/overview_en.

iTFA intake

Based on evidence collected between 2003 and 2013, the JRC found that while average TFA intake in Europe is below the WHO-recommended level of 1% of daily energy intake, products with high iTFA content were available on the European market and some subpopulation groups' average intake exceeded the recommended levels of TFA intake (Mouratidou et al., 2014).

Pre-implementation modelling evaluations

The impact assessment conducted on the iTFA limit assumes that within two years of implementation, iTFA intake would decrease to 0.009% of energy intake, in line with results from observational studies conducted in Denmark (European Commission, 2019a).

Cost savings associated with a lower disease burden due to the iTFA limit were estimated to be between €51 billion and €304 billion (around US$50.7 billion and US$302.4 billion) over an 85-year period as compared to no policy action (European Commission, 2019a; Martin-Saborido et al., 2016).

Health benefits were estimated to be 3.73 million to 66 million disability-adjusted life years[27] saved over an 85-year period as compared to no action (European Commission, 2019a; Martin-Saborido et al., 2016).

Lessons learned

- A mandatory iTFA limit (or PHO ban) is more cost effective than TFA labeling.
- Where consumers do not have a strong grasp of TFA and its health risks, labeling — which depends on consumers making healthy choices based on an understanding of these risks — is less effective than an iTFA limit (or PHO ban). Educating consumers would require a disproportionate effort for public authorities when limited resources could be used more efficiently for other public health efforts.
- It is important to address concerns and look for possible solutions to identified implementation and enforcement issues early on (e.g., how to test for TFA).
- A regional iTFA limit (or PHO ban) like the EU's has the potential to positively influence food manufacturers outside the region . If the reformulated foods are also consumed in the local market or exported to areas outside the EU, other populations may also benefit. If controls are also carried out in exporting countries, as is the case for the EU, there is a potential for knowledge transfer and capacity building on food law controls.

27 Disability-adjusted life years (DALYs) is measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or premature death.

SAUDI ARABIA

AT A GLANCE

- In 2017, Saudi Arabia implemented an iTFA limit of 2% for fats and oils and 5% for all other foods. In 2020, a PHO ban took effect, replacing the previous iTFA limits. In 2021, limits on total TFA content (artificial and natural) were introduced for ruminant products, refined oils, fully hydrogenated oils and baby formula.
- The Saudi Food & Drug Authority (SFDA) conducted several workshops with and for the food industry to address potential issues ahead of implementation and to provide an opportunity for smaller companies to learn from multinationals.
- Seeking advice from countries with longer experience in iTFA elimination helped overcome challenges with the laboratory methodology used to determine iTFA content in food samples.
- Regular post-marketing surveillance of imported and domestic food products and effective sanctions such as withdrawal of manufacturing, import or product licenses ensures compliance.

Overview of Saudi Arabia's policy on trans fat elimination

On November 25, 2015, the SFDA enacted regulation SFDA.FD 2483/2015, limiting iTFA to 2% for fats and oils and 5% for other foods and taking effect in November 2017.[28] The limits were based on experiences of other countries that had passed best-practice iTFA elimination policies and developed in collaboration with the WHO Regional Office for the Eastern Mediterranean (WHO EMRO) (NCD Alliance, 2019).[29]

In December 2018, the SFDA enacted regulation SFDA.FD 2483/2018, introducing a PHO ban effective January 1, 2020 to align with the WHO-recommended best-practice policies for iTFA elimination. In September 2021, the SFDA adopted regulation 2483/2021, which came into effect immediately. The 2021 regulation clarified that the PHO ban replaces the previous iTFA limits, removed the TFA-free claim, included additional TFA labelling rules and introduced limits on total TFA content (artificial and natural) for ruminant products, refined oils, fully hydrogenated oils and baby formula (Annex 5).[30]

28 With the enactment of Regulation SFDA.FD 2483/2015, Saudi Arabia approved the regional GCC standard 2483:2015 on TFA.

29 The case study on Saudi Arabia by NCD Alliance (2019) provides interesting information on the *development* of the Saudi TFA policy.

30 Unless indicated otherwise, all information contained in the case study on the Saudi iTFA policy was obtained through an interview with and written information from two officials at the SFDA (SFDA, 2021).

Since September 2016, total TFA content (ruminant and industrially produced) must be included on food labels (NCD Alliance, 2019).

Saudi Arabia's iTFA policy is part of its Healthy Food Strategy, which includes strategies to reduce sugar, salt and fat in food products, requires calorie labeling in restaurants and cafes, and improves nutrition surveillance through both regulation and voluntary measures (Bin Sunaid et al., 2021; SFDA, n/a). Saudi Arabia specified targets for their population TFA intake: in 2015, the SFDA set a target of reducing TFA intake to <1% of energy intake from food in general, while the Ministry of Health set a similar target of reducing TFA intake to <1% of energy intake from canned food in the National Strategy for Healthy Food and Physical Activity 2015–2025 (Al-Jawaldeh et al., 2021).

Implementation

The SFDA is responsible for implementation of food policies.

To ensure smooth implementation of the iTFA limits, the SFDA granted a two-year transition period to allow for reformulation between 2015 and 2017. The SFDA published guidance on its website on how to reduce iTFA in products and how to replace iTFA with healthier fats. It ran a public awareness campaign to inform consumers of the new iTFA limits.[31] The SFDA also conducted workshops and trainings for industry on how to replace iTFA with healthier fats prior to implementation, including hosting a workshop in which members of the International Food & Beverage Alliance (IFBA) trained smaller companies on iTFA replacement. This workshop allowed SMEs to benefit from the experience of large companies that had already removed iTFA from their products.

To prepare for implementation of the PHO ban, the SFDA circulated the regulation amongst stakeholders, including industry actors. While many had already stopped using PHO or were in the process of phasing out PHO, smaller companies informed the SFDA that they found it difficult and costly to replace PHO despite the two-year transition period (2018-2020). Consequently, the SFDA conducted additional workshops to train smaller companies on how to replace PHO. In addition, the SFDA ran a public awareness campaign and issued guidance after the PHO ban's implementation to educate consumers about the ban and natural TFA derived from ruminant products. Overall, substantial implementation work was not necessary thanks to the SFDA's extensive work preparing the implementation of the previous iTFA limits.

31 When TFA labeling became mandatory in 2016, the SFDA had already run a public awareness campaign to educate consumers on how to read TFA labeling on food products.

The main enforcement challenge in Saudi Arabia was assessment of PHO content in food products.

Nevertheless, the SFDA received many unforeseen questions from the food industry on how the PHO ban relates to the iTFA limits after implementation of the ban. Industry was unsure if the iTFA limits were replaced by the PHO ban or remained in existence alongside the ban, and if the iTFA limits coexisted with the PHO ban, what this would mean for the calculation and labeling of TFA. To address this issue, the SFDA updated the regulation in September 2021 to clarify that the PHO ban replaced the limits, and to introduce limits on TFA (natural and industrially produced) for fully hydrogenated oils, refined oils, ruminant products and baby formula (Regulation 2483/2021) (Annex 5). The SFDA plans to conduct an industry workshop on the updated regulations to address any remaining uncertainties.

The SFDA's iTFA policy was generally praised by civil society. However, the SFDA noticed that consumers did not initially understand the difference between fully and partially hydrogenated oils, and some civil society organizations called for a ban on fully hydrogenated oils once the PHO ban was implemented. However, the SFDA considers fully hydrogenated oils saturated fats and treats them as such, deeming it too costly and severe to ban them. The SFDA also assumes that food prices would increase if fully hydrogenated oils were to be prohibited.

Implementation costs

The SFDA did not conduct an evaluation of implementation costs of the iTFA limits and subsequent PHO ban but assumes that it did not incur implementation costs beyond the normal running of the agency.

There are no publicly available studies on implementation costs to the Saudi food industry. The SFDA assumes that industry mostly incurred costs related to mandatory TFA labeling.

Success factors

Saudi Arabia imports around 80% of its food, mostly from large U.S. manufacturers (including IFBA member companies), which had previously phased out PHO due to the U.S. ban. Therefore, most imported food was PHO-free even before the enactment of the PHO ban. In fact, the knowledge that IFBA products were PHO-free and 94.3% of sampled products complied with the iTFA limits by 2018 (see below under "Enforcement") encouraged the SFDA to strengthen the iTFA limits by replacing them with a stricter PHO ban; they were certain that the PHO ban would not pose a significant additional burden to the food industry. Additionally, IFBA members were experts on reformulation and willing to train SMEs, which enabled successful implementation.

The full support of the government made the implementation of the iTFA limits and the subsequent PHO ban possible. The Saudi Government recognizes the impact of non-communicable diseases (NCDs) on the economy, health systems and quality of life and therefore supports food policies addressing the NCD burden.

The SFDA conducts inspection campaigns and routine checks, reporting results to the public.

Enforcement

The SFDA's Healthy Food Department is responsible for inspection campaigns and sanctioning violations of food legislation. The SFDA's operations units conduct routine checks for all food legislation, including the PHO ban. The SFDA's laboratory analyzes samples for enforcement purposes,[32] while SFDA-accredited labs may conduct tests for the food industry. WHO supported the SFDA's enforcement efforts by organizing training sessions on laboratory analysis of TFA content in food products and providing contacts to appropriate organizations and academics to advise on laboratory methodology.

Since its implementation, the SFDA has only enforced the PHO ban (and not the earlier iTFA limit). However, with the September 2021 amendment introducing TFA limits for refined oils, fully hydrogenated oils, ruminant products and baby formula, the SFDA will have to enforce these new limits alongside the PHO ban.

In addition to conducting inspection campaigns and routine checks, the SFDA has set up a reporting mechanism for the public. Through public awareness campaigns, the SFDA informed consumers to report suspected violations. Consumers may contact the SFDA by phone (toll free number), email or social media

32 The methodology used by the SFDA laboratory to determine the iTFA content of food samples includes:

- gas chromatography–mass spectrometry (GC-MS) / gas chromatography–flame ionization detection (GC-FID) to estimate the amount of TFA in foods in alignment with the WHO protocol to measure TFA (WHO, 2020) (under development at the time of writing).
- iodine Value to determine PHO (under validation at the time of writing);
- total fat content using fatty acid hydrolysis (under validation at the time of writing).

(LinkedIn, Instagram, Facebook, Snapchat, Twitter). The SFDA regularly receives consumer complaints; each complaint triggers an investigation. Complainants are informed of investigation outcomes. Lately, the SFDA has been receiving more consumer complaints on suspected violations, deducing that public awareness of TFA has increased.

Compliance with the iTFA limits (in effect 2017–2019)

The SFDA conducted a monitoring campaign in February 2018 to check compliance of domestic and imported products, sampling and testing 413 food products purchased from supermarkets across the Kingdom. It found that 94.7% complied with the iTFA limits. For non-compliant products, the SFDA ordered a stop in production until manufacturers could provide laboratory analysis showing compliance with the iTFA limits. (SFDA, 2018)

Compliance with the PHO ban (in effect since 2020)

For four consecutive years, the SFDA's Healthy Food Department is required to conduct an inspection campaign to check for compliance with the PHO ban. These yearly campaigns are a strategic objective and key performance indicator for the SFDA. The first inspection campaign was conducted in July 2020, the second will be conducted in 2022.

After four targeted inspection campaigns, the PHO ban will be enforced through routine checks by the SFDA's operations units, which create yearly inspection plans specifying which products will be inspected for compliance with SFDA regulations. If there are indications that there are or could be specific issues regarding the PHO ban, a targeted inspection campaign will take place (for example, if the SFDA should receive complaints about an airport, sea or land border suspected of being an entry point for non-compliant products).

The first inspection campaign of July 2020 included 2,697 high-risk domestic and imported products from 1,117 manufacturers (37% local, 63% foreign), sampled across the Kingdom. Sampled products included pre-packaged foods, margarine, frozen foods and processed foods such as cakes, croissants and donuts.[33] Assessment was done by reviewing the manufacturing techniques and food labels to evaluate PHO content. In case of inconsistencies, laboratory analysis was conducted through high-performance liquid chromatography (HPLC). In the 2020 inspection campaign, 7% of manufacturers and 20% of products were non-compliant. Of the non-compliant products, 200 were domestic and 332 were imported products. Most of the non-compliant products did not contain PHO but violated TFA labeling rules, such

33 Most domestic products that might contain iTFA are dairy products and confectionary made by small producers.

as not listing TFA-containing ingredients in the ingredients list or including incorrect nutritional information on the nutrient panel.[34] (Binsunaid et al., 2021; Al-Jawaldeh et al., 2021)

The results of the SFDA's monitoring and enforcement activities are reported to policymakers and published on their website.[35]

Sanctions for violations

In case of non-compliance with the PHO ban and the TFA limits, a tiered sanctioning approach is followed:

1. Warning;
2. Fine, if the violation is not remedied within the correction period set by the SFDA (up to six months);
3. Withdrawal of the manufacturing or import license and withdrawal of the product license, if the violation is not remedied within the correction period set by the SFDA. Once a manufacturing or import license is withdrawn, manufacturing or importing the product becomes illegal.

Enforcement costs

The SFDA has not evaluated enforcement costs but knows that sampling and particularly laboratory analysis are the only activities incurring substantial costs.

Challenges

The main enforcement challenge was assessment of PHO content in food products. The SFDA contacted well-known organizations around the world, among them Health Canada, the U.S. FDA and WHO EMRO, to understand how to detect PHO. Health Canada, which had followed U.S. FDA guidance[36], advised using iodine value (IV) to determine if a food product contains PHO. This approach was included in the regulation by the SFDA and supported by academics advising WHO EMRO.

Evaluation

The SFDA did not conduct a baseline assessment prior to the implementation of the iTFA limits and uses the results of the compliance monitoring campaign in 2018 as baseline.

The SFDA used the samples collected for compliance monitoring to determine what iTFA was replaced with by assessing ingredient lists. They found that most iTFA was substituted with palm oil, high in saturated fats. Since the SFDA would prefer replacement oils and fats to be high in healthier unsaturated fats, they plan to work on alternative replacement options going forward. The SFDA has not conducted any other evaluations of the iTFA limits and PHO ban.

34 Jradi et al. (2020) analysed food labeling immediately after the TFA labeling requirement took effect, sampling 1,153 imported and domestic products in nine major food chains and five neighbourhood stores in Riyadh between November 2016 and January 2017. Analysing nutrient panels and ingredient lists, they found that 54.5% of products did not meet TFA labeling requirements.

35 Information for the 2018 monitoring campaign can be accessed in Arabic at: https://www.sfda.gov.sa/ar/news/1940. The more recent monitoring results were not published at the time of writing.

36 Food and Drug Administration (2015). Final Determination Regarding Partially Hydrogenated Oils. Available at: https://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils

In the future, the SFDA wants to partner with the Ministry of Health to conduct an evaluation of the TFA policy's impact on public health. They would use the National Health Survey, carried out every five to seven years, for reference. The most recent National Health Survey was conducted in 2021 — too close to the PHO ban's implementation to see an impact; they will evaluate when the results of the next National Health Survey are available.

The only academic evaluation related to the TFA policies that could be identified is by Kamel & Al-Otaibi (2018), who assessed the TFA knowledge and consumption of iTFA-containing foods of 302 participants from Al-Ahsa in 2016.[37] Only 35% of study participants had heard about (partially) hydrogenated oils before; 55.6% thought PHO were not unhealthy while 4% knew PHO was damaging to health; 20.5% indicated that they are interested in food labels. The authors found no significant relationship between education or income level and the frequency of consuming products containing iTFA. They observed a significant positive correlation between participants' education level and hearing about PHO as well as reading food labels. They found a highly negative correlation between participants' income and their awareness about PHO, tendency to read food labels, and drive to purchase foods containing PHO due to their low cost.

Lessons Learned

- The SFDA recommends a step-wise approach if a country is not able to pass a best-practice TFA policy right away. The successful implementation of the 2% and 5% iTFA limits confirmed the feasibility of a TFA policy and gave the SFDA the confidence to go further with the PHO ban, a best-practice policy. The step-wise approach was also advantageous for the food industry, giving them more time to reformulate and relabel their products.
- If a step-wise approach is chosen, it is essential to clarify whether the subsequent policy replaces the first policy or exists alongside. In the latter case, it must be ensured that the two policies are not conflicting to avoid implementation issues.
- Reasonable transition periods are necessary but should not be too long.
- The responsible authority must work with the food industry as they are the main target for regulation. The SFDA recommends solving the industry's issues first, and then implementing the policy.
- The SFDA works closely with WHO EMRO to share their experience on eliminating iTFA with other countries in the region, including capacity building workshops. The SFDA urges other countries to do the same and share their experiences.

37 The participant group ranged in age from 14 to 50 and was not heterogeneous with 87.1% women, 75.5% with a university degree, 76.8% aged 24 or below and 54.3% belonging to the lowest income group as defined by the researchers (<2,500 SAR/month, around US$666).

SINGAPORE

AT A GLANCE

- In 2012, Singapore implemented a 2% iTFA limit for pre-packaged oils and fats for sale or for use as an ingredient in food preparation. The iTFA limit was replaced with a PHO ban in 2021.
- The Singapore Food Agency (SFA) was responsible for the implementation and enforcement of the iTFA limit while the Ministry of Health is responsible for the implementation and enforcement of the PHO ban. While the SFA performed pre-marketing checks, the Ministry of Health conducts post-marketing surveillance.
- Domestic companies could access grants from Enterprise Singapore and technical support from the Health Promotion Board (HPB) to help with reformulation to comply with the iTFA limit and PHO ban.
- The iTFA limit significantly reduced iTFA in the food service sector but not pre-packaged foods because it did not cover imported pre-packaged foods. Nevertheless, the national average TFA intake halved from 2010 to 2018 (2.1 grams per day to 1 gram per day).

Overview of Singapore's policy on *trans* fat elimination

In May 2012, Singapore introduced a 2% limit on iTFA for pre-packaged edible fats and oils for sale or for use as an ingredient in the preparation of foods; it took effect after a one-year transition period.[38] Singapore focused on oils and fats because shortening used for the commercial manufacture of baked goods (such as cakes, pastries, donuts, biscuits and snacks)[39] was the main source of iTFA in the population's diet, accounting for around 60% of iTFA intake (WHO, 2020).

On June 1, 2021, new regulations[40] took effect, prohibiting the use and importation of any edible fat or oil that contains any PHO for use as an ingredient of any other edible fat or oil or any pre-packaged food. The PHO ban replaced the iTFA limit after a one-year transition period (HPB, 2019).

38 The iTFA limit was introduced with the Food (Amendment) Regulations 2012 made under the Sale of Food Act 1973 (Ministry of National Development, 2012).

39 Meals prepared in food outlets such as hawker centres usually do not contain significant amounts of iTFA in Singapore because they are cooked using palm oil, an oil with good stability not requiring hydrogenation (WHO, 2020).

40 Food (Amendment No. 2) Regulations 2020 made under the Sale of Food Act 1973

Since 2012, it has been mandatory to state the amount of TFA on pre-packaged fats and oils (Reg. 79(2) of the Food Regulations). The Food Regulations permit the claim "*A healthy diet low in saturated fat and* trans *fat, may reduce the risk of heart disease. [Name of the food] is free of/low in saturated fats,* trans *fats*" if:

- TFA content is less than 0.5 grams per 100 grams;
- saturated fat content does not exceed 1.5 grams per 100 grams; and
- no more than 10% of calories derive from saturated fat (for the "low in" claim) or the saturated fat content does not exceed 0.5 grams per 100 grams and no more than 1% of the total fat is from TFA (for the "free of" claim).

Additionally, cholesterol may not exceed 100 milligrams per 100 grams; sugar content may not surpass 5 grams per 100 grams (or 2.5 grams per 100 milliliters); and the food product may not contain sodium above 25% of sodium RDA.[41]

Under the Healthier Choice Symbol program of the Health Promotion Board (HPB), a voluntary TFA-free claim is permitted for fats and oil products containing ≤0.5% TFA, for sweets and pastries if the TFA content is ≤0.2%, and for breads and rolls, nut and seed butters, main meals, small meals, convenience meals and beverages if the TFA content is ≤0.1%. Certain other claims also require a low TFA content; for example, ice cream may only bear a "lower in sugar" claim if the TFA content is ≤0.5%. (HPB, 2020)

Implementation

The Singapore Food Agency (SFA) was responsible for the implementation of the iTFA limit while the Ministry of Health is responsible for the implementation of the PHO ban.[42]

Domestic companies could apply for an Enterprise Development Grant from Enterprise Singapore, a government agency championing enterprise development, to help cover product reformulation costs (Ministry of Health, 2019; Enterprise Singapore, 2021). In addition, food manufacturers could access technical support with reformulation to comply with the iTFA limit and PHO ban, provided by the Healthier Choice Symbol program of the Health Promotion Board (HPB).

To facilitate implementation of the PHO ban, the HPB, part of the Ministry of Health, set up a mailbox to address queries or issues about the PHO ban from the food industry and the public. It was not necessary to publish guidelines as the PHO ban mostly affected imported products; domestic products were already in compliance due to the earlier iTFA limit.

To expedite removal of PHO from the market, six major retailers and manufacturers covering around half of available pre-packaged foods in four high-risk categories (snacks, baked goods, prepared meals and fat spreads) pledged to phase out PHO by June 2020, one year ahead of the ban's effective date (WHO, 2020).[43] Due to challenges with the COVID-19 pandemic, HPB was not able to collect samples to check that companies had phased out PHO by June 2020; however, HPB would later confirm that companies had met the pledge objective.

41 TFA content is also restricted for the claim "*Barley beta-glucans / Oat beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.*" The Food Regulations only permit this claim if, among other criteria, the TFA content is ≤1.5 grams per 100 grams for solid foods and ≤0.75 grams per 100 milliliter for liquid foods, and no more than 10% of calories derive from saturated fats and TFA combined (for both liquid and solid foods).

42 Unless indicated otherwise, all information obtained for this case study on Singapore's PHO ban was obtained through an interview and email communication with two officials of the HPB (HPB, 2022).

43 The six companies were Gardenia Foods (S) Pte Ltd, Nestle Singapore (Pte) Ltd, NTUC FairPrice Co-Operative, Prime Supermarket Ltd, Sheng Siong Group Pte Ltd, and Sunshine Bakeries (Ministry of Health, 2019).

The SFA tested oils and fats sampled at factories while the iTFA limit for fats and oils was in effect.

Enforcement

The SFA was responsible for the enforcement of the iTFA limit. The Ministry of Health is responsible for the enforcement of the PHO ban and has set up a dedicated unit to oversee the PHO ban's enforcement. It collaborates with other stakeholders such as the HPB and SFA (Ministry of Health, 2022).

Testing methods for the PHO ban are the same as they were for the iTFA limit; therefore, the Ministry of Health did not have to do any preparatory work as testing methods were already established.

The SFA tested oils and fats sampled at factories while the iTFA limit for fats and oils was in effect. The PHO ban is enforced by the Ministry of Health which does not visit factories and only conducts post-marketing surveillance (i.e., no checks at ports of entry or manufacturing sites; only sampling products purchased in supermarkets and shops).

Only high-risk food products are sampled based on a checklist of products to test. Food products qualify as high-risk if the country of origin does not have an iTFA limit or PHO ban in place and the food category is known to contain PHO (e.g., instant foods, snacks, frozen foods, creamers). Food labeling is also used to determine if a product should be tested. Sampling is done twice a year, but additional testing can be done for seasonal products if they are suspected of containing PHO.

Sanctions for violations

The use and importation of PHO are offenses under Reg. 36A of the Food Regulations. In case of non-compliance, investigations are initiated, and the company is required to remove the non-compliant product from the market (Ministry of Health, 2022). If convicted, companies are fined up to S$1,000 (around US$740) for the first offense, and in case of a second or subsequent conviction, a fine not exceeding S$2,000 (around US$1,480) is applicable (Reg. 261 of the Food Regulations).

Enforcement costs

Enforcement costs are not yet known as the PHO ban has been in effect for less than a year. The Ministry of Health expects that enforcement costs are mostly incurred for laboratory testing and staff costs related to investigative work (Ministry of Health, 2022).

Monitoring and evaluation

TFA intake

The National Nutrition Surveys of 2010 and 2018 showed that the national average TFA intake halved from 2.1 grams per day in 2010 to 1 gram per day in 2018 (Ministry of Health, 2019); most TFA intake consisted of iTFA (HPB, 2019). However, the average daily intake among some subpopulation groups, such as young adults, was at least twice the national average, mostly due to their higher consumption of pre-packaged foods. (HPB, 2019).

The HPB is planning further evaluation of the national TFA intake once the results of the National Nutrition Survey 2021 are published.

TFA sources

The iTFA limit significantly reduced TFA in the food service sector: before the implementation of the iTFA limit, 60% of TFA derived from food services and 40% from pre-packaged foods. By 2018, this had shifted to 10% from food services and 90% from pre-packaged foods (HPB, 2019).

Only high-risk food products are sampled based on a checklist of products to test.

An assessment by HPB of PHO content in 734 samples of pre-packaged foods showed that around 10% contained PHO. Samples were taken from four food categories most likely to contain PHO, including baked goods, snacks, packaged meals and spreads and creamers (HPB, 2019).

iTFA substitution

The Ministry of Health does not track which oils and fats are used to replace iTFA. Because Singapore is located in a region that produces palm and coconut oil, it can be assumed that iTFA is replaced with these oils, which are high in saturated fats (rather than healthier unsaturated fats). However, the National Nutrition Survey 2018 showed that the dietary quality of fats in the Singaporean diet has improved, with saturated fat as a proportion of total fat decreasing from 38% to 36% in the period 2010-2018 (HPB, 2018). The reasons for this improvement have yet to be investigated.

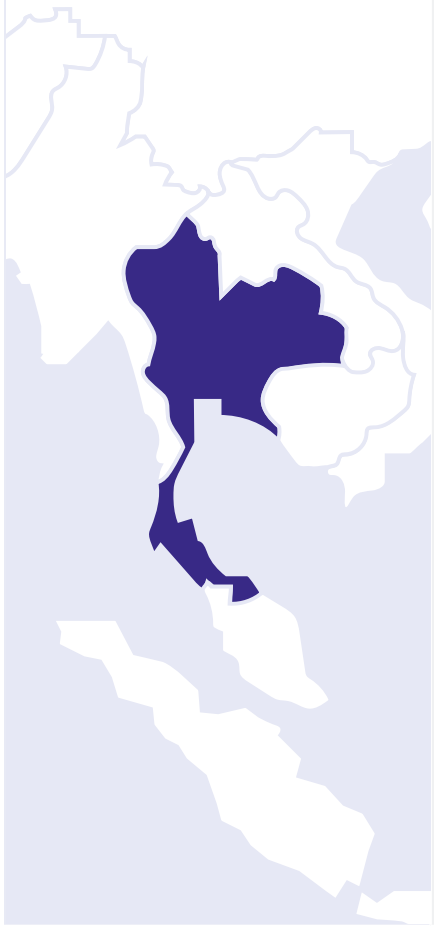
Lessons learned

- An iTFA policy must cover all food products, not just oils and fats, to ensure that this harmful compound is removed from the entire food supply. This is particularly true for countries like Singapore that import a large proportion of the pre-packaged foods consumed in the country. These imported foods would not be covered by a policy applicable only to oils and fats. If (imported) pre-packaged foods are exempt and continue to be significant sources of iTFA, iTFA intake will remain high among those who consume large amounts of pre-packaged foods.
- Implementation of a mandatory iTFA policy can be supported by voluntary industry pledges to phase out PHO ahead of the implementation date.
- Ideally, replacement fats and oils are monitored to determine whether reformulation leads to an increase of saturated fat content. If this is not possible, and national nutrition surveys are conducted regularly, the survey results can be used to ensure that the fatty acid profile of the national diet is moving in the right direction.

An iTFA policy must cover all food products, not just oils and fats, to ensure that this harmful compound is removed from the entire food supply.

THAILAND

AT A GLANCE



- Since 2019, the production, importation and sale of PHO has been banned in Thailand.
- Thailand defined cut-off levels for trans fat content to determine whether a product complies with the PHO ban:
  - *Butter and butter oil:* compliant if TFA is below 6% per 100 grams;
  - *Blended fat, oil products and refined cooking oils:* compliant if TFA is below 2% per 100 grams;
  - *Other food products:* compliant if TFA is less than or equal to 0.5 grams per serving.
- Key to successful implementation and enforcement were the availability of a database on TFA levels in products to inform the implementation and enforcement strategy; collaboration and communication between stakeholders; existing laboratory capacity; the availability of replacement oils; and capable oil and fat manufacturers.
- The Thai Food and Drug Administration (Thai FDA) received scientific and monitoring support from Mahidol University, and the Thai Foundation for Consumers supported the PHO ban's implementation, enforcement and monitoring with consumer education, monitoring, publication of monitoring results and pressure on food manufacturers and restaurant chains to reformulate products and comply with regulation.

Overview of Thailand's ban on partially hydrogenated oils

On July 13, 2018, the Ministry of Public Health published Notification No. 388 B.E. 2561 (2018), banning the production, importation and sale of PHO to reduce the risk of cardiovascular diseases attributable to TFA consumption.[44] Rather than a remedial action, the Thai PHO ban is a preventative measure to avoid a future increase in TFA intake due to a potential rise in imports and sales of Western-style foods (see NCD Alliance, 2019). The PHO ban came into effect on January 9, 2019, after a transition period of 180 days.

The Thai FDA conducted a regulatory impact assessment to determine which approach to iTFA elimination was preferable: iTFA limit, PHO ban or TFA labeling. Mandatory labeling of TFA content was considered too costly for smaller businesses due to analytical costs which were estimated to be ฿409 million (around

44 For information on the *development* of the PHO ban, refer to Chavasit & Garg (2018) and the case study on Thailand in NCD Alliance (2019).

US$13.5 million) (Chavasit et al., 2020). A PHO ban was chosen as the most cost-effective policy choice for both the government and industry to ensure food products are free of iTFA.[45]

It is prohibited to use "free of trans fats" claims to avoid misleading consumers into thinking a product is healthier than competing products, and potentially increasing the consumption of saturated fats (which are often used to replace iTFA) (Chavasit et al., 2020). Claims that a product contains no saturated fats ("free," "free of," "without," "zero," "no") are only permitted if both the content of saturated fats and TFA in one serving size are below 0.5 grams (Notification No. 182 B.E. 2541, 1998).

Implementation

The Thai FDA is responsible for the implementation of food regulations, including the PHO ban.

Thailand used a supply chain approach to policy implementation, working with the three domestic PHO producers that supplied most local and multinational franchise bakeries with fats and oils. The Thai FDA supported these three manufacturers to change manufacturing processes to ensure PHO-free oils and fats were made available to domestic food producers. For this reason, their implementation approach did not have to differentiate between large companies and SMEs.

The transition period was six months. Usually, the Thai FDA sets transition periods of 12 months, but the findings of the Foundation for Consumers on PHO content in fried donuts (see below under "Monitoring and evaluation") convinced the food committee at the Thai FDA of the urgency of the matter (Foundation for Consumers, 2021). In addition, the public hearings and focus groups of the Thai FDA and industry, hosted by academics, showed the readiness of industry to reformulate and the feasibility of a six-month transition (Chavasit et al., 2020).

The Thai FDA communicated with food manufacturers and importers, issuing guidelines on how to ensure compliance with the PHO ban[46] and arranging meetings to communicate and clarify the ban. While the Agriculture Research and Development Agency (ARDA) committed to providing support for product development, fat and oil producers already had the necessary capabilities to reformulate using oil blending techniques and locally available, affordable tropical oils with naturally high levels of saturation.

The Thai FDA also used social media and infographics targeting the public to increase consumer understanding on the difference between iTFA (PHO) and natural TFA.[47]

Implementation costs

Implementation costs to government and food industry actors have not been assessed

Success factors

Key success factors in the implementation of the PHO ban were the collaboration and communication between government, public health professionals, academia and the private sector; and the readiness and capability of food companies to change formulations within the transition period. Because key export markets had already implemented iTFA policies with which Thai manufacturers had to comply, Thailand had an oil industry able of reformulating using local tropical oils. These oils have been used for centuries and are, therefore, culturally acceptable. (Chavasit & Garg, 2018; Chavasit et al., 2019, 2020)

45 Unless indicated otherwise, all information contained in the case study was obtained from written responses to an interview questionnaire and follow-up questions by an official from the Thai FDA (Thai FDA, 2021).

46 Announcement of the Thai FDA re: Explanation on the Notification of the Ministry of Public Health No. 388 B.E. 2561, available in Thai at http://food.fda.moph.go.th/law/data/announ_fda/388_trans_fat.pdf; and Handbook on Compliance with Notification No. 388 B.E. 2561, available in Thai at https://www.fda.moph.go.th/sites/food/FileNews/manual_388.pdf.

47 Available in Thai only: Facebook posting by Thai FDA, https://www.facebook.com/FDAThaiposts/2440529506014197/, and website by the Thai FDA containing health information on products, https://oryor.com/%E0%B8%AD%E0%B8%A2/detail/media_printing/1630?fbclid=IwAR3-gIL7rWM0-KYvZliPRv0u286s9KYh1R98la1XwIRQ5BpjdRDQeu4trT4

Enforcement actions can include randomly sampling and testing targeted food products.

Enforcement

The Thai FDA is the government body responsible for enforcing the PHO ban.

Enforcement actions may consist of randomly sampling and testing targeted food products, including margarine, shortening and baked goods; inspection of production and importation sites; examination of labels; and examination of documents (importers must be able to provide a confirmation letter certifying that the product is free of PHO and stating ingredients, product formulation and specifications, and production processes; alternatively, a certificate of analysis can be supplied).

Because sampling is expensive, only food products that pose a high health risk are tested: mainly imported and domestic oils and fats and domestic baked goods. Identification of high-risk products was enabled by a baseline assessment of TFA levels in food products conducted during policy development in collaboration with Mahidol University. (Chavasit & Garg, 2018; Chavasit et al., 2019)

Post-marketing enforcement is based on health risk, using the following cut-offs for TFA to determine whether a product complies with the PHO ban (Chavasit & Garg, 2018):

- *Butter and butter oil (clarified butter):* TFA content below 6 grams per 100 grams. The 6% cut-off was derived from the baseline assessment of TFA levels in food available in Thailand.

- *Blended fat and oil products and refined cooking oils:* TFA content below 2 grams per 100 grams. The 2% cut-off is based on the EU's iTFA limit (Chavasit et al., 2020; Chavasit & Garg, 2018).
- *Other food products:* TFA content less than or equal to 0.5 grams per serving. The cut-off is based on the FAO/WHO Guideline on Diet, Nutrition and the Prevention of Chronic Diseases, which recommends that TFA intake should not exceed 2.2 grams per day for a 2,000-calorie diet. (Researchers assumed that products containing TFA could be consumed up to five times a day — three meals and two snacks — and divided 2.2 grams by five.) (Chavasit et al., 2019).

The Thai FDA uses a 95% compliance rate as the threshold at which it reduces the frequency of monitoring or the number of food products sampled (see below "Monitoring and evaluation").

In addition to enforcement activities, the Thai FDA requires companies to retain samples of their products in case of unexpected events as part of pre-marketing authorization.

Testing for iTFA

Government and accredited laboratories use AOAC 996.06 as a reference standard method which is an official method for measuring TFA in foods.[48] The efficiency of laboratory testing for TFA had to be improved by training staff, buying equipment and updating lab protocols to support the analysis of food samples.

Sanctions for violations

In case of non-compliance, violators may be fined ฿5,000 to ฿20,000 (around US$165-665) or imprisoned for six months to two years based on Art. 50 of the Food Act B.E. 2522. No fines or prison sentences have been issued thus far. Imported products in violation of the PHO ban can be blacklisted to prevent them from entering Thailand. Business licenses may be suspended and product licenses revoked in case of infringements against the Food Act B.E. 2522.

The close link between the Foundation for Consumers and other stakeholders means that non-compliance can be publicized on the Foundation's website, which is very influential in Thailand and effective at pushing companies to change their business practices and/or comply with laws (Foundation for Consumers, 2021; Chavasit & Garg, 2018).

Enforcement costs

The exact enforcement costs of Thailand's PHO ban are not known, but the Thai FDA states that the main enforcement costs are related to the sampling and analysis of food products.

48 The WHO protocol for measuring TFA (WHO, 2020) is an adapted version of AOAC 996.06.

Success factors

Key enablers of enforcement were the availability of a database on TFA levels in products that could guide the enforcement strategy; laboratory capacity and respective scientific knowledge (Chavasit & Garg, 2018); and a partnership and communication between government, public health professionals, academia, civil society and the private sector.

Monitoring and evaluation

Baseline assessment of iTFA content

As part of the policy development process, the Nutrition Institute at Mahidol University collected baseline data on the TFA content in domestic and imported food products in close collaboration with the Thai FDA. In 2017, 176 samples were collected from retail stores, bakeries, fast food restaurants, and street food vendors in Bangkok, Samut Prakan and Nonthaburi provinces. Sampling focused on foods that had been shown to contain iTFA in previous studies. Analysis of the samples revealed a wide range of TFA content (see Table).

TABLE

Range of TFA content per total product, selected foods (Chavasit et al., 2019)

- Donut frying fat: 0.61–46.5%
- French fries: 0.04-0.08%[49]
- Margarine: 0.08–15.32%
- Shortening: 0.02–43.38%
- Fried donuts: 0.02–5.14%
- Wafer chocolate: 0.03–6.24%
- Popcorn: 0.11–0.16%
- Non-dairy creamer: 0.23–15.43%
- 3-in-1 instant tea and coffee: 0.04–0.11%

The Nutrition Institute also conducted a baseline health risk assessment based on the FAO/WHO Guideline on Diet, Nutrition and the Prevention of Chronic Diseases which recommends that intake of TFA and saturated fat. Because dairy is not widely consumed in Thailand and meat is only consumed in small quantities, exposure to natural TFA is low. Traditional products and cooking oils are low in TFA (but high in saturated fat). Most TFA is consumed through Western-style foods and bakery products, and even these were found not to contain more TFA per serving than recommended by FAO/WHO. Therefore, Chavasit et al. (2019, 2020) concluded that TFA would only be of concern among people who consume high amounts of Western-style foods and baked goods.

In 2018, the Foundation for Consumers worked with technical experts at Mahidol University to test 13 brands of chocolate donuts for TFA content (Figure 4). The analysis, which was conducted by an ISO-certified laboratory, found between 0.073 grams and 4.59 grams of TFA per donut. The Foundation published the findings on its website, which led to one company pledging to reformulate their donuts within 24 hours of publication. Within three days, Tesco Lotus, a large supermarket

49 The Foundation for Consumers analysed iTFA content in French fries, collecting 30 samples in November 2009 and March 2010 from outlets of fast food chains (six large brands, including KFC, Burger King and McDonald's) and three small fast food restaurants in Bangkok and Samut Songkhram Province. iTFA content was on average 0.09 g/100 grams of product (or 0.14 grams/serving) in November 2009 and 0.04 grams/100 grams (or 0.06 grams/serving) in March 2010. (Foundation for Consumers, 2021).

chain with stores throughout Thailand, announced that they will stop using PHO in their donuts. The international donut chain Mister Donut followed suit (though its commitment was limited to the Thai market and did not extend to other markets where Mister Donut operates). (Foundation for Consumers, 2021). .

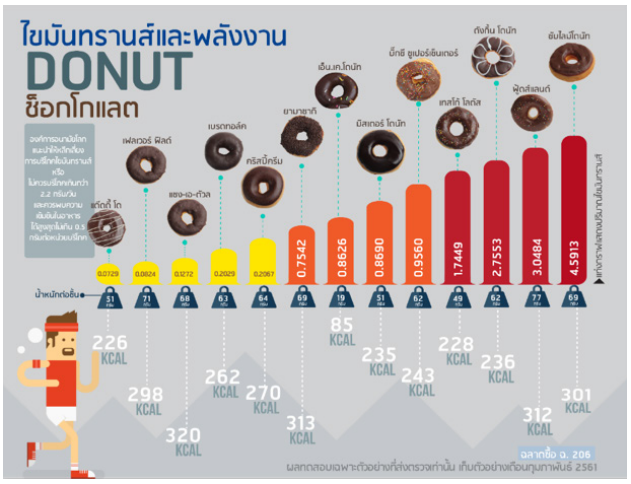


Figure 4. ranking of chocolate donuts by TFA content (g/donut)

The coloured bars show the amount of TFA in g; the small black weights show the weight per donut in g. *Source*: hfocus, 2018

2019 monitoring campaign of iTFA content

Since the PHO ban took effect in January 2019, the Thai FDA has conducted one monitoring campaign. Due to budget constraints, the Thai FDA collaborated with the Foundation for Consumers and the Nutrition Institute at Mahidol University to monitor the iTFA content in bakery goods, such as fried donuts, pies, puffs, pastries, croissants and butter cakes (NCD Alliance, 2019; Chavasit et al., 2020). In the first quarter of 2019, 46 domestic and imported bakery goods were sampled (Chavasit et al., 2020). All complied with the PHO ban: they contained between 0.09 grams and 0.31 grams of TFA per 55-gram serving, a substantial reduction from the baseline assessment conducted prior to implementation, which showed a range of 0.42–1.21 grams of TFA per serving (Foundation for Consumers, 2019a).[50]

Analysis of chocolate donuts by experts at Mahidol university found between 0.073 and 4.59 grams of TFA per donut.

The monitoring campaign also included samples of the same 13 brands of chocolate donuts tested by Foundation for Consumers in 2018 (see above under “Baseline assessment”). The donuts contained between 0.03 grams and 0.14 grams of TFA per 55-gram serving, a significant improvement over the 2018 results (a range of 0.073–0.59 grams of TFA per serving). (Foundation for Consumers, 2019b)

Future monitoring of TFA content

With ฿200,000 (around $6,200 USD) support from the Thai Health Promotion Foundation, an autonomous government agency, the Thai FDA and the Department of Medical Sciences of the Ministry of Public Health are planning to analyze TFA content in packaged and non-packaged foods as part of a broader survey of health-related products. The Thai FDA will sample 40 products considered likely to contain PHO (including creamer, margarine, cookies, cakes, donuts and biscuits) from production, importation and retail sites; the Department of Medical Sciences will analyze the samples. Results are expected towards the end of 2022 (Thai FDA, 2022).

The Foundation for Consumers is also planning a TFA monitoring campaign in 2022 (Foundation for Consumers, 2021).

TFA intake

In a pilot project in partnership with the U.S. Centers for Disease Control and Prevention (CDC) and Resolve to Save Lives, Mahidol University is assessing population TFA intake by measuring TFA levels in blood plasma. Two scientists

50 The results of the 2019 monitoring campaign do not state the total fat content per serving, solely the TFA content.

at Mahidol University were trained by the U.S. CDC to test serum TFA, which was collected as part of Thailand's National Health Examination Survey in 2014 in Bangkok, Chiang Mai and other cities. Results, which have not yet been published, will be used as baseline; serum TFA will be collected and analyzed every five years as part of the National Health Examination. (Chavasit & Garg, 2018)

The costs associated with analyzing 900 serum samples annually over five years was estimated to be US$186 per sample[51], with average costs declining as more samples are processed (Datta et al., 2021). Understanding these costs can facilitate program planning, implementation and scale-up.

Impact on food composition and health

The Thai FDA does not check what PHO is substituted with nor evaluates the health impact of the PHO ban.

Lessons learned

- The availability and accuracy of data on iTFA in the food supply, generated through a baseline assessment prior to policy adoption, helps to inform enforcement activities such as which food products to sample based on risk of non-compliance.
- Implementation is significantly facilitated by the edible oil industry's capacity to reformulate and the availability, accessibility and affordability of culturally acceptable replacement oils and fats.
- Existing laboratory capacity and scientific knowledge facilitate enforcement.
- Partnership and communication between the government, academia, civil society and industry was essential to successful implementation of the PHO ban in Thailand. In particular, the work of the Foundation for Consumers exemplifies how a consumer organization can support government not only with advocacy, but by using monitoring, publication of monitoring results and consumer education to put pressure on food manufacturers and restaurant chains to reformulate products and comply with regulation (Foundation for Consumers, 2021).
- When key export markets have already limited iTFA or banned PHO, as was the case with Thailand, it supports the implementation of a PHO ban (or iTFA limit).

51 Laboratory, personnel, and facility costs constitute 67%, 23%, and 10% of costs, respectively. Fixed costs (e.g., laboratory instruments, personnel) accounted for 60% and variable costs (e.g., chemical supplies) for 40% of costs.

ANNEXES

Annex 1: Methodology

Overview

The case studies were chosen to be representative in policy choice, implementation strategy, geography and political system. Only countries with a fully implemented best-practice policy as of October 2021 were considered. Countries were only included if interviews could be obtained.

Interviews conducted for this report were based on a questionnaire covering implementation, enforcement, monitoring, evaluation and lessons learned. All interviews were conducted in English (except where noted) over Zoom or via written correspondence. Nine interviews with 12 interviewees were conducted. Most interviewees wanted to remain anonymous but are known to the author and Resolve to Save Lives.

The rationale for selection of each case study and details on resources used are given below.

Chile

Chile was one of the first countries in the world to adopt an iTFA limit in 2009. The enforcement of the iTFA limit is linked to monitoring activities for food labeling required by the Sanitary Food Regulations and the Food Labeling and Advertising Law. Its joint enforcement of the iTFA limit and food labeling makes it an interesting case study for other countries interested in a more effective use of enforcement budget.

The case study is based on desk research in English and Spanish using the law database of the Chilean Government for decrees, PubMed, WHO's Global Database on the Implementation of Nutrition Action (GINA), PAHO's baseline report on TFA policies (PAHO, 2022), a case study on Chile by NCD Alliance (2019), a monitoring report by ODECU (2015), and written answers to an interview questionnaire and follow-up questions by an official working on the iTFA limit at the Undersecretariat of Public Health, Ministry of Health.

Denmark

Denmark was the first country in the world to implement a 2% iTFA limit in 2004. Other countries can learn from Denmark's long history of implementing its TFA policyand the long-term trajectory of implementing, enforcing and monitoring an iTFA limit.

The case study is based on desk research in English using PubMed, WHO's GINA, and two in-depth interviews: one with a representative of the Danish Veterinary and Food Administration (DVFA) who has been dealing with the administration of the iTFA limit since 2014, and another with Dr. Anette Bysted of the National Food Institute at the Technical University of Denmark (DTU). Dr Bysted advised the DVFA on laboratory methodology and sampling and conducted studies on TFA content in food products available on the Danish market.

European Union

The EU is the first and only economic or political union to date that has implemented a mandatory 2% iTFA limit which is immediately binding on member states. It provides lessonss on the large-scale implementation of a TFA policy across multiple jurisdictions with different legal systems.

The case study is based on desk research in English using PubMed, documents and information published by the European Commission and the Joint Research Centre (JRC) and an in-depth interview with a representative of DG SANTE, who has been involved with the topic of trans fats at EU level since 2006.

Saudi Arabia

Saudi Arabia was the first country in the Eastern Mediterranean region to implement a PHO ban in line with WHO recommendations. It led the way for the Gulf Cooperation Council (GCC) Standardization Organization to adopt a PHO ban on 1 July 2021, recommended for implementation in all GCC member states (GSO, 2021).[52] Furthermore, Saudi Arabia's step-wise approach to iTFA elimination provides learnings to countries which may already have an iTFA policy in place and would like to strengthen it to align with WHO's best-practice recommendations.

The case study is based on desk research in English using PubMed, WHO's Global Database on the Implementation of Nutrition Action (GINA), a case study report by NCD Alliance (2019), and an in-depth interview with two representatives of the Saudi Food & Drug Authority (SFDA) who were and are directly involved with the development, implementation, enforcement and monitoring of the Saudi iTFA policy.

Singapore

Singapore was the first country in the Western Pacific region to implement a best-practice policy eliminating iTFA from its food supply (WHO, 2020). The implementation and enforcement of Singapore's PHO ban provides learnings from two viewpoints: it used a step-wise approach to iTFA elimination and imports most of its foods. Therefore, its implementation strategy is relevant both for smaller nations and small island states which also mostly import foods.

The case study is based on desk research in English using PubMed, government agencies' websites for regulations and official communications of government agencies and an interview with and written information provided by two representatives of the Health Promotion Board of Singapore who were directly involved in the development of the Singaporean iTFA policy.

Thailand

Thailand's population consumption of iTFA does not exceed WHO's recommended maximum level of 2.2 grams/day (based on a 2,000 calorie/day diet). Nevertheless, a PHO ban was adopted to maintain the low iTFA consumption level and prevent an increase of iTFA consumption and its associated negative health impacts. Implementation and enforcement were a collaborative effort between the government, academia and civil society. Thailand provides implementation lessons for countries contemplating the adoption of a PHO ban, multistakeholder approaches andr preventive action on iTFA consumption.

The case study is based on desk research in English using PubMed, WHO's Global Database on the Implementation of Nutrition Action (GINA), a case study report by NCD Alliance (2019), a webinar on the Thai PHO ban (Chavasit & Garg, 2018), an interview with the former Secretary General of the Foundation for Consumers and written answers to an interview questionnaire and follow-up questions by an official of the Food and Drug Administration Thailand (Thai FDA).

52 The *Gulf Technical Regulation GSO 2483:2021, Partially Hydrogenated Oils/Fats (2021)* is not binding upon member states nor are they obliged to transpose it into national law.

Annex 2: Methodology to distinguish between natural and artificial TFA (Denmark)

- The below is a summary of Bysted (2015) on the differentiation between natural and artificial TFA, which is used for enforcement and monitoring purposes in Denmark.[53] In foods with milk fat as the only fat source, the amount of total TFA equals the amount of natural TFA.
- In foods based solely upon industrially produced fats, the content of total TFA equals the content of iTFA.
- In foods containing mixed fats, e.g., milk fat and partially hydrogenated soybean oil, the amount of natural TFA is calculated from the unique occurrence of butyric acid (C4:0) in milk fat and then withdrawn from the total amount of TFA to get the contribution from iTFA. This calculation is divided into three steps:

  1 The content of milk fat in the product is calculated based on the content of butyric acid (C4:0) in milk fat established to 3.6 grams per 100 grams of fat.[54]

  2 The content of natural TFA is calculated based on the content of TFA in milk fat established to 6 grams per 100 grams of fat. [55]

  3 The, the content of natural TFA is subtracted from the total TFA content to give an estimate of the iTFA content.

Note that the methodology refers to milk fat and no other ruminant fats that might contain natural TFA (e.g., tallow). [56] This is because milk fat is commonly used in Danish food products, together with margarine (for example in baked goods and cookies). Other ruminant fat is rarely used in combination with margarine or other hydrogenated oils in Denmark.

53 Please note that the Danish method makes assumptions about the ratio of butyric acid and total TFA that is not globally valid. Ratios and assumptions would need to be set at levels relevant to another country's food products. Also note that because of the relatively high water solubility and volatility of butyric acid relative to other common dietary fats, reliable measurement of butyric acid by gas chromatography may be difficult. Therefore, to avoid challenges of distinguishing between natural and industrial TFA, countries that mostly manufacture their own food can focus laboratory testing on vegetable oils and fats sold to consumers and used for manufacturing of products. In this way, all identified TFA is iTFA.

54 Note that the EU methodology assumes a butyric acid content of 3.4 grams per 100 grams milk fat (see Annex 4 for details on the EU methodology).

55 This is the same amount as assumed by the EU methodology.

56 The EU methodology includes tallow in its calculations and assumptions.

Annex 3: Academic evaluations of Denmark's iTFA limit

iTFA content

Stender et al. (2006) showed that estimates of average consumption of iTFA ignore a significant percentage of the population whose intake of iTFA is at much higher, and dangerous levels than estimated averages. They compared the iTFA content in a meal of chicken nuggets and French fries purchased between November 2004 and September 2005 in McDonald's and KFC outlets in 20 countries. In the McDonald's meals, the lowest iTFA content was found in Denmark at 1% for each the French fries and chicken nuggets. At the highest end in the USA, iTFA content in French fries was 23% and in chicken nuggets 11%. In KFC meals, the lowest iTFA content was 1% for both meal components in Germany while the highest value was observed in Hungary at 35% in French fries and 31% in chicken nuggets. Denmark had the third-lowest iTFA content at 2% for each meal component.

Leth et al. (2006) tested 253 domestic and imported products in 2002/2003 as a baseline and found 64 of them to contain more than 2 grams iTFA per 100 grams of fat. In 2004/2005, they tested 148 products in the categories that showed elevated iTFA content in the baseline study of 2002/2003 (caramels, industrial bakery products, potato products) and found much fewer products with non-compliant iTFA levels, ranging between 2% and 6% iTFA (the exact number of non-compliant products is not stated in the article).

Bysted et al. (2009) sampled and analysed products in 2002/03, 2004/05 and 2006/07. In 2002/03, 25% of 253 products contained more than 2 grams iTFA per 100 grams of fat. Right after the implementation of the iTFA limit in 2004, 11% of 148 tested products contained more than the permitted 2 grams iTFA per 100 grams of fat, while in 2006/07, 9% of 45 products transgressed the iTFA limit.

Health impact

Restrepo & Rieger (2015) evaluated the iTFA limit's impact on mortality attributable to cardiovascular diseases (CVD). Prior to the implementation of the iTFA limit, Denmark's CVD mortality rate of 441.5 CVD deaths per 100,000 people followed the rate of a weighted average of other OECD countries, which was 442.7 CVD deaths per 100,000 people. Within three years of policy implementation, CVD mortality decreased on average by 4.3% (14.2 deaths per 100,000 people), and deaths from coronary heart disease (CHD) by 10.4% (26.5 deaths per 100,000 people), most of which among the age group ≥55 years, relative to similar countries. For men, CVD deaths between 2004-2006 decreased by 5.8% (24.4 deaths per 100,000 people) and for women by 5.2% (14.3 deaths per 100,000 people). For the period 2004–2012, the authors estimate the decrease to be 22 deaths per 100,000 people.

Nichols et al. (2013) compared mortality rates attributable to CHD across Europe for the period 1980-2009 and found that the largest decrease in the European Union could be observed in Denmark: CHD mortality rates of all ages for males decreased by 72% and for females by 70%. The study did not establish the reasons for Denmark's outperforming all other EU countries.

Annex 4: Analytical approach to determining iTFA content in foods for compliance purposes (European Union)

Annex 4 describes the analytical approach to determining iTFA content in food products for compliance with the EU's 2% iTFA limit, developed by the EU's Joint Research Centre (Ulberth & Wenzl, 2021). The approach's main focus is on food products which contain a mixture of PHO and ruminant fats from dairy or beef tallow.

Laboratory method

Analytical testing is to be done by capillary gas-liquid chromatography with flame ionization detection (GLC-FID) using ISO 16958:2015 | IDF 231:2015. Other standardised, internationally accepted methods with similar performance characteristics, such as AOAC 996.06 and AOCS Ce 1j-07, may be used if it can be proven that they deliver equivalent results.

Fat might be transesterified directly in the test sample, or after the extraction of a representative portion of fat, depending on the analytical method used for the determination of fatty acid methyl esters by GLC-FID.

Approach

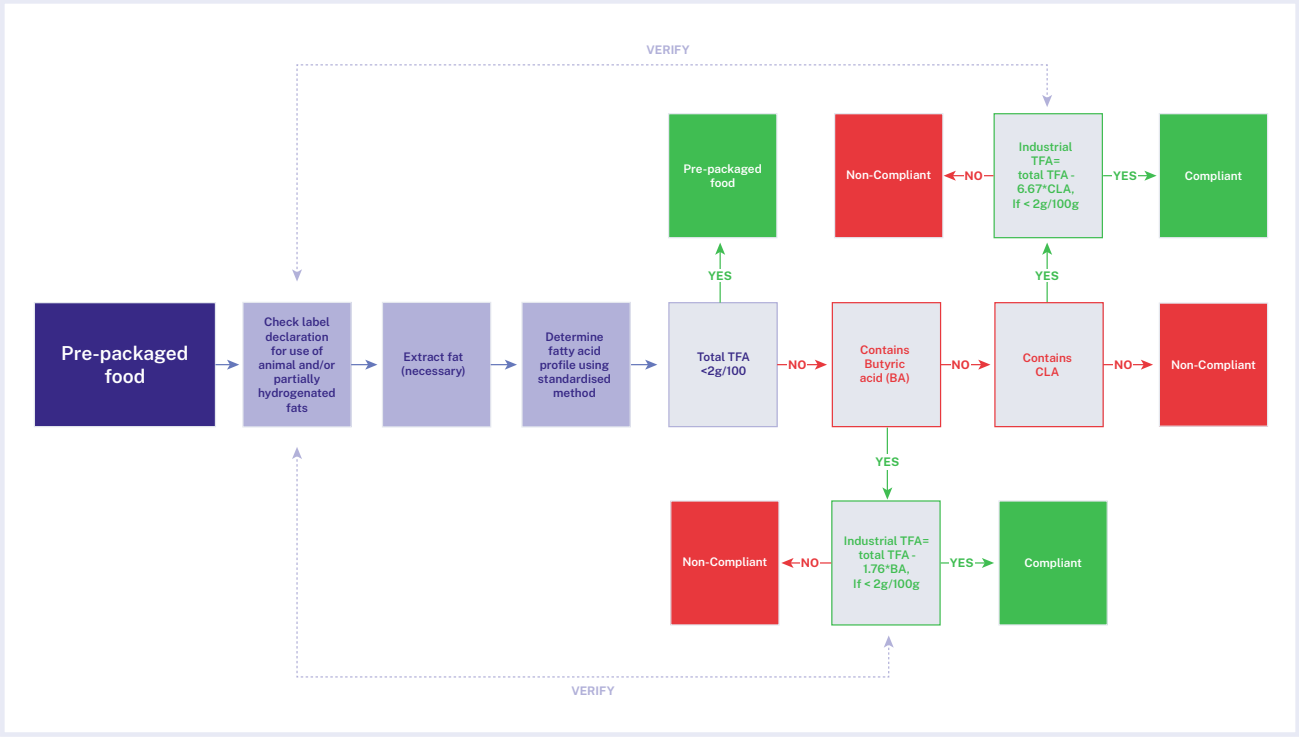


Figure 5. Workflow for checking the compliance of fats and oils against the 2% iTFA limit

The analytical approach builds on the use of:

- the amounts of butyric acid (C4:0) (grams /100 grams of fat);
- total TFA (sum of fatty acids with at least one non-conjugated carbon-carbon double bond in the trans configuration, usually the trans-isomers of hexadecenoic acid (t16:1), octadecenoic acid (t18:1), octadecadienoic acid (t18:2) and octadecatrienoic acid (t18:3)), and of c9, t11-18:2);

- a correction of the TFA content by the TFA content stemming from ruminant TFA (rTFA) is then applied. The contribution of rTFA to the total TFA content of the blend is either estimated via the butyric acid content if the blend contains milk fat or via conjugated linoleic acid if the blend contains ruminant fat (tallow);
- a decision-making algorithm (Figure 5) to identify whether the fat contains:
    - less than the regulated limit for TFA (e.g., less than 2 grams/100 grams fat),
    - only iTFA in amounts exceeding the limit,
    - only rTFA in amounts exceeding the limit,
    - a mixture of iTFA and rTFA in amounts exceeding the limit.

Based on the ingredients list of the tested food product, it should be checked whether it contains ruminant fats (milk fat and/or tallow). If their amounts are specified, this must be recorded for cross-checking the plausibility of the obtained testing results.

Calculations

1 If butyric acid is present besides iTFA and rTFA, the amount of butyric acid is used to approximate

a the amount of milk fat in the mix, and 2) the amount of rTFA from milk (Equation 1).

Equation 1 rTFA [g/100g] = (Butyric acid [g/100 g] * 29.4* 6)/100 = Butyric acid [g/100 g] * 1.76

- **Assumption 1:** Milk fat contains 6 grams TFA/100 grams (for Equation 1). It is a fairly conservative estimate that does not disadvantage food business operators while being effective in protecting public health.
- **Assumption 2:** The factor 29.4 is used to convert the measured amount of butyric acid to milk fat based on an average content of 3.4 grams butyric acid/100 grams of milk fat (for Equation 1).[57]

2 If butyric acid is not present (which is rare) while c9, t11-18:2 is present besides iTFA and rTFA, the amount of c9, t11-18:2 is used to approximate the amount of rTFA originating from bovine fat (tallow) in the mix (Equation 2).

Equation 2 rTFA [g/100 g] = (c9, t11-18:2 [g/100 g])/0.15 = c9, t11-18:2 [g/100 g] * 6.67

- **Assumption:** since the TFA concentration in tallow is similar to milk fat, a factor of 0.15, which approximates the relation of total TFA to c9, t11-18:2 for milk fat, is used to estimate the amount of total TFA in tallow.

3 The subtraction of the amount of rTFA from total TFA gives the amount of iTFA (Equation 3).

Equation 3 iTFA [g/100 g] = total TFA [g/100 g] – rTFA [g/100 g]
N.B. Zero replaces negative values.

57 Note that the Danish methodology assumes a butyric acid content of 3.6 g/100 grams milk fat (see Annex 2).

Annex 5: Regulation 2483/2021 (Saudi Arabia)[58]

TFA limits (Article 4.6)

Type of oil/fat used in the food product	Trans fat content (artificial and natural)
Partially hydrogenated oils	Partially hydrogenated oils are prohibited
Fully hydrogenated oils	<2% of total fat used in the food product
Natural trans fat	≤5% of total fat used in the food product
Refined oils	<2% of total fat used in the food product
Infant formula, follow-up milk, custom milk for private medical use	≤3% of total fat used in baby formula

Iodine value (Article 3.3)

Oils	Degree of hydrogenation	Iodine value (degree of unsaturation)
Partially hydrogenated oils	Not completely hydrogenated or does not reach full saturation	• High degree of unsaturation. • Iodine value is >4.
Fully hydrogenated oils	Complete or almost complete hydrogenation, reaches saturation	• Low degree of unsaturation. • Iodine value is ≤4.

Calculation of TFA (Article 5.2.1.1)

- (TFA in product / total fat) x 100
- Result of equation not to exceed the thresholds of Article 4.6
- Iodine value should not exceed four (4).

Back-of-pack nutrient panel (Article 6)

- The amount of TFA must be mentioned in grams per 100 grams or 100 milliliters, or per package if the package contains a piece or one share of the product, or per portion of the food as long as the labeling indicates how many portions the package contains.
- Total fat content should immediately follow saturated and trans fat content.
- The % of Daily Value for TFA is not required to be included since there is no reference value.

58 This translation is by the author and not an official translation.

- Trans fat must be declared as “trans fat”, even if it is 0 grams.
- A trans fat content of less than 0.5 grams per 100 grams can be rounded down to 0 grams.
- Products not intended for human consumption are exempt from these labeling requirements.

List of ingredients (Article 7)

Fully hydrogenated oils must be listed as “fully hydrogenated oil” or “hydrogenated oil”.

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