



Trans Fat Free by 2023

CASE STUDIES
in Trans Fat Elimination



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Executive Summary

Background



Industrially-produced trans fatty acids (TFAs),^a common in baked goods, pre-packaged foods and some cooking oils, are a major contributor to cardiovascular diseases (CVD) and noncommunicable diseases (NCDs) worldwide,¹ estimated to contribute to more than half a million deaths each year.² TFAs have no known health benefits and can be replaced in foods without impacting their consistency or taste.

The elimination of TFAs from the global food supply is a priority target of the World Health Organization's (WHO) current strategic plan (GPW13 2019 – 2023)³ and is identified as an effective and cost-effective policy measure to save lives. The elimination of TFAs is part of the programmes being scaled up following global political commitment at the United Nations High-Level Meeting on NCDs held in September 2018. Policies to eliminate TFAs can substantially contribute to achieving the global goal of reducing premature deaths from NCDs by one-third by 2030 (compared with 2015) and WHO's strategic priority to deliver better health and well-being to one billion people.

This report presents case studies of six countries in different regions of the world that have enacted policies to eliminate TFAs from their food supply, as recommended by WHO.⁴ The purpose of this report is to provide civil society organisations (CSOs), including national and regional NCD alliances, and policy-makers around the world with examples of successful strategies for enacting and implementing TFA policies, as well as an analysis of barriers, enablers and lessons learned based on the experience of policy-makers, advocates, and researchers involved in such efforts.

The focus of the report is on industrially-produced TFAs in partially hydrogenated oils (PHOs), the most common type of industrially-produced TFA, and not naturally-occurring TFAs present in some meats and dairy products.

^a Except where noted, the abbreviation TFA is used to refer to industrially-produced or artificial trans fats/ trans fatty acids, and does not include ruminant or naturally-occurring TFAs present in some meat and dairy products.

Country-Specific Case Studies

The **six countries profiled in the report** include Chile, Saudi Arabia, Slovenia, South Africa, Thailand, and the United States of America (USA). Each of these countries used a slightly different strategy for TFA reduction or elimination, although some common themes emerged.

Chile used a two-step policy approach, first enacting a TFA labelling regulation followed by a TFA limit. The national TFA limit was supported by the concurrent establishment of regional targets for TFA reduction. Chile's policy success was influenced by factors including multi-stakeholder engagement, ensuring the TFA policy was part of a larger policy framework, and government capacity to implement the regulations.

Saudi Arabia also enacted both a TFA labelling requirement and TFA limit in 2015 in close sequence, followed by a ban on PHOs in 2018 that is currently being implemented. The country's TFA policies were enacted as part of a broader Healthy Food Strategy driven by the Minister of Health and other government leadership. The Saudi government collaborated with partners including the food and oil industries, CSOs, and academia, and benefitted from WHO resources and support in policy enactment and implementation.

Slovenia enacted a TFA limit primarily to address the importation of TFA-laden products from other European countries without TFA policies. The policy was passed, in part, as a result of researcher-advocates conducting and publicising research on the levels of TFAs in Slovenian products and their health harms. The policy process was delayed initially while the European Commission was working to develop a regional TFA limit; however, the Slovenian government ultimately decided to move forward in enacting its own national policy in 2018.

South Africa enacted a TFA limit in 2011 and is still the only country in Africa to have such a policy. The Ministry of Health had begun the process to issue regulation on TFA labelling but decided to enact a TFA limit instead after a private member bill to ban TFAs was introduced in Parliament. It is unclear the extent to which South Africa's TFA limit has been implemented, and data on the impact of the regulation is not available.

Thailand addressed TFAs through a ban on PHOs enacted in 2018 to stop the production and importation of Western-style foods high in PHOs. The Thai government worked with the small number of PHO producers in the country to change their manufacturing process and cut off the supply chain to food manufacturers that used PHOs as ingredients. Factors important for successful policy enactment and implementation included data collection on TFA levels, communication and collaboration among a range of stakeholders, and manufacturers' readiness for change.

USA was the first country to restrict TFAs by prohibiting the use of PHOs and did so by determining that they are no longer "Generally Recognized As Safe" for use in the food supply. The PHO determination was preceded by a federal TFA labelling requirement and state and local TFA policies limiting TFAs in schools and food service, which provided proof of concept, evidence of policy impact, and required or incentivised manufacturers to begin making changes to reduce or eliminate TFAs from their products.

Key Conclusions

Several key conclusions emerge from the case studies. Importantly, these profiles show that reducing or eliminating TFAs from the food supply is both politically and technically feasible. Mandatory TFA policies have now been enacted by 56 countries and territories in all WHO regions, 32 of which have implemented these policies, while the others will bring them into force in the next few years.

Nearly all of the cases show that collaborating across sectors, both within and outside of government, is important for successful policy enactment and implementation. Key agencies within government include those with jurisdiction over health, agriculture and commerce. Key external stakeholders include CSOs, academia, and industry. CSOs – including, but not limited to, disease-specific organisations, medical associations, public health advocacy groups and consumer organisations – can play an important role in mobilising awareness and support for policy enactment, implementation, and enforcement. Academia can also play an important role in conducting and publicising research, serving as an expert resource for government, convening stakeholders, and supporting policy evaluation.

In countries considering TFA policies, research on the extent of the problem and major sources of TFAs in the food supply is important for making the case for the policy and identifying policy targets. However, given the robust international experience, lack of local data should not be an excuse to justify policy inaction. In addition, the impact of TFA policies on NCDs will be even greater if the policy is part of

a broader, coordinated approach to improve diet and nutrition and reduce NCDs.

Following enactment of the policy, guidance and technical assistance for manufacturers and importers can help to support successful implementation. Small and mid-size companies are likely to face the greatest challenges with compliance, but companies may be able to learn from each other. In addition, providing guidance on TFA replacements and monitoring policy impact may help to ensure that the TFA policy does not inadvertently increase consumption of unhealthy saturated fats/saturated fatty acids (SFAs), reducing its health benefits.

In many countries, more research is needed to determine the effects of TFA policies on the levels of various fats in the food supply, their consumption, overall dietary impact, and effects on CVD prevalence and deaths in the short and long-term. Policy leadership and advocacy is also needed to spur further enactment and implementation of best practice TFA policies across the globe.

Taking Action – What Needs to Happen

The NCD Alliance calls on governments to:

Follow WHO recommendations to enact a mandatory 2 per cent limit on industrially-produced TFAs in foods or to ban PHOs. The WHO's REPLACE action package and technical support in-country should be leveraged by policy-makers to protect their populations from the health harms of TFAs.

Embed TFA elimination in a broader, coordinated approach to improve diet and nutrition and reduce NCDs to maximise the impact of TFA policies on NCDs.

Collaborate across sectors within and outside of government to ensure successful enactment and implementation of the chosen TFA elimination policy. A multi-stakeholder approach is essential while being mindful of conflicts of interest.

Involve civil society, such as national and regional NCD alliances, to reach local communities, leverage the media to build public awareness, advocate for systematic change, ensure accountability and support monitoring and compliance with TFA policies.

Learn from the international experience and evidence – lack of local data should not be an excuse to justify inaction on TFA elimination.

Fund local research on TFA sources and consumption and its impact on CVD prevalence and mortality to tailor the policy choice to the local context, add to the existing body of research, and provide a baseline for policy evaluation after implementation.

Provide technical assistance and guidance on replacement fats to food manufacturers, particularly small and mid-sized producers, to ensure successful implementation of the TFA policy.

Budget and plan for monitoring and evaluation of the TFA policy from the beginning.

Introduction

Goals of the Report

This report presents case studies of six countries in different regions of the world that have enacted policies to eliminate TFAs from their food supply, as recommended by WHO.⁵ The report is intended to provide CSOs and policy-makers around the world with examples of successful strategies for enacting and implementing TFA policies. The report also provides best practices, lessons learned, and recommendations based on the experience of policy-makers, advocates, and researchers involved in such efforts.

Countries highlighted in this report are diverse geographically, economically, and politically, have enacted different TFA policies, used varied strategies for enacting and implementing them, and are at different stages in the implementation process. This diversity demonstrates that there are many potential policy paths to reducing or eliminating TFAs from the food supply.

Methodology

The information in this report was obtained directly through interviews or written correspondence with government, CSO, and research stakeholders and experts in the case study countries. Information was also compiled through researching the peer-reviewed literature, media, and reputable CSO and government websites. Criteria for selection of countries profiled in the report include geographic, political, and economic diversity, diversity in policy strategy and approach, and lack of existing reports or case studies that tell the country's story. Only countries that had enacted policies in line with WHO recommendations as of December 2018 were considered for inclusion.

Semi-structured phone interviews were conducted with 10 stakeholders/experts in the case study countries, including one stakeholder within government and one outside of government in most cases. Four additional stakeholders provided responses to questions in writing. In one country, information obtained from a webinar on the country's TFA policy organised by the project funder was utilised in lieu of an interview. Interviewees were identified through internet research and consultation with other TFA, nutrition, and CVD policy experts in the country or region.

Interviewees were asked questions regarding eight topic areas:

1. Rationale for TFA policy action
2. Policy type
3. Overarching strategy
4. Supporters and opponents
5. Advocacy strategies and messages
6. Implementation and enforcement
7. Evaluation
8. Best practices and lessons learned.

All interviews were conducted in English except where noted. All interviews were recorded and transcribed with the interviewee's permission using GoToMeeting. The full list of interviewees is included as an appendix. Exceptions are noted in the footnote.^b

^b Chile: Interviews with Senator Dr. Guido Girardi, Dr. Tito Pizarro Quevedo, and Dr. Lorena Rodriguez were conducted in Spanish. Key takeaways and quotations were then translated into English.

South Africa: Penny Campbell, Antoinette Booyzen and Malose Matlala from the South Africa Department of Health provided responses to interview questions in writing. We were unable to speak with a non-government stakeholder or expert.

Thailand: Information provided by Dr. Visith Chavasit on a webinar hosted by LINKS (<https://www.linkscommunity.org/>), an online community for cardiovascular health and collaborative program of WHO, the U.S. Centers for Disease Control and Prevention, CDC Foundation, and Resolve to Save Lives, was utilised in lieu of an interview with Dr. Chavasit.

USA: Responses from the U.S. FDA were provided in writing by an authorised representative and are attributed to the U.S. FDA.

Background on Trans Fats and Policy Strategies

What Are TFAs?

TFAs are a type of unsaturated fatty acids that occur naturally in meat and dairy products or can be industrially-produced through partial hydrogenation of vegetable oils. The process of partial hydrogenation increases the solidity and stability of the fat.⁶ Modifications to the partial hydrogenation process result in different products used for deep frying and baking, such as oils, margarines, and shortenings.⁷ In meat and dairy products, naturally-occurring TFAs (ruminant TFAs), do not exceed 6 per cent of total fatty acids.⁸ However, in partially-hydrogenated oils (PHOs), up to 60 per cent of total fatty acids may be TFAs.⁹

PHOs were first introduced into the food supply in the late 19th or early 20th centuries as a replacement for fats such as butter and lard.^{10,11} Given the properties of PHOs and that they are more shelf stable and often cheaper, PHOs were commonly used in margarines, vegetable shortenings, packaged snacks and baked goods, and fried foods.¹² While sources of industrially-produced TFAs vary by country, some common sources are included in the graphic below.

The focus of this report is on industrially-produced TFAs in PHOs and food products containing PHOs as an ingredient.

Health Harms of TFA Consumption

TFAs were once touted as a healthier replacement for SFAs when the health harms of SFAs, including increased blood cholesterol and CVD risk,¹³ became known. However, evidence has become clear that TFAs provide no nutritional benefits and are even more harmful than SFAs in increasing CVD risk.¹⁴ TFAs increase CVD risk by increasing the ratio of “bad” LDL cholesterol to “good” HDL cholesterol, promoting inflammation, and causing dysfunction in the lining of the heart and blood vessels.¹⁵ In fact, consumption of 5 grams of TFAs per day has been shown to increase the risk of CVD by 29 per cent.¹⁶ Globally, more than 500,000 deaths each year are due to consumption of TFAs.¹⁷ TFAs have shown to cause health harms even when they comprise only 1-3 per cent of total calories.¹⁸

World Health Organization Recommendations

In 2007, WHO undertook a scientific update on TFAs as part of the implementation of its *Global Strategy on Diet, Physical Activity and Health*.

The WHO Scientific Update on TFA concludes that restaurants and food manufacturers should avoid using industrially derived TFA in food products and that governments should take steps to support alternative fats or oils for TFA replacement. The evidence on the effects of TFA and disease outcomes strongly supports the need to remove [PHOs] from the human food supply. The result would be a substantial health gain for the population at large, with greatest health benefits obtained when replacement oils are rich in [unsaturated fatty acids].¹⁹

In May 2018, WHO released for public consultation draft guidelines on SFA and TFA intake for adults and children to provide recommendations on the

intake of SFAs and TFAs to reduce the risk of CVD. The draft guidelines recommend limiting total TFAs (industrially-produced and ruminant) to no more than 1 per cent of total energy for both adults and children, or 2.2g per day for a 2,000-calorie diet.²⁰ As of the date of publication of this report, the draft guidelines are in the process of being finalised and the WHO continues to recommend a 1 per cent limit for TFAs.

In May 2018, WHO also released the REPLACE action package, a step-by-step guide for eliminating TFAs from the global food supply by 2023. REPLACE provides governments with six strategic action areas. In May 2019, WHO released the REPLACE modules and additional resources to facilitate implementation of the policies and measures at a national level.

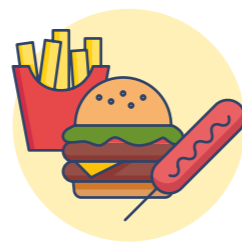
Common Dietary Sources of Industrial Trans Fats



Margarine, vanaspati ghee, vegetable shortening



Baked goods
(biscuits, pies, crackers, buns, cakes, pastries, sweet rolls)



Fried foods
(French fries, chicken nuggets, doughnuts)



Restaurant and street foods
that are baked or fried

| REPLACE | | | | | |
|---|---|--|---|--|--|
| REVIEW | PROMOTE | LEGISLATE | ASSESS | CREATE | ENFORCE |
| dietary sources of industrially-produced trans fat and the landscape for required policy change | the replacement of industrially-produced trans fat with healthier fats and oils | or enact regulatory actions to eliminate industrially-produced trans fat | and monitor trans fat content in the food supply and changes in trans fat consumption in the population | awareness of the negative health impact of trans fat among policy-makers, producers, suppliers, and the public | compliance with policies and regulations |

Source: WHO, https://www.who.int/docs/default-source/documents/replace-transfats/replace-information-sheet.pdf?Status=Temp&sfvrsn=f6eefd4f_2

Strategies to Reduce TFA Consumption

Informed by well-established research on the health harms of TFAs, governments at multiple levels across the globe have taken actions to reduce TFAs in the food supply and inform consumers about their risks. Policy strategies have included:

- Voluntary agreements with industry to reduce or remove TFAs from their products;
- Requirements to add TFA content to nutrition labels;
- Limits on TFA content in fats/oils and in all foods;
- Bans on the use of PHOs.

Strategies used have varied by the level of government at which they are implemented and by country and region of the world.

Research has shown that all of these strategies are effective in reducing TFAs in the food supply.²¹ However, a systematic analysis of 32 studies examining TFA policies showed that TFA limits or bans are more effective than voluntary policies or TFA labelling.²² TFA limits or bans virtually eliminate TFA from the food supply and are likely to have the greatest impact with regard to reducing CVD risk.²³

The First TFA Limit

In 2003, Denmark became the first country to enact a regulation limiting TFAs. Denmark's policy limits TFAs to 2 grams TFA per 100 grams of total fats and oils, excluding naturally occurring TFAs, in all foods sold to consumers.²⁴ Denmark's policy was enacted in March 2003 and took effect on 1 June 2003 with a phase-in period from 1 June to 31 December 2003, during which the TFA limit was 5 grams TFA per 100 grams of total fats.²⁵

Denmark's TFA policy was part of a package of policies to address the high rates of CVD in the country that also included tobacco control laws, new guidelines and improved treatment of hypertension, and policies and partnerships to improve the nutritional quality of the food supply.²⁶ Denmark's TFA policy was precipitated by a study first published in 1993 by Dr. Walter Willett and colleagues at Harvard University in the USA on the impact of TFAs on heart disease risk.^{27, 28}

This was followed by widely-publicised research about the health impact of TFAs in Denmark and recommendations by the Danish Nutrition Council that TFA content be limited through legislation.^{29, 30}



In partially-hydrogenated oils (PHOs)

60% of total fatty acids may be TFAs

Researchers had estimated that 50,000 Danes were at risk for CVD as a result of their TFA consumption.³¹

Denmark's TFA policy has been shown to be effective in reducing TFAs in the food supply and reducing deaths from CVD. A study showed that in the two years after Denmark's TFA policy took effect, TFA content was reduced or removed from products with high TFA content originally, including French fries, microwave popcorn, and bakery products, to the point that TFAs no longer posed a health risk.³² Denmark's TFA policy has effectively removed TFAs from the country's food supply. While TFAs should be replaced with healthier oils containing unsaturated fats to maximise health benefits of their removal, research showed that in Denmark, SFAs were used in approximately two-thirds of products.³³ Despite this, during the three years after Denmark's TFA policy was enacted, CVD mortality dropped faster in comparison to reference countries as a result of the TFA policy.³⁴ In fact, the 70 per cent decline in heart disease mortality rates that occurred in Denmark between 1980 and 2009, likely at least partly due to the country's efforts to address multiple CVD risk factors, including TFA intake, was the largest in the European Union (EU).³⁵

Current Status of TFA Policies

Since 2003, countries on five continents have followed Denmark's lead and enacted policies to limit TFAs or ban PHOs. The number of countries and territories with TFA policies in effect has grown significantly in recent years, from one in 2004 (Denmark) to three in 2009 (Denmark, Switzerland, and Chile)³⁶ to 32 as of March 2019.³⁷ The majority of countries to enact TFA policies thus far have been high and upper-middle income countries.³⁸ However, low- and middle-income countries bear up to 90 per cent of the global CVD burden,³⁹ underscoring the need to extend TFA elimination strategies globally.

The map on the next page shows countries and territories that have enacted a TFA limit or PHO ban.

Countries with a TFA limit of 2 per cent for all foods

Austria
Belgium^c
Bulgaria^c
Chile (page 16)
Croatia^c
Czech Republic^c
Denmark
Estonia^c
Finland^c
France^c
Germany^c
Greece^c
Hungary
Iceland
Ireland^c
Italy^c
Latvia
Lithuania^c
Luxembourg^c
Malta^c
Netherlands^c
Norway
Poland^c
Portugal^c
Republic of Cyprus^c
Romania^c
Slovakia^c
Slovenia (page 22)
South Africa (page 25)
Spain^c
Sweden^c
Uruguay^d
UK^{c, e}

Countries with a TFA limit of 2 per cent for fats/oils and 5 per cent for all other foods

Argentina
Bahrain
Colombia
Iran
Saudi Arabia

Countries with a TFA limit of 2 per cent for fats/oils only

Armenia
Belarus
Ecuador
Georgia^f
Kazakhstan
Kyrgyzstan
Russia
Singapore
Switzerland

Countries with a TFA limit of 5 per cent for fats/oils only

India

Countries with a TFA limit of 4 per cent for foods with a total fat content of <20%, and a TFA limit of 10 per cent for foods with a fat content of <3%

Uzbekistan

Countries and territories with a ban on PHOs

Canada
Chinese Taipei
Guam
Northern Mariana Islands
Peru^g
Saudi Arabia^h (page 19)
Thailand (page 27)
United States (page 29)

^c The European Commission adopted regulation to limit TFAs to 2 grams per 100 grams of fats on 24 April 2019, with a compliance deadline of 1 April 2021.

^d 2018: enactment of TFA limit; November 2019: implementation of 2 per cent limit for oils/fats/margarines and 5 per cent limit for all other foods; 2022: implementation of 2 per cent limit on all foods.

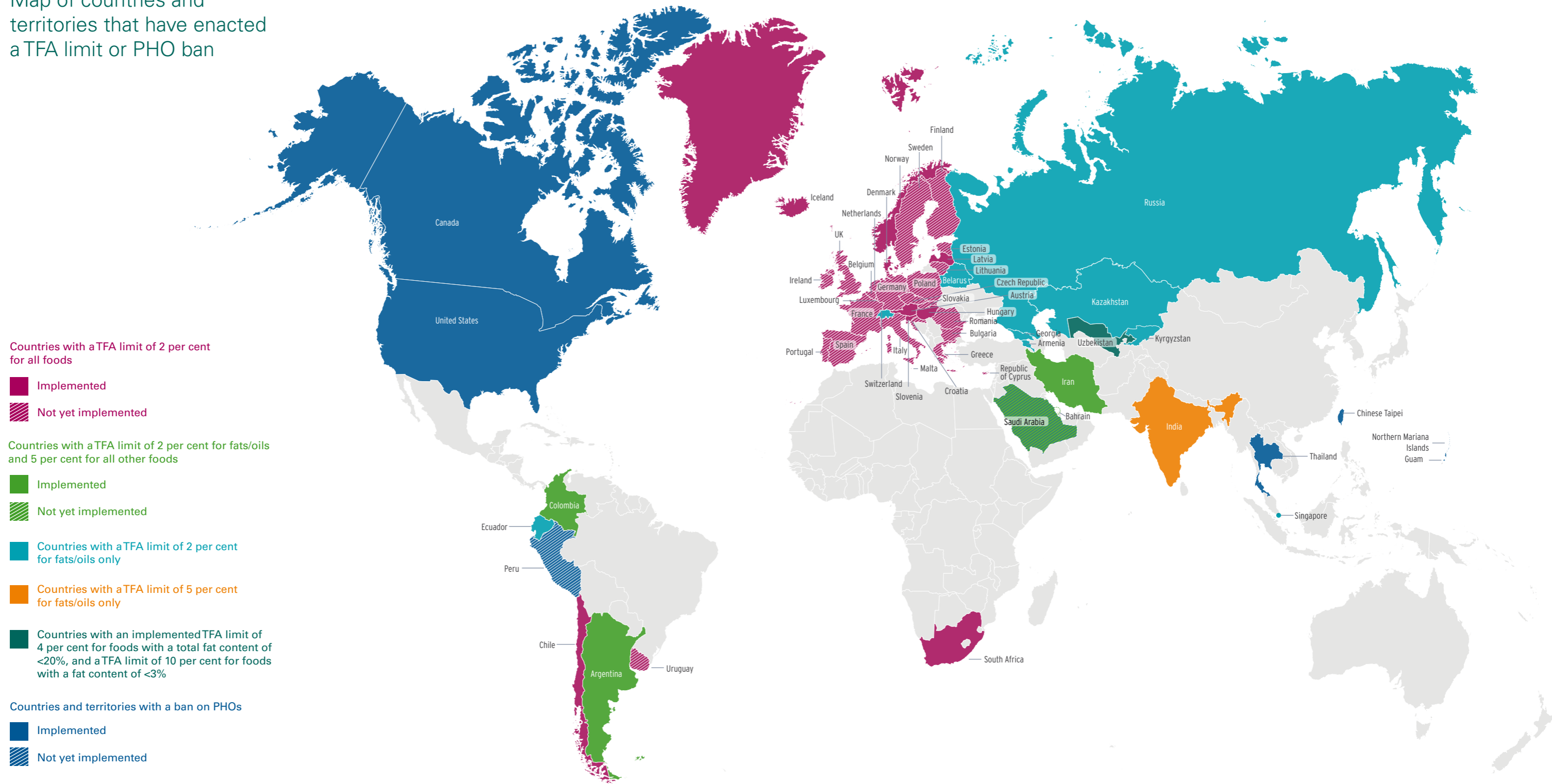
^e The UK will withdraw from the EU based on a referendum held in June 2016 in which a slight majority of those eligible to vote supported leaving the EU ("Brexit"). The UK was set to leave the EU end of March 2019 but the exit was postponed to 31 October 2019. As of the date of the publication of this report, the UK and the EU had not agreed on the terms of Brexit. Consequently, it remains to be seen whether and how Brexit will affect the implementation of the EU TFA limit in the UK.

^f Trans fats are prohibited in infant and children foods as well as settings in which children gather (e.g. schools, kindergartens, children's homes).

^g 2017: enactment of PHO ban; 2018: implementation of 2 per cent limit for oils/fats/margarines and 5 per cent limit for all other foods; 2022: all foods must be free of PHOs.

^h Saudi Arabia enacted a PHO ban in December 2018 which will take effect on 1 January 2020. It has already implemented a 2 per cent TFA limit for fats/oils and a 5 per cent TFA limit for all other foods.

Map of countries and territories that have enacted a TFA limit or PHO ban



Source: Global database on the Implementation of Nutrition Action (GINA). Available at <https://extranet.who.int/nutrition/gina/en>. Supplemented by additional research by author. Includes policies enacted as of March 2019.

Country-Specific Case Studies

Chile

KEY POINTS

Chile used a two-step policy approach, first enacting a TFA labelling regulation in 2006 followed by a TFA limit in 2009 of 2 per cent of total fat in all foods, a best practice policy.

Chile's enactment of a national TFA limit was supported by the concurrent passage of the regional Trans Fat Free Americas Declaration, which was signed by stakeholders across the Americas and established regional targets for TFA reduction.

Factors that influenced Chile's policy success include its engagement of key external stakeholders throughout the process, such as well-respected academic and industry leaders, multi-stakeholder coordination within government, situating the TFA policy within a larger healthy eating policy framework, and government capacity to implement the policy.



The Need for Policy

The Chilean government's policy efforts to reduce consumption of TFAs began in 2006, driven by new research linking TFA consumption with CVD and its rising prevalence in the country. A 2003 National Health Survey found that deaths from heart attacks had increased in the two decades prior and heart disease had become the leading cause of death in the country.⁴⁰ At that time, 41 per cent of the population had two or more major CVD risk factors and 55 per cent had a global CVD risk classified as "high" or "very high."⁴¹ The Ministry of Health determined that the primary reasons for Chile's CVD burden were unhealthy diets and lack of physical activity and decided to focus on improving the poor nutritional quality of the food.

Chile's TFA Labelling and TFA Limit Regulations

The Ministry of Health began to work closely with academia, including Prof. Ricardo Uauy of the University of Chile, consumer representatives, and the food industry to identify strategies to limit TFA

TFA products to use in their recipes. Once oils and margarines that met the new TFA limits were available, producers of other foods that used these products as ingredients had time to reformulate their recipes before the five-year deadline. Given the small number of oil and margarine producers in Chile, focusing on them was an effective way to improve the whole food supply. This approach was proposed by the Ministry of Health following consultation with expert academics and food manufacturers.

The Ministry of Health's regulatory activities on TFAs formed part of a larger framework called the Comprehensive Strategy Against Obesity (*Estrategia Global Contra la Obesidad or EGO Chile*)⁴³ as well as *Vida Chile*, a national health promotion programme including healthy eating, which provided the context for comprehensive food policy actions.

International Influence

Chile's TFA limit was informed by international efforts, both within the Americas and globally. Evaluations of local TFA policies in the USA and the national regulation in Denmark showed policy strategies to be effective, and their results were taken to mean that a TFA regulation in Chile would have similar impacts. TFA experts from the Chilean Ministry of Health also met with representatives from regulatory agencies in Canada and Argentina, who were also exploring strategies to reduce TFA consumption nationally.

In 2008, the Pan American Health Organization (PAHO) convened government and non-government experts within the Americas, including food and oil producers, to discuss the need for country-level actions to reduce TFAs in the food supply. The result of this meeting was the 2008 Trans Fat Free Americas Declaration,⁴⁴ which expressed that TFAs should be limited to no more than 2 per cent of total fats in oils and margarines and no more than 5 per cent of total fats in processed foods, and that unsaturated fats were the recommended replacement for TFAs. Dr. Tito Pizarro Quevedo, Head of the Food and Nutrition Department at the Chilean Ministry of Health at the time, who attended the meeting convened by PAHO on behalf

consumption. In 2006, the Chilean government enacted a TFA labelling regulation, which required that the amount of TFA be declared on the nutrition label. While this regulation had some loopholes (e.g., it did not require TFA labelling for foods with a total fat content below a particular threshold and allowed foods with small amounts of TFA to be labelled as having none),⁴² it was an important first step in a broader strategy to reduce TFAs in the food supply. According to Dr. Lorena Rodriguez, an advisor in the Food and Nutrition Department at the Ministry of Health at the time, the Chilean government already had an eye toward the future when enacting the TFA labelling requirement. As she explained, "if we identify TFA clearly on the label, it would be very easy to introduce a regulatory restriction or a limit."

Chile followed their TFA labelling regulation with a limit on TFAs of 2 per cent of total fat in 2009. The limit applied to all foods but used a two-phase approach to implementation: the TFA limit took effect two years after enactment for oils and margarines, and five years after enactment for all other foods. A shorter timeline was applied for fats and oils so that producers of other foods would have the lower

of the Chilean Government, noted “*this type of leadership from PAHO was very important to boost the work that Chile was doing.... That PAHO was working on TFA was, of course, an impetus and a support to continue developing [Chile’s] regulation.*”

Stakeholder Engagement and Policy Implementation

The Chilean Ministry of Health engaged multiple stakeholders in developing the regulation. Chile has a multi-stakeholder standing committee dealing with food issues, the Committee for the Modification of the Sanitary Regulation of Food (*Comisión Para la Modificación del Reglamento Sanitario de los Alimentos*). It is comprised of several ministries, including health, agriculture, and foreign relations; industry players; consumer organisations; and academia. However, as it deals with a large number of food-related issues, the Committee decided to form a parallel multi-stakeholder commission on TFAs to advance regulation more quickly.

The food industry pushed back initially, but finally came around when nutrition scientist Dr. Gastón Rosselot, who worked with the food industry, took leadership and explained in a commission meeting to industry and government that reducing TFAs in food was possible. As an industry representative and expert on fats and nutrition, Dr. Rosselot’s statement carried weight and paved the way for industry’s collaboration with the Ministry of Health.⁴⁵ The Ministry of Health did not know if the price for food products would increase as a result of a TFA limit, as feared by industry. Consequently, they did not refute nor discuss this argument, but focused on the health care costs resulting from TFA consumption.⁴⁶

Academia’s involvement in the commission was also essential. The Ministry of Health lacked the technical expertise in oil processing and could leverage the expertise of Prof. Uauy to demonstrate that replacement of TFAs with healthy oils was possible, refuting industry arguments claiming that TFAs could only be replaced with SFAs, also detrimental to health.⁴⁷

Following the deadline for full implementation of the TFA limit in 2014, compliance is assumed to be high, although resources for enforcement are limited. Dr. Rodriguez noted that small producers of pastry products had the greatest challenges with implementation. Inspections of production facilities are conducted periodically by the Health Authority.

A percentage of products are then tested in a laboratory by the Institute of Public Health of the Ministry of Health to ensure the labels are correct. While adherence to the TFA limit is strong, variability in food production and technology limitations have prevented 100 per cent compliance. Evaluation of the impact of the regulation on TFA consumption is also limited, as Chile only conducted one national consumption survey in 2010. However, Dr. Rodriguez believes that evaluation is important not only for the TFA regulation, but also for other food policies in Chile.

TFA Policy Best Practices

Dr. Pizarro Quevedo attributes the success of Chile’s policy to two factors: it was part of a larger framework, Chile’s Comprehensive Strategy Against Obesity, and a national, efficient health governance structure capable of implementing mandatory public policies. Dr. Rodriguez believes an additional factor is the multi-sectoral approach Chile uses in food regulation.

“**The participation of all [stakeholders] does not mean that they all have the same weight, because otherwise one would never advance – some would pull in one direction and the others in another direction. But it is very important to have everyone at the table.**”

Dr. Lorena Rodriguez, former Head and Advisor, Department of Nutrition and Food, Chilean Ministry of Health

Next Steps

Chilean Senator Dr. Guido Girardi, the leading champion of Chile’s recent, internationally-known food labelling and advertising law, is considering introducing legislation to take the country’s TFA limit one step further and completely ban the use of PHOs.⁴⁸ He expects pushback from the food industry, but that there will ultimately be compliance. He said, “*The industry can argue, but once [the law is] enacted, they have to comply.... Implementation works.*” Senator Girardi believes that the best strategy for holding companies accountable is using the media. The legislature successfully works with the regulatory agencies to bring visibility to compliance issues. He claimed, “*The biggest punishment for a company is making it public that they are damaging the health of the population illegally.*”

Saudi Arabia

KEY POINTS

Saudi Arabia enacted both a TFA labelling requirement and TFA limit of 2 per cent for fats and oils and 5 per cent for all other foods in 2015, the second country in the region to limit TFAs through regulation. A ban on PHOs was then enacted in December 2018 to align with international best practices.

The country’s TFA policies were enacted as part of a broader Healthy Food Strategy driven by the Minister of Health and other government leadership.

The Saudi government used a multi-sectoral approach to policy development and implementation, collaborating with the food and oil industries, CSOs, and academia. Small manufacturers that were more likely to experience challenges in complying with the regulations were given opportunities to learn from larger ones that already made the necessary changes.

WHO was another particularly important partner and provided resources and support, including tools, guidelines, and training, to the Saudi government to facilitate policy enactment and implementation.

Commitment to NCD Prevention

The government of Saudi Arabia has committed to addressing the country’s high prevalence of CVD and other NCDs. In 2016, approximately 37 per cent of deaths in Saudi Arabia were due to CVD.⁴⁹ In the past four decades, the dietary fat in the food supply has more than doubled from 33 grams per person per day in 1969-71 to 82 grams per person per day in 2014 (the most recent data available), falling from a peak of 96 grams per person per day in 2011.⁵⁰ The recent decline was hypothesized to be due to increased awareness about the importance of a healthy diet.⁵¹ Committed to addressing the country’s diet-related NCDs, the Saudi Food & Drug Authority (SFDA) developed its Healthy Food Strategy, which is part of the country’s broader Vision 2030. According to Meshal Almotairi, Standards Department Manager with SFDA, “*In 2015 our management asked us to have a healthy food strategy.... We want to take all the actions that are needed to reduce obesity and to reduce CVD.*” He noted that in response to this directive, SFDA has taken regulatory action on nutrition labelling, including TFA labelling, and limits on TFAs in the food supply.

Policy Development Process: TFA Labelling and Limit Regulations

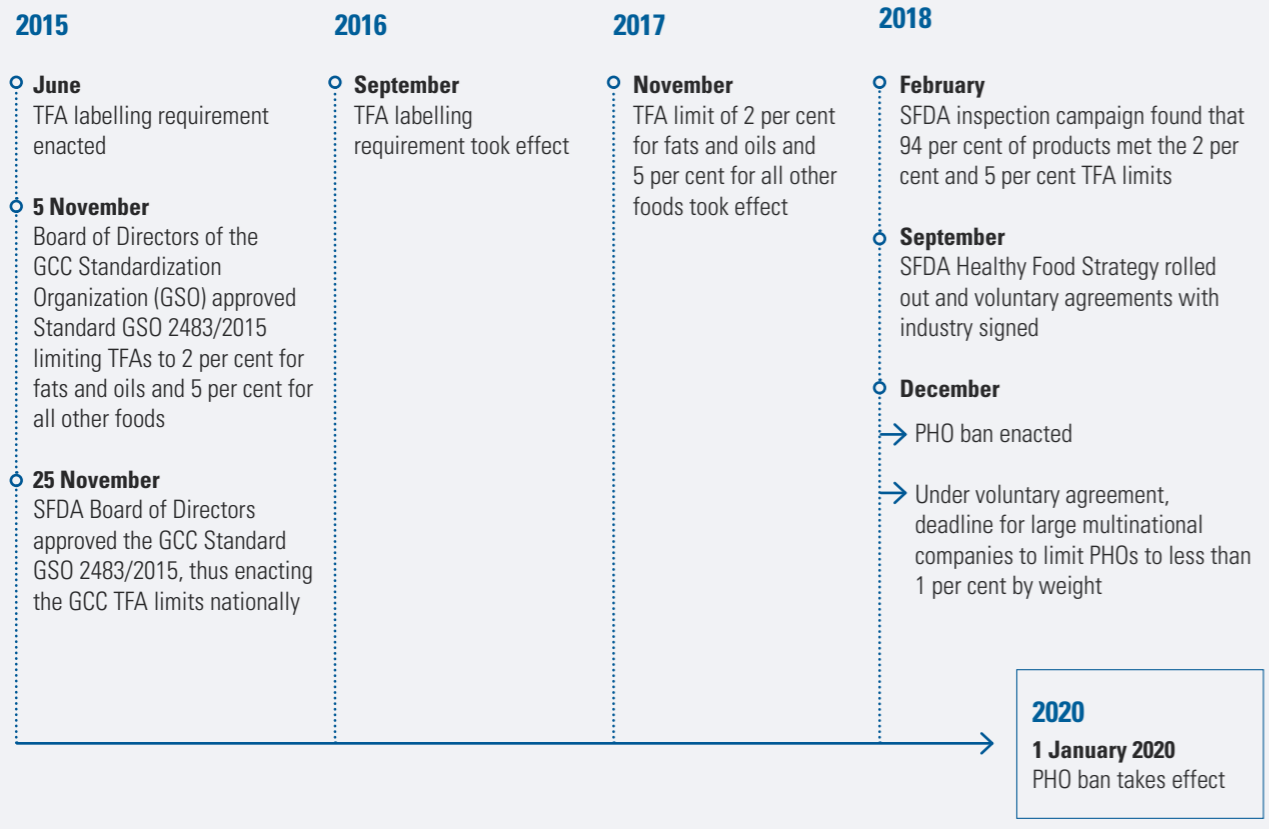
While Saudi Arabia has both a requirement for TFA labelling and a TFA limit, these policies were developed separately. In 2015, SFDA updated its food labelling regulations to require labelling of TFAs on food packages. This regulation took effect just over one year later.

Also in 2015, the SFDA Board of Directors approved a regional Gulf Cooperation Council (GCC) standard limiting TFAs to 2 per cent for fats and oils and 5 per cent for other foods,⁵² making Saudi Arabia the second country in the region to limit TFAs, after Iran. Prior to its adoption, the draft GCC standard was circulated to the World Trade Organization (WTO) and food manufacturers for comment. The standard was largely based on the experience in other countries, including prior voluntary TFA guidelines in Canada preceding its PHO ban,⁵³ and developed with input from WHO’s Eastern Mediterranean Regional Office (WHO EMRO). The TFA limit took effect in November 2017, two years after enactment, in order to give food manufacturers time to reformulate their products.

With the aim of strengthening its TFA regulations to align with international best practices, in December 2018 the SFDA updated its TFA limit to prohibit the use of PHOs by 1 January 2020.⁵⁴ This new PHO ban is unique to Saudi Arabia and not based on a regional GCC standard. However, the country was informed by the experience of recent PHO bans

in other countries including the USA and Canada. Mr. Almotairi noted that the major food companies had told SFDA that they would stop using PHOs when the TFA limits of 2 and 5 per cent for fats and oils and all other foods, respectively, took effect, so a national PHO ban was not expected to pose a significant additional burden.

Saudi Arabia's TFA Policy Timeline⁵⁵



Partnerships to Support Policy Implementation

According to Mr. Almotairi, initially the food industry was opposed to the TFA policies and asked for more time to comply. However, now they are on board. To strengthen its partnership with industry and support implementation of policies to improve nutrition, including removal of PHOs from the food supply, in September 2018 the President of SFDA signed a voluntary agreement with nine multinational food companies that are members of the International Food & Beverage Alliance to reduce TFAs, sugars,

and sodium and stop marketing unhealthy foods to children.⁵⁶ As part of that agreement, the companies agreed to limit PHOs to no more than 1 per cent of the product by weight by the end of 2018, one year before the PHO ban takes effect.⁵⁷ The pledge was announced in conjunction with the release of SFDA's Healthy Food Strategy. It was noted in the media that many of the companies that signed the pledges already had plans to reformulate and launch new products to meet their commitments.⁵⁸

SFDA is also working to support small and mid-size food manufacturers in implementing the TFA requirements by helping them learn from the experience of larger multinational companies. Mr. Almotairi noted that SFDA hosted a workshop for food manufacturers on TFA policy implementation that brought together companies of all sizes and allowed the small and mid-size manufacturers to benefit from the experience of the larger ones that had already reformulated to remove TFAs from their products in other countries. This strategy was successful in helping the small and mid-size manufacturers comply with the policy. SFDA also makes guidance available on its website on how to reduce TFAs in products and replace sources of TFAs with healthier fats.

CSOs, academia, and WHO are also important partners. Mr. Almotairi explained that representatives from CSOs and academia participated in a specialised committee that was involved in the development of the regulations. CSOs and academia also provide support through advocacy and communications, materials on healthy diets, including websites, tools, campaigns, and workshops, and conducting research and evaluation. Dr. Ayoub Al-Jawaldeh, Regional Advisor for Nutrition at WHO EMRO, confirmed that WHO has been a valuable partner in providing resources and technical support to the Saudi government. Dr. Al-Jawaldeh explained that WHO EMRO works with Saudi Arabia and other governments in the region to enhance the technical capacity at the regional and country levels and build capacity through networking and partnership to promote research and evidence generation. Dr. Al-Jawaldeh noted, "Saudi Arabia is an active member of the WHO region.... WHO has tools, guidelines, training, [etc.,....that] have helped Saudi Arabia and all countries in the region to expedite implementation" of evidence-based TFA and other policies.

Dr. Al-Jawaldeh stated that Saudi agencies across government, including the SFDA and the Ministers responsible for health, trade, education, and information, are committed to implementing the TFA policies. He also added, "Saudi Arabia is a good example where we can see harmony and proper coordination within government with different sectors and also with research institutions and with civil society."

Evaluation and Lessons Learned

An inspection campaign conducted in February 2018 by the SFDA found that 94 per cent of the more than 400 food products sampled complied with the current TFA limits.⁵⁹ The SFDA is planning another inspection campaign for early 2020 to monitor compliance with the PHO ban. Mr. Almotairi noted that their greatest challenge is likely to be monitoring compliance, given that a test for PHOs does not exist. SFDA will look to other countries such as the USA and Canada with similar policies for guidance on best practices.⁶⁰ While Saudi Arabia also intends to develop a plan for evaluating the health impact of the policy, Mr. Almotairi believes that the impact on CVD outcomes would be maximised if the TFA policy was combined with other measures for improving nutrition to reduce NCDs, which is why the country is enacting multiple policies as part of its Healthy Food Strategy. In addition to limiting TFAs, the Healthy Food Strategy includes reducing sugar, salt, and fat in food products, requiring calorie labelling in restaurants and cafes, and improving nutrition surveillance through both regulation and voluntary measures.⁶¹

Overall, Saudi Arabia's enablers to enacting and implementing TFA policies included political will, vision, targets, multi-sectoral coordination, and capacity building. As Dr. Al-Jawaldeh explained, "In Saudi Arabia, they have a strong FDA; they have Vision 2030; there is political will from the Minister of Health to implement [policies]. There is also proper coordination between all sectors,... participation from academia, [and a] good working relationship between WHO and the government in Saudi Arabia."

Saudi Arabia's case may serve as a model for other countries to follow in the EMRO region and elsewhere.

“
Saudi Arabia is doing a great job in terms of addressing obesity and NCDs. They are moving forward with many interventions... With this current momentum they are really helping other countries learn from their success story.”

Dr. Ayoub Al-Jawaldeh, Regional Advisor for Nutrition, WHO EMRO

Slovenia

KEY POINTS

Slovenia enacted a TFA limit of 2 grams per 100 grams fats and oils in 2018 to address the importation of TFA-laden products from other European countries without TFA policies, particularly Balkan countries, and to reduce TFAs in foods produced locally by small manufacturers, such as bakeries and pastry shops.

Researcher-advocates played a key role in making the case for policy by conducting and publicising research on the levels of TFAs in Slovenian products and their health harms.

The potential for regional EU policy delayed the Slovenian national policy initially, while they waited for the EU to act. While Slovenia moved forward with enacting and implementing its own national policy, the government still called for regional policy enactment and implementation.



The Need for Policy

Many of the first countries to enact TFA limits were in Europe, including Denmark, Austria, Hungary, Iceland, Norway and Switzerland, and they were seen as leaders on TFA policy from 2003 to 2014.⁶² While the level of TFAs in the food supply had declined during that time period in many European countries, research⁶³ – including a 2014 study led by Danish researcher Prof. Steen Stender⁶⁴ – showed that these declines were not being experienced in all European countries. While deaths from CVD as a share of total deaths was lower in Slovenia than the EU average in 2011,⁶⁵ this status was at risk without policy action. Prof. Stender’s pivotal study found that biscuits, cakes, and cookies purchased from several Western European countries contained no TFAs, but that was not the case for other Central, Eastern, and South-Eastern European countries, including Slovenia.⁶⁶ The researchers found that in these countries, TFA levels in pre-packaged biscuits, cakes, and wafers had not dropped meaningfully since the mid-2000s, in contrast to other, mostly Western European countries where TFA levels had dropped to nearly zero.⁶⁷ A number of products the researchers purchased in Slovenia contained TFAs, with concentrations of up to 9 per cent.⁶⁸ In fact, a follow-up study showed that levels of TFA as a per centage of total fat in biscuits, cakes, and wafers in Slovenia further increased between 2012 and 2014, up to 17.9 per cent.⁶⁹ The majority of the products in Slovenia with high levels of TFAs

were imported from Balkan countries without TFA policies, including Bosnia & Herzegovina, Croatia, Montenegro, North Macedonia, and Serbia.⁷⁰ In the absence of a TFA policy, products containing TFAs were being imported to and distributed in Slovenia, whereas those products by law could not be sold in other European countries with TFA policies in place. International researchers presented this information to the Slovenian government, which Mojca Triler, a senior advisor with the Slovenian Ministry of Health, said was “quite shocking”. In response, the Ministry of Health and Slovenian Research Agency funded a national research study to identify the main sources of TFAs in the food supply and levels of TFA intake in both the general population and key population groups in Slovenia.⁷¹

The Path to Policy

When data on the high levels of TFAs in some foods in Slovenia emerged in 2014, researchers and advocates sought to identify how to use the data to spur action. Slovenian researcher Prof. Igor Pravst with the Nutrition Institute explained that his organisation planned educational events, including a scientific conference and a press conference, to educate Slovenian policy-makers and other key stakeholders about the country’s TFA problem. International researchers, including Prof. Stender, presented their data, which generated substantial media attention.

“

A legal limit on TFAs in foods is the most effective way to protect the entire population, especially vulnerable groups such as children and pregnant women, ... and especially those population groups with the highest consumption of such foods. In addition, consumers who have not reached awareness of presence of TFAs would also be protected.”

Ms. Mojca Triler, Senior Advisor,
Ministry of Health, Slovenia

Researchers and advocates, including the Slovenian Consumers Association, developed educational campaigns about the harms of TFAs and collaborated on a television program “Tarca”,⁷² produced by Slovenia national television, to educate policy-makers and consumers about Slovenia’s exposure to imported foods high in TFAs. In early 2016, Prof. Pravst and colleagues received funding from the Slovenian government to carry out research on TFAs and presented preliminary findings at an October 2016 press conference. The research is ongoing, and further results have been presented to the government through publications and additional public forums. The research found that the proportion of products with PHOs in categories that previously had high levels of PHOs, including vegetable cream substitutes, soups, biscuits, crisps, and snacks, decreased considerably between 2015 and 2017. However, PHO content remained high in some foods, including cakes, muffins, pastries, and biscuits.⁷³ Additionally, packaged margarines in food stores were found to mostly contain minimal levels of TFAs, while a considerable proportion of food operators (primarily bakeries) still used PHOs.⁷⁴ About a quarter of sampled products that were used by food service providers contained more than 2 per cent TFAs, with some having TFA levels as high as 11 per cent of total fats.⁷⁵ The researchers concluded that previous food policy involving voluntary guidelines⁷⁶ and regular public communication of the risks related to the TFA consumption had a considerable effect on the food supply, but had not resulted in sufficient removal of PHOs.⁷⁷

Given that the majority of products high in TFAs were imports,⁷⁸ the Slovenian government realised that commitment from national industry was not

enough to solve Slovenia's TFA problem. They learned that producers in Balkan countries that were importing their products into Slovenia were unable or unwilling to make their products without TFAs because of lack of raw materials, technology, or pricing considerations. Ms. Triler explained the government's conclusion, "A legal limit on TFAs in foods is the most effective way to protect the entire population, especially vulnerable groups such as children and pregnant women,... and especially those population groups with the highest consumption of such foods. In addition, consumers who have not reached awareness of presence of TFAs would also be protected."

Once the Slovenian government decided to move forward with policy, engagement across sectors was needed for enactment. The Ministry of Health began by drafting a proposed decree, which went through the public consultation process with multiple stakeholders, including the Chambers of Commerce, Agriculture, and Food. The decree followed the Danish model of limiting TFAs to 2 grams per 100 grams total fat but was broader in applying the TFA limit to all foods, including foods used as ingredients that were not sold directly to consumers.

In October 2017, the European Commission was notified of the harmonised draft decree, as required by EU procedures for technical regulations. A temporary suspension period of three months was established to give the European Commission and other EU member states time to comment and propose amendments, as is required when national measures could have an impact on EU trade and free movement of goods. During that time, Slovenia received a request for supplementary information from the European Commission and comments from the Austrian government. After the comment period closed on 22 January 2018, national interministerial coordination took place, and the Ministry of Agriculture, Forestry, and Food, which has authority over food regulation, adopted the decree. The decree was officially published on 20 March 2018, and press conferences were held by the Ministry of Health and other supporters to announce the policy, which took effect 15 days later in April 2018. Food products on the market were required to be in compliance with the TFA limit by 7 April 2019.

Regional Policy Interplay

The Slovenian government almost did not move forward with the national TFA policy because they were informed that the European Commission was planning to develop an EU regional policy that would

create a harmonised approach to limiting TFAs. Slovenia delayed issuing its own decree for a year in anticipation of a European Commission report on TFAs in the EU, but the Commission delayed their project. Prof. Pravst believes that one reason the EU TFA policy wasn't a priority was because TFA exposure was no longer a problem in many Western European countries. However, the EU delay was putting Slovenian consumers at risk, so the national government ultimately decided to take action. The European Commission released a draft regulation to limit TFAs to 2 grams per 100 grams of fat in October 2018 and adopted the regulation on 24 April 2019.⁷⁹ The regulation is directly applicable in all EU Member States and has a compliance deadline of 1 April 2021.

Even though Slovenia has enacted its own policy, Ms. Triler believes that a regional EU policy would still be beneficial, given that the majority of products in Slovenia that are high in TFAs are imported from countries without TFA policies, both within and outside of the EU. An EU regulation would also likely have an additional benefit of incentivising food producers in the wider European region, including Russia and Turkey, for example, to reformulate their products to meet the EU regulation so they can export their products into the EU. Therefore, an EU regulation could be expected to reduce TFA content beyond EU borders.

Effective Messages and Tactics

Ms. Triler and Prof. Pravst agree that concerns about the health effects of TFAs and the high levels of TFAs in Slovenian products were the strongest arguments for the policy. Ms. Triler explained, "We had a strong argument that limiting TFAs was important to protect consumer health." The Slovenian government had been pressured to take action primarily as a result of the research, education, and media campaigns by researchers and advocates with CSOs including the Nutrition Institute, the National Institute for Public Health, and the Slovenian Consumers Association. She noted that the relevant national industries were on board because the majority of their products already complied with the decree; however, this was not the case for small food enterprises like pastry shops. Given this, Ms. Triler believes that the policy is important and should improve the situation. The Ministry of Agriculture, Forestry, and Food will be responsible for monitoring compliance, and the Ministry of Health plans to develop a plan for evaluating the impact of the policy on health outcomes over time.

South Africa

KEY POINTS

South Africa is the only country in Africa to enact a TFA limit. The country enacted a TFA limit of 2 grams per 100 grams fat or oil in 2011.

The Ministry of Health had previously issued draft regulation on TFA labelling, but informed by international experience and proposed national legislation, decided to enact a TFA limit instead of finalising the labelling regulation.

Even though South Africa's TFA limit was enacted more than eight years ago, implementation challenges may exist, and data on the impact of the regulation is not available.

South Africa's TFA Policy and TFA Food Sources

South Africa enacted a TFA limit of 2 grams per 100 grams of fat or oil in 2011.⁸⁰ The limit applies to manufactured, pre-packaged, restaurant, bakery, catering, and institutional foods sold in South Africa that contain PHOs as an ingredient, or where such oil is used for deep frying.

According to the South Africa Department of Health, the country decided to enact the regulation as part of a broader approach to address the burdens of NCDs and obesity.⁸¹ While CVD was not the leading cause of death, deaths from CVD were projected to increase among several age groups in the next few decades.⁸²

National level data on sources and levels of TFAs in the food supply was not available prior to the enactment of the regulation. However, it was the opinion of the Department of Health that many store-bought and restaurant foods – including baked goods, margarine, pre-mixed products, deep-fried and pre-fried foods, and snack foods – contained TFAs unless they were labelled as TFA-free or did not contain PHOs as an ingredient.⁸³ A 2011 study found that the oils in South Africa's fast food outlets contained up to 25 per cent industrially-produced TFAs.⁸⁴ However, a study conducted by the Cancer Association of South Africa (CANSA) analysed the TFA levels of 40 margarines in South Africa and found that all of the margarines contained less than 2 per cent industrially-produced TFAs.⁸⁵

Policy Development Process

In addition to local research, South Africa's policy development process was informed by the experiences of the country of Denmark and U.S. localities that were already implementing measures to reduce TFAs, WHO expert recommendations to limit TFA intake,^{86, 87} and a private member bill presented to the South African Parliament.

In July 2007, the Department of Health published proposed draft regulation to require TFA labelling. However, instead of finalising regulation requiring mandatory declaration of industrially-produced TFAs

i Private member bills are bills drawn up by individual members of parliament (at national level) or members of provincial legislature (at provincial level).

on food labels in 2010, the Department of Health decided to proceed with a TFA limit. This decision was made after the Directorate: Food Control was requested to provide an opinion on a private member bill to ban TFAs that was submitted to the South African Parliament in 2008. It was determined that the Minister of Health already had the authority to enact TFA regulations based on the Foodstuffs Act, and legislation, requiring a lengthier policy process, was not needed. The South Africa Department of Health noted that they supported moving forward with a TFA limit, rather than a labelling requirement, to accelerate and fast track the process of reducing this dietary risk factor associated with chronic diseases.

On 3 March 2009, then Minister of Health Barbara Hogan, MP, gave approval for the Department of Health to proceed with developing the draft regulation. The process to develop the policy included:⁸⁸

1. **Conducting** a literature review of TFA limits and bans in other countries and local jurisdictions around the world;
2. **Development** of a discussion document with background details and proposed regulation;
3. **Engaging** relevant stakeholders, including industry, academia, research institutions, and consumer organisations. The public was given an opportunity to submit comments on the draft regulation and representatives of the food industry, scientists, NCD organisations such as CANSA and the Heart and Stroke Foundation, and food science and dietetic organisations were invited to a consultative workshop;
4. **Releasing** a media statement on the intention of the Department of Health to regulate TFAs in prepared foods in South Africa;
5. **Developing** and finalising, after consultation with stakeholders, the draft regulation with a request for expediting its publication and with a request for comments in the *Government Gazette*;
6. **Requesting** the Minister's approval for the publication of the final regulation.

The final regulation was published in the *Government Gazette* on 17 February 2011 and allowed a six-month grace period for the industry to comply with the requirements.

The South Africa Department of Health noted that they supported moving forward with a TFA limit, rather than a labelling requirement, to accelerate and fast track the process of reducing this dietary risk factor associated with chronic diseases.

Policy Response and Implementation

According to the Department of Health, during consultations on the development of the policy, there was both support and opposition. One notable supporter was CANSA. The South African Association for Food Science and Technology (SAAFoST) opposed the policy, stating that the scientific evidence was not strong enough, but did not provide evidence of this until after the policy development process was completed.⁸⁹

As was the case in many countries, it was noted that foods produced by small manufacturers and imported products would be most likely to experience challenges in complying with the regulation, as many major food manufacturers had already reduced the TFA content of their foods, either prior to or following enactment of the regulation.⁹⁰ Some large manufacturers and retailers that claimed to have removed TFAs from their products or reduced them to meet the 2 per cent limit prior to the implementation deadline included Woolworths (private label), Pick n Pay (private label), Shoprite-Checkers, KFC South Africa, and McDonalds South Africa.⁹¹

It remains unclear the extent to which South Africa's TFA policy is being implemented and enforced, as recent studies are not available. Officials at the municipal level and at ports of entry are responsible for enforcement, and while the Department of Health notes that there are "no known challenges on record," they acknowledged that enforcement is focused on food safety, and that they largely rely on the industry to comply with and report violations on its own.⁹² Future research, including a national study to assess compliance with the regulation, could help to determine the extent to which South Africa's TFA policy has been implemented and is having its intended effects on the food supply and the health of South Africans.

Thailand

KEY POINTS

Thailand enacted a ban on PHOs in 2018 to stop the production and importation of Western-style foods high in PHOs due to the health harms of TFAs from PHOs.

Thailand used a supply chain approach to policy implementation, working with the small number of PHO producers in the country to change their manufacturing processes and ensure replacements for PHOs were available. Once oil producers were no longer making products with PHOs, the Thai government could be sure that foods made with these products as ingredients would also be free of PHOs.

Key factors important for policy enactment and implementation included accurate data collection on TFAs in the food supply, continuous and sincere communication among stakeholders – including the government, food and oil producers and importers, and academic researchers – and manufacturers' readiness for change.

TFA Policy as a Preventive Measure

Historically, TFA exposure has not been a significant public health problem in Thailand. Traditional Thai foods are made with tropical oils such as coconut oil and palm oil, which are high in SFAs, but not TFAs or PHOs. In addition, use of products containing naturally-occurring TFAs, such as animal milks and beef, is limited.⁹³ With the increase in consumption of Western-style foods, TFAs in Thailand's food supply have become a greater problem. Products determined to present health risks due to their presence of TFAs in Thailand include shortening, margarine, and deep-fried donuts containing PHOs.⁹⁴ Due to inaccurate analysis, it was originally thought that some local foods produced through repeated deep frying were also high in TFAs, but additional research showed this not to be the case.⁹⁵ However, Thai Food & Drug Administration (FDA) officials were alarmed to learn that multinational food companies who made TFA-free versions of their products for countries with TFA policies, such as the United States, Canada, and many European countries, were selling products that contained TFAs in Thailand.⁹⁶ While the Thai FDA was originally more concerned about consumption of SFAs as a public health issue, they felt compelled to issue regulation to prevent Thailand from becoming a place where Western foods containing TFAs, which were prohibited from many Western countries, were being sold.

A Supply Chain Approach

After deciding to address the issue of TFAs, Thai FDA officials met with researchers, food manufacturers, and importers to determine the best approach. Ms. Mayuree Ditmetharaj, Professional-level Food & Drug Technical Officer with the Thai FDA, said that oil manufacturers in Thailand told them that they could change their process from partial hydrogenation to another process that did not generate TFAs. This information and the fact that Thailand has only three hydrogenation plants led Thai officials to focus on PHOs as the target of their policy, rather than TFAs more broadly. Thai officials also determined that analysing TFA content of foods would be too difficult and costly. Ms. Ditmetharaj said, "We think that cutting off PHOs is more practical and economical than limiting the amount of TFAs in food products." By cutting off the supply chain of fats and oils containing PHOs, Thai officials knew that products made with these fats and oils would also be free of PHOs.

Policy Development Process

According to Dr. Visith Chavasit with the Institute of Nutrition at Mahidol University in Thailand, the policy development process involved four key steps: situation analysis, draft notification, public hearing, and notification.⁹⁷ During the situation analysis step, he and colleagues worked closely with the Thai FDA to understand the extent and sources of TFAs in local and imported foods in Thailand and facilitated communications and convened meetings with stakeholders.^{98, 99} Ms. Ditmetharaj explained that during this time the Thai FDA met with a range of stakeholders, including academics, manufacturers, importers, and food laboratories that would do assessments. They gathered input on policy options and worked with Mahidol University researchers to setup a proprietary database with information on TFA levels in products. After making tentative policy decisions and drafting a notification, which was sent for comments by member countries at the WTO, the Thai FDA held a public hearing. Ms. Ditmetharaj described the public hearing as the most important step for balancing the need for consumer protection with industry and trade considerations. She explained that all stakeholders, including consumers, food producers, importers, academia, and other government agencies, supported the Thai FDA's PHO policy because they knew that TFAs are not good for health and manufacturers have alternatives to using fats and oils with PHOs. She noted that importers would be the most impacted by the policy because they have to communicate the requirements to manufacturers in other countries and ensure that the regulation is followed.

On 13 July 2018, Thailand's Minister of Public Health issued the final notification prohibiting the production, import, or sale of PHOs and foods containing PHOs in Thailand.¹⁰⁰ The policy took effect 180 days following publication, in January 2019. While the Thai government decided to ban PHOs, they decided not to allow "trans fat free" claims due to concerns that a "trans fat free" claim could create a health halo for a product that is high in SFA, an even greater health concern in Thailand.¹⁰¹

Ms. Ditmetharaj noted that the policy is a good example of a successful partnership between government, public health professionals, and the private sector. She credits the availability of a database to collect information on the levels of TFAs in products, communication among stakeholders, and food companies' readiness for change as key factors in the policy's success.

Thailand's TFA policy is a good example of a successful partnership between government, public health professionals, and the private sector. Key factors for success were the availability of a database to collect information on the levels of TFAs in food products, communication among stakeholders, and food companies' readiness for change.

Enforcement and Monitoring

Following enactment of the PHO ban, the Thai FDA has been focused on monitoring and enforcement of the regulation. Thai officials provide guidance to manufacturers and importers and carefully monitor foods on the market. During the phase-in period between July 2018 and January 2019, the Thai FDA worked to educate consumers, manufacturers, and importers that ruminant TFAs from animal products are not banned, just PHOs, and ensure that manufacturers and importers know how to comply with the regulation. According to Ms. Ditmetharaj, the Thai FDA will enforce the regulation by testing products to ensure total TFAs (from PHOs and natural sources) do not exceed 0.5 grams per serving. Given budget constraints, the Thai FDA is also collaborating with civil society on monitoring and enforcement. CSOs are helping by identifying products that are not in compliance and educating stakeholders about the regulation. The Thai FDA partnered with Mahidol University to assess the amount of TFAs in foods before and after implementation of the regulation and found that TFA levels have declined significantly. In the long term, the Thai FDA also plans to collaborate with the Department of Disease Control to monitor the impact of the policy on CVD prevalence.

The ultimate impact of the policy may depend, at least in part, on what is used to replace PHOs. According to Ms. Ditmetharaj, "We are confident that PHOs in Thailand have all been replaced by blended oils, which are produced by mixing the oils of different degrees of saturation." Given that SFA consumption is a much greater public health concern than TFA consumption in Thailand, Ms. Ditmetharaj notes that CVD risk will be most improved if people reduce their SFA consumption as well.

United States of America

KEY POINTS

The USA was the first country to restrict TFAs by effectively prohibiting the use of PHOs in foods in 2015. The government did so by removing PHOs from the list of items "Generally Recognized As Safe" (GRAS) for use in foods.

This determination was preceded by a federal TFA labelling requirement nearly a decade earlier and state and local TFA policies, which served as proof of concept and provided evidence of the cardiovascular health benefits of policies to eliminate TFAs from the food supply.

While the food and beverage industry pushed back on some aspects of the PHO determination and petitioned for continued use of PHOs in certain limited situations, there was consensus within the scientific community regarding the health risks associated with TFAs from PHOs. Furthermore, researchers and advocates were successful in sounding the alarm about PHOs and making the case for their complete removal from the food supply. The U.S. FDA extended certain compliance deadlines but the majority of foods on the U.S. market will no longer contain PHOs by 2020.

PHO's GRAS Status

The USA was one of the first countries to prohibit the use of PHOs in foods as a means to reduce consumption of TFAs. Prior to recent U.S. Food and Drug Administration (U.S. FDA) action, PHOs were considered "Generally Recognized as Safe" (GRAS) for use in foods. According to U.S. federal law, a substance intentionally added to food is a food additive and subject to premarket review and approval by U.S. FDA, unless the substance is generally recognised, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use.¹⁰² As the evidence about the health harms of TFAs grew, public health researchers and advocates urged the U.S. FDA to revoke PHO's GRAS status. Dr. Margo Wootan, Vice President for Nutrition at the Center for Science in the Public Interest (CSPI), a leading nutrition advocacy organisation, explained, "to be considered GRAS, there must be reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. The science shows TFA is not safe. The best approach that was open to us was to petition FDA to revoke the GRAS status of PHOs."

In November 2013, the U.S. FDA issued a preliminary determination, and in June 2015, a final determination that PHOs are no longer GRAS for use in the food supply. The final determination provided for a three-year compliance period to allow industry time to reformulate or to submit a food additive petition to the U.S. FDA to permit specific uses of PHOs. The U.S. FDA noted that its determination was based on extensive research into the health effects of TFAs from PHOs, as well as input from stakeholders received during the public comment period.¹⁰³

TFA Labelling Regulation

The U.S. FDA's determination that PHOs are no longer safe for use in the food supply was preceded by other TFA policies at the federal, state, and local levels. In 1994, CSPI petitioned the U.S. FDA to update the Nutrition Facts label on food packages to require the inclusion of TFAs. Nine years later, the U.S. FDA adopted such regulation, which took effect on 1 January 2006. In response, food manufacturers reformulated their products to reduce or remove TFAs, and TFA intake among the U.S. population declined.¹⁰⁴ Comprehensive exposure assessments by the U.S. FDA showed that many food products



were reformulated to eliminate or substantially reduce the use of PHOs.¹⁰⁵ An independent study of 360 brand name products in U.S. supermarkets that contained TFAs in 2007 also found that approximately two thirds of the products still on the market in 2011 had reduced their TFA content.¹⁰⁶

State and Local TFA Policies

Following the publication of the U.S. FDA's TFA labelling regulation, but prior to its PHO GRAS determination, several U.S. localities and one state enacted their own TFA restrictions. In 2006, under the leadership of Mayor Michael Bloomberg, New York City amended its Health Code to limit the amount of TFAs allowed in food served by licensed food service establishments and mobile food vendors.¹⁰⁷ Nearly 20 other cities and towns, primarily in the Northeast, and the state of California followed suit in the following months and years, prohibiting the use of TFAs in food service facilities.¹⁰⁸ California and other jurisdictions also limited the use of TFAs in schools and other venues under their authority.¹⁰⁹ By 2010, 20 per cent of the U.S. population lived in a jurisdiction that prohibited the use of TFAs or PHOs in food service establishments.¹¹⁰ For advocates at the national level, state and local policies served to both protect people living in these jurisdictions and to build momentum for TFA policies nationally. Dr. Wootan explained CSPI's goals, "We were looking for ways to build momentum and protect people before the FDA took action. Our goal was for a national policy, and we petitioned the FDA for that federal policy, and then worked on state and local policy to protect people... until the FDA acted." Dr. Wootan also noted that state and local policies were helpful in overcoming industry opposition. She explained, "state and local policies were proof of

concept... in part it showed that companies could reformulate their products and still make good-tasting products that people would buy, show them that the sky wasn't going to fall down."

State and local policies also showed that TFA policies were effective in reducing TFA consumption and associated health effects. Evaluations of New York City's policy found that TFA content in restaurant purchases declined in the years after the policy took effect.¹¹¹ A study of nearly 7,000 fast food purchases from 168 New York City restaurants of 11 chains found that between 2007 and 2009, the years just after New York City's TFA regulation took effect, the amount of TFA per purchase decreased by 2.4 grams. In addition, the per centage of purchases without any TFAs increased from 32 per cent to 59 per cent over that same two-year period.¹¹² TFA serum concentration among New York City residents also declined more than 50 per cent over the 10-year period between 2004 and 2014, from before to after the TFA policy was in place.¹¹³ The greatest declines were experienced by people who ate four or more restaurant meals per week,¹¹⁴ attributing them, likely at least in part, to the city's policy.

Further research has found that the declines in TFA consumption resulting from the policies were associated with declines in hospital admissions and CVD deaths. One study found that there was an additional 6.2 per cent decline in hospital admissions for heart disease and stroke in New York state counties that had TFA bans, compared with ones that did not.¹¹⁵ Another study concluded that TFA bans in New York City and other counties in the state resulted in a 4.5 per cent reduction in CVD deaths, resulting in total cost savings of almost US \$4 million per 100,000 people per year.¹¹⁶

Advocacy Strategies and Industry Response

Public health advocates used several strategies to effectively push for a national policy to remove TFAs from the food supply. One such strategy was the filing of citizen petitions by CSPI and by lipid researcher Dr. Fred Kummerow years before the U.S. FDA's PHO GRAS determination. Researchers studying the health effects of TFAs had been key advocates for TFA policies in the years prior to FDA action. Dr. Kummerow, in particular, played a significant role in urging the U.S. FDA to take action in eliminating PHOs from the American diet. In issuing its final determination that PHOs are not GRAS, FDA formally acknowledged and responded to these petitions.¹¹⁷

Advocates also effectively used the media in advocating for U.S. FDA action. Dr. Wootan noted that CSPI and other advocates held press conferences, did exposés, and used traditional and social media. She explained, "We used the policy campaign as an education campaign for the public and really were able to take TFAs from something that almost no consumers had heard of to something consumers were trying to avoid." The media coverage helped to create public demand for a TFA policy.

Civil society advocates also used the media to encourage companies to voluntarily reduce the amount of TFAs in their products, pointing out packaged foods or restaurant foods that were particularly high in TFAs and writing to companies asking them to reformulate. Advocates and researchers also communicated directly with the U.S. FDA, ensuring they were aware of the latest research on TFA consumption and its health effects.

According to the U.S. FDA, some notable supporters of their preliminary determination were public health and consumer advocates such as the American Heart Association, American Medical Association, the National Consumers League, and many individual consumers.¹¹⁸ Some of the parties expressing opposition included the National Restaurant Association, the Grocery Manufacturers Association (GMA), and the Snack Food Association.¹¹⁹ The U.S. FDA noted that they specifically asked for input on the time it would take producers to reformulate PHO-containing food products, suggestions for an adequate time period for compliance, and special considerations for small businesses. They also met in-person at the request of several industry trade associations and food companies in response to the preliminary GRAS determination.¹²⁰ Following the U.S. FDA's final determination that use of PHOs in food is no longer GRAS, GMA, the leading trade association for food, beverage and consumer product companies in the

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USA, filed a petition asking the U.S. FDA to continue to allow specific uses of PHOs.¹²¹ The U.S. FDA denied GMA's petition, but extended the compliance date for foods with specific petitioned uses of TFAs, such as those with small amounts of PHOs used for colour and flavour additives, pan release agents for baked goods, and processing aids.¹²² While some compliance deadlines have been extended, the large majority of products may no longer be manufactured with PHOs as of June 2018, and all products on the U.S. market will be required to be free of PHOs by 1 January 2021.¹²³

The U.S. FDA is enforcing its regulations for both domestic and imported products, monitoring compliance through facility inspections, label reviews, and sample analysis.¹²⁴ Food manufacturing facilities are inspected periodically, and any facility found with unauthorised uses of PHOs may be subject to FDA enforcement and/or regulatory follow-up. Imported food products that declare PHOs may be subject to field and/or label exams, prohibited from entering, or placed on an Import Alert.¹²⁵ While no formal evaluations have yet been conducted on the impact of the U.S. FDA's removal of PHOs from the GRAS list, the consensus is that compliance is high. GMA noted in a May 2018 press release that food and beverage companies have already reduced PHO-related TFAs by more than 98 per cent.¹²⁶ While mean TFA consumption among the U.S. population had already declined by more than 70 per cent to 1.3 grams per person per day in 2003-2006¹²⁷ with enactment of the TFA labelling regulation, additional research showed that TFA plasma levels declined through 2010, due, at least in part, to the TFA labelling regulation, state and local TFA laws, and product reformulation that occurred as a result.¹²⁸ Declines in cardiovascular risk indicators causally linked to TFA consumption also declined between 1999-2000 and 2009-2010.¹²⁹ The federal GRAS policy decision will likely reduce TFA consumption and improve the population's cardiovascular health even further.

Key Conclusions

While each country's TFA policy and path to enactment and implementation is different, there are many common barriers, enablers, and lessons learned. Below are key conclusions and recommendations from the six featured countries' TFA policy success stories.

Feasibility

- Reducing or eliminating TFAs from the food supply is both politically and technically feasible. Mandatory TFA policies have now been enacted by 56 countries and territories in all WHO regions, 32 of which have entered into force while the others will be implemented in the coming years.
- In some countries, such as Slovenia and Thailand, it may be feasible to enact a single policy to limit TFAs or ban PHOs. In other countries, such as Chile and Saudi Arabia, a phase-in approach involving multiple consecutive policies or policies at multiple levels of government may be needed, particularly if the level of TFAs in the food supply is high, major reformulation is needed, or if there is political pushback.

Stakeholder Engagement and Advocacy

- Collaborating across departments within government – including health, agriculture and commerce – and engaging stakeholders – including CSOs, academia, and industry – throughout the policy process may help to support successful enactment and implementation. In several case study countries, collaboration within government was required when the responsibilities for TFA policy development, enactment, and implementation were divided among different ministries or agencies.
- Public hearings, written comment opportunities, and stakeholder meetings are all strategies that were successfully used by governments to gather stakeholder input and support in the case study countries. Clear communication about the goals and requirements of the policy are also key.
- CSOs – including disease-specific organisations, medical associations, public health advocacy groups and consumer organisations – can play an important role in mobilising awareness and support for policy enactment, implementation, and enforcement. CSOs can represent the views of consumers and health/nutrition experts to governments and spur grassroots action at key points in the policy process. They can also develop educational materials for policy-makers and the public, hold workshops to convene stakeholders, and host press conferences to bring attention to an issue. CSOs can also play an important role in bringing public attention to both positive and harmful government and industry actions.
- CSOs and academia can also support enforcement by monitoring industry compliance with a policy and bringing public as well as government attention to violators. Some CSOs and foundations may also conduct or fund research to assess the need for policy or its impact and effective policy design. For example, in Slovenia, a CSO conducted research to identify the main sources of TFAs in the food supply and levels of TFA intake to establish the need for regulation.
- Academia can also play an important role in conducting and publicising research, serving as an expert resource for government, convening stakeholders, and supporting policy evaluation. For example, in Slovenia, researchers served as advocates in raising both public and government awareness about their policy. In Thailand, researchers helped to convene stakeholders to facilitate policy development and are working with government to assess the impact of the policy.
- The media can be an effective tool to use in educating the public and mobilising public support for TFA policies as well as holding companies accountable for reducing TFAs in their products. For example, advocates in both the USA and Slovenia used the media to bring public attention to the health harms of TFAs and the need for policy. Advocates in the USA also used the media to encourage companies with products high in TFAs to reformulate. A legislator in Chile uses the threat of media shaming as a tool to encourage compliance.
- In several case study countries, food companies were supportive of TFA or PHO policy enactment and implementation. Large, multinational food companies have already reformulated their products to comply with TFA policies in countries with existing policies. They often possess the technology to be able to do so in additional countries. In some situations, food companies voluntarily made changes to reduce TFAs in their products without being compelled by policy or prior to the policy implementation deadline. However, in most situations, mandatory policy is necessary to ensure reformulation by all food companies to eliminate TFAs.
- Given the increasing body of evidence from 32 countries and territories that have implemented TFA policies, including those studied in-depth here, it is important to consider further learning opportunities from international experience and potentially valuable inputs that may be gathered from international experts and stakeholders.

Policy Development

- Research on the extent of the problem and major sources of TFAs in the food supply is important for making the case for the policy and identifying policy targets. In some cases, such as the USA, it was important to collect national data. In others, such as South Africa and Chile, international data was sufficient. Lack of local data should not be used as a reason not to consider policy action.
- While reducing or eliminating TFAs from the food supply is important for public health, the impact on NCDs will be greatest when the policy is part of a larger, long-term strategy to improve diet and nutrition and reduce NCDs. Interviewees in nearly all of the case study countries explained that their TFA policy was part of a broader nutrition, CVD, or NCD prevention strategy.
- TFA policies in a growing number of countries are reducing the number of places where products containing large amounts of TFAs/PHOs can be legally sold. As a result, countries that have not historically had a TFA problem may find increasing levels of TFAs in their food supply, as they are “dumped” on unregulated markets. This may create the need for TFA policies in these countries as a preventative measure and to control the importation of products high in TFAs. For example, Slovenia enacted a TFA policy after learning that TFA levels in the country’s food supply had increased following enactment of TFA policies by other European countries. Similarly, Thailand enacted a TFA policy when products containing TFAs were being sold in Thailand when there were TFA-free versions of the same product in other countries.
- WHO can be a useful resource for national governments considering enacting and implementing TFA policies. WHO can provide resources and technical assistance on policy design, implementation, and analysis.

Policy Implementation

- Following enactment of the policy, guidance and technical assistance for manufacturers and importers can help to support successful implementation. Companies may be able to learn from each other. In some countries, bringing companies together to share experiences with reformulation was useful in increasing successful policy implementation.
- Small- and mid-size manufacturers may be more challenged with implementation than larger manufacturers and may need more targeted technical assistance. Larger, multinational companies may already have processes for manufacturing TFA-free products in place in other countries with TFA policies that they could deploy in additional countries.
- Identifying the main sources of TFAs can be helpful in determining strategies for implementation and technical assistance. For example, in some countries, most foods with TFAs were imported, while in others, they were produced locally. Some countries also had a small number of hydrogenation plants that allowed policy-makers to easily reach out to the fat and oil producers directly.
- In several case study countries, it was not known which substances are being used to replace TFAs. Providing guidance on and monitoring TFA replacements may help to ensure that TFA policies are not inadvertently increasing SFA consumption, blunting their health benefits.

Evaluation and Monitoring

- Some countries did not collect baseline data on TFA availability or consumption prior to policy implementation and do not have plans for a robust evaluation. There may be a role for international researchers in conducting TFA policy evaluations to increase the knowledge base about the impacts of these policies.
- More research is needed within countries and internationally to determine the effects of TFA policies on the levels of various fats in the food supply, their consumption, overall dietary impact, and effects on CVD outcomes in the short and long-term.

In alignment with WHO, the NCD Alliance calls on CSOs to advocate for – and governments to enact – mandatory TFA limits or PHO bans, as the best way to protect the population from the health harms of TFAs.



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About the NCD Alliance

The mission of NCD Alliance is to unite and strengthen civil society to stimulate collaborative advocacy, action and accountability. NCD Alliance unites civil society organisations dedicated to improving NCD prevention and control worldwide. NCD Alliance's network includes NCDA members, national and regional NCD alliances, over 1,000 member associations of its founding federations, scientific and professional associations, and academic and research institutions in more than 170 countries.



For more information, visit www.ncdalliance.org

About the Resolve to Save Lives

Resolve to Save Lives is a US \$225 million, five-year initiative funded by Bloomberg Philanthropies, the Bill & Melinda Gates Foundation, and Gates Philanthropy Partners (which is funded with support from the Chan Zuckerberg Foundation). The initiative's goals are to save 100 million lives from cardiovascular disease and to prevent epidemics. Resolve is an initiative by Vital Strategies, a global public health organisation which works in 60 countries to address the world's most challenging health issues.



For more information, visit www.resolve Tosavelives.org

¹ For more information about WHO's REPLACE package, visit <https://www.who.int/nutrition/topics/replace-transfat/>

Additional Information

Additional information and resources on policies to eliminate TFAs are available at the following sites:

WHO REPLACE Package and modules

www.who.int/nutrition/topics/replace-transfat/

Resolve to Save Lives

www.resolvetosavelives.org/

Recap of January 2019 Roundtable hosted by the NCD Alliance and Resolve to Save Lives on elimination of TFAs from the food supply

ncdalliance.org/news-events/news/what-works-to-eliminate-trans-fats-from-the-food-supply

Recording and slides of a March 2019 webinar of the NCD Alliance on global and local advocacy for TFA elimination, hosted on LINKS, an online community for cardiovascular health

ncdalliance.org/news-events/news/trans-fat-elimination-linking-global-advocacy-to-local-action

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Industrially-produced trans fatty acids (TFAs), common in baked goods, pre-packaged foods and some cooking oils, are a major contributor to cardiovascular diseases (CVD) and noncommunicable diseases (NCDs) worldwide, estimated to contribute to more than half a million deaths each year. TFAs have no known health benefits and can be replaced in foods without impacting their consistency or taste.

This report presents case studies of six countries in different regions of the world that have enacted policies to eliminate TFAs from their food supply, as recommended by WHO. The purpose of this report is to provide civil society organisations (CSOs), including national and regional NCD alliances, and policy-makers around the world with examples of successful strategies for enacting and implementing TFA policies, as well as an analysis of barriers, enablers and lessons learned based on the experience of policy-makers, advocates, and researchers involved in such efforts.

