REGIONAL WORKSHOP

Regulatory mechanisms to eliminate industrially-produced trans-fatty acids from the food supply in the Region of the Americas

Mexico City, July 17-18, 2019

PAHO Pan American Health Organization

World Health Organization Americas

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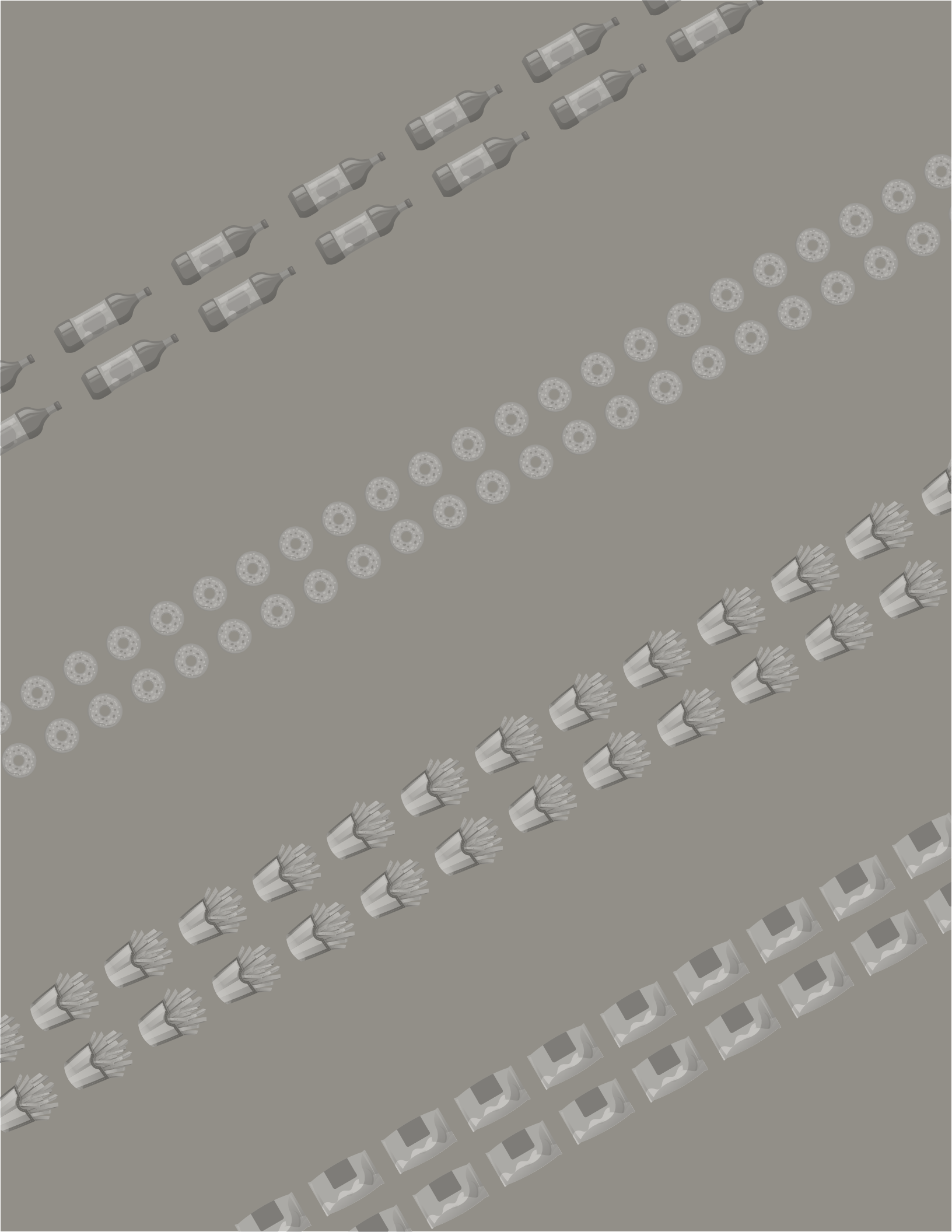
Contents



Summary

The Pan American Health Organization (PAHO) organized and implemented a two-day Regional workshop on regulatory mechanisms to eliminate industrially produced trans-fatty acids from the food supply in the Region of the Americas to help countries identify key elements to include in policies to eliminate industrially produced trans-fatty acids (IP-TFA). The specific objectives of the workshop were to present a range of existing regulatory pathways to eliminate IP-TFAs and discuss their effectiveness, consider policy options for their elimination, and draft roadmaps to guide policy development. Government officials from Bolivia, Colombia, Costa Rica, Guyana, Jamaica, Mexico, Paraguay, and Peru participated in the meeting. Other participants included representatives of the Brazilian Association of Nutrition (ASBRAN), CARICOM's Regional Organization for Standards and Quality (CROSQ), the Institute of Nutrition of Central America and Panama (INCAP), Global Health Advocacy Incubator (GHAI), NCD Alliance, PAHO's sub-regional offices, Resolve to Save Lives (RTSL, an initiative of Vital Strategies), and Salud Justa-Mexico, as well as the author of Peru's Law 30021 on the elimination of IP-TFA in the country.

The first day of the workshop provided the necessary technical information to design an IP-TFA elimination policy, while the second day focused on key elements of policy implementation, monitoring, and enforcement. Both days included technical presentations, discussions using the fishbowl conversation dynamic, participant presentations, plenary sessions, and development of roadmaps by government officials. Materials prepared for the workshop included: a pre-workshop assignment for government officials, discussion questions for the fishbowl exercise, and questions to guide roadmap exercises, related to policy design, implementation, monitoring, and enforcement.

The elimination policy recommended by PAHO/WHO is to limit IP-TFA content to no more than 2% of total fats in all foods and/or ban the use or production of partially hydrogenated oils (PHOs) as an ingredient in all foods. These recommendations were presented by RTSL in the context of possible in-country legal frameworks, political support, financial resource availability, and technical capacity for monitoring policy compliance. In addition, RTSL discussed implementation, monitoring, and enforcement components that countries should include in their policy. Key recommended elements for the design, implementation, monitoring, and enforcement of an elimination policy include collecting and analyzing information on consumption by the population, food sources, complementary regulatory measures (e.g., nutrition- and health-related regulatory measures for products containing IP-TFAs) and other food-related policy. Other measures include the identification of

governmental authorities responsible for the development, implementation, and monitoring of the policy; outline of operational procedures (e.g., consultation with stakeholders); assessment of resource availability; development of an implementation plan that includes clear timelines for adoption, implementation, and enforcement periods; and clear, concise sanctions for non-compliance. Countries were encouraged to use existing mechanisms to adopt, implement, monitor, and enforce IP-TFA elimination policies.

GHAI gave a presentation on international trade considerations and World Trade Organization (WTO) principles associated with policy design, and concluded that resistance to an IP-TFA elimination policy is not very likely because the substance can be readily removed from the food supply and because major users such as the U.S. and Canada have already adopted policies to do so. It was explained that the Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) agreements could be utilized by opposing actors in an attempt to preclude or delay policy adoption. However, it is clear that these agreements may not supersede the right of a country to restrict trade in order to protect the safety and or health of its population.

Specific policies on IP-TFAs in participating countries included a reduction in products containing the substance (Bolivia); limiting IP-TFA content to no more than 2% or 5% of total fats in foods (Colombia); and limiting the content of the substance to no more than 2% of total fats in all foods, accompanied by a ban on PHOs (Peru). As for complementary measures, three countries (Colombia, Peru, and Paraguay) mandate the inclusion of IP-TFAs in the nutrition label, four countries (Bolivia, Colombia, Costa Rica, and Paraguay) have regulatory measures relating to IP-TFA nutrition/health claims, and three countries (Bolivia, Paraguay, and Peru) have guidelines pertaining to including the substance in the product ingredients list. It is important to note that two countries (Bolivia and Peru) have adopted a front-of-package warning label (FOPL) in foods that contain IP-TFAs and that one country (Mexico) requires that IP-TFAs be listed only when citing a product's nutrition/health claims.

Discussions of possible regulatory pathways to eliminate IP-TFAs in pre-packaged foods, oil- producing factories, and fast-food restaurants included enforcement of existing policy, amendments to current national policies that limit IP-TFA content, development of a national policy or a sanitary/phytosanitary measure, amendment of a sub-regional regulation, and drafting a sub-regional standard. The decision on which regulatory pathway is best to follow depends on current political support, technical and monitoring capacity, financial resources, and existing administrative and operational processes.

Government officials indicated that the Ministry of Health (MOH) and/or the food regulatory agency should lead the drafting of an elimination policy. Furthermore, intersectoral work between the lead agency and different governmental bodies such as ministries of Economy and Finance, Justice, Agriculture, among others, was encouraged to ensure the best possible outcome. The process for adopting a national elimination policy was found to be different between countries and it may be impacted by the regulatory pathway that is chosen. A basic description of the process included: creation of a technical working group that includes government officials in charge of nutrition and/or noncommunicable disease policies, legal counsel, laboratory technicians, program management experts, academia, civil society, and international technical experts; preparation of a regulatory analysis of potential impact; drafting of the selected policy; internal review of the policy; consultation (national or international); additional review by other ministries (e.g., economy, commerce, justice etc.) or other government agencies; amendment of existing food policy that may be affected by the elimination policy; final approval and official publication. The adoption of a proposed policy may take approximately three years, depending on the local context.

Government officials stated that it was important for the policy to explicitly identify the agencies in charge of implementation, monitoring, and enforcement. The MOH and/or food regulatory agency were cited as the governmental bodies in charge of leading implementation-related activities, ideally within the existing monitoring and enforcement mechanisms. The importance of integrating IP-TFA monitoring into the regulatory agencies' working plans was mentioned as a key element that may help reduce the cost of implementation and ensure coordination between governmental bodies, regardless of whether policy compliance is determined by inspection of manufacturing facilities, or by laboratory or nutrition label analysis. Inspection, sampling, and analysis may take place at the federal, state, and/or local level, at points of sale, and/or oil factories, depending on available financial and operational resources. This could also be done in conjunction with other governmental agencies. Countries mentioned the need to review and update penalties for non-compliance; some of the proposed sanctions included cancellation or temporary suspension of food registry, fines, and closure of the establishment, among others.

Lastly, educational campaigns to raise awareness of the proposed elimination policy among the public and small businesses were mentioned as a possible complementary component of implementation activities. More specifically, countries mentioned the need to educate the public and businesses, respectively, on the use of healthier fats for everyday consumption and food reformulation processes.

Enablers associated with the adoption of an IP-TFA elimination policy were mentioned during the workshop. These included the existence of a specific IP-TFA policy

and complementary measures; support from non-governmental organizations and United Nations agencies; access to food registry databases; and ongoing work on the technical capacity to test for IP-TFA content in foods.

Barriers associated with the adoption of an elimination policy include limited data on the population intake of IP-TFAs and on food sources, lengthy administrative processes, scrutiny of the possible economic impact of the proposed policy, and limited financial and human resources for monitoring-related activities including inspection, sample collection, and assessment.

CROSQ and INCAP discussed supporting the development of sub-regional or national IP-TFA standards and technical regulations, respectively. CROSQ's process to adopt a sub-regional standard is a lengthy process that requires an initial proposal from a country, revision by CARICOM countries, drafting of the standard by an expert technical team, consultations, and final approval. CROSQ underscored the importance of each country establishing a national committee to actively take part in the drafting of the proposed standard. INCAP can help countries in the region to develop a sub-regional or national policy through a strategy that includes gathering key evidence on IP-TFAs, intersectoral work, review of current food policy, utilization of existing monitoring and enforcement mechanisms, and research on possible financial sources.

Government officials used the information presented throughout the workshop to identify key elements needed to adopt an IP-TFA elimination policy (reduction in IP-TFA-containing foods, 2% limit, PHO ban, or a combination of both) and discuss regulatory pathways that may be suitable to remove this harmful substance from the food supply.

Introduction

Industrially produced trans-fatty acids (IP-TFAs) are commonly used by food manufactures to improve the texture, shelf life, and flavor stability of foods. However, they are also considered an important preventable risk factor contributing to the development of cardiovascular disease (CVD). An extensive body of evidence has demonstrated the negative effects of trans-fatty acids (TFA) intake, as well as the association between total TFA intake and coronary heart disease (CHD). High TFA intake significantly increases the risk of death from any cause by 34%, the risk of CHD death by 28%, and the risk of CHD occurrence by 21%. In addition, the physiological effects on the human body include an increase in low-density lipoproteins and a decrease in high-density lipoproteins.

The best available estimate using a comprehensive analytic approach suggests that in 2010, 537,000 deaths from CHD were attributable to TFA intake around the world; of these deaths, 160,000 were in the Region of the Americas, and 45% of them were premature. These represented 17.9% of all deaths from CHD in Canada and United States and 10.7% in Latin America and the Caribbean. Because these estimates do not include non-fatal CHD events or deaths from other conditions that may be associated with TFA intake, such as stroke, they are conservative estimates of the negative health impact. TFA consumption in the Region was among the highest in the world in 2010, representing 2.9% of energy intake in Canada and the United States and 1.9% in Latin America and the Caribbean, up from 1.7% in 1990.

In 2017, CHD was the leading cause of death in the Americas; more specifically, it was responsible for an estimated 14% of all mortality in Latin America and the Caribbean and 18.5% in Canada and the United States.

Understanding the detrimental effects of IP-TFAs on health, the Pan American Health Organization (PAHO) convened a Trans-Fat-Free Americas Task Force in 2007 to make recommendations about trans-fat use and regulation. The work of the task force resulted in the 2008 Declaration of Rio. This collaborative pledge between the public sector and industry aimed to eliminate the substance from the food supply by limiting its content in foods, mandating its inclusion on nutrition labels of processed foods, and establishing tax incentives to promote its substitution, among other actions. The document also recommended that IP-TFA content should not be greater than 2% of total fat in oils and margarines and not greater than 5% of total fat in processed foods.

Eleven years after the Declaration of Rio, several countries have adopted specific mandatory policies to regulate IP-TFA: Argentina (2010), Canada (2017), Chile (2009),

Colombia (2012), Ecuador (2013), Peru (2016), the United States (2015), and Uruguay (2017). These policies include restricting IP-TFA content in foods and/or banning the production and use of partially hydrogenated oils (PHOs), one of the main sources of IP-TFAs. However, some of these policies do not comply with the elimination policy recommended by the World Health Organization (WHO), which limits IP-TFAs to no more than 2% of total fats in all foods and/or bans the use and production of PHOs. For instance, Argentina and Colombia allow foods other than vegetable oils, fats, and margarines sold for direct consumption to contain IP-TFAs up to a maximum of 5% of total fats. Other countries face challenges pertaining to the monitoring and enforcement components of their IP-TFA policies. Finally, 27 countries in the Americas still have not adopted a policy to eliminate IP-TFAs from the food supply.

PAHO continues to make the elimination of IP-TFAs a priority, most recently with its Plan of Action for the Elimination of Industrially Produced Trans-Fatty Acids 2020-2025, which will track elimination-related policies in the Region of the Americas. Moreover, WHO's 2019-2023 General Programme of Work has set as one of its targets the elimination of IP-TFAs and their replacement with healthier fats and oils. To help countries eliminate IP-TFAs from the food supply, WHO and Resolve to Save Lives (RTSLV) have developed the REPLACE action package, which describes essential steps for adopting and implementing IP-TFA elimination policies.

Recognizing that countries in the Americas continue to need technical support to develop, implement, monitor, and enforce IP-TFA elimination policies, PAHO organized a two-day regional workshop on regulatory mechanisms to eliminate industrially produced trans-fatty acids from the food supply in the Region of the Americas, aiming to: present the range of existing regulatory mechanisms in the Region that aim to eliminate IP-TFAs from the food supply; discuss the most effective regulatory channels and policy options; and discuss a roadmap to establish regulatory mechanisms for the elimination of IP-TFAs in the countries.

Workshop participants included Mexican government officials and international government officials from Bolivia, Colombia, Costa Rica, Guyana, Jamaica, Mexico, Paraguay, and Peru responsible for food regulation and for establishing nutrition parameters for consumption. Other participants included staff from the Brazilian Association of Nutrition (ASBRAN), CARICOM's Regional Organization for Standards and Quality (CROSQ), the Institute of Nutrition of Central America and Panama (INCAP), Global Health Advocacy Incubator (GHAI), NCD Alliance, PAHO's sub-regional offices, Resolve to Save Lives (RTSL, an initiative of Vital Strategies), and Salud Justa-Mexico, as well as the author of Peru's Law 30021 for the elimination of IP-TFA in the country.

In this document, elimination policy refers to mandatory regulatory measures that aim to restrict IP-TFAs, following WHO's recommendations.

Methods

During the morning of the first day of the workshop, staff from RTSL gave a presentation on the legislation module of the REPLACE technical package and on the available policy options to eliminate IP-TFAs from the food supply. In addition, staff from GHAI presented on international trade considerations and World Trade Organization principles associated with policy design. Later in the morning, PAHO staff asked government officials from Colombia and Peru (with input from Jaime Delgado, author of Peru's recently enacted law on the subject) about the IP-TFA elimination policy using the fishbowl discussion method. During this exercise, workshop participants had the opportunity to ask both countries further questions. In the afternoon, government officials used pre-prepared guiding questions to develop an IP-TFA elimination policy roadmap to design a new policy or update an existing one. In the afternoon, country government officials presented their roadmaps and answered questions from the audience.

During the morning of the second day of the workshop, RTSL gave a presentation on the implementation, monitoring, and enforcement components of IP-TFA elimination policies. In addition, PAHO staff asked government officials from Colombia and Peru (with input from Jaime Delgado) about their current implementation process, including policy compliance monitoring and enforcement-related activities. In the afternoon, government officials drafted a roadmap to implement an IP-TFA elimination policy using pre-prepared guiding questions. After that, government officials presented their roadmaps and answered questions from the audience.

PAHO sub-regional offices and CROSQ designed and presented a roadmap to support the development and/or implementation of sub-regional standards and regulations.

During both days, PAHO, GHAI, and RTSLV staff provided technical support to participating countries.

Technical presentations

REPLACE Action Package: Policy options for eliminating trans fats:

In 2018, WHO and RTSL launched the REPLACE action package, outlining six lines of action to make the world trans-fat free by 2023 (figure 1.) Note that the lines of actions cited below, from left to right, do not indicate a specific order to be followed.

Figure 1. REPLACE package lines of action

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	and monitor trans fat content in the food supply and changes in trans fat consumption in the population	compliance with policies and regulations

The package is a product of collaboration between WHO and RTSL and is based on the latest scientific evidence, discussions with WHO regional advisors and experts, and updated WHO guidelines on the intake of saturated fats and trans-fatty acids.

The first module of the package focuses on scope-related activities that include identifying dietary sources and population intake of trans fats; describing current regulatory measures related to nutrition and trans fats; collecting information on supply and the cost of replacement with healthier fats; forming an intersectoral working group with key stakeholders; and establishing a specific policy goal, among other

activities. The second module focuses on determining the best replacement oils and interventions to promote their use. This includes profiles of oils and fatty acids, and healthier alternatives, considering their specific uses in foods. The third module focuses on regulatory measures to eliminate IP-TFAs. More specifically, it provides guidance on policy design, describes policy options, outlines key considerations for selecting an IP-TFA policy, and discusses case studies. The fourth module describes surveillance methods to study the substance in humans and in food samples. The fifth module discusses how to create an IP-TFA awareness campaign with advocacy and communication strategies that include information sheets and a customizable video for public service announcements. The sixth module describes policy enforcement mechanisms, penalties, funding, timelines, and additional case studies.

The two best elimination policies described in REPLACE include a mandatory limit on IP-TFAs to less than 2% of total fat in all foods and/or a ban on the production of PHOs as an ingredient in all foods. A combination of both policies should be adopted by countries where there are high levels of IP-TFAs in refined oils, monitoring of a PHO ban is feasible, existing trans-fat limits are not being effectively implemented, and neighboring countries are following the same proposed policy.

REPLACE states that the following elements are key to effectively restricting IP-TFAs: mandatory labelling requirement and ingredient list; definition of the restricted substance and applicable food categories; specific threshold limits for fats and oils, and a well-defined specific objective for the policy to be adopted.

The legal and political in-country context should be considered when deciding which policy option may be adopted. The country's current legal/regulatory framework may allow for the adoption of one policy option, or both. For instance, a 2% IP-TFA limit should be considered if the legal framework allows for it; a PHO ban should be considered if the existing legal framework covers harmful compounds in foods and there is an updated list of prohibited substances. Complementary measures (e.g. labeling requirements, mandatory inclusion of trans fat on ingredient's list, etc.) are important aspects to be included in an elimination policy, as they may facilitate implementation and monitoring. For instance, a 2% IP-TFA limit should be considered if a mandatory nutrition label regulatory measure is in place and currently being monitored; a PHO ban should be considered if existing regulations require that the substance be included in the country's ingredients list. Although trade agreements are not expected to deter the adoption of an IP-TFA elimination policy, countries should consider mirroring neighboring countries' elimination policies since this may facilitate monitoring-related activities within a specific region. Lastly, the country should assess which option has the most political support in order to determine the feasibility of adopting it. Figure 2 summarizes some of the pros and cons of adopting policies for trans fats limits or for a PHO ban.

Figure 2 Pros and cons of IP-TFA elimination policy.

	TFA limit	PHO ban
PROS	• TFA can be tested in lab • Addresses TFA from oil refinement (depending on how TFA is defined) • Some countries already have TFA limits for other policies (e.g. labeling)	• Targets top of food supply chain • Simple regulatory process in some countries • Enforcement can rely on ingredients lists (if reliable)
CONS	• Need capacity to test TFA, or reliable and mandatory labeling • Likely regulates further down the food supply chain • Can leave populations that consume higher levels of TFA vulnerable	• Cannot test for PHO in lab • Many PHO producers, informal markets, or imported packaged goods pose challenges • Difficult to control partial hydrogenation processing done outside of the country

Note: This figure was adapted from a slide originally presented by GHAI during a LINKS webinar in June 2019.

It is not uncommon for policy proposals to undergo a consultation process that provides an opportunity for the public and industry to provide feedback. During this process, the country should provide all stakeholders with information about healthier options for replacing IP-TFAs, as well as legal requirements and health evidence related to the harm of IP-TFA intake. Nevertheless, it is important that companies do not actively participate in drafting or amending the policy. Rather, they should be given a space to provide feedback throughout the consultation process.

REPLACE action package: Policy implementation, monitoring, and enforcement:

REPLACE highlights the importance of developing an enforcement strategy by identifying the existing food-regulatory authorities responsible for enforcing elimination (authorities may be cited in other food-regulatory policies), considering existing or possible financial and/or human resources as well as current laboratory and non-laboratory capacity for food-related inspection, sampling, and assessment activities.

The regulatory agency responsible for monitoring policy compliance should be empowered to inspect food products and facilities in order to assess IP-TFA content, determine whether the regulatory measure is achieving its objective, and report on any new evidence that may require policy adjustment. The inspectors in charge of monitoring should be able to request shipping records, supply contracts, bills of landing, and other relevant documents from companies to characterize the entire food supply chain, especially where there is a reasonable suspicion that a violation of law has occurred. In addition, this agency should be able to penalize offenders with appropriate sanctions described in the proposed policy or in other governmental food-regulatory regulations.

Countries may consider the following actions to ensure that appropriate resources are available for enforcement-related activities: discussing allocation of financial resources for implementation and enforcement activities with relevant authorities, incorporating IP-TFA enforcement into existing systems, charging business for permits, redirecting financial sanctions to fund enforcement, and using revenue from health-related taxes, among other actions.

Label or lab analysis can be used to determine policy compliance. Label analysis consists of determining whether IP-TFAs must be included in the nutrition label, front-of package warning label, or ingredient list. Label analysis can be especially helpful in monitoring IP-TFA limits or a PHO ban/policy if a mandatory monitoring mechanism for nutrition labeling is already in place. Nevertheless, there are drawbacks to label analysis: challenges include not being 100% certain that the label reflects the actual IP-TFA content in foods, and inspectors need to be aware of common terms industry used to name PHOs (e.g., 'partially-hydrogenated vegetable oil', 'shortening', and 'margarine'). Laboratory analysis with established testing protocols can accurately determine the amount of TFA in foods; however, it can be costly and cannot be used to reliably identify PHOs.

Food inspection could take place at points of sale or in facilities, as frequently as the country deems it appropriate. Inspectors can investigate whether factories, process-

ing plants, and other fat and oil refineries are producing products containing PHOs. Inspectors can also randomly test products at supermarkets or factories to ensure maximum policy compliance. If resources are scarce, inspection-related activities could be shared with other agencies, focusing on companies suspected of policy violation. In addition, it is paramount to have an "offense log" that tracks details related to the offense, including but not limited to inspection date, name of company, and type of sanction. If an offense is discovered, penalties should focus on deterring possible repeat offences, while remaining proportionate to the violation. Penalties may include warnings, additional testing requirements, recall of products, economic fines, and food registration suspension or revocation.

After an IP-TFA elimination policy has been adopted, countries should have a clear timeline for implementation, and a fixed date by which the policy will come into force. Key implementation-related activities include informing stakeholders about legal requirements and ensuring the availability of financial and human resources. It is recommended that policies take effect within between 6 and 18 months. Countries should allow food companies sufficient time for product reformulation, disposal of current supplies, and design of new labels. It is important that monitoring mechanisms already be in place by the date on which companies are required to comply with the policy. The country may have a transition period during which the maximum limit for IP-TFAs decreases over time (for example, an initial 2% IP-TFA limit in fats and oils for the first six months, then expanding the limit to all other food categories after 12 months).

To maximize compliance, it is important to inform stakeholders about the legal requirements by: providing opportunities to review and comment on draft laws and/or regulations prior to enactment of the policy; publishing and distributing the final legal requirements widely; suggesting techniques to help buyers conduct due diligence of suppliers; and providing advance notice about enforcement as the deadline for compliance approaches, among other actions. Prior to enforcement, education and outreach to companies and the public may also help ensure successful implementation of the policy.

International trade law: impact on food policy

International trade law is sometimes used to threaten the adoption of public health-related laws/regulations, in order to preclude or delay policy adoption. At this time, no challenges pertaining to IP-TFA regulatory measures have been presented to World Trade Organization (WTO) committees; therefore, elimination policies may be relatively feasible to adopt.

International trade laws take shape through WTO agreements and bilateral and regional free trade agreements. In general, these trade agreements aim to harmonize regulatory measures and reduce barriers to trade, and arise from disputes between countries. WTO agreements aim to establish a balance between a nation's right to regulate (including regulation of public health-related matters) and facilitation of trade. The right to regulate must be accompanied with certain obligations to facilitate trade, including not engaging in discriminatory practices (i.e. discriminating against certain countries and favoring domestic products over international goods) and not having regulatory measures that are more trade restrictive than necessary to protect human health.

Technical barriers to trade (TBTs) and sanitary and phytosanitary (SPS) measures are WTO trade agreements relevant to the adoption of IP-TFA elimination policy. TBT agreements relate to regulation of front-of-package labelling and nutrition/health-related claims, while SPS agreements are related to food safety and animal/plant health regulation. Countries can dispute both types of agreements if their policy aims to protect the health of the population and does not necessarily restrict trade. However, the application of standards varies form case to case. TBT agreements encourage the use of international standards but allow countries to depart from them if they conclude that a standard is ineffective (e.g. fails to protect population health). SPS agreements require countries to follow international standards (e.g. guidelines, recommendations, etc.); however, countries may not follow a requirement if an international standard related to a policy does not exist or does not fulfill the desired objective (e.g. protect population health). In other words, countries need to provide scientific evidence in order not to follow an international SPS agreement.

The Codex Alimentarius is the main source of standards that countries consider on an ongoing basis when discussing current and potential food-regulatory measures. The Codex aims to protect public health and facilitate trade. However, neither the Codex nor any TBT or other international standard currently regulates IP-TFAs. Therefore, development of an IP-TFA Codex standard could help countries adopt an elimination policy. More specifically, a new standard would be an important precedent for adopting IP-TFA elimination policies that are considered non-restrictive; countries may use this argument to help pass an elimination policy.

Five key components that should be included when drafting an IP-TFA elimination policy include a well-defined policy objective, use of evidence to justify the need for the policy, assessment of less trade-restrictive alternatives, avoidance of discriminatory practices, and compliance of due process and notification requirements. Including these elements not only increases the likelihood of policy adoption but also reduces the likelihood of facing hurdles related to international trade law.

Country information

Bolivia

Policy landscape:

Law No. 775 on Promotion of Healthy Eating, passed by the 2016 administration, provides for the creation of a regulatory framework to implement the provisions of the Law.

The second transitional provision of the Law mandates a gradual process of reducing the TFA content of foods, and article 16, paragraph four, indicates that processed foods and non-alcoholic beverages containing "trans fats" must bear the following wording: Contiene Grasas Trans ("Contains Trans Fats"), in legible capital letters, in contrasting colors against the background, and in a clearly visible place.

The Bolivian Standard for Prepackaged Food Labeling 314001 (2009) and Supreme Decree 26510 (2002), which define the guidelines for nutritional labeling, do not require that TFAs be mentioned in the nutrition facts panel. However, Standard 314001 states that refined oils other than olive oil may bear the term "Oil" in the list of ingredients, alongside the descriptor "vegetable" or "animal" and the qualifier "hydrogenated" or "partially hydrogenated", as appropriate. Refined fats may be termed "Fats" in the list of ingredients, with the added descriptor "vegetable" or "animal", as appropriate.

The 2017 Regulation on Labeling of Foods for Human Consumption stipulates that any nutritional and/or health claims must follow the rules of the USFDA and Health Canada.

Current evidence and TFA source:

Although information on TFAs in the country is limited, it can be affirmed that the leading sources of TFAs are baked goods, fast-food products, and oils.

Possible regulatory pathway:

The Ministry of Health, specifically the food and nutrition unit, could develop a proposal for technical regulation pursuant to the provisions of Law No. 775. This proposal for technical regulation could apply to processed foods and non-alcoholic beverages.

Government agencies and international organizations could provide technical assistance for its development. Once the proposal is prepared, the Ministry of Health and its team of technical experts would carry out a thorough review. If the proposal is approved by the Ministry, it would be shared with other ministries, government agencies/committees, and the food industry for comment, in an attempt to seek consensus for policy-building. In due time, the proposal would also be shared with the World Trade Organization for possible comments.

Implementation, monitoring, and enforcement:

Implementation, monitoring and enforcement of the proposed policy could be the responsibility of the National Service of Agricultural Health and Food Safety (Servicio Nacional de Sanidad Agropecuaria y Seguridad Alimentaria, SENASAG), in close coordination with the Ministry of Health. This agency could develop an implementation plan to systematically collect, analyze, and disseminate information on compliance with the policy and TFA intake. Responses to violation of the technical regulation would include economic sanctions, withdrawal of marketing authorization, closure of establishments, and revocation of import permits, among others.

As part of the plan, a campaign to raise awareness of the harmful health effects associated with TFA intake could be developed jointly with the Ministry of Communications. The implementation plan could include a technical and operational guideline to help small and mid-sized businesses comply with the policy.

Product inspection and analysis to ensure compliance with the policy could be carried out once a year. The results of these analyses would be presented in an annual report, which would be made available to the general public.

Enablers and barriers:

The regulatory measures set forth in Law No. 775 would facilitate adoption of a policy to reduce TFA exposure. The involved ministries could provide technical support for the development, implementation, and monitoring of the policy proposal.

The main challenges in adopting a policy proposal include the large number of government agencies that would review the policy proposal and the limited national evidence on TFA intake. Finally, the lack of economic resources to enforce the policy through monitoring activities is a particular challenge that could delay the process of proposal adoption.

Colombia

Policy Landscape:

Law No. 1355 (2009) defines obesity and the chronic noncommunicable diseases associated with it as a public health priority and establishes measures for their control, care, and prevention. Article 7 of this law defines the need to regulate and control the TFA content of foods and the requirements for these products. This provision led to Ministerial Resolution 2508 (2012), which established a technical regulation stating the nutritional requirements for TFAs and foods containing saturated fats. The technical regulation was drafted jointly by the Ministry of Health and the National Institute for Food and Drug Surveillance (INVIMA), considering the evidence available at that time and the recommendations of the Declaration of Rio (2009).

The technical regulation stipulated that the TFA content of fats, vegetable oils, and spreadable margarines sold directly to consumers cannot exceed 2 g TFA per 100 g fat. Furthermore, the regulation dictates that the TFA content of fats and vegetable oils used as raw materials in the food industry, bakeries, restaurants, or catering services can contain up to 5 g TFA per 100 g fat. The regulation applies to both imported and domestic products, and excludes meat and milk, as well as any products of ruminant origin.

It bears stressing that the current regulation was classified as a technical barrier to trade at the time of its creation; therefore, the approval process was lengthy and included several consultations (national and international) and reviews by government agencies. However, although the regulation took three years to adopt, it included a 6-month nationwide grace period before compliance was enforced.

The island of San Andres is not subject to the 2012 technical regulations.

INVIMA is the agency in charge of inspection, surveillance, and enforcement of these regulations. Broadly, all foods that are monitored by the agency must be included in its annual sampling plan, which determines the frequency of monitoring based on the potential hazard posed by each food to the population. Analyses and inspections are done through laboratory tests (gas chromatography) and/or assessment of nutritional labeling. INVIMA is in charge of monitoring at the national level, while MoH offices do so at the local level.

In 2016, one-time laboratory tests were carried out on 90 products to assess compliance with the technical regulation. The results showed that all products complied with the established TFA limits. Subsequently, 5,800 and 4,800 products were inspected in 2017 and 2018 respectively, to measure the TFA and saturated fat content for inclusion in nutrition facts labeling. The results showed that less than 1% did not comply with the regulation which mandates that TFAs be declared on the nutrition label.

Although there are sanctions for noncompliance with the regulation, these are somewhat unclear and rarely enforced.

The regulatory measures applicable to TFAs, statements on the nutrition labeling, and nutrition and/or health claims can be found in Resolution No. 333 (Requirements for nutritional labeling of packaged foods for human consumption, 2011). This resolution stipulates that TFA content must be declared in grams per serving, according to the following requirements:

"The amount of trans fat should be expressed in grams per serving, rounded to the nearest unit if the content exceeds 5 g and to the nearest 0.5 g if the content is less than 5 g. If the total trans-fat content per serving of food is less than 0.5 g, it is to be expressed as zero (0)". The inclusion of trans fats in labeling is not mandatory for foods that contain less than 0.5 g of total fat per serving, except when any nutrition claim is made regarding total fat, fatty acids, or cholesterol content; in this case, the trans-fat content will be stated as zero (0). If the TFA content is not stated, the wording "Not a significant source of trans fat" (No es una fuente significativa de grasa trans) should appear at the end of the nutrition facts table.

Additionally, Resolution No. 333 stipulates that the term "fat-free" can be used for skim milk as long as it meets certain requirements, such as containing less than 0.5 g of TFA, among others.

Other policies that could help the adoption of a new policy to eliminate TFAs are Law 9 (health measures) (1979), Resolution 2154 (technical regulations on the sanitary requirements for oils and fats of vegetable or animal origin that are processed, packaged, stored, transported, exported, imported, and/or marketed in the country for human consumption) (2012), and Resolution 719 (establishing a classification of foods for human consumption according to their public health risk) (2015), among others.

Current evidence and TFA source:

The country has not quantified what proportion of TFAs comes from natural versus industrial sources. Additionally, specific information on TFA intake is limited. However, according to the data on intake frequency of some food groups, such as packaged foods and fried goods, the leading sources of TFAs in the Colombian diet include snack foods, sausages, creme-filled cookies, and baked goods, considering that partially hydrogenated oils are still used as an ingredient.

Data on intake frequency from the 2010 National Nutritional Status Survey (ENSIN) show that 95.2% of Colombians consume fried foods; 32% consume them daily, 58.8% weekly, and 3.8% monthly. Cured meat products (e.g., sausages, ham, mortadella), are consumed on a weekly basis by 73.6% of the population between the ages of 5 and 64. Children and adolescents aged 9 to 18 reported even higher intake of these products on a daily and weekly basis; consumption is greater in urban areas.

Packaged foods are also an integral part of the Colombian diet; 69.6% of respondents consume them; 15.2% consume them daily and 45.5% weekly. These foods are particularly preferred by children and adolescents. In addition, fast foods were also identified as part of the Colombian diet, consumed by at least 25% of the population at least once weekly. Higher socioeconomic level is associated with increased intake of fast foods in Colombia.

Possible regulatory pathway

The MOH could amend the current technical regulation to limit TFA content to no more than 2% of total fats in all foods (excluding products of ruminant origin) through a technical review process and a corresponding regulatory impact analysis.

The evidence to substantiate this amendment would come from the latest ENSIN (data on TFA intake) and from the national food registry database. Likewise, the following factors should be considered when drafting an amendment to the current regulations: the existing nutrition labeling policy, political will, disease burden and costs related TFA intake, and the existing national plan of action to eliminate TFAs and restrict saturated fats.

Once the draft amendment is ready, it will be subject to several national and international consultations, as well as reviews by various government agencies, including the Ministry of Commerce, which must approve the proposal.

Another regulatory path to the elimination of TFAs would be the development of a sanitary or phytosanitary measure banning partially hydrogenated oils from all

foods. This regulatory path could prove shorter; however, other sources of TFAs would remain unregulated.

INVIMA, academia, international organizations such as the Pan American Health Organization/World Health Organization (PAHO/WHO), and civil society are expected to support the development of a policy to eliminate TFAs.

Finally, the process of adopting an elimination policy would take approximately 2-3 years.

Implementation, monitoring, and enforcement

MOH and INVIMA are the agencies that could supervise the implementation, monitoring, and enforcement of the policy at the local and national levels, respectively. ENSIN could provide monitoring data on TFA intake, which could be useful for post-implementation policy evaluations. Additionally, educational materials to raise public awareness of the health hazards associated with TFA intake and appropriate methods for the disposal of TFA-containing oils, among other aspects, could be included in a policy implementation plan. The current technical capacity of INVIMA allows laboratory tests every 2-3 years and annual monitoring of compliance with the nutritional labeling policy. The results of this monitoring would be published in an annual agency report, which would be available to the general public.

Implementation of the proposed policy could take approximately 6-12 months.

Enablers and Barriers

Law No. 1355 and Resolution 2508 establish an important legal precedent that allows amendment of the current regulation or development of a new TFA elimination policy. In addition, the technical capacity, facilities, and experience of INVIMA regarding inspection, surveillance, and enforcement should ensure good implementation of the policy proposal.

Barriers to adopting and implementing the policy proposal include the numerous government commissions that would have to review the document, which might delay policy adoption.

In addition, although there is nutritional information for approximately 3,000 products in a national database, it is not organized in a way that allows search and extraction of necessary data.

Costa Rica

Policy Landscape

In Costa Rica, only voluntary measures have been implemented to reduce the TFA content of packaged foods and oils. Other subregional guidelines are found in Central American Technical Regulation RTCA 67.01.60:10, on the nutritional labeling of prepackaged food products for human consumption intended for the population aged 3 years and older (2010). The regulation provides guidelines for declarations of nutritional properties in foods containing TFAs; however, the regulation does not mention any obligation to include TFAs in the nutrition facts panels of all foods, except for those who wish to declare it.

Other, existing policies that could help adopt a policy to eliminate TFAs are General Health Law No. 5395 (1973) and the Protocol to the General Treaty of Central American Economic Integration, Law No. 7629 (1996), among others.

Current evidence and TFA source

The study Progressing towards the elimination of trans-fatty acids in foods commonly consumed in four Latin American cities (2017) found that, in San José, creme-filled or chocolate-covered cookies contained the greatest amount of trans fat.

Possible regulatory pathway

One possible regulatory path to the elimination of TFAs would be an amendment to the Central American Technical Regulation on the nutritional labeling of prepackaged food products for human consumption intended for the population aged 3 years and older. This amendment would make compliance with the technical regulation mandatory and would mandate the inclusion of TFAs in the nutrition facts panels of all foods containing them.

This regulatory path would require a consensus decision on the part of the countries of the region about the parameters of TFA elimination, and it would be led by the Ministries of the Economy and Foreign Trade.

Yet another regulatory path could be the adoption of a national technical regulation to limit TFA content to no more than 2% of total fats in all foods. This policy option could be led by a working group that includes technical experts from the MOH, dietitians, academics, and the Costa Rican Institute for Research, Education, and Health (INCIENSA), among others. The working group would develop a regulation proposal based on a regulatory impact analysis. This regulatory path would require review of the proposal by several departments within the MOH, national and international public consultations, and approval by the Regulatory Improvement Department of the Ministry of the Economy before it can be officially adopted.

The estimated time for adoption of a nationwide technical regulation would be approximately 2-3 years.

Implementation, monitoring, and enforcement

Implementation of the policy proposal could be led by the MOH with the support of INCIENSA and other local agencies, through the development of an annual operational plan that specifies a food evaluation schedule and other activities related to policy implementation, which INCIENSA would define a priori. The MOH would supervise monitoring and compliance at the national level, while its non-centralized offices would do the same at the regional and/or local level.

The penalties for noncompliance with the adopted policy would be based on the provisions of General Health Law No. 5395 (1973). Some of the penalties mentioned in the law include economic sanctions, product withdrawal from the market, and seizure, among others.

Finally, the National Learning Institute could support implementation of the policy by developing educational materials or courses to disseminate information about the relationship between TFA intake and harmful effects on health, or about the maximum threshold limit for TFAs in food products.

Enablers and Barriers

One of the factors that could facilitate adoption of a policy to eliminate TFAs is the availability of a well-equipped laboratory, staffed by technicians with the capacity to conduct evaluations. In addition, Costa Rica has at its disposal an extensive database

of packaged food products and their nutrient content, which could help monitor policy compliance.

Barriers to the adoption and implementation of the elimination policy proposal include limited financial resources, the slow review process by different government entities, failure to mandate inclusion of TFA content in the nutrition facts panel on packaged foods, and limited national evidence of TFA intake.

Guyana

Policy Landscape:

Currently, the country has no regulatory measure to eliminate TFAs. In addition, no other complementary regulatory measures such as mandatory inclusion of TFAs in nutrition label have been found in the country.

Current evidence and TFA source:

Currently, there is no available evidence regarding TFA consumption or sources in the country.

Possible regulatory pathway:

A possible regulatory pathway to adopting a TFA elimination policy may be to develop a standard seeking to limit TFA content in all packaged foods to no more than 2-5% of total fat and/or to ban PHOs. This may be done by including such standards in the Food and Drug Regulation (1977). This action is expected to be upheld by the Food and Drug Act (1971), which clearly states that food-related policies (labelling, packaging, sale, etc.) must comply with established standards found in the Regulation; not doing so is a federal offense. A standard may be included in the Food and Drug Regulation, solely on the initiative of the Ministry of Public Health (MOPH).

Evidence to support the adoption of the standard may come from international studies, WHO or PAHO reports, and information from the Guyana Bureau of Standards, and the MOPH.

Expected supporters of a TFA elimination policy include the MOPH chronic and non-communicable diseases unit and advocacy groups, among others.

Implementation, monitoring, and enforcement:

The implementation plan for the proposed policy would include inspection, sampling, and testing activities, as well as public notification of non-compliant offenders. The implementation plan includes a six-month public notification period regarding

the PHO ban and/or a 2-5% TFA limit on nutrition labels. A front-of-package-labelling (FOPL) policy would be implemented at the same time. Moreover, the proposed policy would give all stakeholders 180 bays before enforcement takes place.

The Government Analyst – Food and Drug Department (GA-FDD) would be the lead agency responsible for inspection and analysis which will use laboratory analysists, inspectors, and public health workers to test, monitor, and enforce the proposed policy. The inspection may occur once a year at the beginning, but its frequency may increase until no TFA is found in samples. If a product is not compliant with the policy, the government may decide to restrict its commercialization whether it is imported or domestically manufactured. Sanctions may include revocation of import permit, refusal of entry of the commodity, and/or revocation of food license in the case of domestic products, among other actions.

Pre- and post-assessment of TFA levels in foods would be a part of the proposed policy implementation plan. These actions would be done in collaboration with universities and the MOPH food policy unit.

Social media campaigns may be developed to raise awareness about TFA consumption and its negative impact on health.

Implementation of the proposed elimination policy will take approximately six months.

Enablers and Barriers:

One vital factor that enables the adoption of the proposed policy is that the MOPH can include the standard in the Food and Drug Regulation without consulting any other stakeholders; therefore, limited opposition is likely.

In addition, current work on FOPL and the establishment of the presidential commission on noncommunicable diseases—which is currently working to reduce the amount of sugars, salt, and eliminate TFA—can build momentum for the adoption of the proposed policy.

Currently, the GA-FDD is developing a testing methodology for assessing TFA content in foods.

Lastly, coronary heart disease is the leading cause of death in Guyana, and this may be used to underline the urgency of eliminating TFA from the food supply.

Barriers to adopting the TFA elimination policy include, among others: limited local data on foods containing TFA, laboratory and technical capacity for food assessment, and the exposure to TFA-containing imported foods in the country. In addition, it may be difficult to achieve political consensus on this policy and collaboration from the food industry.

Jamaica

Policy Landscape:

Currently, there are no specific regulatory measures to eliminate TFA in the country. In addition, no other complementary regulatory measures, such as mandatory inclusion of TFA content in nutrition panels, have been found to be adopted in the country. Nevertheless, the country has several food-related policies that may be used to support the adoption of a mandatory TFA-elimination policy, including: Food and Nutrition Security Policy (2013), Public Health Act (1985), Public Health (Food handling Establishment) Regulations (1998), and Processed Food Act, among others.

Current evidence and TFA source:

Currently, there are no local studies on TFA in the country. Nevertheless, earlier in 2019 the College of Health Sciences at the University of Technology Jamaica was the recipient of a grant to assess the trans-fatty acid profile of spreadable fats, edible oils, cookie products, snacks, and fast foods from transnational and local restaurants and bakeries across Jamaica, to lay the groundwork for the development of national standards and policy.

Possible regulatory pathway:

A TFA elimination policy that limits the content of TFA to no more than 2% in all packaged foods and/or a PHO ban may be drafted by the Ministry of Health and Wellness (MOHW) with direct support of the Bureau of Standards of Jamaica Agency (BSJ).

The first step may be to gather evidence regarding food production, food supply, major sources of dietary TFA, and food consumption patterns. More specifically, information from international data bases, upcoming laboratory food assessments, and the Jamaica Health and Lifestyle Survey can be used for this purpose. It is worth noting that the survey contains food consumption pattern information; therefore, the country may be able to use this source to extrapolate TFA consumption in the population.

The country may also find it advantageous to assess how current food-related policies are implemented, monitored, and enforced, and their possible effect on a TFA elimination policy, as well as possible support from various stakeholders.

All this information may help the country identify the most efficacious regulatory pathway and establish the primary and secondary objectives of the proposed policy.

The process of drafting a TFA elimination policy could include consultation with stakeholders (e.g., Jamaican Manufactures and Exporters' Association, Manufactures' Quick Service Restaurants, etc.), identification and evaluation of possible complementary TFA-related actions (e.g. labelling, incentives to reformulate, etc.), existing monitoring mechanisms, and political support for the proposed policy. Moreover, a cost-benefit analysis on the proposed policy and a consultation should be done before sending the proposal to cabinet.

Implementation, monitoring, and enforcement:

Using existing monitoring and enforcing mechanisms to assess policy compliance may be beneficial for the country. The Ministry of Industry, Agriculture, and Commerce and Fishery (MICAF), through the BSJ, and the National Compliance and Regulatory Authority (NCRA) may lead national monitoring and enforcement activities, conducting inspections and sanctioning offenders. Product testing would be carried out at BSJ laboratories, while the NCRA would carry out inspections (collecting samples) at checkpoints of entry and sale, as well as in manufacturing plants. In addition, the NCRA oversees notification of companies that are non-compliant with the policy. Public health inspectors from MOHW may support NCRA monitoring activities.

MOHW could dictate the appropriate sanctions to be enforced by the NCRA and help to raise public awareness by producing educational materials on the negative health impact of TFA consumption.

The frequency of monitoring is expected to consider the risk of the product and its compliance with the adopted policy.

Lastly, as part of the implementation process, a baseline and post-implementation evaluation should take place to assess the impact of the proposed policy.

Enablers and Barriers:

One enabler for the adoption of a proposed elimination policy is that the country has recently upgraded two of its laboratory facilities to assess TFA, saturated fats, sugar, and salt in prepackaged foods. Moreover, staff were trained to use the equipment by

the end of 2019. Therefore, laboratories will be able not only to assess TFA content in products in Jamaica, but can also assist other nearby countries in monitoring-related activities.

Another enabler is that the country has plans to conduct a study on foods sold in Jamaica in general, and foods sold or served specifically in schools.

A key player in the process of drafting a policy may be the National Food Industry Task Force, which includes government officials, academia, and health advocates. This task force has subcommittees on product reformulation, labelling, food marketing (to children), communication, and advocacy. The task force could help speed up the process of adopting a TFA elimination policy, since many of its members are stakeholders that often take part in long policy consultation processes.

Barriers to adopt an TFA elimination policy include the cost of lab technicians, technical officers, inspectors, and maintenance of equipment. Lastly, there are no local studies on TFA food content, which may delay development of a draft proposal.

Paraguay

Policy Landscape:

The country does not have a specific policy to eliminate TFA. Nevertheless, some TFA regulations are present in Southern Common Market (MERCOSUR) resolutions. For example, GMC MERCOSUR Resolution No. 46/03, on Nutrition Labeling of Packaged Foods, mandates inclusion of TFA content per serving on the nutrition facts label. GMC MERCOSUR Resolution No. 1/12, on Nutrition Claims (2012), stipulates conditions for the claim "Does not contain trans fats" on the product label. The conditions are as follows: the product does not contain more than 0.1 g of trans fat per 100 g or 100 ml (as appropriate for prepared foods) or per serving, and it is considered low in saturated fat.

GMC MERCOSUR Resolution No. 6/94, on the Declaration of ingredients on packaged food labels (1994), states that refined oils other than olive oil can be listed as "blended oil" on the list of ingredients, with the qualifier "vegetable" or "animal", depending on the origin of the fat. The qualifier "hydrogenated" or "partially hydrogenated", as appropriate, should be added when mentioning any vegetable oil or any oil whose specific origin (vegetable or animal) is indicated.

Article 14 of Paraguay Law No. 532 on the Prevention and Comprehensive Care of Diabetes (2014) seeks to promote policies and/or regulations to help reduce exposure to risk factors for diabetes and other chronic noncommunicable diseases. In addition, Law No. 836 (the Health Code) empowers to government agencies to inspect and analyze foods and penalize the owners of establishments which sell foods that pose a hazard to health.

The aforementioned policies could serve to promote the adoption of a policy with the specific purpose of TFA elimination, since they establish a legal framework to deal with noncommunicable diseases.

Finally, the National Institute of Food and Nutrition (Instituto Nacional de Alimentación y Nutrición, INAN) is currently working on a draft resolution for the reduction of TFA content in foods sold in the country.

Current evidence and TFA source

There is limited evidence on TFA sources in Paraguay; however, a 2017 study on processed foods as a source of total TFAs in urban areas of Paraguay was conducted by the Department of Food Biochemistry of the Faculty of Chemical Sciences of the National University of Asunción. This paper presents the first data on the TFA content of traditionally consumed foods in Paraguay such as chipa and highlights the importance of controlling the composition of locally sold, unlabeled foods, as well as the need to reformulate these foods with a view to lower TFA content, based on current international nutritional recommendations for the prevention of cardiovascular diseases.

The study found that the highest total TFA levels were found in margarine, chocolate chip cookies, chipa, French fries, corn snacks, and fried meat patties.

Possible regulatory pathway

A policy to eliminate TFAs could include a ministerial resolution approving a technical regulation that establishes hard limits on the TFA content of packaged foods and processed foods sold at fast-food establishments. This technical regulation would be developed by the Ministry of Public Health and Social Welfare (MSP), with support from INAN and other technical experts from different government agencies.

As part of the process of developing this technical regulation, a technical working group would gather additional information on possible sources of TFAs in processed products, oil production plants, and fast-food establishments. The working group would also explore possible agreements with academia and private laboratories, as well as funding sources, to ensure that all essential elements are in place for successful implementation of the regulation.

The technical regulation would gradually limit the amount of TFAs in packaged and fast foods to no more than 2% of the total fat content. This regulation would require that, at the end of a first stage (24 months), the TFA content of oils and margarines not exceed 2% of total fats; other foods would be subject to a 5% limit for the same period. Then, at the end of a second stage (48 months), the 2% limit would be mandatory for all foods sold in the country.

After developing the proposal for a technical regulation, it would be taken to a nationwide, updated consultation, and the comments received during this consultation would be taken into account. The World Trade Organization (WTO) would be notified of the proposed regulation.

Implementation, monitoring, and enforcement

In order to implement the proposed regulation, the MSP and INAM would jointly develop an implementation plan taking into account the available financial and human resources. The MSP would be responsible for issuing and/or updating any penalties associated with the technical regulation, pursuant to the Health Code (Law No. 836/80). INAM would be responsible for monitoring through inspectors based at each state capital, who would travel to different parts of the country to verify compliance with the regulations. Some monitoring activities might involve: inspection and sampling of establishments that produce oils and processed foods, as well as inspection of labels of imported and domestic products.

Simultaneously, the country could systematically compile the information collected through these monitoring activities in a single database, which would provide quick access to key information for a possible policy evaluation.

Finally, as part of the implementation plan, INAN could develop a campaign for the general public and small and mid-sized businesses, with the aim of raising awareness of this new regulation.

Enablers and Barriers

Existing regulations for TFAs, as well as other regulations related to the prevention of chronic noncommunicable diseases, could facilitate the adoption of a TFA elimination policy.

Another factor that could facilitate adoption of an elimination policy is the fact that proposals arising from INAM are not subject to extensive government reviews; therefore, the process is not expected to take too long. Finally, the ongoing development of a proposal to reduce the trans-fat content of commercial foods, led by INAN, places the country in an ideal situation to ban TFAs once and for all.

The main barriers to the adoption of a TFA elimination policy include limited national evidence on TFA intake and the lack of personnel and technical capacity to conduct inspections and sampling of existing facilities. Finally, the penalties associated with noncompliance with the regulation would have to be updated.

Peru

Policy Landscape

Law No. 29751, the Consumer Protection and Defense Code (2010), stipulates that foods containing TFAs must reflect this on their labels, including the percent content. The law also states that every food must prominently display on their labels a name that reflects its true nature, without confusing or misleading the consumer. This law was one of the first legal actions taken with a focus on TFA regulation.

Law No.30021 on the promotion of healthy food for children and adolescents (2013) regulates TFAs through front-of-package warning labels and a gradual reduction of TFAs until their complete elimination. This law applies to prepackaged foods, domestic or imported, that contain IP-TFAs. Broadly, the penalties for noncompliance may be borne by the importers, manufacturers, distributors, and inspectors of the affected products.

Specifically, the law mandates that TFA-containing products bear the following message on a front-of-package warning label: “Contiene Grasas trans: Evitar su consumo.” The nutritional parameters that are used to determine whether a product should carry a front-of-package warning label are listed in the Advertising Warnings Manual within the framework established by Law No. 30021, Law for the Promotion of Healthy Food for Children and Adolescents and its regulations (2018). Imported products can carry a sticker on the front of packaging to comply with this aspect of the law.

Monitoring of compliance with the front-of-package labeling requirement is carried out by the National Institute for the Defense of Competition and the Protection of Intellectual Property (Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual, INDECOPI), which has begun to monitor compliance by reviewing labels in supermarkets and at other points of sale.

To support this monitoring activity, civil society, together with academia, the Pan American Health Organization/World Health Organization (PAHO/WHO), the Ministry of Health (MOH), and other government entities, have formed a standing working group (Puesta en Marcha de la Ley de Alimentación Saludable) to ensure proper implementation of the healthy food law.

The law also provides for the development of a regulation to gradually reduce TFA until a complete ban is in effect. The Regulation establishing a process of gradual reduction towards elimination of trans fats in industrially processed foods and non-alcoholic beverages (2016) was adopted by Supreme Decree No. 33-2016-SA, and was developed taking into account international evidence on TFAs.

The regulation provides for a grace period of up to 18 months before fats, vegetable oils, and margarines are required to contain no more than 2 g of TFAs per 100 g or 100 ml of fat. All other industrially processed foods and non-alcoholic beverages may contain no more than 5 g of TFAs per 100 g or 100 ml of fat. It also stipulates that TFAs generated by the partial hydrogenation process cannot be used in any processed foods or non-alcoholic beverages once the regulation has been in force for 54 months.

In the case of products containing IP-TFAs generated by processes other than partial hydrogenation, the national health authority will only grant exceptional authorization if it is shown, on the basis of scientific and technological evidence, that the TFA content has been reduced as much as possible, depending on the technology used for processing, and that there is no industrial replacement for total elimination, with TFA content not allowed to exceed 2 g of TFA per 100 g or 100 ml of fat, and with a view to gradual elimination as permitted by technological progress.

The regulation will be monitored by the General Directorate of Environmental Health (Dirección General de Salud Ambiental, DIGESA).

It is worth stressing that the healthy food law does not provide for regulation of TFAs in restaurants. Penalties for noncompliance with the policy include a ban of sale of the noncompliant product, fine, closure of the establishment, and withdrawal of the health certificate, among other actions.

In Peru, there is no specific regulation mandating nutritional labeling to which the requirement of including TFAs could be added, although this is addressed in passing in the Consumer Protection and Defense Code, as noted above. Nor is there any regulation relative to nutrition and/or health claims which could pertain to TFAs. Peruvian Technical Standard NTP 209.038 (2009) stipulates that refined oils other than olive oil may appear in lists of ingredients as aceite (“oil”) alongside the term “vegetable” or “animal”, as appropriate, and the qualifier “hydrogenated” or “partially hydrogenated”, as appropriate; refined fats can be listed as grasas (“fats”) alongside the qualifier “vegetable” or “animal”, as appropriate.

Current evidence and TFA source

Although the evidence on TFAs is limited, margarines, vegetable fats, fried goods, cookies, cakes, and hot chocolate mixes, among other foods popular in the country, may have high levels of TFA.

Possible regulatory pathway

A regulatory path to amend Peru's current policy regarding TFA elimination was not discussed, as its regulation already follows PAHO/WHO recommendations.

Implementation, monitoring, and enforcement

Implementation of the current policy would be strengthened by a plan of work that includes interventions to generate evidence on the TFA content of pre-packaged products, strengthen the technical capacities of government agencies, mobilize civil society to support implementation of the law, and secure the necessary financial resources, among others. Development of this implementation plan could be led by the MOH, DIGESA, and INDECOPI.

Evidence could be generated through research on the TFA content of specific products by using the database of records managed by DIGESA. In turn, the MOH and National Institute of Health (Instituto Nacional de Salud, INS) could promote studies on the impact of the healthy food law and collect information relevant to the intake of TFAs by the population.

The improvement of technical capabilities, specifically access to laboratory equipment and training for those responsible for monitoring and enforcing compliance with the law, could be achieved through government funding and/or agreements with third-party laboratories. Additionally, improvement of technical capacities could include the owners of small and mid-sized businesses.

As a result of the described interventions, monitoring of supermarkets and oil processing plants is expected to occur up to three times a year. The results of such monitoring would be made known to the public through reports.

The penalties for noncompliance have already been defined by the MOH and by INDECOPI.

Enablers and Barriers

Law No. 30021 and Supreme Decree No. 33-2016-SA facilitate the country's efforts to monitor compliance with the law.

INDECOPI could continue and increase monitoring of compliance with front-of-package warning labels through inspections at the point of sale. DIGESA, in turn, could use nutritional information already on file for approved products to evaluate and compare TFA content before and after implementation of the regulations, which would allow measurement of the impact of the law.

Civil society has supported previous work on the consumer protection front regarding front-of-package warning labels, especially by filing complaints; it is therefore expected to be an ally in the implementation of gradual TFA elimination as well. It is also expected that supermarkets, aware of the penalties for noncompliance with the law, will continue to demand front-of-package warning labels on all TFA-containing products and, in turn, will comply with the mandate of gradual reduction.

Additionally, the laboratories at the National Food and Nutrition Center (Centro Nacional de Alimentación y Nutrición, CENAN) could help monitor compliance with the law as long as they have the necessary equipment.

Some barriers to implementation of the TFA regulation components of the healthy food law include: lack of equipment and technical capacity to monitor compliance, lack of current evidence on the TFA content of products, and lack of data on current TFA intake.

Although civil society has been taking important steps to support the healthy food law by participating in a multisectoral committee that supports its implementation, a subgroup of the mentioned committee could be established to provide constant monitoring of TFA elimination.

Finally, the charge levied by INDECOPI on any citizen or consumer organization wishing to report noncompliance with the front-of-package labeling regulation is extremely high (equivalent to US$420), which greatly hinders monitoring by civil society.

Mexico

Policy Landscape:

According to Official Mexican Standard NOM-043-SSA2-2005 (Basic health services. Promotion and education for health in dietary matters. Criteria for providing guidance.), the population should be informed of the importance of limiting intake of foods rich in TFAs (among other nutrients) to a minimum, and the use of vegetable oils should be preferred. According to Official Mexican Standard NOM-247-SSA1-2008, (Products and services. Cereals and their products. Cereals, cereal flour, meal, or semolina. Cereal-based foods, edible seeds, flours, semolina, or blends thereof. Baked goods. Sanitary and nutritional provisions and specifications. Test methods.), the TFA content of baked goods must be declared and expressed as TFA per 100 g or 100 ml or per serving or per container. It also stipulates that supplemental nutritional information on TFAs is optional.

NOM-051-SCFI/SSA1-2010 (General labeling specifications for prepackaged foods and non-alcoholic beverages. Commercial and health information) mandates the inclusion of TFAs in the nutrition facts labeling of prepackaged products if any specific nutrition claim is made.

Official Mexican Standard NOM-037-SSA2-2012 (for the prevention, treatment, and control of dyslipidemias) associates TFA intake with development of cardiovascular diseases, reductions in high-density lipoprotein (HDL) cholesterol, and increases in low-density lipoprotein (LDL) cholesterol.

There are no policies in Mexico to establish mandatory parameters or guidelines for any nutrition or health claims regarding TFAs.

Furthermore, it should be noted that General Health Law regulates the right to health protection and empowers the Ministry of Health and governments of subnational entities to carry out prevention and control of noncommunicable diseases.

Current evidence and TFA source

The 2006 and 2012 National Health and Nutrition Surveys (Encuesta Nacional de Salud y Nutrición, ENSANUT) contained modules to collect data on frequency of food intake, which can be used to estimate the TFA intake of the population. For

example, an analysis of 2006 ENSANUT data, combined with dietary content tables from a study on fats, diet, and health (Grasas, dieta y salud. Tablas de composición de ácidos grasos de alimentos frecuentes en la dieta Mexicana), estimated that the TFA intake of Mexican adolescents (aged 12-19 years) and adults (aged 20-60 years) was 0.5 g/day on average, with TFAs accounting for 0.4% of total daily energy intake. Subsequently, an analysis of 2012 ENSANUT data found that the median intake of trans-fatty acids in adults was 0.25 grams (IQR: 0.05-0.59).

The follow-up study in 2007 found that unsalted margarine, hamburger patties, and seasonings contained the highest amounts of TFAs. The foods analyzed in that study were obtained from convenience stores, street vendors, supermarkets, and fast-food restaurants in the city of Cuernavaca.

Possible regulatory pathway

Mexico has an established regulatory process that could be used to adopt a TFA elimination policy. Updated evidence that demonstrates the burden of trans fats on the health of the population is needed to help establish elimination of TFAs as a priority on the public agenda. Possible elimination policies could include limiting TFAs to no more than 2% of the total fat content in products, banning partially hydrogenated oils (PHOs), or both. If the country were to adopt a 2% elimination policy, it would have to modify the Regulation for Sanitary Control of Products and Services by decree; if it were to adopt a policy to ban the use or production of PHOs, NOM-247-SSA-1 would have to be modified instead. Either process would be led by the Federal Commission for Protection against Health Hazards (Comisión Federal para la Protección contra Riesgos Sanitarios, COFERIS), and would require a regulatory impact analysis (a mandatory process in Mexico) to be submitted to the National Commission for Regulatory Improvement (Comisión Nacional de Mejora Regulatoria, CONAMER). In addition, the aforementioned modifications could lead to changes in Mexican voluntary standards related to TFAs; these changes would be the responsibility of the Ministry of Finance.

It bears stressing that the adoption and/or modification of a standard depends on its inclusion (through a registration process) in the national standardization program, a process which takes place once yearly. If the proposed standard is not included in the program, the advisory boards responsible for carrying out the administrative processes necessary for adoption and/or reform of standards will not be able to review it.

As a transitional bridge to an elimination policy, Mexico could adopt a regulation that mandates the listing of TFAs on nutrition labels. It is noteworthy, that after this workshop, Mexico took action on improving its labeling regulations, and in January 2020, the relevant norm was amended to require a mandatory TFA declaration in nutrition facts tables, and also the application of a front-of-package warning when total energy from trans fats in a product is equal to or greater than 1%.

The Law on Federal Metrology and Systematization sets forth a standardization process that includes the establishment of a multisectoral working group made up of academia, industry, civil society, and government representatives, among others; preparation of a regulatory impact study for the proposal; review of the regulatory impact study by CONAMER; review of the proposed modification to the standard by the standardization advisory boards; approval of the proposal; and publication in the official gazette.

Implementation, monitoring, and enforcement

COFEPRIS could be the government entity responsible for implementation, monitoring, and compliance with the proposed changes to the regulations. The Health Operations Commission (Comisión de Operación Sanitaria, COS), a part of COFEPRIS, would carry out surveillance activities such as inspection at the point of sale. The Health Authorization Commission (Comisión de autorización Sanitaria, CAS), which authorizes import and export of medicinal products, could support monitoring activities, as could the Commission for Analytical Control and Coverage Expansion (CAAyAC, the national laboratory), which has the necessary equipment to analyze food samples in their facilities. In addition, CAAyAC could leverage the National Laboratory Network at the regional level, as well as third-party laboratories, to expand monitoring capacity. The Health Development Commission (Comisión de Fomento Sanitario, CFA) could support awareness-raising activities aimed at the population.

The Federal Health System (Sistema Federal Sanitario, SFS) is the authority in charge of liaising among all federal authorities and COFEPRIS, which enables the conduct of federal activities at the state level through commissions responsible for surveillance, monitoring, and enforcement.

The Federal Prosecutor's Office for Consumer Protection (PROFECO) could also support assessment of compliance with the regulation measure at points of sale through laboratory analyses or evaluation of labels. In addition, there is a mechanism in place for the general population to monitor compliance with standards. This practice, known as a community health complaint, is formally available but rarely used.

Finally, public awareness campaigns could be funded with financial resources from the Undersecretary for Health Promotion and Prevention.

The General Health Law establishes the penalties for noncompliance with regulatory measures set by COFEPRIS. These penalties include warnings, total or partial shutdown of operations, economic sanctions, and product recalls from the market.

Part of the implementation process would include notifying the World Trade Organization (WTO).

The estimated time frame for implementation of the elimination policy would be one year, which is enough for companies to reformulate and/or dispose of their products.

Enablers and Barriers

The country has multiple government entities that could support monitoring of compliance with a TFA elimination policy. The CAS, CAAyAC, PROFECO, and the National Laboratory Network would facilitate inspection, sampling, and evaluation of TFA content of the AGT in domestic and imported products, both at the nationwide and subnational levels. The SFS would ensure that all actions taken by COFEPRIS at the federal level are replicated at the state level. Public awareness campaigns could be led by the Undersecretary for Health Promotion and Prevention. In addition, ENSANUT maintains a database of population-wide food consumption habits, which would facilitate estimation of TFA intake. These components would all facilitate implementation of a TFA elimination policy.

Barriers to the adoption of an elimination policy include limited coordination between current standards related to TFA regulation. Furthermore, some of the existing supplemental measures (such as mandatory inclusion of TFAs in nutrition labels) are actually not mandatory at all, and/or have a limited scope.

ASBRAN, CROSQ, and INCAP information:

The Brazilian Association of Nutrition (ASBRAN)

The Brazilian Association of Nutrition (ASBRAN) and the Federal Council of Nutrition engage in advocacy to support the work of the national health surveillance agency (ANVISA) and the Ministry of Health aimed at adopting the best possible policy option to eliminate IP-TFAs.

The two authorities currently involved in the regulatory process to eliminate IP-TFAs are ANVISA and the House of Deputies and Senate. In 2016, ANVISA prioritized IP-TFA restriction in the regulatory agenda; in 2017 a proposed policy sought to ban PHOs, but it was later changed to a limited approach by which IP-TFAs could account for as much as 5% of the total fat in food products. In 2018, ANVISA published a report describing IP-TFA sources, population intake, policy options, and other relevant data.

ASBRAN advocated for rejection of the 5% proposal and was able to stop the process by establishing public health-related arguments, for example citing the fact that mean IP-TFA consumption in Brazil is 1.4% of daily caloric intake. In addition, ANVISA recently published a regulatory impact analysis study that evaluates different policy options, including a 5% limit, a 2% limit, or a combined option of 2% limit and PHO ban.

Currently, Brazil has adequate equipment to test for IP-TFA content in foods; however, carrying out these tests in the entire country may be a challenge due to its size.

ASBRAN recommends an IP-TFA elimination policy that combines the 2% limit for all foods with a PHO ban, due to sub-par oil refinement processes and high levels of PHO in ultra-processed foods and baked goods.

It is noteworthy that Brazil took action after this workshop. In December 2019, ANVISA enacted its IP-TFA elimination regulation, which includes the introduction of a 2% limit for IP-TFA starting in 2021, and a second, final phase that introduces a PHO ban by 2023.

CARICOM Regional Organization for Standards and Quality (CROSQ)

In order to support IP-TFA elimination in the Caribbean, CROSQ would help in the development of an IP-TFA regional standard that would eventually be included in Caribbean countries' regulations. This regulatory measure seems a viable alternative since many countries are prioritizing NCDs, especially cardiovascular disease. Regulating one of the NCD risk factors (IP-TFAs) may help reduce the burden of these diseases in the Region.

The first step for the development of the standard by CROSQ is for a country to submit a proposal outlining the need to develop a standard. The proposal is then evaluated by all Member States to determine its relevance. If 75% of them agree it is necessary, a broad-based committee of experts is set up to develop a working draft of the standard. Experts on this committee include key stakeholders with up to three government officials, manufacturers, industry respresentatives, healthcare workers, nongovernmental organizations, and consumer interest groups, among others.

When the expert group reaches consensus on the working draft of the standard (a new standard, an adapted current standard, etc.), the document is given to countries for comments within 60 days. CROSQ recommends that countries create a national committee to follow the development of the standard and to provide official national comments on the working draft. CROSQ then collects and provides the comments to the broad-based committee which, in turn, analyses them and makes amendments, if appropriate. CROSQ then sends the revised standard to the countries, which ultimately send their final position on the standard to the CROSQ secretariat. A technical management committee reviews the process that led to the standard in order to ensure that all comments were addressed and enough time was given to the countries to submit their comments. If the process is deemed satisfactory, the technical management committee recommends the standard to the CROSQ Council which endorses the document and submits it to the Council of Trade and Economic Development Ministries (COTED) for final approval.

Since the CARICOM is governed by the Revised Treaty of Chaguaramas (ROTC), an approved regional standard should be adopted by the countries instead of their national standard. Once the regional standard becomes a national standard, national IP-TFA regulations can be develop, considering the requirements and parameters set by the standard.

CROSQ encourages countries to follow good practices when developing regulatory measures. These include: preparation of a state impact assessment (SIA) and or a regulatory impact assessment (RIA); consultations with key stake holders; drafting of the regulation, considering current policy on the topic; presentation to the ministry and cabinet; adoption of the regulatory measure; and entry into force.

Finally, it is important that when countries engage in the development of a regional standard to eliminate IP-TFAs, they understand the importance of creating a national committee to submit official comments on the proposed document. This national committee should include key stakeholders in order to ensure that all comments from a country are summarized in one file and sent to CROSQ. This process will reduce the likelihood that unofficial comments from a single country may be interpreted as the official position. In addition, national consultation processes pertaining to the proposed regional standard should be conducted with enough time to ensure all stakeholders, including the public, can raise their voice. CROSQ considers both actions important to ensure the transparency of the process leading to the approval of a regional standard to eliminate IP-TFAs.

Institute of Nutrition of Central America and Panama (INCAP)

INCAP could support the elimination of IP-TFAs through the development of a subregional strategy or policy model. At the national level, it could help countries develop their plans of action. Regardless of the nature of the strategy or policy model, INCAP highlights the importance of obtaining data on IP-TFA-containing products in the subregion and identifying those most consumed by the population. It also recommends reviewing current regulations related to restriction or control of IP-TFAs or other foods and raising awareness of the problem among decision makers, as a means of securing political support for the strategy and/or policy proposal. These actions could lay the necessary groundwork for the development of a regulatory measure that takes into account the political and regulatory panorama of each country.

A subregional strategy would aim at the development of a subregional technical regulation; national strategies would aim at the development of country-specific laws and/or regulations. Regardless of the type of strategy and/or policy adopted, it should clearly stipulate the following: technical parameters corresponding to the maximum limits for IPTFAs and/or a ban on partially hydrogenated oils; the time frame for gradual reduction of TFA content until their total elimination; the agencies in charge of monitoring compliance (e.g., the national food control authority); sampling frequency (e.g., annual); and penalties for noncompliance, among other aspects.

INCAP recommends the use of existing monitoring mechanisms to assess compliance with regulation, thus minimizing costs. Product inspections could take place at factories and at points of entry into the country, thus ensuring a substance check at key points in the food chain. As a first step, compliance could be assessed when the manufacturer, packager, or importer requests marketing authorization for the product (whether for the first time or renewal). For imported products that have previously demonstrated compliance, entry could be authorized if they bear a certificate of analysis that confirms compliance with the current regulation. Analysis should be performed at an independent laboratory: never by the manufacturer, packager, or importer.

Finally, INCAP will continue to advocate for approval of the proposed Healthy Food Law in Guatemala (which takes TFAs into account), the Front-of-Package Nutrition Labeling (EFAN) initiative in Central America, and for review of the Central American Technical Regulation on Nutrition Labeling so that listing of TFAs is made mandatory. It will also continue to support countries in the development and implementation of plans of action.

Conclusions and recommendations

Conclusions

The workshop provided a space to learn about the various existing IP-TFA policies, regardless of whether they specifically aim to eliminate the substance or are of a complementary nature. In addition, the workshop allowed government officials and subregional organizations to share potential regulatory mechanisms that may be used to develop a new policy or amend an existing one.

Government officials' proposed IP-TFA elimination policies are diverse, due to differences in existing IP-TFA and/or food-regulatory measures, available regulatory pathways, and available resources. For instance, Bolivia's objective is to create a regulation to implement Law 775, while Costa Rica's objective is to either develop a new national regulation or amend an existing subregional one. Nevertheless, all participating countries (except for Bolivia) mentioned the possible objective of either limiting IP-TFA content to no more than 2% of total fat in packaged foods and/or banning the use and production of PHOs. Paraguay was the only country that also mentioned the possibility of extending the proposed policy to fast food restaurants.

The most common regulatory pathway mentioned in the workshop was the development of a national regulation to operationalize, amend, or develop a new IP-TFA elimination policy. Other regulatory pathways mentioned during the workshop include the development of health/phytosanitary regulatory measures or a subregional regulation or standard. The development of an elimination policy may be led by the MOH, with the help of other government agencies responsible for food safety, development of nutrition parameters, or nutrition-related surveillance, among others. Policy approval may be lengthy, taking approximately three years for a thorough review by various governmental agencies, along with consultations processes. Evidence on IP-TFA food content and intake were deemed key to developing a sound regulation that can successfully overcome scrutiny throughout the revision process. Human and financial resources, as well as coordination between the MOH and other governmental agencies, were considered necessary to ensure successful adoption of a policy. It is important to note that implementation, monitoring, and enforcement-related activities were considered during the design roadmap exercise for an IP-TFA elimination policy.

The regulatory agency may lead the implementation, monitoring, and enforcement activities by developing an implementation and coordination work plan with the MOH and other relevant agencies. It was decided that a maximum of 18 months is enough time for companies to make the transition to healthier products. In addition, countries mentioned the need to notify the WTO as a part of the implementation process.

The implementation work plan may describe monitoring and enforcement activities, as well the agencies responsible for these activities. Using existing monitoring and enforcement mechanisms to evaluate policy compliance is the best approach, since it is more likely to reduce the financial burden in the system. This approach may require coordination between governmental agencies for inspections, sample collection, testing, and sanctioning at the national and subnational levels. Inspection-related activities and food testing should take place as frequently as possible, using laboratory analysis where available. Nevertheless, 1-3 inspections per year, along with analysis of nutrition labels, may be a good option for monitoring. Most countries mentioned that sanctions have long existed for non-compliance with food-related regulatory measures, but they are rarely enforced. Therefore, existing sanctions should be reviewed and updated. In addition, existing enforcement mechanisms should be revitalized to increase compliance. Lastly, education campaigns for the public and for small and medium-sized businesses could be included during the implementation phase of the policy.

Recommendations

Overall, PAHO recommends that countries adopt a new IP-TFA elimination policy and/or amend their current policy, limiting the substance to 2% of total fats in all foods, while also banning the use and production of PHOs. This combined option ensures maximum protection for the population. Non-industrially-produced trans-fatty acids containing food products could be regulated by measures that seek to decrease their availability (e.g. banning these products in schools). It is recommended that an IP-TFA elimination policy be adopted even if local data shows that population consumption is not high; adopting a regulatory measure will prevent substance exposure due to product importation.

The elimination policy should include as much information as possible on IP-TFA population intake and food sources and should be supported by a reliable monitoring mechanism. Nevertheless, lack of a significant amount of evidence or limited monitoring capacity should not impede the process of drafting a policy. Relevant data from

international sources or studies can be used to build a strong case for policy adoption, as can data on nutrient content found in food registration systems. Moreover, specific provisions of the policy that explicitly designate a monitoring agency will ensure that appropriate resources are provided to meet the needs of the regulation.

IP-TFA elimination policy development should be led by the MOH and/or the food regulatory agency in coordination with academia, surveillance agencies, civil society, and other actors. It is important to note that the food industry should not be actively involved in drafting the policy in order to avoid possible conflict of interests. Industry and other stakeholders may participate in the consultation process or working groups so as to ensure equal representation by all parties. This will lead to an equal power dynamic among all parties.

It is recommended that when choosing a regulatory pathway (e.g., a technical regulation, health/phytosanitary measure, law, regional standard, etc.), countries should consider all the challenges that the pathway presents. For example, adoption of a national technical regulation may be more feasible in some countries than adoption of subregional standards/regulations that require consensus among all countries involved and usually involve additional administrative and operational processes.

It is recommended to use existing monitoring mechanisms that include laboratory or labeling analysis. In addition, civil society should be considered a potential partner to support monitoring-related activities such as filing complaints or reporting products that violate the policy.

PAHO recommends that countries adopt an IP-TFA elimination policy as soon as possible to help prevent coronary heart disease, the leading cause of death in the Americas.

Appendix 1

Participant list

Organization	First Name	Last Name	Position
Ministry of Health	Marisol	**Mamani**	
Ministry of Health and Social Protection	Elisa María	**Cadena Gaona**	*Subdirector, Nutritional Health*
Ministry of Health	Alejandra	**Chaverri Esquivel**	*Nutritionist Standardization and Control Unit, Office for Regulation of Products of Health Interest*
CARICOM Regional Organisation for Standards and Quality (CROSQ)	Fulgence	**St. Prix**	*Technical Officer, Standards*
PAHO	Olivia	**Brathwaite**	*Coordinator, Subregional program on NCD control and prevention*
INCAP	Mónica	**Guamuch**	*Laboratory chief, Food composition*
Ministry of Health	Marlan	**Cole**	*Director, Government Analyst, Food & Drug Department*
Ministry of Health	Deonne	**Caines**	*Technical Officer, National Food Industry Task Force*
Ministry of Public Health and Social Welfare	Zuny Mabel	**Zarza**	*Chief, Regulatory Affairs Unit (National Food and Nutrition Institute—INAN)*
National Health Institute	Silvia Gladys	**Robles Cebrián**	*Food Sciences and Technology Office, (National Center for Food and Nutrition, National Health Institute)*
Universidad San Martin de Porres	Jaime	**Delgado**	*Director, Consumption Institute*
PAHO	Enrique	**Gil**	*Subregional advisor, Chronic Noncommunicable Diseases*
Resolve to Save Lives	Lindsay	**Steele**	*Senior Program Officer*

Brazilian Nutrition Association (Associação Brasileira de Nutrição - ASBRAN)	Isabela Fleury	**Sattamini**	*Coordinator of the advocacy project "A collective effort to change the scenario of Trans Fat in Brazil"*
Global Health Advocacy Incubator (GHAI)	Kyra	**Berasi**	*Legal Advisor*
NCD Alliance	Luis	**Encarnación**	*Senior Capacity Development Officer*
Salud Justa Mexico	Erick	**Ochoa**	*Director*
Salud Crítica OSC	Ana	**Larrañaga**	*Director General*
PAHO	Alejandro	**Álvarez**	*Consultant, Risk Factors and Nutrition Unit*
PAHO	Fabio	**Gomes Da Silva**	*Regional Advisor, Nutrition and Physical Activity*
PAHO	Miguel	**Malo**	*Advisor, Noncommunicable Diseases*
PAHO	Cristián	**Morales**	*Representative of the Pan American Health Organization / World Health Organization in Mexico*
PAHO	Natalia	**Polgovsky Escurra**	*Consultant, Products, PAHO*
Federal Health Secretariat	Dr. Hugo	**Lopez Gatell**	*Subsecretary, Prevention and Health Promotion*
Americas Management Office	Zulema	**Guerra Carpio**	*Department Chief, Inter-American System*
COFEPRIS	María Guadalupe	**Arizmendi Ramírez**	*Specialist Inspector*
COFEPRIS	María Elena	**Palafoz López**	*Specialist Inspector*
Camara de Diputados	Gonzalo	**Solis López**	*Advisor*
MORENA	Carmen	**Medel Palma**	*Secretary*

Workshop Materials:

A. Concept note and Agenda.

Concept Note

Workshop on regulatory mechanisms to eliminate industrially produced trans-fatty acids from the food supply in the Region of the Americas

Mexico City, Mexico
17-18 July 2019

1. Background:

Every year around the world, approximately 540,000 deaths are attributable to consumption of industrially produced trans-fatty acids (IP-TFAs), 160,000 of them in the Americas. High trans-fat intake increases the risk of death from any cause by 34% and from coronary heart disease by 28%, and it increases the occurrence of coronary heart disease by 21%.

Trans-fatty acids are unsaturated fatty acids that come from either natural (ruminant) or industrial sources. Industrial processes add hydrogen to vegetable oils to convert liquid oil into solids. These "partially hydrogenated" oils prolong the shelf life of manufactured food products and are often used for deep frying and as an ingredient in baked goods. High intake of trans-fatty acids is due mostly to consumption of IP TFAs.

In 2007, PAHO convened the Trans-Fat-Free America Task Force, an initiative that issued the Declaration of Rio de Janeiro in 2008, with voluntary commitments to remove IP-TFAs from the food supply. While significant progress has been made, this goal has not been achieved, and trans-fatty acids continue to be used in at least 27 Member States. An important lesson learned was that voluntary measures were not sufficient.

In 2018, WHO launched the REPLACE action package to help governments implement the elimination of IP-TFAs from the food supply. IP-TFA elimination is also included in the WHO 13th General Programme of Work. This year, PAHO is presenting the Directing Council with a proposal for a Plan of Action for the Elimination of IP-TFAs 2020-2025, developed through extensive consultation with Member States.

This workshop was organized to support the countries' commitment to adopting and implementing regulatory mechanisms for the elimination of IP-TFAs from the food supply in the Americas.

2. Objectives:

- Present the range of existing regulatory mechanisms in the Region that aim to eliminate IP-TFAs from the food supply.
- Discuss the most effective regulatory channels and policy options.
- Discuss a roadmap to establish regulatory mechanisms for the elimination of IP-TFAs in the countries.

3. Invitees:

- Government officials responsible for food regulation.
- Government officials responsible for establishing nutrition parameters for consumption.

4. Venue:

PAHO-Mexico
Calle Montes Urales 440, Lomas - Virreyes, Lomas de Chapultepec III Secc, 11000 Mexico City, Mexico

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Agenda

Workshop on regulatory mechanisms to eliminate industrially produced trans-fatty acids from the food supply in the Region of the Americas

Venue: Montes Urales No. 440, Planta Baja
Col. Lomas de Chapultepec, Alcaldía Miguel Hidalgo, CDMX. C.P. 11000. Mexico

17-18 July 2019
PAHO-Mexico
Mexico City, Mexico

Day 1: 17 July 2019

Opening session		
08:30 – 09:00	Registration	
09:00 – 09:20	Opening remarks	**Mr. Cristian Morales Fuhrimann** *PAHO-Mexico Representative Office* **Dr Hugo López-Gatell,** *Sub-secretary of Prevention and Health Promotion Federal Health Secretariat*
09:20-9:30	Group photo	
09:30-09:45	***Presentation: Structure of the meeting (objectives, expected results, methods, agenda)***	**Fabio da Silva Gomes,** *Nutrition and Physical Activity Advisor, PAHO/WHO*
9:45 – 10:00	Break	
Policy options and regulatory pathways for the elimination of industrially produced trans-fatty acids.		
10:00 – 13:00	**Policy options and regulatory pathways**	RTSL
	Presentation on the Legislation Module and policy options (REPLACE)	GHAI
	Presentation on international trade considerations and World Trade Organization principles associated with policy design	COL
	Country experiences: Fishbowl activity:	PER
	Presentation on comparing policy options	PAHO/WHO
13:00 – 14:00	Lunch	

14:30 – 15:30	**Regulatory Pathways: Policy Design** ***Individual country exercise: Roadmap to design a policy, and barriers***	Countries
15:45 – 16:00	Break	
16:00-17:15	***Country group exercise: Presentation and discussion of selected policy, design, barriers, and solutions***	Countries
17:15 – 18:00	***Rapporteur presentation and discussion***	All attendees

Day 2: 18 July 2019

09:00 – 09:15	Summary of 1st day	PAHO/WHO
Implementation, monitoring, and enforcement		
09:15 – 10:00	**Mechanisms for implementation, monitoring, and enforcement** ***Presentation of implementation, monitoring, and enforcement (REPLACE)***	RSTSL
10:00 – 10:15	Break	
10:15 – 12:30	***Country experience: Fishbowl activity***	COL PER
12:30 – 14:00	Lunch	
14:00-15:30	**Regulatory pathways: Implementation, monitoring, and enforcement** ***Individual country exercise: Roadmap of the implementation, monitoring, and enforcement mechanism of chosen policy, and barriers***	Countries
15:30-15:45	Break	
15:45– 17:00	***Group exercise: Presentations on implementation, monitoring, and enforcement mechanisms, barriers and solutions.***	Countries
17:00-17:30	***Rapporteur presentation and discussion***	All attendees
17:30-18:00	Wrap-up	PAHO/WHO

B. Pre-workshop materials

Pre-workshop: Policy Landscape Assessment

The Policy Landscape Assessment will help you to collect background documents that will be used throughout the workshop, including existing laws and studies that address food safety and nutrition. Please answer the following questions to the best of your ability and bring hard and digital copies of all relevant documents.

Name_____

Title _____

Country _____

1. **Studies:** Are there any recent studies on level of trans fat in your population or in certain foods? Please provide reference and bring a copy of any studies.

   _____
   _____
   _____
   _____

2. **Sources of TFA.** If known, what are the primary sources of trans fats in the food supply?

   _____
   _____
   _____
   _____

3. **Testing Facilities.** Does your country have access to laboratories or other technological methods for testing the level of trans fat in foods? Describe the testing capabilities:

   _____
   _____
   _____
   _____

4. **TFA laws.** Does your country have any specifics legislation, regulation, or other legal measures on trans fats or partially hydrogenated oils? Include international and regional technical regulations (e.g. Gulf Cooperation Council). Please provide reference and bring a copy:

_____
_____
_____
_____

5. **Other relevant laws.** Does your country have a Food Act or other legislation that broadly addresses food safety and nutrition? Include constitutional provisions, and international and regional trade obligations, if applicable. Please provide reference and bring a copy:

_____
_____
_____
_____

If you have additional time, please complete the Policy Tracking Worksheet, available at: https://www.who.int/docs/default-source/replace/re-policy-tracking-worksheet.xls

C. In-workshop materials:

Fishbowl discussion activities questions: Policy Design

1. Was there anything specific in the country that prompted the adoption of your current law or regulation to eliminate/reduce IP-TFAs?
2. What law or regulation does your country have to eliminate IP-TFAs and what was the regulatory pathway to adopt it? (For example, ARG made a change in its food code). Did it include a combination of options? (2% limit and PHOs)
3. Does the country exclude any foods from the regulation?
4. Does the law or regulation apply to domestic and international products?
5. What type of evidence did your country use to justify the adoption of a regulatory adoption?
6. Does the country currently have different IP-TFA limits for different foods? (2% vs 5%)
7. How long did it take for your country to develop and adopt the current regulatory policy?
8. Does the country have any IP-TFA regulatory measures pertaining nutrition/ health claims? (e.g. “no trans fats”) What about mandatory nutrition labeling for IP-TFAs?
9. Does the country require PHOs to be listed in the ingredients list? What other names do PHOs currently have in the ingredient list?
10. Does the country have a regulatory policy for saturated fats?
11. Did international trade influence the country’s current regulatory policy?
12. Was it required to prepare an impact regulatory analysis for the present the policy proposal?
13. Does the country require pre-market registration for food products? If so, describe the mechanisms.
14. What was the timeframe given to the industry to comply with the regulatory measure?
15. What was the main challenge the country face when developing the regulatory measure?
16. How did the industry react to the regulatory measure?
17. What stakeholders supported the regulatory measure?
18. Does regulatory measure require an ongoing review process?
19. How do you think the regulatory measure could be improved?

Fishbowl discussion activities questions: Implementation, monitoring, and enforcement

1. How does the country monitor policy compliance? What agencies are responsible for monitoring policy compliance?
2. How does the country monitor policy compliance in domestic and international products?
3. Do monitoring activities differ in evaluating prepackaged foods vs oil production facilities?
4. Are there any monitoring activities at customs? If so, can you describe the mechanism ?
5. Does the country use laboratory analysis to monitor policy compliance? What about nutrition labeling analysis? If so, please describe process.
6. Describe the country's laboratory technical capacity.
7. What are some of the human and financial resources provided to food-monitoring activities?
8. Does monitor occur at the national and subnational levels?
9. Does the country monitor policy compliance in restaurants?
10. Which agency oversees enforcement? What are some of the enforcement-related activities that take place?
11. What are the sanctions associated with the regulatory measure? Which agency imposes the sanction?
12. Did the country do a post evaluation of the regulatory measure? If so, describe.
13. Did the country engage in education-related activities with manufactures, producers, distributers about the regulatory measure? What about for the public?
14. Did the country produce a technical document describing possible healthier replacement oils to distribute among small and/or medium-size businesses?
15. What barriers does the country face in terms of the implementation, monitoring, and enforcement of the regulatory measure? What possible solutions do you see to these?
16. Did the country notify the World Trade Organization regarding the regulatory measure? What was the timeline to do this?
17. How long did it take for the regulatory measure to be fully implemented?

D. Guiding questions: Roadmap exercises

Roadmap exercise: Policy design questions

Questions:

1. What would your country's roadmap look like if it wanted to adopt a policy/norm/regulation that combines a PHO ban and 2% maximum level of IP-TFA in foods?
2. What are some of the milestones you need to reach in order to draft a policy/norm/regulation that combines a PHO ban and 2% maximum IP-TFA?
3. How many regulatory pathways are there to reach the drafting of the policy/norm/regulation that combines a PHO ban and 2% maximum IP-TFA? Is there more than one? If so, what are some of the advantages or disadvantages of each one? (consider aspects such as feasibility of being adopted, implementation, monitoring, enforcement, and sanctions)
4. What actors, institutions, agencies are likely to support the regulatory pathway you choose to eliminate IP-TFAs? What about the ones likely to be against your proposal?
5. What are some of the components that your policy/norm/regulation needs in order to become an actual draft?
6. What is the scope of the policy/norm/regulation that combines a PHO ban and 2% maximum level of IP-TFA in foods?
7. Does your country have enough evidence to generate a solid justification for the problem? If so, what is it? If not, where do you think you can get it?
8. What are some of the current health and/or nutrition policies/norms/regulations you can use to support the current proposed policy/norm/regulation?
9. Are there any national health/nutrition plans or strategies that mention the elimination of IP-TFAs? If so, which ones? How do you think you can use them to support your proposed choice of policy/norm/regulation?
10. Does your country require a cost/benefit analysis as a part of the draft?
11. Is there an international trade agreement that may negatively impact the passage of your proposal?
12. Once you have developed a draft, does it have to be reviewed by Congress and the Senate? (perhaps only one government body?)
13. Does your policy/norm/regulation need to be reviewed by a special committee and or specific government agency? If so, how does this affect the drafting of your policy/regulation/norm?

14. What are some of your country's current IP-TFA-related policies? List them and the products they apply to. Do you think you can use this mechanism and expand it to eliminate-IP-TFAs?
15. Does your country require a list of ingredients for all packaged products? If so, does this include trans fats?
16. Is pre-market registration required for food products in your country? How do you think this could impact your proposal?
17. Does your proposal include any provision regarding "informal" use of IP-TFAs?
18. Which national agency can you seek technical assistance from for the development of the policy/norm/regulation?
19. Is it possible to include actions such as public health awareness campaigns and development of materials in your proposal?
20. Is there a public consultation that needs to take place for your proposal?
21. What is a realistic timeframe for your proposal to be adopted and implemented?
22. How is your proposal measuring its impact?
23. How is your proposal aligned with PAHO's proposed Plan of Action?

Roadmap exercise: Implementation, monitoring of compliance, and enforcement questions:

1. What mechanism will the country use to implement the regulation?
2. What mechanism will the country use to monitor compliance with the regulation and enforce it? Will this be federal, provincial, or local enforcement?
3. What sanctions will the country impose in the case of non-compliance with the regulation?
4. After the regulation is adopted, when will it come into force?
5. Will there be different monitoring compliance and enforcement mechanisms, depending on where the products come from? (international vs domestic)
6. How frequently will compliance be monitored?
7. How does the country plan to monitor compliance at oil-producing companies?
8. What resources (human/financial) will be used in the implementation, monitoring of compliance, and enforcement of the regulation?
9. Does the country plan to have a periodic report on the compliance with the regulation, and will this be made available to the public?
10. Will the country have access to testing/laboratories facilities to help monitor

compliance with the regulation? If so, list them; if not, consider partnering with local institutions or regional laboratories that can help you with this.

11. Will the country have a guide to help businesses comply with the regulation?
12. Does the country plan to do a pre- or post-regulation assessment of IP-TFA levels in products, restaurants, or oil-producing companies?
13. Does the country plan to include questions about IP-TFA consumption in nutrition-related surveys?
14. How does the country plan to disseminate information about the regulation to domestic and international entities?
15. How does the country plan to make the population aware of the regulation? Is the country planning to do a public health/education campaign?
16. How does the country plan to monitor compliance in the informal sector?
17. Are there any foods or restaurants that the country will monitor especially closely for compliance with the regulation?

The Pan American Health Organization (PAHO) organized the workshop to help countries determine the key elements to include in policies aimed at eliminating industrially produced trans fatty acids (IP-TFA). The specific objectives of the workshop were to present the range of existing regulatory pathways to eliminate IP-TFAs and to address their effectiveness, to analyze options for phase-out policy and to develop roadmaps to guide policy formulation. Government officials from Bolivia, Colombia, Costa Rica, Guyana, Jamaica, Mexico, Paraguay and Peru participated in the meeting. In addition, representatives from the Brazilian Nutrition Association (ASBRAN), the CARICOM Regional Organization for Standards and Quality (CROSQ), the Institute of Nutrition of Central America and Panama (INCAP), the Global Health Advocacy Incubator (GHAI), the NCD Alliance, PAHO subregional offices, Resolve to Save Lives (RTSL, an initiative of Vital Strategies) and Salud Justa-México also attended the meeting.

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