Validation Programme for Trans Fat Elimination

Frequently Asked Questions

May 2023

Policy, monitoring and enforcement requirements

1. **How do I know if my country qualifies for the Validation certificate?**

   To qualify, countries must demonstrate with official documentation that a best-practice trans fat policy is in effect and that adequate policy monitoring and enforcement systems are in place.

   What is considered adequate monitoring and enforcement activities will vary by country. For example: countries have different sources and prevalence of partially hydrogenated oils (PHOs) or industrially produced trans fat in their food supplies, and monitoring activities may target high risk sources and sites; additionally, countries' policies have been in effect for different amounts of time, and policies in effect for a long time may have less frequent or less comprehensive monitoring if compliance has already previously been established.

   We encourage countries with best-practice policies in effect that have done some monitoring and enforcement to submit applications. The Trans Fat Elimination Technical Advisory Group (TFATAG) – the independent group of experts responsible for evaluating country applications -- will follow up if they have questions during the evaluation process.

2. **My country wants to receive the validation certificate, but we haven't done any monitoring or enforcement of our best-practice policy yet. Should we apply?**

   If you have a best-practice policy in place, but no monitoring and enforcement activities have been done, we encourage you to submit an expression of interest to WHO to receive the Validation certificate, and then to consider a formal application once your systems are in place. In receiving your expression of interest, WHO can offer to support and accompany you during the process of developing the monitoring system and on the application for Validation.

3. **What is the timeline for monitoring and enforcement activities?**

   Countries should be able to demonstrate that policy monitoring systems are currently functional. The timeline for activities will depend on how the country is handling compliance monitoring. For example, countries may do trans fat monitoring as part of existing food inspection processes (e.g., for sanitation and hygiene, or for pre-market licensing/permitting/registration of food businesses) which could be annual; or they may do targeted surveillance of high-risk products or manufacturers with the frequency of these assessments based on findings from previous assessments. For example, countries with policies that have been in effect for a long time and where high compliance was already established may only do control checks for high-risk products on an intermittent basis.

   The TFATAG will be discussing and finalizing more detailed criteria on acceptable activities and timelines for monitoring and enforcement activities during the first TFATAG meeting this summer. The final technical criteria will be made available on the Validation programme webpage.

We encourage countries to submit details and data from the most recent monitoring.

4. **What if our policy went into effect a while ago and we conduct less frequent or less comprehensive monitoring, since high compliance was already established many years ago?**

   This is great, and we encourage you to submit an application with details and documentation of the monitoring activities when high compliance was determined up through the most recent monitoring. You should include rationale for how monitoring is currently done in the country, including if done on a more intermittent basis. The TFATAG will evaluate and make its recommendation on the granting of the Validation certificate taking all of this into account.

5. **What is the monitoring requirement for countries that mostly import food products and where there is no domestic manufacturing of fats and oils?**

   Countries that import food products should demonstrate what monitoring activities are done to ensure that foods and ingredients (e.g., fats and oils) entering the country do not exceed the 2% limit of industrially produced trans fat or do not contain PHOs. If there are no domestic plants that manufacture foods or ingredients that could contain industrially produced trans fats or PHOs, countries may include documentation to demonstrate this, for example, a list of registered food/ingredients manufacturers in the country with details on the products they make.

6. **Is sampling and laboratory testing required for validation?**

   No, it is not required, but sampling and laboratory testing is one of the options for monitoring activities of the Validation programme. Though countries are recommended to conduct sampling and lab testing to understand how much trans fat is in the food supply, they may use other monitoring activities as appropriate for their food supply. For example, countries may review and analyze labels if trans fat labeling is mandatory and reliable in the country; or they may do facility inspections if there are known domestic fats/oils suppliers and food manufacturers in the country that are responsible for the trans fat burden in the country; or, if trans fat is imported, they may review documents at ports of entry to ensure that imported goods contain no PHOs or less than 2% industrially produced trans fat.

7. **Is there more detail on the Validation Programme and how it will evolve overtime including requirements for periodic validation?**

   Yes, there is a draft protocol that will be considered by the TFATAG. WHO will convene the first meeting of the TFATAG in summer 2023. During this meeting, the TFATAG will discuss the draft technical criteria and requirements. The technical requirements document will be finalized after that meeting and made available for future application cycles.

<u>Documentation and data requirements</u>

8. **What documents must be submitted as part of the application?**

   All required documents should be submitted. This includes the official policy document that shows the country has a best-practice policy already in effect, plus reports or other documents which show the monitoring and enforcement systems are in place. This could include reports from facility inspections, laboratory analysis, label analysis, monitoring protocols, compliance violation reports, enforcement protocols, for example.

In addition, countries should submit a completed application form which includes space for a short narrative description of the best-practice policy including date that became effective, the monitoring activities conducted to ensure compliance with best-practice policy, and the enforcement activities that are conducted to track and hold violators accountable.

9. **How much detail should be submitted with the application? For example, do we need to submit lab results?**

   A report with information on the products monitored and analysis results should be included. If not already in the report, we suggest also including a description of the sampling and lab methodology followed for the analysis. The TFATAG will be evaluating country applications. Should they require further details or documents, they will follow up with countries during the evaluation process.

10. **What lab protocol is required to be followed for the Validation purposes?**

    Detailed technical criteria will be discussed and determined by the WHO TFATAG, including what lab protocol is required for validation purposes, the frequency of monitoring and enforcement and the data requirement. Countries are encouraged to submit descriptions of their current monitoring and enforcement activities, along with documentation (e.g., reports or other official documentation).

Application process and expectations

11. **When will be the next opportunity to apply for Validation?**

    Validation will always be open for countries to apply. WHO will convene the TFATAG annually to evaluate country applications and make recommendations on the granting of the Validation certificate to the WHO Director General (DG). Since the first TFATAG meeting will take place in summer 2023, countries must submit applications by 30 May 2023 in order to be included in this initial review process. Depending on the volume of country applications that we receive, we may increase the frequency of the TFATAG meetings and application evaluations.

12. **My country needs more time to prepare our application. Is there a possibility of extension?**

    The deadline for the initial round of country applications is 30 May 2023. However, the programme is always open to country applications. So if you cannot meet the initial deadline, we encourage you to apply as soon as your country is ready. We may be able to include you in the current cycle of reviews, or we may include you in the next TFATAG meeting/reviews.

    If your country needs more time, we encourage you to reach out to us (nfs@who.int) so we can discuss the most appropriate approach for the situation in your country.

13. **When will my application be reviewed, and what is the timeline for decisions regarding the granting of certificates?**

    The first meeting of the TFATAG is scheduled to take place in summer 2023. During this initial meeting, the TAG will evaluate country applications and prepare recommendations to the WHO DG. It is possible there will be follow up questions to applicant countries, which would need to be responded to by countries. The WHO DG will then make the decision on whether to grant the certificate to applicant countries, and officially inform the authority of the decision.

Ideally, applicant countries will be informed of whether or not they received the certificate by the end of the year. However, because this is the first cycle of applications and TFATAG evaluation, this could change and we appreciate your understanding as we roll out this process.

14. **For how long is the certificate valid? And what is the process for reapplication, if there is one.**

    Validation certificates are valid for three years. Every three years, countries must submit updated data to WHO in the form of the required documents to renew their Validation certificate.

15. **Is this a long-term commitment?**

    The Validation certificate is good for three years, after which point countries who want to renew their validation will need to resubmit relevant documentation to demonstrate they still meet the criteria. It is not required for countries to renew their certificate after the first three years. Additionally, WHO will convene the first meeting of the TFATAG this summer. During this meeting, the TFATAG will evaluate the first round of country applications and discuss the technical criteria and requirements. Receiving validation should not be an added burden for countries; it should be recognition for what countries are hopefully already doing to ensure compliance with their policy.

16. **Is the Validation Programme part of REPLACE?**

    Yes, it is meant to encourage the implementation of REPLACE. REPLACE is a WHO initiative and framework for countries to implement elimination of industrially produced trans fats through enacting and implementing best-practice policies (find more about REPLACE here). The Validation Programme takes this a step further and validates that countries have successfully implemented their best practice policies with adequate monitoring and enforcement systems. Both REPLACE and the Validation programme are WHO trans fat elimination initiatives. They are complimentary initiatives in support of the WHO's goal for global elimination of industrial trans fat.

17. **What is the benefit to the country by getting validated by WHO?**

    Validation of trans fat elimination gives countries an opportunity to audit the processes established and to receive public acknowledgement of the progress achieved. It confirms to the people in that country, and to the international community, that the country has a normative framework in place to eliminated industrially produced trans fat and its harms. By eliminating industrial trans fat, countries will have eliminated an NCD risk factor, a major milestone. Just as eradication of polio is certified as a major public health achievement, WHO is recognizing elimination of trans fat in a similar way – as an significant public health achievement worth official recognition and celebration.

18. **Can NGOs or companies apply to Validation?**

    No. The validation certificate is for WHO member states only.

Available support

19. **Will there be financial support to help my country meet the requirements and receive the validation certificate?**

    WHO is available to provide technical support to countries. Currently there is not available financial support. Please reach out to us (nfs@who.int) if you require any support and we can explore what can be done.