

REGIONAL WORKSHOP

# Regulatory impact analysis for the development of policies to eliminate industrially- produced trans-fatty acids in the Americas

Washington, D.C., September 11-12, 2019

**PAHO**



Pan American  
Health  
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Americas



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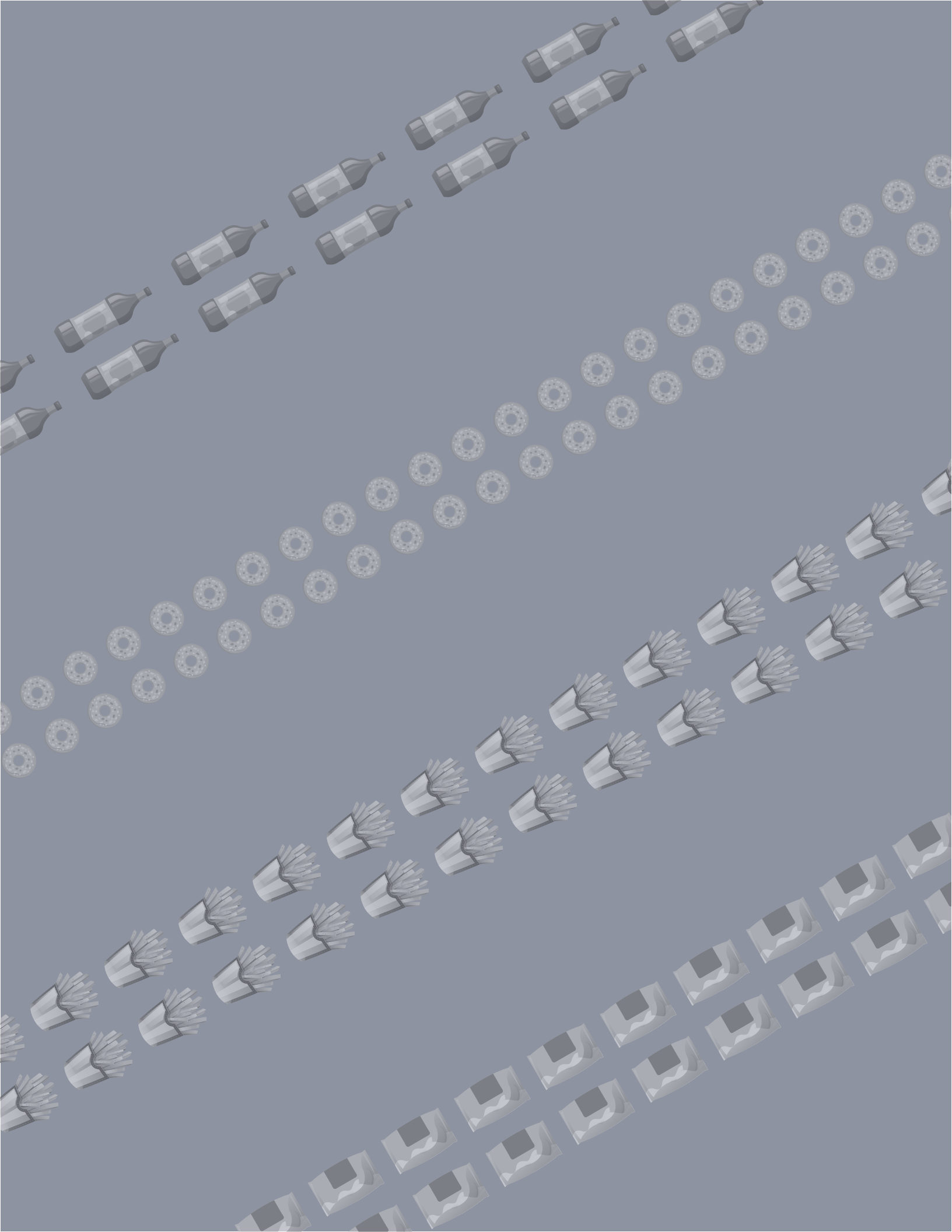
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# Summary

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The Pan American Health Organization (PAHO) convened a two-day Regional workshop on regulatory impact analysis for the development of policies to eliminate industrially-produced trans-fatty acids in the Americas in order to discuss pre-regulation analyses that can support and help guide the process to develop an IP-TFA elimination policy. The specific objectives of the workshop included identifying the need to perform a pre-regulation analysis to support and guide IP-TFA elimination policies; discuss possible models for pre-regulation analysis pertaining to IP-TFA elimination policies or similar food-regulatory policies; and define essential elements and information gaps pertaining to the preparation of pre-regulation analyses. Government officials in charge of food regulation, preparation of regulatory impact analysis, and nutrition policies, from Argentina, Brazil, Costa Rica, Guyana, Jamaica, Mexico, and Paraguay participated in the workshop. In addition, staff from the Anaas foundation, CARICOM's Regional Organization for Standards and Quality (CROSQ), Global Health Advocacy Incubator (GHAI), NCD Alliance, Resolve to Save Lives (an initiative of Vital Strategies) (RTSL), and Salud Justa-Mexico also attended the meeting.

The first day of the workshop provided technical information on available policies to eliminate IP-TFAs from the food supply and activities related to their implementation. In addition, there was discussion of key elements needed to prepare pre-regulation analyses to support and guide the adoption of food-related regulatory measures and country case studies related to IP-TFA policies. The second day of the workshop provided technical aspects of the different economic models that may be used to prepare pre-regulation analyses.

Both days included plenary discussions and the development of key aspects of a pre-regulation analysis in the context of policies aiming to eliminate IP-TFA from the food supply.

Materials prepared for the workshop included: pre-workshop assignment for government officials, discussion questions for the fishbowl exercise, and guiding questions for the exercise on building a pre-regulation analysis.

WHO's recommended elimination policy 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) in all foods. The recommendations are the basis for the REPLACE action package, which contains six modules to help countries implement IP-TFA elimination policies. The modules encourage countries to review dietary sources of IP-TFA and the

landscape required for policy change; promote the replacement of IP-TFA with healthier fats and oils; legislate or enact regulatory actions to eliminate IP-TFA; assess and monitor trans-fat content in the food supply and changes in trans-fat consumption in the population; create awareness of the negative health impact of trans fats among policy-makers, producers, suppliers, and the public; and enforce compliance with policies and regulations. Other key steps in the development of a policy are: assessing the evidence of the magnitude of the problem, mapping governmental authorities for regulatory-related activities, collecting and analyzing existing law, and outlining the need for procedural requirements.

Key aspects that led to the successful drafting, adoption, and implementation of IP-TFA elimination policies in Chile and the USA, for instance, include: using national or international evidence to support the need for an elimination policy, considering changes in health and/or nutrition-related policies, having a multisectoral working group, providing technical assistance to producers and importers, and conducting a pre- and post-regulatory evaluation, among others.

In the context of health, various economic models may be used to evaluate costs and/or outcomes of one or more policy alternatives. Cost-benefit, cost-effectiveness, cost-utility, and cost-consequence analysis, which measure different outcomes, are economic models that can be used to assess the possible impact of IP-TFA elimination policies.

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Information collected before and during the workshop revealed that four countries (Argentina, Brazil, Costa Rica, and Mexico) have laws or regulatory measures that mandate preparation of a pre-regulation analysis evaluating aspects of a food-related regulatory policy proposal. Two countries (Jamaica and Paraguay) have a guideline on pre-regulation analysis.

Most government officials identified the high content of IP-TFA in processed and ultra-processed food products and/or the high intake of the substance as the problem needing policy action. Furthermore, some possible solutions discussed included the adoption of recommended WHO/PAHO IP-TFA elimination policies, development of public health campaigns, and amendment of existing complementary measures (e.g. regulation of nutrition/health claims), among others. Limiting IP-TFA content to no more than 2% of total fats in all foods and/or a ban on PHO as an ingredient was the most cited option by government officials.

Pre-regulation analysis, though not RIA per se, is a practice in the Region that helps countries develop evidence based IP-TFA policies. However, it was also emphasized that not having an in-depth economic or pre-regulation analysis should not preclude the development and proposal of an IP-TFA elimination policy.



# Introduction

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Industrially-produced trans-fatty acids (IP-TFA) are commonly used by food manufacturers 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 acid (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.

Although some improvement has been seen in the Region of the Americas regarding IP-TFA restriction in foods, 27 countries have not yet adopted PAHO/WHO's recommended policy. The most recent effort from WHO is the REPLACE action package (2018), the result of collaboration between WHO and Resolve to Save Lives. The package recommends that IP-TFA content in all foods should not exceed 2% of total fats and/or a ban on the production of PHO as an ingredient in all food. The action package calls for the development of evidence-based policies.

Evidence-based policies can be achieved through the preparation of pre-regulation analyses. Analyses of regulatory impact are recommended by the Organization for Economic Cooperation and Development (OECD) and may be required to present

a food-regulatory measure. A pre-regulation analysis reinforces the transparency of regulatory decisions and justifies them, and it builds public trust in regulatory institutions and their decision makers. A pre-regulation analysis is a framework for assessing the possible effects (including direct and indirect costs) of a new or modified regulation. It is a structured process that includes consultations with all stakeholders that may be affected by the regulation, systematically evaluates benefits and costs early in the decision-making process, and allows for the introduction of performance indicators to track policy effectiveness over time. Basic components of a pre-regulation analysis include identification of the problem and the different policy options to solve it, definitions of baseline conditions, predictions of possible reactions to policies, cost-benefit evaluation, and other supplementary analyses, when necessary.

Some of the countries that have adopted IP-TFA policies have analyzed the possible impact of these regulations on health, the economy, and the environment. For example, the United States of America estimated that adopting a policy that partially bans PHOs would have a net economic benefit of approximately \$130 billion. Some other countries have not conducted a pre-regulation impact assessment, but have guidelines, toolkits, or processes to systematically evaluate various alternatives when preparing a food-related regulatory measure.

10 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 impact analysis for the development of policies to eliminate industrially-produced trans-fatty acids in the Americas, aiming to: identify the need to perform a regulatory impact analysis of IP-TFA elimination policies in the countries of the Region; discuss the possible regulatory impact of IP-TFA elimination policies and other similar policies to regulate food content; define essential elements to perform this analysis; and define information gaps and essential elements that countries need to complete pre-regulation analyses.

Workshop participants included government officials in charge of food regulation, preparation of pre-regulation analyses, and nutrition policies, from Argentina, Brazil, Costa Rica, Guyana, Jamaica, Mexico, Paraguay, as well as staff from Anaas foundation, CARICOM's Regional Organization for Standards and Quality (CROSQ), Global Health Advocacy Incubator (GHAI), NCD Alliance, Resolve to Save Lives (an initiative of Vital Strategies) (RTSL), and Salud Justa-Mexico.

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

## Methods

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During the morning of the first day of the workshop, staff from RTSL presented the REPLACE technical package and available policy options to eliminate IP-TFAs from the food supply. In addition, staff from PAHO's legal office gave a presentation on the key elements of a pre-regulation analysis and the basis for preparing one. Later in the morning, there were plenary discussions about models of pre-regulation analyses. In the afternoon, NCD alliance staff presented examples of countries that have successfully adopted IP-TFA policies. Later, government officials used pre-prepared guiding questions to define a problem, and objectives to solve it in the context of development of IP-TFA elimination policies. They also presented the results of their discussion and answered questions from the audience.

During the morning of the second day, PAHO staff from Health Systems and Services presented on the methods to estimate the economic impact of IP-TFA, followed by plenary discussions. In the afternoon, government officials used pre-prepared guiding questions to analyze possible policy options to eliminate IP-TFAs, selected one, presented the results, and answered questions from the audience.

# 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 TFA and the landscape for required policy change	the replacement of industrially-produced TFA with healthier oils and fats	or enact regulatory actions to eliminate industrially produced TFA	and monitor TFA content in the food supply and changes in TFA consumption in the population	awareness of the negative health impact of TFA among policy-makers, producers, suppliers and the public	compliance with policies and regulations

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. It is important to emphasize that: a) evidence-based elimination policies are desirable, but a lack of information on the economic impact of a proposed measure should not preclude development and adoption of an elimination policy; and b) the main objective of an elimination policy should be clearly stated in order to ensure there is no misinterpretation.

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. Some of the pros and cons of each recommended policy are described in Figure 2.

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

	TFA limit	PHO ban
<b>PROS</b>	<ul style="list-style-type: none"> <li>• TFA can be tested in lab</li> <li>• Addresses TFA from oil refinement (depending on how TFA is defined)</li> <li>• Some countries already have TFA limits for other policies (e.g. labeling)</li> </ul>	<ul style="list-style-type: none"> <li>• Targets top of food supply chain</li> <li>• Simple regulatory process in some countries</li> <li>• Enforcement can rely on ingredients lists (if reliable)</li> </ul>
<b>CONS</b>	<ul style="list-style-type: none"> <li>• Need capacity to test TFA, or reliable and mandatory labeling</li> <li>• Likely regulates further down the food supply chain</li> <li>• Can leave populations that consume higher levels of TFA vulnerable</li> </ul>	<ul style="list-style-type: none"> <li>• Cannot test for PHO in lab</li> <li>• Many PHO producers, informal markets, or imported packaged goods can pose challenges</li> <li>• Difficult to control partial hydrogenation processing done outside of the country</li> </ul>

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

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.

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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.

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, processing 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, type of sanction, etc.

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.

## ***Regulatory impact analyses: Definition, objectives, and need***

Regulatory impact analyses (RIA), considered a good regulatory practice, assess and measure the potential benefits, costs, and effects of implementing new regulations or changing existing ones.

In health settings, RIA require a thorough evaluation of regulatory and/or non-regulatory options (including no action) to ensure the best achievable state of health for the population. Within the context of the regulatory process, RIA assess the possible impacts of a regulation or policy. To do so, the objective of the regulation must be defined; for example, a regulation may have the objective of registering a food product, instructing the population, or empowering a government agency to conduct certain activities, among other purposes. In addition, RIA consider the nature of the regulation (legal vs. administrative), its intended duration (temporary vs. permanent), its consistency with other regulations of the same type, and its direct and indirect economic, health-related, social, and environmental costs. RIA also aim to determine the best regulatory option to address the problem at hand, while ensuring that all stakeholders have been given the opportunity to express their opinions on the matter and suggest possible solutions.

RIA not only evaluate regulatory proposals and their possible effects in a systematic, comprehensive, and multidisciplinary manner, but also assess their effectiveness by monitoring short- and/or medium-term outcome indicators.

## *Regulatory impact analyses: Examples*

One of the presentations led by NCD Alliance discussed the cases of six countries that have adopted successful IP-TFA elimination policies. The following sections will provide greater detail on cases of countries included in the presentation and that pertain to the Region of the Americas: Chile and USA.

The regulatory process in Chile, conducted with a view to IP-TFA elimination, began in 2006, when the inclusion of TFAs on nutrition labels was made mandatory. In 2009, it was established that IP-TFA content could not exceed 2% of total fat in all foods. This measure, developed cooperatively by the Ministry of Health and other government agencies, was adopted in a two-stage process. The first stage established a two-year period for vegetable oils and margarines to comply with the regulation; the second stage set a 5-year deadline for all other foods. The evidence used to develop the regulations was obtained from studies conducted in the United States, Canada, and Argentina. Once the regulation was defined, the Ministry of Health developed the Plan of Action to Reduce the Intake of Industrially-produced Trans-fatty Acids in Chile as part of an established regulatory process. Years later, the collected evidence shows high adherence to this measure by industry. This success is attributed to the involvement of external actors, including academia and industry; multisectoral coordination; a wide-ranging political framework conducive to regulation; and broad institutional capacity.

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The regulatory process for IP-TFA elimination in the U.S. began in 2006, when the inclusion of TFAs on nutrition labels was made mandatory. This led to a reformulation of products and decreased intake of TFAs; states and cities began to adopt their own IP-TFA limits or bans. In 2013, the FDA made the preliminary decision to revoke the status of partially hydrogenated oils (PHOs) as generally recognized as safe (GRAS). A final decision to this effect was adopted in June 2015, and most foods on the market are expected to be PHO-free by 2020–2021. During this process, stakeholders had the opportunity to comment on the regulation through consultation channels. The FDA adopted this regulation taking into account a thorough investigation into the health effects of IP-TFA and PHO, as well as a series of stakeholder contributions received during the public comment-gathering period. The FDA conducts monitoring activities to determine IP-TFA exposure through inspections of production facilities, label review, and sample analysis.

The examples cited during the presentation demonstrate that the reduction and/or elimination of IP-TFAs is both politically and technically feasible. It is recommended that regulations to reduce and/or eliminate IP-TFAs be evidence-based, take international experiences into account, involve different stakeholders, and contain pre- and post-implementation evaluation mechanisms.



## *Analysis of economic impact in the context of industrially-produced trans-fatty acids*

This presentation discussed the fundamental of economic evaluation models, as well as their possible uses. Different types of economic evaluations can compare one or more policy alternatives, focusing on the costs and/or consequences (for example, years of life lost, quality-adjusted life years, etc.) associated with a disease. The type of economic evaluation to use depends on the objective at hand. However, it is advisable that the costs and consequences of several alternatives be evaluated when seeking to develop a health policy. Economic evaluation methods that allow assessment of costs and consequences include cost-benefit, cost-effectiveness, cost-utility, and cost-consequence analyses, all of which differ significantly among one another in terms of the assessed outcome (monetary outcome, QALYs, DALYs).

Cost-benefit analysis is based on welfare economics, takes supply and demand into account, presumes that people seek to maximize their benefit, and is the most widely used method to compare policies across sectors and/or interventions. The outcome of interest is a monetary unit or metric, and the analysis presumes that the government is willing to pay to obtain a health benefit. Cost-effectiveness analysis, a more specific method for health cost analysis, ranks interventions taking into account their ratios by effect (e.g., life years gained, number of events avoided, etc.). The outcome is a health effect (QALYs or DALYs), and the analysis does not allow simultaneous evaluation of several outcomes nor of related decisions and/or interventions. Cost-utility analysis is very similar to cost-effectiveness analysis but allows evaluation of different outcomes and different related decisions and/or interventions.

Economic costs are not necessarily related to financial expenditure, but rather to opportunity cost. In turn, the costs associated with health, human resources, technology, infrastructure, climate, etc. could be direct or indirect in the health, environmental, social, or other fields. Cost determination may be carried out from a systematic standpoint (e.g., national health system-wide), from an individual standpoint (e.g., patient-specific), or both.

Outcomes can be measured through calculation of mortality, morbidity, or both.

# Country information

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## Argentina

### *Landscape of Pre-regulation Analyses*

Adoption of any policy related to food regulation is contingent upon compliance with the requirements set by the National Food Commission (*Comisión Nacional de Alimentos*, CONAL). This technical agency was established by Decree 815/99 and is responsible for all advisory, support, and monitoring tasks of the National Food Control System (*Sistema Nacional de Control de Alimentos*). CONAL, which operates under the purview of the Ministry of Health and Social Development, is made up of the National Service of Agri-Food Health and Quality (SENASA) and the National Administration of Drugs, Foods, and Medical Technology (ANMAT), represented by the National Food Institute (INAL); the Ministry of Agriculture, Livestock, and Fisheries; the Department of Health Regulation and Management; representatives of the consumer defense enforcement authority; and the Provincial Health Authorities and Government of the Autonomous City of Buenos Aires.

CONAL evaluates the short-, medium-, and long-term feasibility as well as the possible impacts to the economy (benefits for the region, country, sector, etc.), trade (benefits or barriers), and industry (feasibility of in-country manufacturing, type of companies or ventures, cost variation, etc.) of the proposal. It also evaluates its consistency with national and international standards. Finally, CONAL determines whether the proposal is justified from the standpoint of health (a key condition for its adoption).

The process of presenting a food regulation policy involves an official request to present the proposal to CONAL; corroboration of compliance with proposal requirements by the CONAL secretariat; evaluation by CONAL; a consultation with the Advisory Council of the National Food Commission (CONASE); a 30-day public consultation; any necessary modifications stemming from the consultation; and final approval by CONAL.

For the IP-TFA policy proposed in 2010, Argentina worked intersectorally with the Ministries of Health, Agriculture, Science and Technology; SENASA; the National Institute of Health and Industrial Technology (INTI); chambers of commerce; and the Argentine Trans Fats Association (ASAGA), among other entities.

## ***Background, Problem and Objective***

Article 155, paragraph 3, of the Food Code of Argentina established in 2010, through Joint Resolution 137/2010 and 941/2010, that the TFA content of foods could not exceed 2% of the total fat content in vegetable oils and margarines intended for direct consumption or 5% of the total fat content in other foods. These limits do not apply to fats of ruminant origin, including milk fat. The regulation came into effect in 2014.

The problem that led to the regulation of IP-TFA was their high content in food products, their excessive intake by the population, and their impact on the development of noncommunicable diseases.

Given this situation, a working group was formed in order to develop a policy proposal. This group used international regulations (EU, FDA NO GRAS, CODEX), national standards (CAA), and regional regulations (MERCOSUR); publications of official agencies, such as FAO, PAHO/WHO; proof of approval in other countries; and national health statistics, such as leading causes of death and risk factors, to substantiate the need to impose limits on IP-TFAs.

In turn, the Federal Food Control Program developed a federal intersectoral strategy to strengthen the promotion, enforcement, and surveillance of the proposed reduction in trans-fat content. This strategy included four key areas:

- 1- ***Monitoring program for trans-fat content in food***, with the overarching objective of collecting information about trans-fat content in foods.
- 2- ***Federal coordination***: Since Argentina is a federal country, food control is based on coordinated work among the authorities with jurisdiction at the national, provincial, and municipal levels.
- 3- ***Intersectoral meetings***: as described in item 5.
- 4- ***Education and communication***: To raise consumer awareness and educate the private sector on this matter, educational materials promoting awareness and efficient communication were published. A guideline for small and mid-sized businesses was also published.

In addition, within the framework of the Federal Food Control Program, ANMAT Ordinance 10873/2017 established the Comprehensive Plan for Inspection of Food Establishments, Food Products and Food Contact Materials (PIF). This Plan sets forth the Control and Surveillance Program for the Reduction of Trans Fat Content in Foods.

The problem identified in the existing regulations (2010) was that they did not explicitly mention applicability to margarines and vegetable oils used as raw materials. Conse-

quently, there was some confusion about the scope of the regulations. The cause was determined as failure to explicitly stipulate that the regulations applied to margarines and vegetable oils used as raw materials.

The objective identified was to amend the 2010 policy so that it would explicitly mention its applicability to margarines and vegetable oils used as raw materials.

## ***Policy Options and Justification***

Possible policy options to address the problem

<b>Policy options</b>	<b>Possible effects</b>
Maintain existing regulations	No effect on clarifying the scope of the policy.
Awareness-raising campaign	Would not address the fact that the policy does not explicitly cite its applicability to margarines and vegetable oils used as raw materials.
Set new limits for margarines and vegetable oils used as raw materials.	Could lead to regulatory excess and cause confusion in the public, because two different types of limits would exist.
Amend existing regulations	Less likely to confuse the public, while explicitly defining the scope of the policy.

After assessing all policy options, the decision was made to amend the existing regulations, concluding that this was the best course of action to address the problem, taking into account the aspects required by CONAL.

The analysis by the National Food Commission and its Advisory Council led to modification of article 155, paragraph 3, of the Food Code of Argentina, as per filing *EX2018-50446539-APN-DERA#ANMAT* of the Ministry of Health and Social Development, Department of Regulation and Health Management. Article 155, paragraph 3, now reads “2% of total fats in vegetable oils and margarines intended for direct consumption and 5% of total fats in other foods, including ingredients and raw materials. These limits do not apply to fats of ruminant origin, including milk fat.” It should be noted that the new regulations are not yet in force.

Monitoring mechanisms and costs associated with implementation of the proposed regulation are already established as part of the current regulation.



## *Landscape of Pre-regulation Analyses*

To adopt a food-related policy, as proposed by the National Sanitary Surveillance Agency (ANVISA), it is necessary to prepare a regulatory impact analysis (RIA).

The process of preparing an RIA is participatory and includes a working group that encompasses civil society, government officials, academia, industry, etc. It also includes an in-depth situation analysis that can be used when drafting the proposed policy.

An RIA document is subject to consultation where the public can provide feedback. A policy option is selected considering existing regulatory measures, possible impacts on health (e.g. deaths averted) and the economy (e.g. reduced medical expenditure), and public feedback, among other factors. A policy is then drafted and a resolution is published.

## *Background, Problem, and Objective*

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Brazil is currently in the process of developing a policy to restrict and/or eliminate industrially-produced trans-fatty acids (IP-TFA) from the food supply. The information below is based on the current process in the country.

Voluntary measures to reduce IP-TFAs started in 2008. In addition, it is mandatory for IP-TFAs to be included in nutrition labels; however, IP-TFA consumption is higher than recommended by the Pan American Health Organization/World Health Organization (PAHO/WHO).

The identified problem was that the population's caloric intake of IP-TFAs exceeds 1% of total daily caloric intake. The situation not only negatively impacts the population's health, but also the financial resources of the system. For instance, 18,000 deaths were associated with excessive consumption of IP-TFAs (2010), and costs associated with the substance came to about 37 billion reales in 2015. Causes associated with the problem include the production of processed foods containing IP-TFAs, the relatively low cost of foods containing IP-TFAs, the palatability of these foods, consumer unawareness related to IP-TFA consumption, limited education campaigns about IP-TFA-related harm, difficulty of determining the presence and quantity of the sub-

stance in products, due to limited regulatory measures, and subpar oil-refinement techniques, among others.

The objective was to reduce IP-TFA consumption in the population to less than 1% of total daily caloric intake. Furthermore, specific objectives may include: elimination of products that include IP-TFAs; limit IP-TFA content to no more than 2% of total fat in oils; ensure that the public has clear information to discern the presence and quantity of IP-TFAs in products.

## *Policy Options and Justification*

The considered policy options and their possible effects are listed below. None of the policy options described below applies to ruminant trans fats, and not all types of packaged foods are included.

<b>Policy options</b>	<b>Possible effects</b>
Limit IP-TFA content to no more than 2% of total fats in oils and fats and to no more than 5% of total fats in the rest of products.	Limited health impact due to high IP-TFA threshold; eliminate IP-TFAs from other sources, except from partially hydrogenated oils (PHOs); alignment with nine countries that have a similar policy; limited desire to develop technology to ameliorate the problem; no effect on cost for industry to implement the measure, but high cost for government, due to variety of products that need to be monitored; limited amount of time given for industry to comply with regulatory measure.
Limit IP-TFA content to no more than 2% of total fats in all foods.	Intermediate health impact because of low IP-TFA threshold; eliminates all non-PHO IP-TFAs; alignment with 34 countries that have a similar policy; some desire to develop technology to ameliorate the problem; moderate cost for industry due to reformulation and some cost for government, due to monitoring-related activities; adequate time provided for industry to comply with regulatory measure.
Ban of use and production of PHOs	Considerable health impact because it eliminates a major source of IP-TFAs; eliminates only trans fats from PHOs; alignment with three countries that have a similar policy; major desire to develop technology to ameliorate the problem; costs for government if it is necessary to monitor products not covered by this policy; longer than usual time provided to comply with regulatory measure.

The preferred proposed policy limits IP-TFA content to no more than 2% of total fat in all products and includes a PHO ban. This will ensure maximum protection for the population.

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

## **Costa Rica**

### *Landscape of Pre-regulation Analyses*

In Costa Rica, Law 8220 – Protecting citizens from excess administrative requirements and procedures (2002) (revised 2011) – mandates a cost-benefit analysis for any nationwide regulation proposals which include procedures, requirements, and/or procedures with which citizens must comply before the public administration. In addition, there is also a Central American guide to good practices which will soon include a manual on regulatory impact analysis. When proposing a subregional regulation, there is no requirement to present a cost-benefit analysis.

Usually, the Ministry drafts a proposal that includes a cost-benefit analysis, which is reviewed by a special committee. Subsequently, an internal review is carried out by the general directorate and by the Ministry of Industry and Commerce, which issue a binding opinion. Finally, the proposal is submitted for public consultation, modified if necessary, and adopted.

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### *Background, Problem and Objective*

Voluntary restrictions on trans-fatty acids have been in force in the country since the 1990s. Some studies have reported that TFAs account for less than 1% of the total daily calorie intake. Nevertheless, cardiovascular disease accounts for 29.3% of all deaths.

The problem identified was that the country does not have a specific regulation for TFAs nor a limit on the IP-TFA content of foods. Possible consequences include a lack of government monitoring to estimate the amount of IP-TFAs in food and the exposure of specific groups (e.g., low-income populations) to IP-TFAs. Possible causes of the problem include existing voluntary measures and failure to monitor IP-TFAs.

The objective is to control and monitor the IP-TFA content of packaged foods.



## Policy Options and Justification

The policy options considered, and their possible effects, are cited below.

Policy options	Possible effects
Limit IP-TFA content to no more than 2% of the total trans-fat content of foods at the subregional level.	Modify the current Central American technical regulations on nutritional labeling to make them mandatory and include TFA content on nutritional labeling (amending the regulation would be a slow process, but the cost of implementation through labeling would be low); modify the Central American regulation that sets limits for these nutrients; this measure would be slow to adopt, due to the long consensus process required.
Nationwide ban on partially hydrogenated oils (PHOs)	Build a team to conduct a cost-benefit analysis; monitoring could be relatively less expensive (through labeling); no regulation on international products; the consensus process would be shorter.
International ban on partially hydrogenated oils (PHOs)	Low cost of implementation (monitoring through labeling); massive international impact; could lead to the creation of a Central American food registry; this measure would be slow to adopt, due to the long consensus process required.
No change to existing policy	Uncertainty regarding IP-TFA intake in the country would continue; population exposure would continue; cardiovascular diseases would continue to rise; imported products containing IP-TFAs would continue to enter the country; there would still be no monitoring system to evaluate IP-TFA content.



## *Landscape of Pre-regulation Analyses*

The country does not require a regulatory impact analysis (RIA) to adopt a food-regulatory policy.

## *Background, Problem, and Objective*

A presidential commission on NCDs has renewed its commitment to work on industrially-produced trans-fatty acids (IP-TFAs) and is committed to tackling this cardiovascular disease risk factor. The country conducted a food consumption survey in 2002 to assess the intake of oils, fats, and carbohydrates. Since then, no consumption survey has taken place.

The identified problem was that the country has a high noncommunicable disease (NCD) rate; especially cardiovascular disease. Consequences of the problem may include an increase in CVD-related deaths and disability. In addition, 70% of the health budget is spent on NCDs. The causes of the problem may include high consumption of IP-TFA-containing products, physical inactivity, and lack of knowledge about IP-TFAs.

The overall identified objective may be to limit the IP-TFA content to no more than 2% of total fats in foods and to ban the use and production of partially hydrogenated oils (PHOs). In addition, overall complementary objectives may include assessing IP-TFA intake in the population, increase physical activity, and increase awareness of IP-TFA use and consumption.

## *Policy Options and Justification*

Due to the high rate of ischemic heart disease, the country may consider limiting IP-TFA content in foods, banning PHOs, and developing an education campaign for the public.

Nevertheless, due to the current burden of disease and its relationship to IP-TFAs in food and population intake (information from international sources), a food-regulatory policy may be most appropriate. Barriers may include the food industry questioning the measure, limited laboratory capacity, and limited resources for implementation, including monitoring-related activities.

## Jamaica

### *Landscape of Pre-regulation Analyses*

A specific governmental guideline must be followed to be able to submit a food-regulatory policy proposal to Cabinet. These guidelines include a consultation with all stakeholders and an analysis of possible alternatives to solve the problem. There is not a standardized process to prepare RIA; however, the time to prepare one is estimated to be 6 months.

### *Background, Problem, and Objective*

In 2007, in a meeting with the Member States of CARICOM, Jamaica agreed to reduce and eliminate trans-fats from the population's diet. This was further reinforced in 2017 in a Caribbean Public Health Agency (CARPHA) high-level meeting that discussed the development of a roadmap to reduce industrially-produced trans-fatty acids (IP-TFAs) in the food supply.

The identified problem was the high IP-TFA content in processed foods (international and local products). Consequences may include increased consumption of the substance in the diet, development of cardiovascular disease, financial burden on the health system due to increased expenditure to treat IP-TFA-related diseases, lower quality of life, and reduced productivity. Causes related to the problem may include factory-like production of low-cost processed foods, unregulated food production in the country, presence of imported IP-TFA-containing products due lack of existing regulation, and presence of fast-food restaurants. The identified objective was to reduce the population's exposure to IP-TFA-containing products.

## Policy options and justification

The considered policy options and their possible effects are listed below.

Policy options	Possible effects
Maintain existing IP-TFA policy	No change in the prevalence of cardiovascular disease or possible increase; does not address the problem cited above.
Industry self-regulation or voluntary reformulation	Manufacturers may not be compliant due to lack of sanctions; some companies may opt out because it is not mandatory; companies may reformulate their products in order to compete.
Develop a mass education campaign for the public	This may only help a very limited segment of the population (persons with disposable income) and may require a significant amount of money; it may promote industry reformulation; it may require costly investment by government.
Legislation (overall legislation effects, effects of IP-TFA limits in foods, and PHO ban)	<p><b>Overall legislation:</b> All industry would be subject to the requirement; requires approval, implementation and monitoring, and enforcement mechanism; decreases risk of dumping; may require increase in resources to maintain monitoring and enforcement activities; may require mandatory nutrition facts panel and FOPL; possible high return on investment in health.</p> <p><b>IP-TFA limit in food:</b> requires a definition of which foods this will be applied to (all foods or packaged foods) as well as specific limits; if considering packaged foods, it may leave a vast amount of foods out, since Jamaica has a large informal food sector.</p> <p><b>Ban on PHO:</b> enforcement mechanism at the upper level may be simple; important IP-TFA source being eliminated; possible amendment of Food and Drug Act may be required; possible amendment of a regulation to include PHO as a substance not safe for consumption; may incentivize reformulation; may have an effect on international markets (banning products containing this substance)</p>

The preferred policy option is a combination of a 2% limit on all foods and a PHO ban, which offers the best protection for the population; it addresses the loopholes between a ban and simple limit.

 **Mexico**

## *Landscape of Pre-regulation Analyses*

Mexico has the General Regulatory Improvement Law, the Federal Law on Metrology and Standardization, several agreements and programs for regulatory improvements, and regulatory impact analysis, among other established actions to evaluate food policy measures. One example is the guideline for improvement of school meals, proposed by the Ministry of Health and Education and reviewed by the Regulatory Improvement Commission. This agency analyses the proposal to assess possible alternatives, evaluates the included monitoring and compliance activities, and verifies that the public consultation process is conducted properly.

## *Background, Problem, and Objective*

Commitments to promoting healthy eating include the National Strategy for the Prevention of Overweight and Obesity and Diabetes, the Plan of Action for the Prevention of Obesity in Children and Adolescents, and a nationwide regulation for beverages provided in schools. In addition, the General Health Law (which mentions the importance of good nutrition, as well as nutritional labeling) and NOM-051 (the commercial and health information standard) set guidelines for the regulation of front-of-package labeling and for the distribution of food and beverages prepared and processed in schools.

The problem identified was the high intake of TFAs by the population. Some of the consequences related to the problem could include a high prevalence of overweight and obesity, deaths from coronary heart disease, negative effects on food systems due to the mass production of processed foods, and coronary heart disease leading to increased absenteeism. Causes related to the problem could include high intake of processed and ultra-processed foods by children and adolescents, as well as by low-income populations. Information on the problem and related factors could be found in the National Health and Nutrition Survey (ENSANUT), the national weight and height registry, and economic analyses of the impact of obesity.

The objective identified was to provide the necessary information for the public to increase their intake of healthy foods and discourage the intake of TFA containing foods.

## *Policy options and justification*

The options discussed to address the problem include developing campaigns to raise awareness of the harmful effects of TFA intake; intersectoral work with food programs to reduce the TFA content of foods; updating existing legal and/or regulatory instruments; raising taxes on foods with high energy density; and establishing a national registry of products that violate related standards.

TFAs could be regulated through a sanitary intervention – specifically, one regulating front-of-package labeling. This would provide the greatest measure of protection to the population.

 **Paraguay**

## *Landscape of Pre-regulation Analyses*

Paraguay has a good regulatory practices guideline, which includes methodology for risk and impact assessment of food regulation proposals. Such a proposal could be developed by the National Food and Nutrition Institute (*Instituto Nacional de Alimentación y Nutrición*, INAM) and should include evidence on the problem, an analysis of consistency with existing regulations, information on the regulated sector, etc. Once developed, the proposal goes through a series of consultation processes, both internal (other Ministry of Public Health agencies or other government entities) and external (general population).

## *Background, Problem, and Objective*

Paraguay currently does not have any policy to regulate the TFA content of food. Work is ongoing on a national regulation that would limit the IP-TFA content in foods of both locally produced and imported foods. At first, this regulation would mandate that the TFA content should not exceed than 2% of the total fat content of vegetable oils and margarines destined for direct consumption and 5% of the total fat content of other foods. The second stage would impose a 2% limit for all products. Additionally, there may be a third stage in which partially hydrogenated oils (PHOs) are banned.

There are only limited data on the TFA content of local foods. However, it is known from local studies that *chipas* made with PHOs and cookies tend to contain high TFA levels. There are no data on TFA intake in the country. However, data from the national risk factor survey stipulates that noncommunicable diseases have been among the five leading causes of death since 2004. It can be concluded that TFAs are among the critical nutrients that contribute to disease development.

Some measures taken regarding the regulation of TFAs include mandatory statements on the presence of these nutrients in labeling and the promotion of healthy foods by adding dietary guidelines to the primary education curriculum. In addition, the country has made international commitments to the reduction of trans fats.

## *Policy Options and Justification*

Policy options to restrict the content of TFAs were not evaluated, since a nationwide technical regulation to gradually reduce the TFA content of packaged foods is under development.

The above-mentioned technical regulation proposal is advantageous since the first stage could be adopted immediately, while giving the industry enough time to reformulate products and change labels. In addition, a grace period will allow government agencies to prepare for implementation and monitoring of the regulation, as well as to devise an awareness campaign for the general public. Regarding impact, these regulations are expected to help prevent the development of cardiovascular diseases and deaths attributable to them. Likewise, a reduction in public spending on treatment of and/or hospitalization for cardiovascular diseases is expected, as are lower absenteeism rates.

INAM needs equipment for quantification of trans fats; a laboratory is already available, as are technicians willing to be trained in new modalities. The cost of the necessary equipment has been estimated at approximately US\$ 250,000. As an alternative, agreements could be made with national laboratories and/or monitored companies could be made to cover part of the expenses.



# CROSQ Information

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## *CARICOM Regional Organization for Standards and Quality (CROSQ)*

### **Landscape of Pre-regulation Analyses**

CROSQ discussed the importance of good regulatory practices and how they relate to pre-regulation analyses. The organization highlighted the importance of preparing a pre-regulation analysis to evaluate the possible impacts that a policy restricting IP-TFA might have on World Trade Organization (WTO) agreements. In addition, the organization suggested that preparing pre-regulation analyses may help a country's lawmakers pass a technical regulation more readily.

Regional guidance was developed in order for CARICOM countries to apply good regulatory practices. This guidance may be published soon.

### **Background, Problem, and Objective**

CROSQ works with 15 Bureau of Standards in the Region and encourages countries to adhere to and/or maintain WTO agreements on Sanitary and Phytosanitary Measures and on Technical Barriers Trade. CROSQ is aware that the importance of preparing a pre-regulation analysis is well understood by ministries of trade and foreign affairs around the Region. Nevertheless, such analyses are not very common because countries may perceive them as time-consuming, requiring a lot of data, and complex.

The identified problem was that foods contain a high content of partially hydrogenated oils (PHOs), which in turn increases the probability of developing cardiovascular disease (i.e. heart disease). This negatively impacts the economy of countries (increase in overall health expenditure) and individuals (increase in out-of-pocket medical expenses), leading to a less productive workforce and a less competitive business environment in the country. Causes of the problem may include the low cost and ready availability of PHO and non-PHO IP-TFA, as well as the limited regulatory measures pertaining to their production and use.

The objective is to remove IP-TFA from the food supply. This may be done by developing national roadmaps and strategies to tackle NCDs at the government level. For the ministries of health and/or trade, specific objectives may include ensuring sufficient financial and human resources for a national technical regulatory team, and setting

up an intersectoral working group for government officials and industry to discuss this matter. In addition, governmental bodies may set up monitoring and enforcement mechanisms and develop public health campaigns for the population to be made aware of the negative effects of IP-TFA consumption.

## Policy Options and Justification

The considered policy options and their possible effects are listed below.

Policy options	Possible effects
Maintain existing IP-TFA policy	No change in the prevalence of cardiovascular disease and other noncommunicable diseases associated with IP-TFA consumption
<b>Create information and education campaign to raise public awareness</b>	Industry and consumers will be well informed of the harms of IP-TFA and alternatives (but it would not work by itself)
<b>Non-intrusive government actions</b>	Non-intrusive government actions may create a new market with healthier products (but it would not work by itself)
<b>Develop a new standard for voluntary food certifications and conformity assessments</b>	Consumers may be confused about the different voluntary food certifications. Also, this may create a different playingfield for domestic and international products.
<b>Incentive and non-incentive actions by government (e.g. tax breaks)</b>	This may create a financial deficit for the government, if there is considerable investment.
Self-regulation and voluntary codes of practice	Companies may not be compliant if there is no credible association/entity that can help them self-regulate.
Co-regulation by government and private industry	May be challenging to engage with all companies and have a single model for cooperation.
<b>Prescriptive regulations</b>	This option will work, but only if there is enough time for the companies to adjust.

CROSQ-recommended countries may have a combination of various policy options (**highlighted in bold**) to protect consumers and expand business at the same time.

# Conclusion and recommendations

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## Conclusion

The workshop provided a space to learn about the pre-regulatory analysis that countries engage in as a part of the process of developing a food-regulatory policy, specifically pertaining to IP-TFA elimination policies.

PAHO/WHO's recommended elimination policy is to limit IP-TFA content to no more than 2% of total fats in all foods and/or ban the production or use of PHO as an ingredient in all foods. The REPLACE action package includes important details about implementation, monitoring, and enforcement of elimination policies that countries are encouraged to follow. Development of an elimination policy proposal should include evidence that highlights the need for action and a thorough evaluation of the possible options considered, as well as the rationale for a selected option. However, developing a proposal does not require the preparation of an RIA per se. In fact, various countries that participated in the workshop have guidelines, regulations, or systems in place that allow them to systematically evaluate different policy options and assess their possible health impacts and their effects on current food-related policies and other areas. Therefore, preparing an RIA may not be necessary for an IP-TFA elimination policy proposal. In fact, preparing an RIA may unnecessarily delay the adoption of an elimination policy in some countries.

Local evidence on food content, population intake, and the economic burden of IP-TFAs was identified as an information gap that makes it difficult for countries to conduct a thorough pre-regulatory analysis or RIA needed to propose an elimination policy. International data associated with health or economic burden of IP-TFA may be used in lieu of national sources. Economic models used in health such as cost-benefit or cost-effectiveness analyses may be used to predict the economic and health-related outcomes of different IP-TFA-related policies.

The development of a sub-regional technical regulation to eliminate IP-TFAs may be an option for some countries; however, it may take longer to adopt a regulatory measure by this route than by a national regulatory measure.

Despite limited local evidence on IP-TFAs, countries have at their disposal international sources and mechanisms to evaluate the best possible option for an IP-TFA elimination policy.

## ***Recommendations:***

Based on the discussions that took place during the workshop, PAHO makes the following recommendations:

- Countries are encouraged to use in-country evidence that highlights the need for action to develop IP-TFA elimination policies. However, if no local evidence is available, international data should be used to make a case for the proposed policy.
- Countries are encouraged to go beyond PAHO/WHO's IP-TFA elimination recommendation (e.g. limiting IP-TFA content in foods to 1% of total fat).
- Countries are encouraged to adopt an IP-TFA elimination policy as quickly as possible, whether at the national or sub-regional level.
- Countries are encouraged to adopt complementary measures (e.g. front-of-package labelling) to support overall adoption of an elimination policy.
- Countries are encouraged to adopt a 2% IP-TFA limit for all foods. If some products have a 5% limit, the population will not meet the WHO recommendation to limit the intake of TFA to less than 1% of the total daily energy intake.
- Countries are encouraged to adopt an elimination policy even if their daily energy intake from trans fats is below 1%. This enables countries to take a preventive measure against a potential health problem.
- Countries are encouraged to analyze the domestic supply of IP-TFA-containing oils instead of trying to assess the content of each product. This way the country can estimate IP-TFA in the food supply.

# Appendix 1

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## Participants list

### Argentina

#### **Claudio Matias**

*Magno Food Evaluation and Registry Office,  
National Food Institute – ANMAT*

### Brazil

#### **Eduardo Fernandes Nilson**

*Acting Coordinator, Food and Nutrition Bureau  
(Coordinación General de Alimentos y Nutrición)*

### Costa Rica

#### **Alejandra Chaverri Esquivel**

*Nutritionist, Standardization and Control Unit,  
Office for Regulation of Products of Health Interest*

### Guyana

#### **Dinte Conway**

*Director, Food Policy*

### Jamaica

#### **Deonne Caines**

*Technical Officer and Nutritionist,  
National Food Industry Task Force,  
Ministry of Health and Wellness*

### Mexico

#### **Zaira Alejandra Valderrama Alvarez**

*Subdirector of Intersectoral Health Policy,  
Health Promotion Directorate*

### Paraguay

#### **Zuny Zarza**

*Chief, Regulatory Affairs Unit  
(National Food and Nutrition Institute - INAN)*

### Mexico SaludHable

#### **Erick Antonio Ochoa**

*Director, Salud Justa México*

### NCD Alliance

#### **Luis Encarnacion**

*Senior Capacity Development Officer*

### CROSQ

#### **Deryck Omar**

*Chief Executive Officer, CARICOM Regional  
Organisation for Standards and Quality*

### GHAI

#### **Vineeta Gupta**

*Director, Resolve Projects*

### GHAI

#### **Kyra Berasi**

*Legal Advisor*

### GHAI

#### **Patricia Sosa**

*Director, Latin American Programs*

### RESOLVE

#### **Aaron Schwid**

*Legal Director of Policy and Programs  
at Vital Strategies*

### Anaas

#### **Blanca Llorente**

*Research Director*

### PAHO/WHO

#### **Camilo Cid**

*Regional Advisor, Health Economics  
and Financing*

## Materials

### A. Concept note and Agenda.

#### Concept Note

#### **Regional Workshop on regulatory impact analysis for the development of policies to eliminate industrially-produced trans-fatty acids in the Americas**

*September 11-12, 2019*

*Pan American Health Organization/World Health Organization (PAHO/WHO)  
525 23rd St NW, Washington D.C., USA*

#### 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%. industrially-produced trans-fatty

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The development of evidence-based policies to eliminate IP-TFAs from the food supply is a priority for the Pan American Health Organization/World Health Organization (PAHO/WHO). The WHO REPLACE action package is a tool designed to help countries in the process of eliminating IP-TFAs; one of its modules urges countries to produce evidence for the development and monitoring of these policies.

Regulatory impact analysis (RIA) is a practice recommended by the Organization for Economic Cooperation and Development (OECD) and is required as part of the process of developing standards and regulations in several countries in the Region. It is a key step in the development of evidence-based policies. RIA reinforces the transparency of regulatory decisions and justifies them, as well as increasing public confidence in regulatory institutions and their decision makers. Some basic components of this analysis are: identification of the problem and the different policy options to solve it; definitions of baseline conditions, predictions about possible reactions to the policies, a cost-benefit evaluation, and other supplementary analyses, when necessary.

Some of the countries that have adopted IP-TFA policies have analyzed the possible impact of these regulations on health, the economy, and the environment. For example, the United States of America estimated that adopting a policy that partially bans PHOs would have a net economic benefit of approximately \$130 billion. trans-fatty.

In some countries of the Region, where policies to eliminate IP-TFAs have not yet been adopted or require improvements, completion of an RIA may be a required step in their regulatory process.

This workshop was organized to identify the need for countries to conduct this analysis and to support them at this stage, as needed, in the development or strengthening of policies to eliminate IP-TFAs.

## 2. Objectives

- Identify the need to perform a regulatory impact analysis of IP-TFA elimination policies in the countries of the Region.
- Discuss the possible regulatory impact of IP-TFA elimination policies and other similar policies to regulate food.
- Define essential elements to perform this analysis.
- Define information gaps and essential elements that countries need to complete the regulatory impact analysis.

## 3. Participants

- Government officials in charge of food regulation.
- Government officials in charge of the preparation of regulatory impact analyses.
- Government officials in charge of nutrition policies.

## 4. Location:

Pan American Health Organization Regional Office  
525 23rd St NW, Washington, DC, USA 20037

## 5. Contact:

**Dr. Fabio Da Silva Gomes**

*Regional Advisor on Nutrition and Physical Activity, PAHO/WHO*

E-mail: [gomesfabio@paho.org](mailto:gomesfabio@paho.org)

Tel: +1 202 974-369

## Agenda

### Regional workshop on regulatory impact analysis for the development of policies to eliminate industrially-produced trans-fatty acids in the Americas

September 11-12, 2019

Pan American Health Organization/World Health Organization (PAHO/WHO)  
525 23rd St NW, Washington D.C., USA

#### September 11, 2019 (Room C)

Opening session		
08:30 – 09:00	Registration	
09:00 – 09:20	Opening remarks	Fabio da Silva Gomes, Nutrition and Physical Activity Advisor, PAHO/WHO
09:20 – 9:30	Group photo	
09:30 – 09:45	Structure of the meeting (objectives, expected results, methods, agenda)	Fabio da Silva Gomes, Nutrition and Physical Activity Advisor, PAHO/WHO
9:45 – 10:25	Elimination of industrially-produced trans-fatty acids from the food supply	Aaron Schwid RTSL
10:25 – 10:40	Break	
Regulatory Impact Analysis: Definition, objectives, need and models.		
10:40 – 11:20	Presentation on the definition, objectives, and the need to perform a regulatory impact analysis	Ignacio Ibarra Legal Advisor, Health-Related Law Office of the Legal Counsel PAHO/WHO
11:20 – 12:30	<i>Fishbowl activity: Regulatory Impact Analysis models</i>	Fabio da Silva Gomes and participating countries
12:30 – 14:00	Lunch	
14:00 – 14:45	Regulatory Impact Analysis, country examples	Luis Manuel Encarnación Senior Capacity Development Officer NCD Alliance
14:45 – 15:00	Break	
15:00 – 17:05	Activity: “Building an RIA” Problem and objectives	Countries



**September 12, 2019****Morning session (Room B), afternoon session (1017)**

09:00 – 09:15	Summary of 1st day	PAHO/WHO
09:15 – 10:00	<i>Analysis of economic impact in the context of industrially-produced trans-fatty acids</i>	Camilo Cid Regional Advisor, Health Economics and Financing PAHO/WHO
10:00 – 11:30	<b>Activity: “Building an RIA”</b> Available policy options and positive and negative impact	Countries
11:30 – 11:45	Break	
11:45 – 13:00	<b>Activity: “Building an RIA”</b> Justification of selected option	Countries
13:00 – 14:30	Lunch	

**Regulatory Impact Analysis : Essential elements, information gap and key information**

14:30 – 15:30	<i>Fishbowl activity: Cost-Benefit Analysis</i>	Fabio da Silva Gomes and participating countries
15:30– 15:45	Break	
15:45 – 16:45	<i>World Café activity: Needed Evidence to do an IRA</i>	All participants
16:45 – 17:15	Wrap up	PAHO/WHO
17:15 – 17:30	Closing remarks	

## B. Pre-workshop questions and guiding questions for exercise “Preparing an RIA”

### **Regional workshop on regulatory impact analysis for the development of policies to eliminate industrially-produced trans-fatty acids in the Americas**

September 11-12, 2019

Pan American Health Organization/World Health Organization (PAHO/WHO)  
525 23rd St NW, Washington D.C., USA

#### **Pre-workshop questions**

1. Is it mandatory to prepare a regulatory impact analysis (RIA) in your country in order to submit a regulation proposal? If so, specify if it is mandatory for all types of proposals. Additionally, name and/or attach the government document that makes it mandatory.
2. Is it mandatory to prepare an RIA to submit a food regulation proposal? If so, name and/or attach the government document that makes it mandatory. Additionally, provide information and/or attach a previously prepared RIA for a food regulation proposal.
3. If it is not mandatory to prepare an RIA in your country to submit a food regulation proposal, does a government entity prepares one anyway? provide information and/or attach a previously prepared RIA for a food regulation proposal.
4. If an RIA *per se* is not prepared for food regulation proposals, is there any type of pre-regulatory evaluation done? If so, what is the methodology used during this evaluation? Additionally, is there more than one evaluation done for the same regulation?

Describe an example and/or attach a previous evaluation.

5. Please complete the following information about an RIA that was prepared to regulate trans-fatty acids or another type of food. If your country does not prepare an RIA, answer the following questions by thinking about the possible process of preparing an RIA with the objective of adopting a regulation to eliminate trans-fatty acids.

- Name of the governmental agency and/or team in charge of preparing an RIA.

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- Approximate time (in months) taken to complete an RIA.

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- Activities and process related to the preparation of the RIA (for example: preliminary report, internal and external consultations , etc.)

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- Information sources used as evidence to state the problem:

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- Elements to be considered in order to evaluate policy options (for example: possible impacts on health, environment, operational processes, human and financial resources, etc.)

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- Methodology to analyze the economic impact of the proposal (for example: cost-benefit analysis, cost-effectiveness analysis, etc.)

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- Describe the monitoring and evaluation mechanisms of the proposed policy.

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- Additional activities pertaining to the preparation of an RIA (For example: consultations, meetings with key stakeholders).

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- Name the governmental body that reviews the RIA and describe the review process.

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### **Activity: “Building a Regulatory Impact Analysis”**

Please use the following questions to develop an outline to prepare a regulatory impact analysis in the context of the elimination of trans-fatty acids.

1. **Problems and objectives:** This section seeks to identify the problem to be solved through the development of a problem tree analysis and by thoroughly describing the current situation related to the problem, its causes and consequences. Afterwards, you should be able to write down SMART objectives that would help solve the problem.

- What is the problem and what impacts does it have on the health of the population, the environment, the economy?
- What sources of information are available to demonstrate the problem and its consequences? (If you don't have them, what sources could you use?)
- What or who is affected by the problem?
- Have legal measures, international commitments, voluntary initiatives been taken before to solve the problem? What was the result of these?
- What are the objectives of the regulation?

**2. Policy options available to solve the problem and possible negative and/or positive effects:** This section seeks to identify the available policies that can help achieve the objectives mentioned above. For example: limit on 2% of trans fats in packaged foods, ban on partially hydrogenated oils, voluntary reformulation of food, educational campaign for the population, “no action”, among others). Additionally, it is suggested to evaluate the political and operational feasibility of each option during the analysis process.

- What are the possible options to solve the problem?
- What are the possible advantages and disadvantages of the options? And what possible impacts (positive / negative) would have on (legal: affecting other regulations, economic: high cost of adopting, among others)
- What are some of the regulatory pathways available in your country?

OPTIONS	List advantages and disadvantages	IMPACTS			Operational Cost	Administrative and operational burden
		Health	Economy	Legal		
OPTION 1						
OPTION 2						
OPTION 3						
OPTION 4						

**3. Rationale for the chosen option:** This section seeks to describe the logic that led to choosing the selected option.

- What choice did you select and why?
- Why were other options not selected?
- Have complementary measures been taken to strengthen the positive impacts and minimize the negative ones?

## C. Discussion (FISHBOWL) questions:

### Regulatory impact analysis models--related questions:

- Briefly describe your country's regulatory context pertaining to trans-fats policy. What is the relationship between the regulatory policy context on trans fats and the impact analysis studies or pre-regulation analysis done in your country?
- Is it mandatory to prepare an RIA or other type of analysis to propose regulations? In what cases is this true and which specific laws make it mandatory?
- Which agencies led the development of an RIA or other type of analysis? What agencies help conduct this exercise? How long did it take for the study to be finalized?
- How did you go about defining the problem? What resources were presented the problem and its consequences?
- Were there any legal actions, international commitment or volunteer initiatives proposed in the past to solve the problem? Which were the results in those cases and how was the information addressed/used for the regulatory impact analysis or other type of pre-regulation analysis done?
- What was the main aim of the regulatory proposal?
- Which possible actions were considered to solve the problem?
- What were the main advantages and disadvantages pertaining the policies proposed? How were the health, administrative, operative and economic impact estimated?
- What was the final choice and the main reasons for this decision?
- Is there any special agency or commission dedicated to review the Regulatory Impact Analysis?
- Which consultation methods were used?
- Which difficulties were found during the process?
- Which law/regulation makes the RIA or other type of analysis mandatory ?
- What agency reviews the RIA or other pre-regulatory analysis?
- Describe the process for reviewing the proposed regulation? (commissions, duration, time to make changes, etc.

- Was there a guide/manual for government entities to use to prepare an RIA and/or another type of regulatory analysis in your country?
- Was any essential requirement included as part of an RIA or other type of analysis related to a food-regulatory proposal process?
- What process is required to present a food-related regulatory proposal?

Thinking about an RIA on trans fats:

- Which government entity could lead the activity?
- Which agencies could be part of teamwork for preparing the analysis?
- Where could one find evidence-based information to support the problem?

### **Cost-benefit analysis:**

- What is a cost-benefit analysis and what other types of analysis are there to economically justify policies related to the elimination of trans-fatty acids? \*or: What type of analysis did your country do?
- In which circumstances is it more beneficial to prepare a cost-benefit analysis rather than a cost-effectiveness analysis?
- Which economic measurements are related to the abovementioned analysis? (for example, B/C ratio measures: For every dollar spent on X, you will save Y dollars or net benefit: B-C), or: What measures did your country use?
- What direct and indirect costs should be considered in an IP-TFA elimination policy? (substitute cost of healthy fats, product brand costs, etc.), or: What type of costs did your country include?
- What are some of the limitations associated with the methodologies used to calculate direct-indirect costs?
- What type of direct and indirect benefits should be considered in an IP-TFA elimination policy? or: What type of benefits did your country include?
- What are the information resources used for estimating direct and indirect costs for a policy position to eliminate trans fats? \*additionally: Which resources did you use to obtain the necessary data?
- What information sources were used to estimate direct and indirect benefits for a policy position to eliminate trans fats? \*additionally: Which resources did you use to obtain the necessary data?

The Pan American Health Organization (PAHO) convened a two-day Regional workshop on regulatory impact analysis for the development of policies to eliminate industrially-produced trans-fatty acids in the Americas in order to discuss pre-regulation analyses that can support and help guide the process to develop an IP-TFA elimination policy. The specific objectives of the workshop included identifying the need to perform a pre-regulation analysis to support and guide IP-TFA elimination policies; discuss possible models for pre-regulation analysis pertaining to IP-TFA elimination policies or similar food-regulatory policies; and define essential elements and information gaps pertaining to the preparation of pre-regulation analyses. Government officials in charge of food regulation, preparation of regulatory impact analysis, and nutrition policies, from Argentina, Brazil, Costa Rica, Guyana, Jamaica, Mexico, and Paraguay participated in the workshop. In addition, staff from the Anaas foundation, CARICOM's Regional Organization for Standards and Quality (CROSQ), Global Health Advocacy Incubator (GHA), NCD Alliance, Resolve to Save Lives (an initiative of Vital Strategies) (RTSL), and Salud Justa-Mexico also attended the meeting.

**PAHO**



Pan American  
Health  
Organization



World Health  
Organization  
REGIONAL OFFICE FOR THE  
Americas

525 Twenty-third Street, NW  
Washington, D.C., 20037  
United States of America  
[www.paho.org](http://www.paho.org)