

**WHO Validation Programme for Trans Fat Elimination**  
**Technical Criteria for Monitoring and Enforcement Systems**  
**(1<sup>st</sup> edition, January 2024)**

Member States' applications for the WHO Validation certificate must demonstrate that adequate monitoring and enforcement systems are in place to ensure compliance with best-practice *trans*-fatty acids (TFA) policy.<sup>1</sup> Member States' monitoring and enforcement systems must meet the below technical criteria.

## **I. Required monitoring system features**

There are two options for the 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 industrially produced TFA (iTFA)) and key food categories that tend to contain high levels of iTFA<sup>2</sup>. 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.

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

Sampling of food items is conducted at food outlets<sup>3</sup> that are common sources/venues of iTFA intake among the population. For monitoring food items sampled at food outlets, priority should be given to laboratory testing, but in the event laboratory testing is difficult due to cost or technical challenges, countries may choose to conduct label assessment or a hybrid approach.

#### **1. Laboratory testing**

Measuring the TFA content of the food items sampled at food outlets. Testing must follow procedures described in the WHO simplified protocol<sup>4</sup> or the WHO reference protocol<sup>5</sup> or by a method that is equivalent<sup>6</sup> to the WHO simplified protocol or the WHO reference protocol.

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<sup>1</sup> Best-practice policy: i) mandatory national ban on the production, use or sale of partially hydrogenated oils (PHO ban); or ii) mandatory national restriction that limits iTFA to a maximum of 2% of total fat in all fats, oils and foods (iTFA 2% limit); or iii) a combination of the PHO ban and iTFA 2% limit

<sup>2</sup> Key food categories may include: 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.

<sup>3</sup> Food outlets may include: supermarkets/markets; bakeries; restaurants; informal food markets.

<sup>4</sup> Simplified protocol for measuring trans-fatty acids content as a percentage of total fatty acids in food products: WHO laboratory protocol: Geneva: World Health Organization; 2023. <https://apps.who.int/iris/handle/10665/366690>

<sup>5</sup> Global protocol for measuring fatty acid profiles of foods, with emphasis on monitoring trans-fatty acids originating from partially hydrogenated oils: WHO laboratory protocol: Geneva: World Health Organization; 2020. <https://apps.who.int/iris/handle/10665/338049>

<sup>6</sup> For example, official methods of the Association of Official Analytical Collaboration (AOAC), the American Oil Chemists' Society (AOCS) and the International Organization for Standardization (ISO).

**OR**

2. Label assessment

Analyzing labels of food products sampled at food outlets to identify foods that list PHO (or similar)<sup>7</sup> as an ingredient or declare levels of TFA that exceed 2% of total fats or oils and that are likely to come from non-ruminant sources.<sup>8</sup> This approach requires mandatory TFA labelling (a policy document on TFA labelling should be provided by the applicant government).

**OR**

3. Hybrid approach

Conducting a label assessment as described above, but submitting a smaller subsample of foods for laboratory testing per WHO protocols or equivalent.

**OR**

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

The inspection could be conducted on-site at food manufacturing facilities and at ports of entry, or by examination of relevant documentation.

1. For domestically produced products:

For oil and fat factories/processing plants and manufacturing facilities of other foods that are likely to contain iTFA, the following activities must be conducted to make sure that the foods produced are compliant with the regulation:

- a. Examining documentation (e.g. receipts, records, inventory, labels, laboratory reports, recipes) that facilities maintain on purchased materials and manufacturing of their products or examining their practice (e.g. assessing if the oil and fat factories are engaged in partial hydrogenation). This can be done as part of regular inspection or on an ad-hoc basis as needed (e.g. renewal of the facility operating permit).

**OR**

- b. Sampling and testing vegetable oils and fats and other foods processed in the domestic factories. Testing must adhere to laboratory criteria (following procedures described in

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<sup>7</sup> PHO may appear on the ingredients list as “partially hydrogenated vegetable oil”, “hydrogenated vegetable oil”, “hydrogenated vegetable shortening”, or other similar terms.

<sup>8</sup> If total TFA > 2% of total fat, and the product contains fat from industrial and ruminant sources: the following are some acceptable approaches for estimating the quantities of TFA from industrial vs. ruminant sources:

- Using information on the iTFA content in the source vegetable fat/oil product, in combination with the total TFA in the food sample. This information can be obtained by measuring the iTFA content in the source vegetable fat/oil product or by inquiring with the fat/oil supplier, food manufacturers or importers;
- Looking at individual fatty acids as markers of dairy fats in mixed fats; and
- Testing mixed food products in a laboratory and measuring the ratio of the amount of butyric acid and total TFA. For example, the European Commission has published a technical report ([https://publications.jrc.ec.europa.eu/repository/bitstream/JRC125335/JRC125335\\_01.pdf](https://publications.jrc.ec.europa.eu/repository/bitstream/JRC125335/JRC125335_01.pdf)), which describes a workflow using this approach to estimate the amount of iTFA in food products containing mixtures of PHO and ruminant fats, such as dairy fat and beef tallow. Each country or region must establish the average C4:0 and iTFA values of their dairy products.

the WHO simplified protocol<sup>4</sup> or the WHO reference protocol<sup>5</sup> or by a method that is equivalent<sup>6</sup> to the WHO simplified protocol or the WHO reference protocol).

**AND**

2. For imported food products:

The following activities must be conducted to make sure that they are compliant with the regulation:

- a. Checking documentation of imported products 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).

**OR**

- b. Analyzing labels of imported products at ports of entry to identify foods that list PHO (or similar)<sup>7</sup> as an ingredient or declare levels of TFA that exceed 2% of total fats or oils and that are likely to come from non-ruminant sources.<sup>8</sup> This approach requires mandatory TFA labelling (a policy document on TFA labelling shall be provided by the applicant government).

**OR**

- c. Sampling and testing of imported food products at ports of entry, following procedures described in the WHO simplified protocol<sup>4</sup> or the WHO reference protocol<sup>5</sup> or by a method that is equivalent to the WHO simplified protocol or the WHO reference protocol.

## **II. Required enforcement system features**

For food products that do not comply with the regulation, the applicant/concerned Member State must have effective enforcement mechanisms as follows:

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 non-compliance, etc.)

### **III. Required Documentation**

Member States must present the following protocols, reports and other documentation to demonstrate that the monitoring and enforcement systems are functioning.

- monitoring and enforcement protocols or description of procedures for both imported and domestic products

#### **AND**

- monitoring and enforcement reports for both imported and domestic products (e.g. compliance violation reports, facility inspection reports, product analysis reports). These can be anonymized to protect confidentiality if needed.

#### **AND**

- In case countries are submitting results on label assessment
  - A policy document on mandatory TFA labelling

#### **AND**

- Information on the percentage of food products assessed that declare the TFA content on the label