Step-by-step
Applying to the Validation Programme for Trans Fat Elimination

World Health Organization

Executive Summary

This document aims to guide national competent authorities to complete the Trans Fat Elimination Validation Certificate Application Form. National competent authorities are eligible to apply for Trans Fat Elimination Validation when they can answer the following questions positively and provide the supporting evidence.

- The country has a best-practice **trans-fat elimination mandatory policy in effect.**
- The country has an **established monitoring programme** covering both domestically produced and imported food products to ensure compliance with the best-practice policy.
- The country has an **established mechanism to implement enforcement activities** to track and hold violators of the policy accountable.

The document will provide an explanation of the types of evidence necessary to support the application. In addition, it will give details of the validation process and the assessment of the applications.

Readiness Checklist		
Policy	**TFA Policy in place**	☐
	Policy is best-practice	☐
	Policy is in effect	☐
	Policy is mandatory	☐
	Labelling policy (where relevant)	☐
Monitoring	**Monitoring protocol**	☐
	Monitoring protocol exists	☐
	Representative sample for analysis and examination (sampling design)	☐
	Validated lab method used (where applicable) and/or effective labelling regulation	☐
	Domestic and imported foods covered (where applicable depending on country context)	☐
	Monitoring reports available	☐
Enforcement	**Enforcement protocol, including penalty**	☐
	A systematic tracking of inspections and offences is in place (including a risk-based approach)	☐
	Penalties to violations are in place	☐
	Enforcement reports available	☐

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Abbreviations

AOAC	Association of Official Analytical Collaboration
AOCS	American Oil Chemists' Society
ISO	International Organization for Standardization
iTFA	Industrially produced trans fats
PHO	Partially hydrogenated oil
SOP	Standard operating procedure
TFA	*Trans*-fatty acids
TFATAG	Trans Fat Elimination Technical Advisory Group
WHO	World Health Organization

Glossary

This glossary comprises all the key terms used in the present publication. The definitions are extracted from WHO REPLACE Trans Fat-Free terminology (https://www.who.int/teams/nutrition-and-food-safety/replace-trans-fat).

TFA	Trans fat, or trans-fatty acids, are unsaturated fatty acids that come from either natural or industrial sources. Naturally occurring trans fat come from ruminants (cows and sheep). Industrially- produced trans fat are formed in an industrial process that adds hydrogen to vegetable oil converting the liquid into a solid, resulting in "partially hydrogenated" oil.
PHO	Partially hydrogenated oils (PHO) are fats that have undergone a process called hydrogenation, where hydrogen is added to liquid vegetable oils to make them more solid at room temperature. Partially hydrogenated oils are often used in processed foods, such as baked goods, snacks, and margarine, because they improve texture and shelf life.
TFATAG	The WHO Trans Fat Elimination Technical Advisory Group (TFATAG) is the principal advisory group to the World Health Organization (WHO) that makes recommendations to WHO on the granting of the WHO Validation Certificate, a recognition that countries can receive for having best-practice TFA elimination policies and monitoring and enforcements systems in place.
Trans Fat (TFA) Evaluation Team	The TFA Evaluation Team are sub-groups of the TFATAG, composed of up to three of the TFATAG members. Each TFA Evaluation Team will examine the Member States' applications including all the supporting documentations. The TFA Evaluation Team will prepare an evaluation report of the Member States' applications to be further reviewed and assessed by the TFATAG which will then make recommendations on the granting of the WHO Trans Fat Validation Certificate to the WHO Director-General.
Best-practice TFA policy	Legislative or regulatory measures that limit industrially produced TFA (iTFA) in foods in all settings, and are in line with the recommended approach

Monitoring system	- (Option A) Laboratory testing or label assessment of food items sampled at food outlets; or - (Option B) Inspection of manufacturing facilities and at ports of entry. In both options, it must be demonstrated that the monitoring activities cover reasonably suspected major sources (e.g. specific products previously found to be high in iTFA and key food categories that tend to contain high levels of iTFA. The monitoring system must cover both domestic and imported sources. Member States may combine different options (e.g. laboratory testing and label assessment; laboratory testing and inspection of documentation) to cover a wide range of iTFA sources.
Enforcement system	1. Systematic tracking of inspections and offences (ideally in a database) and inspections that are targeted based on high risk (e.g. high-risk food categories, repeat offenders, facilities with ability for partial hydrogenation). AND 2. Imposing penalties on violators, as appropriate for the local legal system (e.g. warnings, ticketing, fines that increase based on severity, stop-sale orders, profit disgorgement, product recalls, suspension or termination of business license or import permit, public disclosure of noncompliance, etc.)

1 Introduction

1.1 Background

There are two types of trans-fat (TFA): industrially produced and naturally produced TFA. Industrially produced trans fats (iTFA) are formed in an industrial process that adds hydrogen to vegetable oil, converting the liquid into a solid or semisolid and resulting in partially hydrogenated oil (PHO). On average, TFA concentrations in PHO are 25–45% of total fat. Naturally occurring TFAs come from ruminants (such as cows and sheep), are found in their meat and in dairy foods, but in much lower concentrations. Frying or refining oil at high temperatures for longer durations of time leads to modest increases in TFA concentrations[1].

Replacing iTFA with healthier oils and fats in the food supply is a low-cost solution for governments to save the lives of their citizens. Experiences in several countries demonstrate that iTFA can be replaced by healthier oils. Costs of implementing best-practice interventions (i.e. regulatory limits on TFA) are well under the commonly accepted thresholds of cost-effectiveness. Thus, the World Health Organization (WHO) recommends TFA elimination as a cost-effective intervention for especially low- and middle-income countries to reduce coronary heart disease[2].

Experiences in several countries demonstrate that mandatory approaches are more effective than voluntary approaches in reducing TFA in the food supply and in the population[3].

1.2 WHO best-practice policies

There are different best-practice approaches that can be used to eliminate TFA from the food system. Countries can:

- ban the use and production of PHOs,
- limit the content of iTFA to a maximum of 2% of total fat in all fats, oils and foods, or
- a combination of the PHO ban and iTFA 2% limit.

A process to evaluate and validate the status of Member States in their efforts to eliminate iTFA is essential to establishing accountability and accelerating progress. The purpose of the WHO Validation Programme for Trans Fat Elimination is therefore to support and recognize Member States for having a normative framework in place to eliminate iTFA from their national food supplies by granting them with a WHO Validation Certificate of Trans Fat Elimination.

1.3 Objectives of the guidance for trans-fat validation

The primary objective of this guidance is to assist Member States in applying for validation of their TFA elimination efforts. The guidance offers a comprehensive overview to help national competent authorities demonstrate how their country meets the technical criteria for validation, including how their efforts to eliminate TFA from the food supply are both effective and sustainable. By following these procedures, Member States can demonstrate progress toward TFA elimination in line with global recommendations.

[1] Martin, C. A., Milinsk, M. C., Visentainer, J. V., Matsushita, M., & De-Souza, N. E. (2007). Trans fatty acid-forming processes in foods: a review. *Anais da Academia Brasileira de Ciências*, *79*, 343-350.
[2] Countdown to 2023: WHO 5-year milestone report on global trans fat elimination 2023. Geneva: World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO.
[3] Downs SM, Thow AM, Leeder SR. The effectiveness of policies for reducing dietary trans fat: a systematic review of the evidence. Bulletin of the World Health Organization. 2013;91:262-9h.

2 Overview of the validation procedure

Validation of TFA elimination is a voluntary procedure and needs to be initiated by national competent authorities. The country needs to introduce a mandatory policy that is following one of the two WHO best-practice policies (or a hybrid of these two). This needs to be accompanied by adequate monitoring to ensure compliance and enforcement activities that can track and hold violators to account. When this is introduced and implemented, the responsible national authority can apply for validation. The process involves an objective and independent evaluation of a country's declaration of TFA elimination by experts.

For countries that introduced the regulations and monitoring for TFA elimination several years ago and where it is now imbedded into national food safety or food control legislation, there may not be recent, documented efforts on TFA monitoring. This will make it more challenging to collate the specific documentation necessary to complete the form. For these countries, it will be important for responsible authorities to highlight their historic efforts, and they will need to show how current efforts in food monitoring include TFA.

To monitor and enforce the ban, countries can select food items at food outlets and either test these using validated laboratory methods or through label assessments, though the latter also requires that a mandatory labelling policy including TFA be in place. Alternatively, countries may inspect food manufacturing facilities and at ports of entry. Again, countries may base the inspection on laboratory analysis or the checking of documentation and labels (for imported goods).

Countries should combine the different approaches as is deemed most effective and appropriate for their food system and for the likely mix of sources of iTFA in country. The application form provided for submission to WHO, together with this document outline these elements and indicate the types of supporting documents (documents, methods and records) that will be necessary for each of the criteria. The completion of the documents can be done in consultation with the WHO Secretariat (tfa@who.int) team.

The Trans Fat Elimination Technical Advisory Group (TFATAG) will review the application form and accompanying evidence/documentation and based on this assessment make a recommendation for validation. Their recommendation will be discussed with and provided to WHO. The WHO Director-General will make the final decision on validation.

3 Criteria for validation of TFA elimination

WHO validation of TFA elimination requires national competent authorities to complete the "Trans Fat Elimination Validation Certificate Application Form" (see Annex 1), and provide clear and comprehensive evidence that their country has:

- a best practice policy in place, which is mandatory and is in effect;
- an adequate monitoring programme in place that can identify non-compliant food products in the country that contain PHO or more than 2% of iTFA; and
- an adequate enforcement that can track and hold violators accountable.

It will likely be unfeasible for countries to regularly check all food products, especially when laboratory analysis is used to determine TFA level. Countries will therefore likely select food products suspected to be at higher risk of containing iTFA, for their monitoring activities. In the evaluation of the application the TFATAG will need to understand the rationale for this selection. Providing historical scientific information on food products that did or could have contained PHO or iTFA, or literature that forms the basis of the selection process will facilitate this understanding.

The TFATAG will base its evaluation on the evidence (supporting documents) provided with the "Trans Fat Elimination Validation Certificate Application Form". The TFATAG is an international group of experts and therefore:

- All supporting documents should be prepared in English. Alternatively, official documents can be submitted in languages other than English, but in this case, please include a summary of each document in English with a translation in English of the relevant sections.
- When referencing documentation, **the precise section or page containing the relevant information** should be specified. This facilitates efficient retrieval of the required details.

4 Steps in validation of trans fat elimination

WHO officially initiates a validation procedure once an official request for validation is submitted by the responsible authority (e.g., Ministry of Health, Ministry of Agriculture etc), to the WHO Director-General, through the WHO Headquarters Department of Nutrition and Food Safety. An initial part of the national preparation for validation is the gathering of essential documentation and records needed to substantiate the TFA's elimination validation. However, official validation is not possible until the policy is implemented.

1. **Readiness assessment**: National competent authorities can self-assess their country's readiness for validation with WHO assistance and using this document.
2. **Collate documents needed for validation programme**: In an effective elimination programme, records relating to monitoring and enforcement measures are generated routinely. Key documents needed are described further below in the section Completion of the application form.
3. **Verification and submission plan**: In consultation with the WHO Secretariat (tfa@who.int) team, national competent authorities can discuss the collated documents to formulate a plan of action and timeline for validation.
4. **Submission of application form and supporting documents**: National competent authorities finalize the "Trans Fat Elimination Validation Certificate Application Form", with the accompanying evidence and submit it to the WHO secretariat (tfa@who.int).
5. **Independent evaluation**: The TFA Evaluation Team (a subgroup of the TFATAG) conducts an independent evaluation of the submitted application form and accompanying documentation. Once the Evaluation Team has reviewed the application and accompanying evidence, then the application will be discussed amongst the entire TFATAG and a decision will be made on whether validation should be recommended or whether further information is needed.
6. **Validation**: Based on the recommendation of the TFATAG the WHO Director-General will make a final decision and WHO officially informs the government of the country in a letter to the responsible authority.

5 National preparation for validation for trans-fat elimination

5.1 Oversight and Management

When a decision has been made to eliminate iTFAs from the country or a decision has been made to apply for validation, it can be helpful to organise a meeting with the WHO Secretariat team. The WHO secretariat can help guide national competent authorities through the steps and application form to ensure that all relevant information is captured in the submitted application.

5.2 Key Sources of Documentation in an Effective Elimination Programme

The following are some key sources of documentation that will be helpful and should be collated and included in the application.

Legislation

The legislation, regulation, or mandatory directive is the cornerstone of the elimination programme and a crucial document for the application. The relevant parts of the legislation should be identified and translated to English (e.g. TFA restriction, enforcement authority and enforcement penalties). TFA legislation is often added into existing regulations on food safety or nutrition, which already have provisions around enforcement. In that case it is important that those provisions are highlighted in the active legislation and a listing of wrap-around policies are listed and summarized.

Monitoring

In many countries, different governmental bodies will be responsible for the monitoring and enforcement of the TFA elimination policy. This will mean the authority responsible for the application will not always have direct access to the results of the monitoring or the results of the enforcement and litigation. Therefore, it is important that the governmental bodies that will be responsible for the monitoring and enforcement are included in, or in direct communication with the authority responsible for the application.

The monitoring system that will provide the evidence that the country has a **framework in place to eliminate iTFA from their national food supplies** requires two important parts:

1) Documentation of either laboratory analysis or label analysis (or factory inspections) to show that the system can identify food products containing iTFAs (or PHO) or identify producers that introduce iTFAs into the food system (this is for both approaches based on label or laboratory analysis). All the evidence of this system should be clear and documented in the application.

2) Documentation to demonstrate a system for how foods are sampled for laboratory or label analysis to ensure that products that are likely to contain iTFA are examined. There needs to be clear evidence that the food products analysed are those that represent the greatest risk and that the overall strategy is adequate to identify and catch products in violation with the policy. This may be based on background documents developed during a situational analysis performed prior to the introduction of the policy.

Enforcement

To ensure compliance with the policy, countries must have effective enforcement mechanisms in place to track and hold violators accountable. This enforcement mechanism can be linked with the monitoring activities and be integrated into existing national enforcement mechanisms. National competent authorities should be able to show that there is a systematic tracking of inspections. If there have been offences, documentation should provide evidence of them and resulting punitive action. These monitoring and enforcement protocols and reports will demonstrate that the entire system is functioning and effective.

In some cases, it is possible that violations are detected but that companies or food producers adapt their practice before prosecution. Examples of such effective implementation of the TFA elimination policy are relevant evidence in the application. These could be in the form of changed compositions of food products or the closure of PHO production systems.

5.3 Completion of the application form

The Trans Fat Elimination Validation Certificate application form will need to be accompanied with supporting evidence for each of the criteria outlined above. It is important that each piece of evidence be submitted electronically (PDF or similar) and be signposted, date stamped and accompanied with an English translation of the relevant sections. It should not be based on webpage links or overarching documents without signposting. In the following chapters we provide detailed information on the types of documentation that can be used as evidence in the application

For most countries, the monitoring and enforcement of the TFA elimination policy are likely to be part of the national food safety or food control programme. This can make it difficult for the authority to highlight recent or specific evidence on TFA. The TFA Evaluation Team will consider the documentation that shows an effective food safety or food control programme that includes TFA. However, the documentation must show evidence that it does include TFA.

5.3.1 First Section of the form

	Checklist ("Yes" means a supporting document is provided)	**Please provide a brief description**	**Documentation**[4] **(Please specify the document title and the exact section or page of the relevant info)**
Best-practice TFA regulation is implemented	Yes: ☐ No: ☐	Please provide a brief description of the best-practice TFA regulation, including its effective date.	Policy document on best-practice policy

This is the introduction of the national responsible authority presenting their country's efforts to reach the elimination of the iTFAs and/or PHOs from the food system:

Types of evidence required:

- **policy document (detailing the aims and approaches to eliminate iTFA) and the relevant legislation/regulation documents, date of passage, date of implementation, and that it is mandatory.**

Further types of evidence (optional):

- details of the responsible authority;
- details of organisation involved and their roles (government departments, agencies, laboratories, universities, etc.);

[4] Expected documentation is indicated as an example.

- information on changes in food composition or product availability due to the introduced legislation (such as reports, national studies etc, detailing methods and findings).

Adequate monitoring system is in place	Yes: ☐ No: ☐	Please provide an overview of the monitoring activities to ensure compliance with the best-practice policy, including the number of samples tested and/or labels reviewed per year, and sampling plan.	Monitoring protocol

Within this section the TFATAG will be looking for an overview of the evidence of an effective monitoring system and evidence outlining why this system is suitable for the country. The exact details can be given in the 3rd section of the form.

Type of evidence required:

- **document that provides an overview of the methods used for monitoring (whether by laboratory testing or label assessment) with full details in section "I. Monitoring system" of the form.**

Adequate enforcement system is in place	Yes: ☐ No: ☐	Please provide an overview of the enforcement activities to track and hold violators accountable, including enforcement actions available and those actually taken.	Enforcement protocol

This part should outline how this legislation is brought into practice, how inspections are organised (when different from monitoring) and how it is enforced. In this section the TFATAG will be looking for evidence that the national responsible authority is able to enforce the legislation. The introduction of the legislation might already be an effective tool. Communication around the legislation may have enabled companies to change their production or sourcing prior to the policy coming into effect. Evidence around this can be presented here. It is expected that the enforcement is aligned with the monitoring (previous question), and this should be made clear. Evidence of enforcement actions will be useful as well.

Types of evidence required:

- **details on the results of the enforcement programme will be in the section "II. Enforcement system".**

Further types of evidence (optional):

- communication with food producer and importers prior to legislation introduction (including the number of producers or importers that the agency has written to, met with, or otherwise communicated with);
- evidence of a response of food producers and importers (including the number of producers or importers that have responded).

5.3.2 Second section of the form

This section determines which further questions need to be completed.

TFA policy implemented in the country*	**PHO ban** 1	☐
	2% iTFA limit	☐
Monitoring and enforcement systems in place*	**Option A: Laboratory testing or label assessment of food items sampled at food outlets** 2.1	**Option B: Inspection of manufacturing facilities and at ports of entry**
	Domestic and imported products: 2.2 Laboratory analysis: ☐ (Answer Q1) Label analysis: ☐ (Answer Q2)	**Domestic products:** Checking documentation: ☐ (Answer Q3) Laboratory analysis: ☐ (Answer Q4) **Imported products:** Checking documentation: ☐ (Answer Q5) Laboratory analysis: ☐ (Answer Q6) Label analysis: ☐ (Answer Q7)
	In case a combined approach is taken, describe the combination: 2.3	
Date of Implementation*	MM/DD/YYYY 3	

1) TFA policy implemented in the country: National competent authorities should highlight here if their policy is focused on the ban of PHO or a limit of 2% of iTFA of fats, oils and food (or both).

2) Monitoring and enforcement systems in place:

2.1) Countries can base their monitoring and enforcement on A) laboratory testing or label assessment of food items sampled at food outlets and/or B) inspection of manufacturing facilities and at ports of entry. This determines if left hand side A) or the right-hand side B) of the next section needs to be completed.

2.2) Countries can base their monitoring on laboratory analysis and/or on label analysis with checking documentation. Ticking the specific boxes shows which questions need to be completed in the following part of the form.

2.3) When national competent authorities find that their policy does not fit with the above tick boxes, they can outline here how their policy and systems are different.

3) Date of Implementation: This is the date the policy came into effect and monitoring and enforcement began.

5.3.3 Third section of the form

I. Monitoring system

Option A: Laboratory testing or label assessment of food items sampled at food outlets

Q1. Laboratory analysis

	Checklist ("Yes" means a supporting document is provided)	**Please provide a brief description**	**Documentation**[5] **(Please specify the document title and the exact section or page of the relevant info)**
Q1. Laboratory analysis			
Validated laboratory method is used	Yes: ☐ No: ☐	What is the lab method used (e.g. WHO, Association of Official Analytical Collaboration (AOAC), American Oil Chemists' Society (AOCS), the International Organization for Standardization (ISO))?	Lab method / protocol

Provide the details of the method used and the laboratory which is responsible for the analysis. Are the methods based on (inter)nationally accepted protocols? The TFATAG expect that the method used is based on fatty acid methyl esters (FAMEs) using a gas chromatography–flame ionization detector (GC-FID) system equipped with a 100 m fused silica capillary column coated with 100% biscyano propylpolysiloxane stationary phase. It is expected that most countries will use a laboratory that is accredited by an independent / international quality assurance scheme. It will then be sufficient to provide the method codes and evidence of the accreditation. In other cases, the TFATAG will be looking for the full details of the methods. It is possible that analyses were done historically with now superseded methods. When non-standard methods were used, provide the standard operating procedures and information on the quality assurance and quality control. Provide information about the laboratory and its selection.

Type of documentation expected:

- **information on the laboratory method and laboratory accreditation; and**
- **if the laboratory uses (or used) methods other than accredited methods provide details on the methods (Standard Operating Procedure (SOP) and results) and quality control and assurance.**

Further types of evidence (optional):

- commissioning documents, it is possible that the analysis was done by an external or contract research organisation. In that case, provide a commissioning document for this work.

[5] Expected documentation is indicated as an example.

Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size? What rationale and/or data were used to inform the sampling strategy.	Sampling plan

Provide details of the selection process for the inspection of food products, why these foods, why this number, and why this rate (number of samples per year). Who is responsible for the sample collection, sample transfer and result interpretation? Providing these details helps the TFATAG understand the monitoring process and determine whether this is likely an effective system.

Type of evidence required:

- **sampling plan.**

Further types of evidence (optional):

- commissioning documents
- rationale for sample selection (type and numbers) that enable effective monitoring.

Reports/ documentation on lab analysis	Yes: ☐ No: ☐	Please provide a brief description of the results of the lab analysis including the TFA content in the samples.	Lab analysis reports

The combination of sampling and analysis will help indicate the current presence of iTFA in the national food supply. It is expected that regular reporting will be performed on the outcomes of the laboratory assessments. The TFATAG will consider these reports alongside other evidence provided, to determine whether the monitoring activities are sufficiently rigorous.

Type of evidence required:

- **report of laboratory analysis results.**

Q2. Label analysis			
Policy on TFA labelling is implemented	Yes: ☐ No: ☐	Please provide a brief description of the TFA labelling regulation and describe any exemptions or voluntary features.	Policy document on TFA labelling

Where labelling is used to monitor TFA contents in foods, countries rely on the information provided by food producers on the PHO and TFA content of the products. This form of monitoring will require mandatory labelling requirements for TFA (or PHOs). It will also require traceability of the label information (in other words, on what information is the label based). To have an effective labelling policy requires monitoring of the label quality (the presence of the label and that it meets policy specifications). The TFATAG will be looking for the evidence that all food products carry reliable labelling and that these are used to identify whether food products are compliant with the best-practice TFA policy.

Type of evidence required:

- **legislation or regulation on food labelling.**

Further types of evidence (optional):

- information on food products sold with and without packaging (such as at food service outlets)
- information on the reliability and traceability of food labelling
- commissioning documents for the work of label inspection.

Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size? What steps were taken to verify the general accuracy of nutrition labels, particularly in respect of trans fat?	Sampling plan

The selection process of food products for label inspection, why these foods, why this number and why this rate (number of samples per year). What is the rationale and how does the rationale provide certainty about the effectiveness of the monitoring process? Who is responsible for the label inspection, consistent quality of the inspections and result interpretation?

Type of evidence required:

- **sampling plan.**

Further types of evidence (optional):

- commissioning documents
- methods (SOPs and results) for training of label inspection
- rationale for sample selection (type and numbers) the enable effective monitoring.

Reports on label analysis exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the label analysis including the TFA content in the samples. Please indicate the % of products declaring TFA content.	Label analysis reports

The combination of sampling and label inspections will provide approximate evidence on the presence of iTFA or PHO in the national food supply. It is expected that regular reporting will be performed on the outcomes of the label assessments. The TFATAG will consider these reports alongside other evidence provided to determine whether the monitoring activities are sufficiently rigorous.

Type of evidence required:

- **report of results (including information on label quality and PHO/TFA content and on the proportion or number of products that were non-compliant).**

Option B: Inspection of manufacturing facilities and at ports of entry

Q3. Checking documentation – at manufacturing facilities			
Inspection plan exists	Yes: ☐ No: ☐	What is the basis for selecting the facilities? How often were the inspections carried out? Were they done as part of regular inspection or independently? What is the number and proportion of facilities inspected for each year since inspection began? Were the facilities inspected remotely?	Inspection plan

The inspection of manufacturing facilities requires that an adequate system is in place and that companies are obligated to report on their food manufacturing or production activities. The TFATAG will be looking for evidence that within the country there is comprehensive knowledge of all manufacturing and food producing facilities. In addition, the national responsible authority needs to know which facilities have the potential to produce PHO or iTFA that can be used in food production. Furthermore, inspectors should be trained to understand manufacturing processes and be able to make an independent judgement on the inspection about the risk of PHO or iTFA generation in manufacturing. It is also important to highlight if inspection visits were scheduled or unannounced.

Type of documentation required:

- **inspection plan for manufacturing facilities that includes TFA. Where not available, then a justification for the selection of specific facilities for inspection should be provided.**

Further types of evidence (optional):

- commissioning documents for work of facility inspection.

Relevant documentation and/or practice was examined at manufacturing facilities	Yes: ☐ No: ☐	What types of documents and practices were examined (e.g. documents: receipts, records, inventory, labels, laboratory reports, recipes; practice: assessing if the factories are engaged in partial hydrogenation)?	Inspection protocol

Without the aid of laboratory analysis, inspectors will have to rely on detailed documentation (e.g. receipts, records, inventory, labels, laboratory reports, recipes) that facilities maintain on purchased materials and manufacturing of their products, or on examining their practice (e.g. assessing if the oil and fat factories are engaged in partial hydrogenation). It is expected that inspectors have knowledge of food production to be able to make an accurate assessment of the manufacturing facility. This requires well trained, independent inspectors. The TFATAG would like to see evidence of an auditable inspection process.

Type of documentation required:

- **inspection protocol for manufacturing facilities.**

Further types of evidence (optional):

- the SOPs for the inspectors that allow them to make decisions on the risk of the manufacturing facilities introducing PHO or iTFA into food production.

Inspection reports exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the facility inspection.	Inspection reports

The national responsible authority needs to show that the checking of documentation at manufacturing facilities is effective in identifying violations and provide the authority with certainty that there is no introduction of PHO or iTFA into the national food system. It is expected that regular reporting will be performed on the outcomes of inspections. The TFATAG will consider these reports alongside other evidence provided to determine whether the monitoring activities are sufficiently rigorous.

The TFATAG will be looking for comprehensive and traceable reports.

Type of evidence required:

- **report of findings from facility inspections.**

Q4. Laboratory analysis – at manufacturing facilities			
Validated laboratory method is used	Yes: ☐ No: ☐	What is the lab method used (e.g. WHO, Association of Official Analytical Collaboration (AOAC), American Oil Chemists' Society (AOCS), the International Organization for Standardization (ISO))?	Lab method / protocol

Provide the details of the method used and the laboratory which is responsible for the analysis. Are the methods based on (inter)nationally accepted protocols? The TFATAG expect that the method used is based on fatty acid methyl esters (FAMEs) using a gas chromatography–flame ionization detector (GC-FID) system equipped with a 100 m fused silica capillary column coated with 100% biscyano propylpolysiloxane stationary phase. It is expected that most countries will use a laboratory that is accredited by an independent / international quality assurance scheme. It will then be sufficient to provide the method codes and evidence of the accreditation. In other cases, the TFATAG will be looking for the full details of the methods. It is possible that analyses were done historically with now superseded methods. When non-standard methods were used, provide the standard operating procedures and information on the quality assurance and quality control. Provide information about the laboratory and its selection.

Type of documentation expected:

- **information on the laboratory method and laboratory accreditation; and**
- **if the laboratory uses (or used) methods other than accredited methods provide details on the methods (SOPs and results) and quality control and assurance.**

Further types of evidence (optional):

- commissioning documents, it is possible that the analysis was done by an external or contract research organisation. In that case, provide a commissioning document for this work.

Inspection plan exists	Yes: ☐ No: ☐	What is the basis for selecting the facilities? How often were the inspections carried out? Were they done as part of regular inspection or independently (specifically focused on trans fat)? What is the number and proportion of facilities inspected per year since inspections began?	Sampling plan

The inspection and analysis of product from manufacturing facilities requires an adequate system in force that obligates companies to report on manufacturing and production of foods. The TFATAG will be looking for evidence that within the country there is comprehensive knowledge of all manufacturing and food producing facilities. In addition, the national responsible authority should know which facilities have the potential to produce PHO or iTFA that can be used in food production. Furthermore, it is important to have a sampling protocol (when, where and how often).

Type of documentation required:

- **inspection plan, with protocols, for manufacturing facilities that addresses TFA; or**
- **where not available, then a justification for the selection of specific facilities for inspection should be provided.**

Further types of evidence (optional):

- commissioning documents for inspections.

Reports on lab analysis exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the lab analysis including the TFA content in the samples.	Lab analysis reports

The combination of sampling and analysis will provide evidence on the current presence of PHO or iTFA in the national food supply. It is expected that regular reporting will be performed on the outcomes of the laboratory assessments. The TFATAG will consider these reports alongside other evidence provided to determine whether the monitoring activities are sufficiently rigorous.

Type of evidence required:

- **report of inspection findings.**

Q5. Checking documentation – at ports of entry			
Inspection plan exists	Yes: ☐ No: ☐	How often were the inspections carried out? How many products were inspected each year since inspections began? What is the number or proportion of products inspected?	Inspection plan

The inspection of ports of entry requires an adequate system in force that obligates companies to report the import of foods products and ingredients with detailed enough composition data or ingredient lists. The TFATAG will be looking for evidence that within the country there is comprehensive knowledge of all the relevant imports. In addition, the national responsible

authority should have an inspection system with officers trained to inspect food products with PHO or iTFA.

Type of documentation required:

- **inspection plan that includes TFA for ports of entry.**

Further types of evidence (optional):

- commissioning documents for work of the inspections at port of entry.

Relevant documentation and/or practice was examined at ports of entry	Yes: ☐ No: ☐	What types of documents were examined at ports of entry (e.g. bills of lading, tariff and customs declarations) or before entry (e.g. import registration submitted by importers, certificate of conformity, laboratory analysis report)?	Inspection protocol

The targeting of inspections of imports requires a sufficient understanding of what foods are imported. This means that inspections need to be based on documentation that accompanies the imported food product. The TFATAG will want to understand what documentation is used to determine inspections. What is the level of information that is needed and what happens to imports with insufficient detail?

Type of documentation required:

- **inspection reports for monitoring at ports of entry.**

Further types of evidence (optional):

- information on the number or frequency of import registrations where TFA was considered as a risk.

Inspection reports exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the facility inspection.	Inspection reports

The national responsible authority needs to show that checking documentation at ports of entry is effective and provide them with certainty that there is no introduction of PHO or iTFA into the national food system. It is expected that regular reporting will be performed on the outcomes of inspections including on violations. The TFATAG will consider these reports alongside other evidence provided to determine whether the monitoring activities are sufficiently rigorous.

Type of evidence required:

- **report of findings.**

Further types of evidence (optional):

- monitoring protocol for imported food products
    a. Example of acceptable completed documentation for import
    b. Example of rejected documentation that prohibited import.

Q6. Laboratory analysis – at ports of entry			
Validated laboratory method is used	Yes: ☐ No: ☐	What is the lab method used (e.g. WHO, Association of Official Analytical Collaboration (AOAC), American Oil Chemists' Society (AOCS), the International Organization for Standardization (ISO))?	Lab method / protocol

Provide the details of the method used and the laboratory which is responsible for the analysis. Are the methods based on (inter)nationally accepted protocols? The TFATAG expect that the method used is based on fatty acid methyl esters (FAMEs) using a gas chromatography–flame ionization detector (GC-FID) system equipped with a 100 m fused silica capillary column coated with 100% biscyano propylpolysiloxane stationary phase. It is expected that most countries will use a laboratory that is accredited by an independent / international quality assurance scheme. It will then be sufficient to provide the method codes and evidence of the accreditation. In other cases, the TFATAG will be looking for the full details of the methods. It is possible that analyses were done historically with now superseded methods. When non-standard methods were used, provide the standard operating procedures and information on the quality assurance and quality control. Provide information about the laboratory and its selection.

Type of documentation expected:

- **information on the laboratory method and laboratory accreditation; and**
- **if the laboratory uses (or used) methods other than accredited methods provide details on the methods (SOPs and results) and quality control and assurance.**

Further types of evidence (optional):

- commissioning documents, it is possible that the analysis was done by an external or contract research organisation. In that case, provide a commissioning document for this work.

Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size?	Sampling plan

If only a sub-sample of food products are assessed using laboratory methods, then the responsible authority should provide the rationale for the selection process of food products for inspection, why these foods, why this number and why this rate (number of samples per year). How does this rationale provide certainty about the effectiveness of the monitoring process? Who is responsible for the sample collection, sample transfer and result interpretation? Providing these details helps the TFATAG understand the monitoring process and determine whether this is likely an effective system.

Type of evidence required:

- **sampling plan.**

Further or alternative types of evidence:

- commissioning documents

- rationale for sample selection (type and numbers) that enable effective monitoring.

Reports/ documentation on lab analysis	Yes: ☐ No: ☐	Please provide a brief description of the results of the lab analysis including the TFA content in the samples.	Lab analysis reports

The combination of sampling and analysis will provide evidence on the current occurrence of PHO or iTFA in the country. It is expected that this will lead to a report to the responsible authority. The TFATAG will consider these reports alongside other evidence provided to determine whether the monitoring activities are sufficiently rigorous.

Type of evidence required:

- **report of findings.**

Q7. Label analysis – at ports of entry			
Policy on TFA labelling exists	Yes: ☐ No: ☐	Please provide a brief description of the TFA labelling regulation and describe any exemptions or voluntary features.	Policy document on TFA labelling

Where labelling is used to monitor TFA contents in foods, countries rely on the information provided by food producers on the PHO and TFA content of the products. This form of monitoring will require mandatory labelling requirements for TFA (or PHOs). It will also require traceability of the label information (in other words, on what information is the label based). To have an effective labelling policy requires monitoring of the label quality (the presence of the label and that it meets policy specifications). The TFATAG will be looking for the evidence that all food products carry reliable labelling and that these are used to identify whether food products are compliant with the best-practice TFA policy.

Type of evidence required:

- **legislation or regulation on food labelling.**

Further types of evidence (optional):

- information of reliability to food labelling
- commissioning documents for work of label inspection.

Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size? How many ports of entry are there and how many were included in the sampling plan?	Sampling plan

The selection process of food products for label inspection, why these foods, why this number and why this rate (number of samples per year). What is the rationale and how does this provide certainty about the effectiveness of the monitoring process? Who is responsible for the label inspection, consistent quality of the inspections and result interpretation?

Type of evidence required:

- **sampling plan.**

Further types of evidence (optional):

- commissioning documents
- methods (SOPs and results) for training of label inspection
- rationale for sample selection (type and numbers) that enable effective monitoring.

Reports on label analysis exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the label analysis including the TFA or PHO content in the samples. Please indicate the amounts of TFA in each product and indicate the overall % of products declaring TFA content and the % of products declaring non-compliant TFA content.	Label analysis reports

The combination of sampling and label inspections will provide evidence on the current occurrence of food products with inadequate labelling and the occurrence of PHO or iTFA in the country. It is expected that this will lead to a report to the responsible authority. The TFATAG will consider these reports alongside other evidence provided to determine whether the monitoring activities are sufficiently rigorous.

Type of evidence required:

- **report of findings (including label quality and TFA content).**

II. Enforcement system

The effectiveness of the legislation to eliminate TFAs will be dependent on the ability to enforce it. In the previous parts of the form, national competent authorities should have provided details on how to detect potential violations of the TFA best-practice policy. In this section, national competent authorities should provide clear evidence that they are enforcing their TFA policy and that this enforcement system can in turn be effective in preventing the introduction of PHO or iTFA into the national food system. In some cases, it is possible that companies or food producers will be found to include PHO or iTFAs in their products and that after discovery, the company changes its practice before prosecution. Examples of such effective implementation of the TFA elimination policy are important evidence in the application. These could be in the form of changed compositions of food products or the closure of PHO production systems.

	Checklist ("Yes" means a supporting document is provided)	**Please provide a brief description**	**Documentation[6]** **(Please specify the document title and the exact section or page of the relevant info)**
A systematic tracking of inspections and offences is in place	Yes: ☐ No: ☐	Are inspection reports of trans fat levels and designation of whether they are not compliant with the regulation compiled in a database, website or reports?	Database, website, reports

[6] Expected documentation is indicated as an example.

Provide information on actions taken, when food products or production facilities are identified that are in breach of the PHO ban or the 2% iTFA limit. Provide the relevant legislation and evidence of the organisational structures that can effectively enforce the legislation. Demonstrate that violations of the policy are documented and tracked.

Type of documentation required:

- **full text of the regulation and/or operational document and a database or records of violations and enforcement.**

Further types of evidence (optional):

- clear information on the structure and organisation of the agency or agencies that enforce the TFA legislation;
- documentation showing what procedures are followed when a product or producer is in breach of this legislation (provide guidelines and regulations).

Risk-based inspections are conducted	Yes: ☐ No: ☐	Were high-risk food categories[7], repeat offenders, facilities with ability for partial hydrogenation (e.g. hydrogeneration towers) inspected?	

Explain how inspections are targeted based on risk (high-risk food categories, repeat offences, key facilities with ability to perform partial hydrogenation or who may refine oils at high temperatures). Provide evidence of how previous inspections are used in the follow-up with producers, what is done with repeat offenders and how does the policy ensure that repeat offenders are identified. Which agency is responsible for policy enforcement.

Type of documentation required:

- **the policy documents dealing with risk-based inspections (clearly signposted for the relevant sections).**

Further types of evidence (optional):

- evidence that risk-based inspections are carried out;
- evidence of follow-up inspection of offenders;
- evidence that the repeat offenders are dealt with according to the policy or documentation that there are no repeat offenders.

Penalties for violations are in place	Yes: ☐ No: ☐	What are the penalties authorized by law? How many times were various penalties actually imposed on sellers, importers, or manufacturers of high-trans fat foods?	Violation reports

Clear evidence is needed to show that agencies can (or have) impose(d) penalties to prevent the introduction of products that contain PHO or too much iTFA from entering the market. Are graduated sanctions possible and are these applied?

[7] For example, baking fats (e.g. shortening); cooking/frying oils; vegetable ghee, spreads (e.g. margarine); baked goods (e.g. biscuits, cakes, pastries, doughnuts); baked snacks; non-dairy creamer; confectionaries; fried entrees; fried snacks; frozen foods.

Type of documentation required:

- **evidence of violation reports.**

Further types of evidence (optional):

- evidence of sanction or legal action;
- details of policy dealing with products found to contain PHO or too much TFA (clearly signposted to the relevant sections).

Other relevant information (optional)
Describe any other relevant information regarding implementation, monitoring and enforcement of the policy that might be relevant to the TFA validation application. Describe any efforts to monitor aggregate trans fat levels in the typical diets of national populations and vulnerable or disproportionately exposed sub-populations. Describe any efforts and findings of aggregate trans fat consumed by analyzing representative samples of blood or human breastmilk.

5.4 Self-assessment of readiness for validation

The steps used by the TFATAG to assess the application for validation are detailed in the next section. With this document it is possible for national competent authorities to perform a self-assessment of readiness.

5.5 Submission of the form and supporting documentation

Once the competent authorities from a country have completed the application form including supporting documentation, and have confirmed that the information is clear, up to date, signposted and translated into English, then they can proceed with the submission to the WHO Headquarters Department of Nutrition and Food Safety at tfa@who.int.

6 Application Assessment and Validation

Once the application has been received, a Trans Fat Evaluation Team will be appointed, consisting of up to three TFATAG members who will be responsible for the detailed assessment. The aim of the TFA Evaluation Team is to understand the country's approach to TFA elimination using the information made available in the application. The TFATAG will use the assessment form, which will be accompanied by a guiding document (in prep) to ensure that all applications are fairly assessed.

6.1 Types of assessment

The TFA Evaluation Team will consider the history of the country's TFA elimination journey.

For countries where legislation around TFA precedes the REPLACE program (before 2018), the monitoring and enforcement are likely to be part of the country's existing food control system. This may make it difficult for the responsible authority to extract specific evidence on TFA. The TFA Evaluation Team will consider documentation that shows an effective food safety programme that includes TFA.

Countries that have passed their policies after the launch of the REPLACE package, will ideally have suitable documentation already available that will support the TFATAG's assessment of their application.

6.2 Assessment process

The first step for the TFA Evaluation Team is to independently assess the type of TFA policy using the first 2 sections of the application form. This determines which section of the form needs to be completed.

The second step is that the TFA Evaluation Team members independently check if the supporting documentation is in place and that it provides sufficient evidence for the policies outlined in the form.

It is essential that there is evidence for the country that there is:

1) a best-practice TFA regulation in effect, including its effective date
2) an adequate monitoring system is in place
3) an adequate enforcement system is in place.

The evidence will consist of documentation on the following points:

1) both domestic and imported food products covered
2) major iTFA food sources and categories covered
3) representative sample size for analysis and examination
4) for laboratory analysis: WHO laboratory protocol or equivalent used
5) for label analysis: Labelling regulation exists
6) for checking documentation: Sufficient information made available and relevant sections of broader reports are highlighted or otherwise signposted
7) a systematic tracking of inspections and offences and risk-based inspections
8) graduated sanctions to violators
9) monitoring and enforcement protocol for both domestic and imported products
10) monitoring and enforcement reports for both domestic and imported products.

The third step is that the TFA Evaluation Team members independently assess the policy and the supporting evidence. There are three key points that need to be in place supported by evidence:

1. The country has a best-practice TFA elimination policy in effect that is:
    a. clearly described
    b. in effect
    c. is mandatory.
2. The country conducts adequate monitoring activities to ensure compliance with the best-practice policy.
    a. Are the monitoring activities clearly described?
    b. Are monitoring activities likely to be adequate to detect domestically-produced and/or imported iTFA/PHO to ensure compliance with the best-practice TFA policy?
3. The country conducts enforcement activities to track and hold violators accountable.
    a. Is there a clear description of the system that demonstrates effective enforcement of the best-practice policy?

Members of the TFA Evaluation Team will then meet and discuss their findings. These will be aligned and jointly the "Assessment of Country Applicants for the WHO Validation Certificate" form will be completed.

The findings of the TFA Evaluation Team will be presented to the rest of the TFATAG during biannual meetings. Other members will be provided with the completed evaluation form and linked evidence. The WHO Secretariat may also suggest a short call to discuss these elements. At a general meeting of TFATAG, the full committee will come to consensus on a recommendation. The TFATAG recommendation will be conveyed to the WHO Director General, who will make a final decision on validation. The government will be informed of the decision in a letter to the responsible authority.

7 Revalidation

After 5 years of being granted the recognition, national competent authorities will be requested to submit a revalidation application. This will need to demonstrate that the country has continued its efforts to maintain its normative framework to eliminate iTFA from its national food supply. National competent authorities should submit their continued efforts in monitoring and include any enforcement action that has taken place since the original application. If the country was validated with a recommendation to improve certain aspects of the original application (missing evidence or suboptimal practice), then it will be expected that at revalidation there is evidence showing the requested improvements have been made or additional evidence has been supplied.

Annex 1. Trans Fat Elimination Validation Application Form

WORLD HEALTH ORGANIZATION

Trans Fat Elimination Validation Certificate Application Form

To apply for the WHO Trans Fat Elimination Validation Certificate, please complete and submit this form, along with the required attachments, to WHO Headquarters Department of Nutrition and Food Safety at nfs@who.int.

Requirements:

1. * indicates required question (pages 2, 3, 11).
2. All supporting documents must be prepared in English. Alternatively, documents can be submitted in languages other than English, but in this case, please include a summary of each document in English.
3. When referencing documentation, please specify the precise section or page containing the relevant information. This facilitates efficient retrieval of the required details.

Applicant Information		
Country:	_____	
Authority/ Agency:	_____ *Name*	
	_____ *Address*	
Primary Point of Contact:	_____ *Name*	_____ *Title*
	_____ *Phone number*	_____ *Email address*
Secondary Point of Contact (optional):	_____ *Name*	_____ *Title*
	_____ *Phone number*	_____ *Email address*

	Checklist ("Yes" means a supporting document is provided)	Please provide a brief description	Documentation[1] (Please specify the document title and the exact section or page of the relevant info)
Best-practice TFA regulation is implemented*	Yes: ☐ No: ☐	Please provide a brief description of the best-practice TFA regulation, including its effective date.	Policy document on best-practice policy
Adequate monitoring system is in place*	Yes: ☐ No: ☐	Please provide an overview of the monitoring activities to ensure compliance with the best-practice policy, including the number of samples tested and/or labels reviewed per year, and sampling plan.	Monitoring protocol
Adequate enforcement system is in place*	Yes: ☐ No: ☐	Please provide an overview of the enforcement activities to track and hold violators accountable, including enforcement actions available and those actually taken.	Enforcement protocol

[1] Expected documentation is indicated as an example.

TFA policy implemented in the country*	**PHO ban**	☐
	2% iTFA limit	☐
Monitoring and enforcement systems in place*	**Option A: Laboratory testing or label assessment of food items sampled at food outlets**	**Option B: Inspection of manufacturing facilities and at ports of entry**
	Domestic and imported products: Laboratory analysis: ☐ (Answer Q1) Label analysis: ☐ (Answer Q2)	**Domestic products:** Checking documentation: ☐ (Answer Q3) Laboratory analysis: ☐ (Answer Q4) **Imported products:** Checking documentation: ☐ (Answer Q5) Laboratory analysis: ☐ (Answer Q6) Label analysis: ☐ (Answer Q7)
	In case a combined approach is taken, describe the combination:	
Date of Implementation*	MM/DD/YYYY	

I. Monitoring system

Option A: Laboratory testing or label assessment of food items sampled at food outlets

	Checklist ("Yes" means a supporting document is provided)	**Please provide a brief description**	**Documentation[2] (Please specify the document title and the exact section or page of the relevant info)**
Q1. Laboratory analysis			
Validated laboratory method is used	Yes: ☐ No: ☐	What is the lab method used (e.g. WHO, Association of Official Analytical Collaboration (AOAC), American Oil Chemists' Society (AOCS), the International Organization for Standardization (ISO))?	Lab method / protocol
Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size? What rationale and/or data were used to inform the sampling strategy.	Sampling plan
Reports/ documentation on lab analysis	Yes: ☐ No: ☐	Please provide a brief description of the results of the lab analysis including the TFA content in the samples.	Lab analysis reports
Q2. Label analysis			
Policy on TFA labelling is implemented	Yes: ☐ No: ☐	Please provide a brief description of the TFA labelling regulation, and describe any exemptions or voluntary features.	Policy document on TFA labelling
Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size? What steps were taken to verify the general accuracy of nutrition labels, particularly in respect of trans fat?	Sampling plan

[2] Expected documentation is indicated as an example.

Reports on label analysis exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the label analysis including the TFA content in the samples. Please indicate the % of products declaring TFA content.	Label analysis reports

Option B: Inspection of manufacturing facilities and at ports of entry

Q3. Checking documentation – at manufacturing facilities			
Inspection plan exists	Yes: ☐ No: ☐	What is the basis for selecting the facilities? How often were the inspections carried out? Were they done as part of regular inspection or independently? What is the number and proportion of facilities inspected for each year since inspection began? Were the facilities inspected remotely?	Inspection plan
Relevant documentation and/or practice was examined at manufacturing facilities	Yes: ☐ No: ☐	What types of documents and practices were examined (e.g. documents: receipts, records, inventory, labels, laboratory reports, recipes; practice: assessing if the factories are engaged in partial hydrogenation)?	Inspection reports

Q4. Laboratory analysis – at manufacturing facilities			
Validated laboratory method is used	Yes: ☐ No: ☐	What is the lab method used (e.g. WHO, Association of Official Analytical Collaboration (AOAC), American Oil Chemists' Society (AOCS), the International Organization for Standardization (ISO))?	Lab method / protocol
Inspection plan exists	Yes: ☐ No: ☐	What is the basis for selecting the facilities? How often were the inspections carried out? Were they done as part of regular inspection or independently (specifically focused on trans fat)? What is the number and proportion of facilities inspected per year since inspections began?	Sampling plan
Reports on lab analysis exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the lab analysis including the TFA content in the samples.	Lab analysis reports

Q5. Checking documentation – at ports of entry			
Inspection plan exists	Yes: ☐ No: ☐	How often were the inspections carried out? How many products were inspected each year since inspections began? What is the number or proportions of products inspected?	Inspection plan
Relevant documentation and/or practice was examined at manufacturing facilities	Yes: ☐ No: ☐	What types of documents were examined at ports of entry (e.g. bills of lading, tariff and customs declarations) or before entry (e.g. import registration submitted by importers, certificate of conformity, laboratory analysis report)?	Inspection reports
Inspection reports exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the facility inspection.	Inspection reports

Q6. Laboratory analysis – at ports of entry			
Validated laboratory method is used	Yes: ☐ No: ☐	What is the lab method used (e.g. WHO, Association of Official Analytical Collaboration (AOAC), American Oil Chemists' Society (AOCS), the International Organization for Standardization (ISO))?	Lab method / protocol
Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size?	Sampling plan
Reports documentation on lab analysis	Yes: ☐ No: ☐	Please provide a brief description of the results of the lab analysis including the TFA content in the samples.	Lab analysis reports
Q7. Label analysis – at ports of entry			
Policy on TFA labelling exists	Yes: ☐ No: ☐	Please provide a brief description of the TFA labelling regulation, and describe any exemptions or voluntary features.	Policy document on TFA labelling
Sampling plan exists	Yes: ☐ No: ☐	What is the basis for the sample collection? How many samples were collected and analyzed? Is it a representative sample size? How many ports of entry are there and how many were included in the sampling plan?	Sampling plan

Reports on label analysis exist	Yes: ☐ No: ☐	Please provide a brief description of the results of the label analysis including the TFA or PHO content in the samples. Please indicate the amounts of TFA in each product and indicate the overall % of products declaring TFA content and the % of products declaring non-compliant TFA content.	Label analysis reports

II. Enforcement system

	Checklist ("Yes" means a supporting document is provided)	**Please provide a brief description**	**Documentation[3] (Please specify the document title and the exact section or page of the relevant info)**
A systematic tracking of inspections and offences is in place*	Yes: ☐ No: ☐	Are inspection reports of trans fat levels and designation of whether they are not compliant with the regulation compiled in a database, website or reports?	Database, website, reports
Risk-based inspections are conducted*	Yes: ☐ No: ☐	Were high-risk food categories[4], repeat offenders, facilities with ability for partial hydrogenation (e.g. hydrogeneration towers) inspected?	
Penalties for violations are in place*	Yes: ☐ No: ☐	What are the penalties authorized by law? How many times were various penalties actually imposed on sellers, importers, or manufacturers of high-trans fat foods?	Violation reports

[3] Expected documentation is indicated as an example.
[4] For example, baking fats (e.g. shortening); cooking/frying oils; vegetable ghee, spreads (e.g. margarine); baked goods (e.g. biscuits, cakes, pastries, doughnuts); baked snacks; non-dairy creamer; confectionaries; fried entrees; fried snacks; frozen foods.

Other relevant information (optional)
Describe any other relevant information regarding implementation, monitoring and enforcement of the policy that might be relevant to the TFA validation application. Describe any efforts to monitor aggregate trans fat levels in the typical diets of national populations and vulnerable or disproportionately exposed sub-populations. Describe any efforts and findings of aggregate trans fat consumed by analyzing representative samples of blood or human breastmilk.