REPORT:
INTERCOUNTRY REGULATORY CAPACITY BUILDING VIRTUAL WORKSHOP TO ELIMINATE INDUSTRIALLY PRODUCED TRANS-FATTY ACIDS
2–3 December 2020
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INTERCOUNTRY REGULATORY CAPACITY BUILDING VIRTUAL WORKSHOP TO ELIMINATE INDUSTRIALLY PRODUCED TRANS-FATTY ACIDS

2–3 DECEMBER 2020
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EXECUTIVE SUMMARY

A key diet-related risk factor implicated in cardiovascular disease is trans-fatty acids (TFA). TFA are unsaturated fatty acids with at least one double carbon–carbon bond in the trans configuration. They can be produced industrially by the partial hydrogenation of oils (PHO), but also occur naturally in meat and dairy products from ruminant animals, such as cattle, sheep and goats. Industrially produced TFA (iTFA) are most frequently found in baked and fried foods, prepared snacks, and partially hydrogenated cooking oils and spreads. TFA in the form of PHO were originally introduced into the food supply as a replacement for butter, but in the past 2 decades, there has been a huge body of literature on the harmful metabolic effects of TFA, specially on the relationship between TFA consumption and coronary heart disease (CHD).

High consumption of TFA is strongly associated with increased risk of CHD and related mortality. TFA increases levels of LDL (unhealthy) cholesterol and decreases levels of HDL (healthy) cholesterol. There is also some evidence that TFA may increase inflammation and endothelial dysfunction. Replacement of TFA with unsaturated fatty acids, in particular with polyunsaturated fatty acids, decreases the risk of CHD, in part, by preventing negative effects of TFA on blood lipids.

Elimination of industrially produced TFA is one of the priority targets identified in the WHO’s 13th General Programme of Work which guides WHO’s work during 2019 – 2023. Globally almost 260,000 deaths are attributed to the consumption of TFA.

WHO recommends that the total TFA intake be limited to less than 1% of total energy intake, which translates to less than 2.2 g/day of TFA in a person with a 2,000-calorie diet. Elimination of industrially produced TFA will contribute greatly to reducing premature deaths from non-communicable diseases, one of the health targets (Goal 3.4) of the United Nations Sustainable Development Goals, through decreasing the risk of CHD mortality. In this regard WHO published the REPLACE action package consisting of the action framework and accompanying six modules, to provide technical guidance to countries on the process of eliminating TFA.

Workshop objectives

To discuss the policy process and mechanisms involved at each step of the policy cycle (policy development, implementation, enforcement and monitoring)

To enable countries to prepare draft, practical and implementable legislative and regulatory actions to eliminate TFA from diets

To share country experiences and best practices in implementing relevant legislative and regulatory actions.

To consider a realistic and effective enforcement strategy to implement relevant regulatory or legislative actions.
TFA in South-East Asia Region countries

WHO South-East Asia Region countries are now initiating actions towards the elimination of TFA from diets. This process is being supported by WHO and Resolve to Save Lives (RTSL). Two countries, India and Thailand, have already implemented regulations to reduce TFA in its food supplies. Of the two, Thailand has the best practice regulation of a ban on PHO, while India at present has a regulatory limit of 5% PHO in fats and oils.

Other countries in the Region have initiated actions to work towards eliminating TFA from food supplies. In this regard, five countries, Bangladesh, Bhutan, Maldives, Nepal and Sri Lanka are at various stages of the policy process. In Bangladesh, the Bangladesh Standards and Testing Institute (BSTI) has initiated the process of developing a TFA standard. In Sri Lanka the food regulatory authorities have recommended regulating TFA and in Maldives, a policy landscape analysis is completed, and WHO is engaging with stakeholders on next steps. Projects are underway in Bhutan and Nepal to assess the dietary sources and consumption of TFA, evaluate the policy landscape on edible oils and fats.

WHO SEARO, considering the challenges and bottlenecks identified, including the dearth of regulatory capacity in many Member States organized a capacity building workshop on TFA legislation and monitoring for five countries in the Region to spur on action on WHO recommended best-practice policies for eliminating industrially produced TFA.  

This virtual intercountry workshop was held with collaboration of WHO HQ and RTSL with the primary objective of building country capacity on developing, implementing and enforcing regulatory actions to eliminate trans fats from diets.

The workshop consisted of 4 technical sessions held over 2 days, and was attended by participants from 4 countries and WHO country offices.
Session 1: Introductory session (overview and background)
Tuesday 2nd December

1.1 REPLACE and Broader Nutrition Policy Framework

Dr Chizuru Nishida, WHO HQ provided an overview of healthy diet policies and the background to the REPLACE framework. WHO’s work on assessing the role of dietary fats and oils in human nutrition go back to 1977, but it was in 2002 when the role of TFA in diet related non communicable diseases was highlighted at a WHO/FAO expert consultation. This served as the basis for many actions on healthy diet, including Codex nutrition labelling guidance which recommended countries to consider inclusion of TFA as mandatory nutrient in countries where the level of TFA intake is a public health concern. In 2007, a scientific update designated TFA as an industrial additive with no known health benefits. In 2018 TFA elimination initiative was launched with the REPLACE action framework which developed as a roadmap for countries to implement actions to reduce and eliminate industrially produced TFA. In 2019, the 6 REPLACE modules were developed to provide strategic action steps (Figure 1) to support sustained elimination of industrially produced TFA from the food supply.

Figure 1. REPLACE action framework
Global experience has shown that the healthy dietary regulations are interlinked with one another. Policies such as nutrition labelling, restriction of marketing of foods to children, fiscal and public food procurement all work towards improving the overall food environment. To support this work, WHO provides many policy/guideline implementation tools

- FOPL guiding principles
- Marketing tools
- SSB taxation tools
- Sodium reduction: global sodium benchmark
- Public food procurement and service action framework
- Global nutrient profile models
- TFA elimination tools (i.e. REPLACE action package, food analysis lab protocol)

The steps in the policy cycle for regulatory actions to promote healthy diet were described, which would apply to trans fats, as for any regulatory policies.

**Common political and technical challenges that impede policy progress; information based on lessons learnt from other policy development processes across countries**

Both political and technical challenges exist in developing and implementing policies. Political challenges include inadequate policy coherence across sectors, lack of legislative frameworks, poor coordination mechanisms and limited sustainable human and financial resources. Further, industry influence may undermine policy advocacy, implementation and even enforcement. Many countries also lack an advocacy base with limited NGOs/civil society capacities or have inadequate involvement of existing organizations (i.e. academia, professional organizations) in supporting effective implementation of policies.

Technical issues include capacity limitations at different levels of the policy development and implementation cycle, resulting in weak enforcement and monitoring of policy implementation. These weaknesses are often exploited by industry to seek self-regulation. Most countries conduct national surveys, but unavailability or inadequacy of data, non-inclusion of relevant indicators related to diet and nutrition, and inadequate disaggregation of data to address inequities are issues. Often, collected data are not used to inform policy formulation. Data on indicators such as cross-border shopping and tax evasion are also generally unavailable.

**1.2 The Science of Trans Fat**

The structure and properties of fatty acids were described by Dr Rain Yamamoto of WHO HQ. The most common form of oils and fats is triglyceride, where three fatty acids chains are attached to the glycerol backbone. Both the type of fatty acid and the placement can affect the functional properties of oils and fats, including their melting point, crystallization characteristics (solid fat creates a granular mouthfeel/texture) and resistance to oxidation. TFA are fatty acids with at least one double carbon–carbon bond in the trans configuration. (Table
1) Structurally saturated fatty acids and TFA are similar in shape and this means that they can pack well, with this property being convenient for food processing.

**Table 1: The differences between fatty acids**

<table>
<thead>
<tr>
<th></th>
<th>Unsaturated fatty acid (PUFA / MUFA)</th>
<th>Saturated fatty acid (SFA)</th>
<th>Trans-fatty acid (TFA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure</td>
<td><img src="image" alt="Structure" /></td>
<td><img src="image" alt="Structure" /></td>
<td><img src="image" alt="Structure" /></td>
</tr>
<tr>
<td>Common dietary sources</td>
<td>• Fatty fish&lt;br&gt;• Olive, soy, sunflower, corn oils</td>
<td>• Meat and dairy products&lt;br&gt;• Tropical oils like Palm oil and coconut oil</td>
<td>• Margarine, shortening&lt;br&gt;• Baked goods (e.g. pies, pastries, biscuits)&lt;br&gt;• Fried foods&lt;br&gt;• Meat and dairy products</td>
</tr>
<tr>
<td>Health impact</td>
<td>Healthy</td>
<td>Unhealthy</td>
<td>Unhealthiest!</td>
</tr>
<tr>
<td>At room temperature</td>
<td>Liquid</td>
<td>Semi solid</td>
<td>Semi solid</td>
</tr>
<tr>
<td>Oxidative stability</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

Ruminant TFA is naturally occurring and produced in ruminant animals through bacteria in their stomachs that has enzyme to convert cis double bond to trans double bond, but most TFA in human food supplies are from industrial TFA (iTFA). Partially hydrogenated oils (PHO) became popular in 1950-1970 as a cheaper option instead of animal fats. Partial hydrogenation breaks up unsaturated bonds, and converts them partly to saturated bonds and partly to trans unsaturated bonds, which raises the melting point and resistance to oxidation. Therefore, hydrogenation can create oils and fats with a variety of properties. Majority of iTFA is from PHO (Figure 2). A minor component is from the heating of oils. TFA are used to increase the shelf life of foods and oils by lowering their oxidation potential as well as to alter the texture. PHO are most frequently used in baked and fried foods, prepared or pre-packaged snacks and food, and cooking oils and spreads.

**Figure 2: Types of Trans fatty acids**
As there is no difference in the health effects of the different types of TFA, WHO’s recommendation, given below, includes both iTFA and rTFA intake and is for individuals.

Because the largest source of TFA is PHO, the best-practice policy that WHO recommends countries to implement are either banning production and sales of PHO or setting 2% limits on iTFA in foods.

In principle, PHO in products should be replaced with formulations that contain as little saturated fatty acids and as much unsaturated fatty acids, such as mono and polyunsaturated fatty acids, as possible. (figure 2). However, a study in 2009 shows that, in many countries where TFA regulations are implemented, though TFA content reduced, the saturated FA content increased for bakery goods. Therefore, more reformulation efforts are needed. Technical solutions for PHO replacement are provided in the REPLACE module 2.

Table 2: PHO alternatives by health impact and solid fat functionality

<table>
<thead>
<tr>
<th>PHO alternatives by health impact and solid fat functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSITIVE HEALTH IMPACT (lower SFA + more PUFA)</td>
</tr>
<tr>
<td>- High PUFA oil with antioxidants</td>
</tr>
<tr>
<td>- High oleic oils, moderate PUFA</td>
</tr>
<tr>
<td>- High oleic oils with no/low PUFA</td>
</tr>
<tr>
<td>- Liquid palm fractions</td>
</tr>
<tr>
<td>- Animal or tropical fats</td>
</tr>
<tr>
<td>- Semi-solid palm fractions</td>
</tr>
<tr>
<td>- Animal or tropical fats</td>
</tr>
<tr>
<td>- Fully hydrogenated oil</td>
</tr>
<tr>
<td>- Coconut oil</td>
</tr>
<tr>
<td>- Palm kernel oil</td>
</tr>
<tr>
<td>Not recommended:</td>
</tr>
<tr>
<td>- Hardstocks interesterified with low PUFA oils</td>
</tr>
<tr>
<td>- Hardstocks blended with low PUFA oils</td>
</tr>
<tr>
<td>- Hardstocks interesterified with some liquid oils</td>
</tr>
<tr>
<td>- Hardstocks interesterified with some MUFAs</td>
</tr>
<tr>
<td>Not recommended:</td>
</tr>
<tr>
<td>- Other hardstocks blended with high PUFA oils</td>
</tr>
<tr>
<td>Not available</td>
</tr>
</tbody>
</table>

1.3 Global and Regional Trans Fat Elimination Progress

The state of progress of countries in the Region was presented by Dr Angela de Silva. Progress is slow, compared to the WHO trans fat policy global progress scorecard. In SEA Region only two countries- India and Thailand have regulations/legislations to eliminate TFA. The other countries are yet at various stages of the policy process. Many countries are currently assessing the sources of TFA in food supplies, and carrying out policy landscape analysis. As seen in Thailand, If the level of TFA in oils and foods is not too high, as seen from recent analysis in some countries, it is timely to bring in regulations. Global experience shows that industry tends to dump high TFA products to countries where there are no regulations. Often,
TFA can be categorized as a contaminant or undesirable substance, depending on country context.

Challenges to policy development and implementation in the Region include the lack of data on sources of TFA in diet and on PHO – production, sources of import, poor awareness of TFA effects among all stakeholders, lack of information about TFA levels in foods, with most products lack nutrition labelling. One key factor for many countries are the agricultural and economic policies for coconut and palm oil. This would lead to opposition towards the use of polyunsaturated oils as replacement. Inadequate lab capacity and imported products which are not regulated, in terms of cake, bakery fat in bulk also need to be considered.


Session 2: Policy landscape assessment:

2.1 Entry points and initial drafting considerations for TFA elimination

In order to develop policies to eliminate TFA, a policy landscape assessment is essential. The details and steps in the policy process were discussed by Simone Bösch, RTSL.

1. Evidence base to support legislative or regulatory actions to eliminate industrially produced TFA

Evidence is usually needed on the sources and prevalence of each source of TFA in the food supply and their paths through the supply chain, if local vs imported foods contribute to TFA content in the food supply, and local evidence on the quantity of TFA in national food supply chain. Information on in-country PHO production and/or estimated population intake is useful and economic analysis maybe needed on the cost of removing TFA (regulatory costs as well as industry costs to replace oils).

2. Mapping of government bodies responsible / have authority to regulate policy actions related to food and nutrition, including TFA

A mapping of responsible entities, i.e. if single or multiple food regulator(s) and their level of operation (National, subnational and/or local authority) need to be identified. Identification of who does what- is essential: e.g. a lead national ministry or agency that develops the regulation as well as agencies with the authority to regulate, monitor and enforce TFA elimination, set standards, test products for compliance, enter and inspect facilities, issue administrative sanctions, respond to consumer complaints.
3. **Examination/analysis of existing laws and regulations that address food and nutrition issues which may affect TFA**

TFA-related provisions may be found in the different legal measures related to public health such as non-communicable diseases, food safety, nutrition, and in the areas of fats and oils, nutrition labeling, import tariffs, consumer protection and customs and border control.

4. **Charting government procedures and procedural requirements to enact TFA restrictions**

There may be standard formal procedural requirements that are necessary to enact policies which need to be understood. These may include an impact analysis, a legal requirement to solicit feedback from stakeholders or have a public consultation. Where industry may need to be consulted, there should be clear rules to ensure transparency, manage conflicts of interest to minimize interference in the policymaking process. Notification of restrictions may be required to be provided to regional bodies or trade bodies. Ensuring that these criteria are fulfilled makes for smoother passage/enactment of regulations.

While several policy options exist for eliminating TFA, there are only 2 best practice policies.

**Policy option #1:** Set a mandatory limit on the amount of industrially-produced TFA in ALL food.

The definition of the restricted substance (WHO definition) is important. The threshold needs to be considered- 2g of iTFA or less per 100 g of total fat in all foods. Limited exceptions for naturally occurring TFA such as cheese and meats are difficult, so generally the restrictions apply only to iTFA and no ruminant.

However, for labelling both iTFA and ruminant TFA needs to be reported.

**Policy Option #2:** Ban production or use of PHO as an ingredient in ALL foods.

A definition of the restricted substance is important. Definition of applicable food categories is also needed. An ingredients list is helpful as a complementary measure. PHO cannot be measured, but ingredients list may contain vegetable oils, or hydrogenated oils.

**Other partial or interim measures:** This includes mandatory or voluntary labelling, voluntary reformulations, or limiting TFA in foods in specific settings, e.g., public institutions such as schools

Important technical considerations for deciding which policy option should be selected are given in Table 3. Information on the major source of TFA; existing compliance mechanisms- if weak compliance system in place, implementation will be difficult, but could be strengthened. Capacity for lab testing of TFA using WHO standards is important, but if the country lacks capacity, a regional laboratory could be identified. Information on disparities in TFA consumption across the population maybe important- while overall intake maybe low, there maybe pockets of populations with high intake. A prior availability of likely replacements for PHO are also helpful. There may also be interim measures in place, such as a list of prohibited
substance, where TFA could be included. Assessing TFA measures in neighboring trading partners/countries is also a useful exercise.

Table 3: Decision guide for setting TFA policies (also available in the REPLACE module)

<table>
<thead>
<tr>
<th>Considerations</th>
<th>TFA limit should be considered if:</th>
<th>PHO ban should be considered if:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing Authority</td>
<td>Existing food and nutrition laws allow for the inclusion of a 2% limit</td>
<td>Existing food and nutrition laws cover harmful compounds in foods AND there is a maintained list of prohibited substances in food</td>
</tr>
<tr>
<td>Interim measures already in place</td>
<td>Interim measures that require TFA assessment, such as for labelling—particularly if the policy is effective and being enforced</td>
<td>Narrowly applied PHO ban in place—such as for infant formula—particularly if the policy is effective and being enforced</td>
</tr>
<tr>
<td>Trade</td>
<td>Neighboring countries or countries within an economic union have similar policy</td>
<td>Neighboring countries or countries within an economic union have similar policy</td>
</tr>
<tr>
<td>Political Support</td>
<td>Influential support likely</td>
<td>Influential support likely</td>
</tr>
</tbody>
</table>

At the end of session 2, Thailand presented their TFA policy process, evidence for setting a policy, current status and challenges faced.

2.2 Thailand experience

Thailand implemented a TFA regulation to ban production, import and sale of PHO, and any food that contains PHO. Despite the low levels of TFA in most foods, regulatory measures were enacted since there was no regulation to block the influx of PHOs and foods containing them from other countries, taking into consideration that many countries were developing TFA regulations and there was a risk of high TFA products being dumped in Thailand. The oil industry had capacity for development of replacement oils, and there was capacity to monitor a regulation through analytical testing of TFA. The need for export products to be free of TFA
since many countries were implementing policy measures to restrict TFA levels was also a consideration. A PHO ban was selected because, only 3 hydrogenation plants are available in the country, and it was felt to be a more economical strategy as comparing to controlling TFA in foods.

Criteria of the Thai FDA for monitoring are given below:

Post Marketing Monitoring
- Butter/Butter oil: < 6%
- Blended fat/oil product: < 2%
- Refined cooking oils: < 2%
- Others: < 0.5 g/serving

Nutrient Claim (which is not yet finalized)
- No Claim allowed or
- Trans fat-free: (1) Trans fatty acid < 0.5 g/serving and
  (2) Saturated fatty acid < 5 g/serving

The success of policy implementation can be attributed to regular communication among stakeholders, with support and commitment by the regulator i.e. Thai FDA, technical strengths of local producers, strong scientific knowledge used as supporting evidence and availability of ingredients and processes for alternative choices.

Session 2, Group activity 1: Considering a TFA policy based on country contexts

The 4 country teams supported by facilitators deliberated on one of two best practice TFA policies for their country. Annexure 1 contains the breakout worksheets) Results of the group work are given below:

**Bangladesh**

Policy option 1: Mandatory national limit of 2 g of industrially produced TFA per 100 g of total fat in all foods (“2% limit”)

5. Existing authority: Bangladesh Food Safety Authority (under Ministry of Food) in collaboration with, Bangladesh Standards & Testing Institution (BSTI) (under Ministry of Industry), and Noncommunicable Disease Control (NCDC) Programme under Ministry of Health and Family Welfare (under Multisectoral Action Plan Committee).

6. Advantages of policy option 1: Feasible in Bangladesh’s context considering recommendation from different stakeholders and time frame. The time frame will allow time for industries to rebuild their system according to the new policy

7. Disadvantages: Need a strong monitoring, assessment and surveillance system; requires development of national and divisional laboratories and capacity building for monitoring both in terms of lab facilities and human resources

8. Cost implications: Increase cost in terms of resources and time.
9. Political will: Government is very committed to reducing iTFA.

A PHO ban was not discussed.

**Bhutan**

Background information: Food safety is under the Ministry of Agriculture, which is often challenging in terms of coordination. Regulations include the General Food Act, food standards (Codex) and mandatory food labelling (country of origin etc, but NOT nutrition labelling) but there is nothing specific to TFA. The country has not taken action on TFA so far. The National NCD strategy states the elimination of TFA as an action (by 2025). Currently there is no strong food import control system at the border (Bhutan is dependent on imported foods) – pilot testing of implementation plans to be done soon to strengthen border control. MoH has initiative in research/lab analysis (not MoA) – TFA analysis is not done yet but a landscape analysis is being done (knowledge/perception of consumers; iTFA levels in cooking oil; amount of TFA in street foods and bakery foods in market is planned) and data will be available over the next few months.

Further discussion is needed as to which agency takes the lead in TFA regulations, but it will most likely/probably be the MoA with strong support and evidence from MoH and other relevant agencies. The participants discussed that it is too early to choose one option or the other since more awareness on TFA needs to be created and evidence gathering of dietary sources and policies around TFA are needed.

**Maldives**

An overall discussion took place, with the main conclusion being that Maldives does not currently have legal authority to issue either best practice regulation, so they will be focused on getting the Food law passed through parliament. The Food Law has been pending approval for the past 8-10 years. The participants did not have a strong view of which of the two best practices they would ultimately choose. The country does not produce oil or fats locally, and majority of their food is imported. Therefore, harmonizing their regulation with their main importing partners (India, Thailand, Sri Lanka) may be the best strategy.

**Sri Lanka**

Policy option 1: Mandatory national limit of 2 g of iTFA per 100 g of total fat in all foods ("2% limit")

1. Existing authority: Ministry of Health – Directorate of Environmental and Occupational Health and Food Safety. Food Advisory Committee advises the MoH in food-related matters; the FAC has already recommended the regulation of TFA.

2. Advantages
   - Almost all food contains less than 2% TFA, thus, implementation would be easy at this point as industry not affected.
   - Most food products are locally produced.
– Government could partner with private labs for TFA analysis since it does not have adequate capacity.

– The existing enforcement pathway for other food safety issues could be used for TFA regulation implementation. A regulation is in existence regarding TFA being in the mandatory ingredient list in food packaging. Mandatory nutrient panel including TFA will be adopted soon (in the last phase of the regulatory process).

– The country has successfully implemented other food policies such as an SSB tax or FOPL to reduce NCDs. So, resistance is not expected, particularly as there are commitments to reduce NCDs.

3. Disadvantages: no other interim measures than labelling that are supportive of a TFA limit.

4. Cost implications:
   – Costs would be incurred to increase capacity for implementation, create a laboratory / increase capacity of the Ministry’s laboratory.
   – Evidence shows that there are low levels of TFA in food, so cost to industry is likely to be low.

Policy option 2 (best practice): Mandatory national ban on the production or use of PHO as an ingredient in all foods (“PHO ban”)

1. Advantages: Mandatory ingredients list is compulsory. Nutrient panel including TFA content will soon be mandatory.

2. Disadvantages: As far as the participants are aware, no PHO manufacturers in Sri Lanka. Oils/fats containing PHO would be imported (SL produces coconut oil and some palm oil).

3. Cost implications: not discussed due to time constraints

4. Political will: NCD is well supported

The debrief included a poll to see which policy options were considered by countries and what were the main factors that steered them one way or another. And, countries shared the main reasons for considering one or the other policy options as given above. A discussion was held based on poll results and TFA policy consideration rationale.

Session 3: Designing an Implementation Strategy (3rd December)

3.1 Developing an implementation strategy

The focus of this session was on developing an implementation strategy for a TFA elimination policy. The plenary was by Aaron Schwid, Director Public Health Law, RTSL

The three key phases to implementation are the development, launch and implementation phases.
Development phase

During this phase, fact gathering is needed prior to designing. A realistic inventory can help countries to identify the best enforcement approach by highlighting strengths and weaknesses in existing mechanisms. TFA laws and regulations might be implemented with minimal additional expense and effort, if existing resources are used. Therefore, countries should take stock of their current enforcement resources, including all human, equipment, financial, and other since TFA regulation might be part of a broader implementation system to support healthy diets. The inventory could build upon the scoping and mapping exercises available in the Review, Assess and Legislate Modules of REPLACE. An appropriate inspection strategy should be designed to assess compliance. Four main techniques are recommended to assess violations—laboratory testing, facility investigation, review documents and records and label analysis. For testing, a certified laboratory should conduct scientific tests on samples of foods to determine the precise levels of TFA, to ensure that legal limits are kept. Laboratory testing may need specialized equipment and facilities, as well as significant expertise and training to perform accurate testing, which is often challenging for low-resource countries with limited or no laboratory facilities. Laboratory tests cannot reliably identify PHO (as distinct from other TFAs), so this option should not be used to enforce a PHO ban without additional validation. However, excess levels of TFA usually indicate the presence of PHO, because PHOs are the primary source of TFA and tend to raise the level of TFA in foods.1

1 See the REPLACE A module for further explanation of assessment methods and criteria for laboratory selection. See Module A, p. 6 “Monitor compliance with regulation or legislation on TFA content in food” and Step 5, page 10 “analyse TFA and SFA in food samples for detailed description”
Launch phase

When launching, a clear timeline is needed for implementation and notice must be provided to industry to prepare for a change in legal requirements, to build capacity among regulatory staff etc. usually a timeline of 12-18 months is given.

Implementation phase

Monitoring across the supply chain is important, and enforcement results should be shared with authorities and public, and if needed to refine the legislation further.

Critical control points

No country can check all suppliers and food manufacturers for TFA. Therefore, it is important to identify critical control points. Thailand for example determined and identified the domestic plants for PHO, where compliance could be affected.

Facility Investigation: Inspectors can investigate whether factories, processing plants and other fat and oil refineries are engaging in the process of partial hydrogenation – a major source of TFA. Regulations should provide inspectors with the power to inspect establishments where partial hydrogenation might occur, and to search industrial premises if necessary. This is especially efficient if oil manufacturers are in the country, and when a large amount of TFA in the food supply can be traced to a handful of domestic producers. In most cases, inspectorate officials will already be monitoring these facilities, so existing inspection sites and protocols need only be updated to include TFA-specific compliance requirements.

Review Documents and Records: Government inspectors can review customer and shipping records, supply contracts, bills of lading, and other documents that shows foods/ingredients across the full supply chain. Regulations should provide inspectors the power to request relevant documents, if there is a reasonable suspicion that a violation of law has occurred.

Food label analysis: Inspectors can review certain labels on packaged foods to determine if the product complies with limits. TFA quantities should be required to be disclosed on nutrition tables and PHO (or equivalents) listed along with other ingredients. This is a quick way to quickly enforce both a TFA limit or a PHO ban, especially when scientific testing is not widely available. However, there are limitations to this approach: some countries have not required disclosure of TFA in nutrition facts panels or PHO in ingredients lists; labels are rarely available on bulk or prepared foods; and inspectors must rely on the information in the label without scientific testing. Additionally, PHO may appear on the ingredient list in different forms, e.g., ‘partially-hydrogenated vegetable oil’, ‘shortening’ and ‘margarine’, so awareness of common terms for PHO is necessary. Other issues with labels include claims of zero TFA- in which case, there has to be conditions ensure that saturated fat is limited. This will ensure industry conveying a false impression of healthfulness.
**Incorporation of TFA into permit schemes**

Licensing, registration, or permitting schemes can be an efficient anchor for TFA enforcement measures. By incorporating TFA restrictions into existing pre-market registration or licensing schemes, governments can communicate new standards to a wide range of stakeholders and hold them to those standards with minimal additional effort or cost. This is done in New York City. Many countries already require businesses that manufacture, process, pack or hold food to register and maintain a license to operate within the jurisdiction. Similar requirements may be in place for importers. Restaurants maybe required to declare that no menu items contain more than the permissible threshold of industrially-produced TFA to maintain their operating permit. If no current pre-market registration or licensing schemes exist, countries might consider establishing a limited registration or licensing scheme for stakeholders who are most likely to handle TFA, such as producers and importers of PHO. There are many advantages of linking TFA to permits since businesses accustomed to following permit rules, and it reinforces ideal that eliminating TFA is easy (doesn’t need new legislation), and trained inspectors already visiting facilities (and have authority to do so). There is lower burden of proof required and quicker enforcement than courts. The threat of losing a business license is powerful incentive and permit fees (and fines for violations) can fund implementation activities. Businesses will also demand suppliers comply with rules, providing another indirect enforcement method.

**Imported food products and their challenges**

Monitoring compliance at the border for imported products poses specific challenges. Coordination between food and border agencies are vital to address this problem. TFA regulations may increase countries’ capacity to monitor compliance at their borders, especially for countries with robust nutrition labelling laws. The FDA of USA uses import alerts which could be sent out for products when customs officials see PHO listed as an ingredient or TFA levels exceed legal limits on nutrition facts panels, or when they receive alerts from other countries that a manufacturer of an imported good has been cited for a violation. Additionally, some countries use databases of products that commonly contain iTFA and customs officials can screen and test for these products at the border. Many countries have porous borders which make enforcement difficult, with limited capacity at ports and complicated trade rules, liability and jurisdiction challenges.

**Holding violators accountable**

The punishment should be proportionate and could be on a scale of the violation/company etc.

Reducing or eliminating TFAs from the food supply is both politically and technically feasible. Policies have been enacted and implemented in all regions and momentum continues to grow. Governments have a wide range of policy implementation and enforcement options that can be tailored to national circumstance with an eye towards problem solving so that every country can successfully implement and enforce TFA regulations. Country case studies on how New Yok and Thailand implemented the PHO ban are provided in Annexure 2.
Session 4: Group session on Action Planning

The group session on action planning was supported by facilitators and defined the next steps and timelines for action following workshop, both in the short and medium term. The actions included gathering additional evidence, consultation with stakeholders, training, educational campaign, lab development, materials and, regulatory drafting etc and are given below.

**Bangladesh**

(a) **Key persons within the country who will carry out and support the drafting/revision process**

**Government:**
- Bangladesh Food Safety Authority (BFSA) (under Ministry of Food) will lead in collaboration with, Bangladesh Standards & Testing Institution (BSTI) (under Ministry of Industry), and Noncommunicable Disease Control (NCDC) Programme under the Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare (under Multisectoral Action Plan Committee).
- National Nutrition Service (NNS), DGHS
- Bangladesh National Nutrition Council (BNNC)
- Directorate of National Consumer Rights Protection

**Non governmental Organization:** National Heart Foundation of Bangladesh (NHFB)

**International NGO:** Global Health Advocacy Incubator (GHAI), USA- a concern of Campaign for Tobacco Free Kids, USA

(b) **The chain of command required to approve the draft regulation and steps required for official approval.**

1. BFSA will prepare zero draft which will be endorsed by Food Safety Technical Committee and Board (Draft-1).
2. Draft-1 will be on BFSA’s website for 45 days, meanwhile it will be sent to government and non-government stakeholders for comments (inclusion of comments- Draft-2)
3. BFSA will send Draft-2 to Ministry of Foods who will convene an inter ministry meeting (inclusion of comments- Draft-3)
4. Draft-3 will be sent to Ministry of Law for vetting. After vetting, Draft 4 which is the Final Draft will be given a Statutory Regulatory Order (SRO) number.
5. Then it will be published in gazette as an SRO. (not an act, so it does not need to be sent to cabinet and parliament divisions)

(c) **Other entities/stakeholders beyond the MoH and regulatory agency to be consulted prior to developing a draft regulation**

*In addition to Government, nongovernment Organizations*
National Heart Foundation of Bangladesh
Consumer Association of Bangladesh
Progga
GAIN (I-NGO)

Research institution/ academia
Institution of Nutrition and Food Science, University of Dhaka
Nutrition division, Icddr, b

Development partner/ UN Agencies
WHO
FAO

(d) Additional information/research is required to finalize the principles of this regulation?
- TFA content in PHO - published
- TFA content in different food items- upcoming

Additional information/research
- Research on Imported food and raw material, evaluation research, prioritization research/ Industry mapping
- Updating 2013’s Food Composition Table for Bangladesh

(e) Three key actions taken after the workshop to move forward TFA regulations/legislation in your country.
- **Step 1:** In the next 7-8 months, the draft regulation will be finalized.
- **Step 2:** 2-3 months after the finalization of the regulation, Bangladesh Standards & Testing Institution (BSTI) will set different standards for different food, fat and oil products. The industry will need to comply with those standards for production. The standards will be developed in consultation with Bangladesh Standards & Testing Institution (BSTI) and encourage reformulation.
- **Step 3:** An action plan/ road map addressing different action area focusing on FoPL/ and complementary best practices will be developed, and will continue simultaneously with step 1 (envisaged to be completed in 5-6 months).

(f) Further support needed from WHO/RTSL for the above steps/actions
- Technical, consultancy, Laboratory and capacity building support

(g) Identify any regulatory support is needed in order to move forward with the drafting process once other actions are completed
- If any concern is raised by industries or any stakeholder, support for collation and collection of evidence will be requested.
Bhutan

(a) **Key persons within your country who will carry out and support the drafting/revision process**

- Leading government to agree whether TFA is an important issue.
- Policy level discussions with relevant agencies and lead agency will be the Ministry of Health.

(b) **Chain of command required to approve if a draft regulation is developed- steps are required for official approval.**

1. Policy decisions from the government
2. Landscape analysis leading to roadmap for identifying government and stakeholder actions.
3. Drafting of nutrition labelling or revisions of existing mandatory labelling.
4. Technical capacity building (lab, inspectors)
5. Stakeholder engagement and support (Informal sectors, Industry, Consumers)
6. Consumers awareness and health educations

Sound Scientifics evidence and awareness, stakeholders consultations, development of policy/regulations and approved by the PM/cabinet.

(c) **Other entities/stakeholders beyond the MoH and regulatory agency who should be consulted prior to developing a draft regulation.**

Health and Food Safety Authority, Ministry of Agriculture and Forest, Ministry of Economic affairs, Gross National Happiness Commissions, Consumers Protections Office, BHUTAN Chamber Commerce Industry.

(d) **Additional information/research is required to finalize the principles of this regulation**

Laboratory capacity, Inspectors Capacity, Food Labelling Inspections/survey (robust data)

No further discussions were held since Bhutan is yet in an early stage of the policy cycle, and awaiting data on dietary sources of TFA.

Maldives

(a) **A. key persons within the country who will carry out and support the drafting/revision process?**

- Nutrition: Health Protection Agency
- Maldives FDA for legislation/ regulatory role
- Multisectoral coordination under Ministry of Health
- Public Health Act and Food Act: Duplication exists- need clarity on who will be the leading agency
- Ministry of Agriculture and Fisheries- Food security and food related mandates
Ministries of Trade, Finance, Gender, School,
Attorney General Office for legal aspects
Civil Society Organizations - NCD Alliance, Soc. for Health and Nutrition, Diabetes Association

(b) **Chain of command required to approve this draft regulation and steps are required for official approval.**
- Stakeholder consultations on draft regulations
- FDA drafts
- AG Office approves
- Public opinion/ involvement of organizations
- Social council for final approval
- Parliament endorsement is the final step

(c) **Other entities/stakeholders beyond the MoH and regulatory agency who should be consulted prior to developing a draft regulation.**
- CSOs/ Public opinion
- Industry groups
- Importers

Comments incorporated/ addressed in draft regulation

(d) **Additional information/research required to finalize the principles of this regulation**

(e) **Evidence generation**
- Market survey on TFA in progress
- Dietary consumption data would be useful for advocacy
- Dietary study planned
- STEPS Survey: include more about dietary information
- 84% prevalence of NCDs

(f) **Three key actions/steps to be taken with regard to moving forward with TFA regulations following the workshop**

Step 1: [Shortly] Discuss with the High-Level Committee on NCDs on TFA and share the findings of the study on TFA with advocacy for Food Bill to be endorsed. (COVID notwithstanding)

HLC meeting may be delayed

Step 2: Work on public awareness on NCDs and TFA. Also advocate to include TFA in the list of foods that are adulterants

Step 3: By [Dec 2021], work will start on formulation and implementation of nutrition labeling
(g) **Further support needed from WHO/RTSL for the above steps/actions**

Technical and financial support

– for advocacy workshops and stakeholder consultations

– Generate evidence

  • Sources of transfats in foods/diet
  • NCD prevalence/burden and link between NCDs and Transfats
  • Implementation capacity inventory- Staff, equipment, financing, transport....
  • iTFA/ rTFA-- shift the burden to the company to prove the proportions of TFA
  • benefit from other countries making their legislation stricter: use available platforms for country conversations will be useful

(h) **Regulatory support needs in order to move forward with the drafting process once other actions are completed**

– Lab capacity building

– Better informed STEPS Survey

**Sri Lanka**

(a) **Key persons within the country who will carry out and support the drafting/revision process**

Ministry of Health – Directorate of Environmental and Occupational Health and Food Safety

(b) **What is the chain of command required to approve this draft regulation? What steps are required for official approval. Be specific.**

(1) Approval from Food Advisory Committee of the Ministry of Health to start regulatory process (already received)

(2) Drafting regulation by a special committee consisting of government analysts, food technology specialists, food safety unit of the MoH, Sri Lanka Standard Institute, Industrial Technology Institute, and food scientists and microbiologists.

(3) Stakeholder consultation and consensus (meeting): all relevant food industries (those importing or producing products with TFA), present the draft regulation for comments

(4) Decision on inclusion of food industry comments in the draft (decision by special committee)

(5) Notify WTO and include comments in draft regulation

(6) Send draft regulation to the Legal Drafting Department

(7) Correct draft as per feedback from the Legal Drafting Department

(8) Send final draft to Legal Drafting Department

(9) Legal Drafting Department proofreads and translates the English final draft into Sinhala and Tamil

(10) Send for approval of Minister of Health (in all three languages)
(11) Send approved regulation to Cabinet of Ministers for approval and gazetting
(12) Gazette notification (in all three languages)
(13) Approval by the Parliament- if not approved, the regulation is deemed rescinded

No deadlines / mandatory timelines for each step.

(c) **Other entities/stakeholders beyond the MoH and regulatory agency who should be consulted prior to developing a draft regulation**

There is no rule on who needs to be consulted (apart from industry). It depends on the situation. The Ministry of Agriculture and Livestock; Ministry of Trade; Consumer Affairs Institute; development agencies (WHO, WFP, FAO); representatives of civil society; nutrition-related teams in MoH.

(d) **What additional information/research is required to finalize the principles of this regulation?**

(1) There are two sets of analysis at present, one supported by WHO/MoH and one of the Medical Research Institute of MoH.

(2) Possibly more sampling of commonly consumed foods to be analyzed for TFA content, but at present adequate information is available.

(3) Economic analysis of cost of TFA consumption for the Sri Lankan health system if needed.

(e) **Three key actions to be taken following the workshop in order to move forward TFA regulations/legislation**

Step 1: Within one month, obtain the approval of the Food Advisory Committee to commence the regulatory drafting process.

Step 2: Within six months, adopt the mandatory nutrient declaration.

Step 3: Within six months, have a draft regulation on TFAs

Step 4: Within one year, adopt the draft regulation on TFAs

(f) **Further support needed from WHO/RTSL for the above steps/actions**

No governmental capacity for laboratory checks, need to use non-governmental labs. Therefore, the main need is help in developing governmental laboratory capacity.
CONCLUSION

From the discussions, the following conclusions were drawn:

- WHO’s framework and modules provide the technical information needed by Member States to move on with the policy process of eliminating iTFA.
- The participants of the workshop have a good understanding of the science of TFA, the policy process needed to work towards elimination of iTFA and, on the steps needed to design a robust implementation strategy.
- The four Member States are at different levels of progress along the policy cycle for iTFA elimination.
  - Bangladesh is drafting a regulation, having obtained data on dietary sources of TFA, and identified that the regulation will include a ban on TFA as well as PHO.
  - Sri Lanka has received approval for going ahead with the drafting of a regulation to eliminate iTFA from the food supply. Sri Lanka has also drafted nutrition labelling regulations which include mandatory declaration of TFA.
  - Maldives has just completed a policy landscape analysis and identification of dietary sources of TFA. They will start policy discussions among the government stakeholders as an initial step, while also working towards categorizing iTFA as an adulterant. Since discussions are going on regarding nutrition labelling, the inclusion of TFA in labelling regulations would be considered.
  - Bhutan is also in the early stages of evidence generation, having just completed a policy landscape analysis. The country is awaiting data from the dietary assessment for TFA and will initiate awareness actions and discussions between MoH and MoA.
- Concerns were raised about the issue of replacement oils. Specifically on the political and economic issues related to the recommendation of limiting the use of oils with a high saturated fatty acid content, especially in the coconut and palm oil producing countries. The elimination of TFA and replacement oils needs to be considered holistically.
- Inadequate laboratory capacity was identified as a problem which need technical support from WHO and other agencies.
- In the next 12 months, WHO, together with RTSL, will support regulatory and laboratory capacity-building in countries on request, support countries in their dietary assessments, and advocate for implementation of best-practice regulations to further the elimination of iTFA from diets.
REFERENCES


ANNEXURE I  
SESSION 2, BREAKOUT GROUPS: CONSIDERING A TFA POLICY BASED ON COUNTRY CONTEXTS

Instructions

Please go through the below best-practice policy options and discuss which of them is most feasible taking your country context into consideration. Please answer for each the following questions:

1. **Existing authority**: Is there existing authority to adopt such a measure? If so, which government agency, ministry or other authority would be responsible?

2. **Advantages / disadvantages**: What are the advantages and disadvantages of the policy option? List all the pros and cons you can think of. Helpful questions to ask are:
   
   (a) Do interim measures exist, and if so, are they supportive or not of the policy option?
   
   (b) Does the policy option align with neighbouring countries’ policies or those of other major trading partners or blocks?
   
   (c) Do laboratories exist that can test for TFA?
   
   (d) Is there an existing enforcement structure in place that can support and ensure implementation?
   
   (e) Does the policy option fit your country’s TFA profile (burden and sources)?

3. **Cost implications**: What would be the cost implications of each policy? Think about costs that are involved both to adopt and implement the policy option.

4. **Political will**: Is there political will for the policy option?

Looking at the answers, which of the policy options appears to fit your country context the best? Which is the easiest / least burdensome to implement to achieve your goal of TFA elimination?

**Policy option 1 (best practice)**

Mandatory national limit of 2 g of industrially produced TFA per 100 g of total fat in *all* foods ("2% limit")

1. Existing authority:
2. Advantages (pros):
3. Disadvantages (cons):
4. Cost implications:
5. Political will:
Policy option 2 (best practice)

Mandatory national ban on the production or use of PHO as an ingredient in all foods (“PHO ban”)

1. Existing authority:
2. Advantages (pros):
3. Disadvantages (cons):
4. Cost implications:
5. Political will:
ANNEXURE 2
SESSION 4, ACTION PLANNING

1. What additional information/research is required to finalize the principles of this regulation?

___________________________________________________________________________________________________

___________________________________________________________________________________________________

2. How will you finalize the first draft of this regulation in proper legal language? Set deadlines.

___________________________________________________________________________________________________

___________________________________________________________________________________________________

3. What is the chain of command required to approve this draft regulation? What steps are required for official approval. Be specific.

___________________________________________________________________________________________________

___________________________________________________________________________________________________

4. Outside the chain of command, who should be consulted on this draft regulation? Be specific.

___________________________________________________________________________________________________

___________________________________________________________________________________________________

5. What steps will you take -
   a. in the next two weeks?
      ____________________________________________________________

   b. in next two months?
      ____________________________________________________________

   c. In the next six months?
      ____________________________________________________________

6. Who are key contacts within your country to support the drafting/revision process?

___________________________________________________________________________________________________

___________________________________________________________________________________________________

7. Who are key contacts from outside your country to support the drafting/revision process? (If none or not applicable, leave blank.)

___________________________________________________________________________________________________

___________________________________________________________________________________________________
New York City

New York City (NYC) led the USA in limiting TFA in restaurants in 2007. An amendment to NYC’s Health Code phased out the use of industrially-produced TFA in all food service establishments that required a NYC Health Department permit, including restaurants, caterers, mobile food-vending units, and mobile food-vending commissaries. The regulation was implemented in two stages:

On July 1, 2007 (6 months from passage of the regulation after a draft regulation had been published and comments from affected industries received and addressed), food service establishments in NYC were not allowed to use partially hydrogenated vegetable oils (PHO), shortenings, or margarines for frying, pan-frying (sautéing), grilling, or as a spread unless their product labels or other documents from the manufacturer showed that these ingredients contained less than 0.5 grams of TFA per serving. Food establishments could continue using TFA-containing oils and shortenings for deep frying cake batter and yeast dough until the regulation took full effect on July 1, 2008. On July 1, 2008, no food containing PHO, shortenings, or margarines with 0.5 grams or more TFA per serving could be stored, used, or served by food service establishments. To enforce this, after substantial media coverage and clear regulatory information had been sent to every licensed establishment, NYC health department inspectors incorporated the TFA regulation into their routine restaurant health inspections. According to U.S. labeling regulations, foods with >0.5g of TFA per serving must list the amount of TFA in the product. During their regularly scheduled inspections, restaurant inspectors examined the ingredients statements of packaged foods stored by the restaurant. If PHO was listed, they referred to the Nutrition Facts panel to determine if the level of TFA present in the food was above the permitted threshold. Additionally, NYC’s Board of Health reserved the right to perform laboratory testing to ensure compliance. Finally, NYC used Administrative Tribunal hearing officers to assess fines amounting to between $200 and $2,000 for each violation, with penalty increases for repeat violations. The NYC Health Department routinely analyzed violations and repeat violators, using these data to meet with the restaurant industry to help drive compliance. It also periodically reported publicly its inspection findings and violation rates.

Case study: Thailand’s experience enforcing its ban on PHO

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

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

- Prohibits the production, importation and distribution of PHO and its products in Thailand
- Establishes non-compliance with the law will subject offenders to imprisonment for 6 to 24 months along with fines of 5,000 to 20,000 baht (USD 150-600)
- Entered into force on 9 January 2019, 180 days after publication, to allow for an orderly transition

To enforce this, Thailand identified a critical control point in the supply chain: three in-country processing plants capable of partially hydrogenating oil. It regulates all upstream production of PHO by monitoring those sites. Downstream, Thailand’s FDA established monitoring procedures that target critical control points for post-marketing TFA compliance: testing food samples that are the main sources of TFA. Targeted testing saves costs because widespread testing is expensive. It also ensures that money is not wasted testing foods not likely to have high levels of TFA. Food surveys used for surveillance and monitoring will be done in partnership with the FDA, ThaiHealth and local universities, which makes continued enforcement sustainable and affordable. Importers of food products must ensure that imported products do not contain PHO or use ingredients that contain PHO. Thai FDA inspectors at the port may request evidence that products do not contain PHO for the following products or ingredients: margarine; shortening; creamer; whipping cream; and bakery products (e.g., biscuits, cakes, pastries, and cookies). Finally, the Agriculture Research and Development Agency committed to provide full support for situational analyses and product development as needed under the ban.
The contribution of trans fatty acids (TFA) to cardiovascular disease morbidity and mortality is well known and elimination of industrially produced TFA is a priority target in the WHO’s 13th General Programme of Work. WHO Regional Office for South-East Asia collaborated with WHO HQ and Resolve To Save Lives to organize a regulatory capacity building workshop to accelerate actions implementing best-practice policies for eliminating industrially produced TFA. The virtual intercountry workshop for the five countries in WHO South-East Asia Region contributes to country capacity on developing, implementing and enforcing regulatory actions to eliminate trans fats from diets.