Global Health Advocacy Incubator

Key Considerations for Regulating Trans Fat

How to Design a Measure to Fit Your Country's Legal and Food Systems

August 2021

Global Health Advocacy Incubator

Summary

The Global Health Advocacy Incubator (GHAI) has developed a practical tool to guide policymakers, civil society organizations, and other public health stakeholders as they develop measures to eliminate industrially produced trans-fatty acids (TFA) from the food supply.

In this document, "measures" refers to laws, regulations, or other compulsory legal instruments.

This document sets out **six key questions** to help you choose a type of trans fat measure, and then tailor it to best fit your country's legal and food system.

Countries with existing TFA measures serve as **helpful examples**, illustrating why these questions are important and relevant for your work.[i]

These country examples are mentioned throughout the document, and more detailed information about them is included in the **Appendix**.

This tool is informed by countries' experiences regulating TFA, including what has worked well and what has been less effective. These lessons can benefit other countries that are looking to protect their populations from TFA.

Using this tool as a guide, countries can work with confidence toward the World Health Organization (WHO) goal to eliminate industrially produced TFA from the food supply.[ii]

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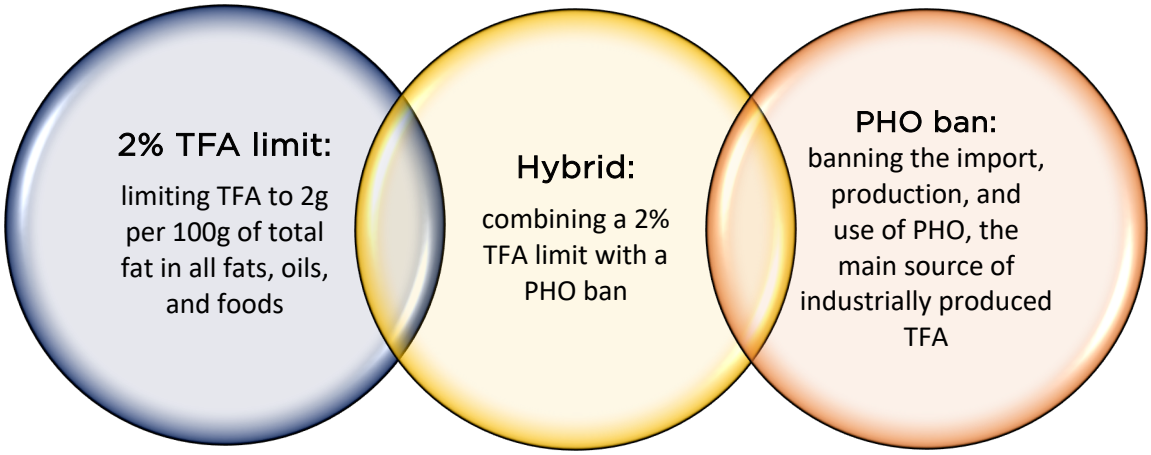
Introduction

Industrially produced trans-fatty acids (TFA) have been linked to heart disease. As a result, the World Health Organization (WHO) has made global TFA elimination a priority.[iii] WHO has called on governments to enact mandatory measures to protect public health by eliminating industrially produced TFA from national food supplies. A small amount of TFA from ruminant sources occurs naturally in food but is not considered a public health risk, as the vast majority of TFA in food comes from industrial production.

With the REPLACE action package, WHO has provided governments with a strategic approach to eliminate industrially produced TFA, with the goal of global elimination by 2023.[iv] WHO recommends two types of TFA measures:

- TFA limits, and/or
- Partially hydrogenated oil (PHO) bans.

In some cases, countries have opted for a hybrid of these two kinds of measures, as illustrated below:



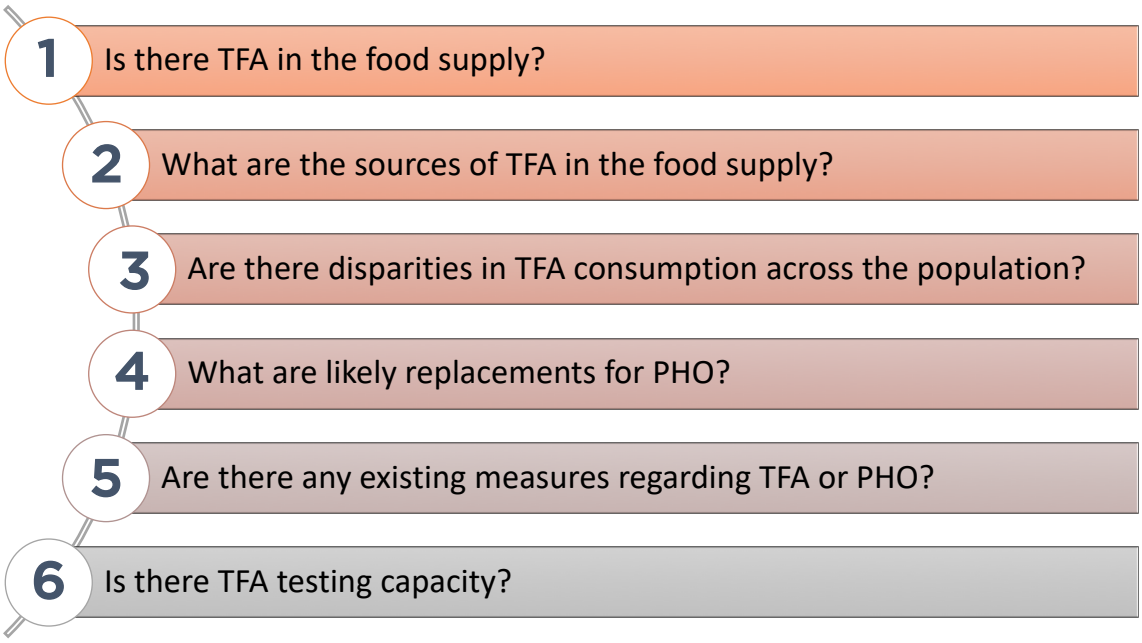
The goal of these types of measures is identical: They are designed to eliminate industrially produced TFA from the food supply. At least 40 countries have passed mandatory TFA measures aligned with best practices endorsed by WHO, which has made clear that "[r]eplacing industrially produced TFA with healthier oils and fats is feasible and cost-effective, and will save lives."[v]

To effectively regulate TFA, a country must first determine which type of WHO-recommended measure is most appropriate, based on factors related to its legal and food system. Countries have varied food systems, cultures, and products. This means that TFA enters national food supply chains, and reaches consumers, in diverse ways. Moreover, countries' legal and regulatory systems vary. Along with helping you choose which type

of measure is a good fit for your country, these factors are important to consider when designing, drafting, implementing, monitoring, and enforcing a TFA measure.

To be effective, a TFA measure should be **tailored** to a country's **legal and food system**. What works well in one country **might not** be a good fit elsewhere.

The following key considerations – set out as six questions – are designed to help policymakers, civil society organizations, and other public health stakeholders choose between the best practice endorsed by WHO, and then create a tailored measure that best fits a country's legal and food system. Throughout this document, we have included practical tips for incorporating these considerations into your measure.



In some contexts, it may not be possible to answer all of these questions. That should not preclude or stall the development of a TFA measure. The exercise of going through these questions and answering as many as you can – and noting which you cannot answer – will help you design an effective TFA measure.

Identifying which questions you cannot answer can inform the way you design your measure. For example, if you cannot answer Question 2 about sources of TFA in the food supply and you are unable to commission this research before designing your measure, you can account for this in the design of the TFA measure itself. For example, by allowing regulators to gather information about products that still contain TFA and foods that have been reformulated, or by allowing for additional guidelines regarding enforcement or implementation to be developed.

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QUESTION ONE

Is there TFA in the food supply?

Determining if TFA is currently in the national food supply is an important starting point when designing a TFA measure. It is necessary to identify **baseline data** about TFA in the food supply – or to know whether you need to generate such data. Answering this question is also integral to building an evidence base, which can be used to monitor a TFA measure's impact once approved and implemented, and to defend the measure if it is challenged politically or legally.

Baseline data are important for informing monitoring efforts and tracking a measure's efficacy. If you have no or limited information about how much TFA is in the food supply, then you should determine whether it is possible to generate some baseline data. For example, in **South Africa**, a 2% TFA limit was approved before baseline data was generated on the presence of TFA in the food supply. The absence of baseline data makes monitoring and determining the impact of the measure more difficult.

What if you find that there is little or no TFA in the food supply? In such circumstances, it is still important to regulate TFA as a preventative measure. As more countries around the world regulate TFA, there is a risk that those without regulations could become TFA "dumping grounds" as the food industry seeks new markets for its high-TFA products.

In summary, this question is important:

- To confirm whether TFA is an existing public health problem in your country, or is a potential future issue that can be addressed prophylactically;
- To establish baseline data to monitor the impact of the measure once passed; and
- To build an evidence base in case of a legal or political challenge.

How to gather information to answer this question:

- Contact national ministries of health or food and drug safety, and request food composition tables reporting TFA. If this is not available, consider asking regional bodies if they have any relevant data.

- Conduct sampling of products that are likely to contain PHO and conduct testing to determine their levels of TFA. For information about creating a sampling protocol, see resources developed by Resolve to Save Lives and the Global Health Advocacy Incubator on how to rapidly assess TFA levels in fats and oils as well as in foods.
- Refer to information printed on products, such as TFA amounts on nutrition labels or PHO listed on ingredients lists.

Once you have gathered your information:

If you find you have **little to no TFA in your country's food supply**, see Drafting Tip #1.

Drafting Tip #1: Preventative measures

- In some contexts, there may be little TFA in the food supply. However, it can still be important to regulate TFA as a preventative measure. For example, **Thailand** found that TFA was not a major issue in its food supply. Nevertheless, the Thai Food and Drug Administration enacted a PHO ban to stop the production and importation of PHO, with the goal of preventing TFA from becoming a more significant issue.
- If a TFA measure is designed to be preventative, then it is important to incorporate this notion into the measure's objectives when drafting it, in case of legal challenges.
- It is also helpful to build monitoring and evaluation mechanisms into a TFA measure from the beginning, so that you can track whether the measure is achieving your objectives at keeping TFA out of the food supply.

If you find **you do not know how much TFA is in your food supply**, you will need to collect baseline data. It may be possible to quickly generate some preliminary data to inform policy design, and should also be built into the measure itself; see Drafting Tip #2.

Drafting Tip #2: Gathering baseline data

If you cannot generate any baseline data or only have a small data sample, then you should design your measure such that information is gathered during implementation. This can be done by specifying that an implementing ministry or agency is mandated to gather data on the measure itself, potentially both before and during implementation.

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QUESTION TWO

What are the sources of TFA in the food supply?

In order to determine which type of WHO-recommended TFA measure may work best in your country, it is important to know **how** TFA gets into the food supply. This information will also help you tailor a measure to best fit national context. For example, it may help you determine at what levels of the food supply chain to prioritize resources when establishing monitoring and enforcement provisions in the TFA measure.

TFA can enter national food supplies in varied ways. Generally, the greatest source of TFA is PHO, which is produced through the process of hydrogenation, in which hydrogen atoms are pumped into unsaturated fats until they are semi-saturated. TFA can get into the food supply in the form of standalone PHO, and in products that contain PHO as an ingredient. Depending on the jurisdiction, PHO may be produced locally, imported, or a combination of both. The size of producers and importers can vary significantly.

This question is important for:

- Determining which type of WHO best practice measure is best suited for your country;
- Determining whether TFA sources are domestic, imported, or both;
- Determining whether you can trace TFA sources to the top of the food supply chain (to the main producers, manufacturers, or importers); and
- Identifying the best points in the supply chain to monitor and enforce the measure.

How to gather information to answer this question:

- To identify relevant oil producers and importers, contact ministries of commerce, industry, or others about import and export data and industry licenses.
- It may also be important to conduct a mapping of domestic PHO producers and importers of high-TFA products, to learn more about how TFA first enters the national food supply and to identify how they should be regulated. Refer to GHAI's PHO market mapping guide[vi] to learn more about ways to identify sources of industrially produced TFA in the food supply.

- When identifying the sources of TFA in your country, it is helpful to distinguish between domestically produced and imported products, so that you can determine what type of measure may be a good fit.
- When assessing whether ingredients lists are reliable, note that PHO is not always described consistently. For example, the generic term "hydrogenated oil" is sometimes used, yet this does not specify whether such oil is partially hydrogenated (and thus containing high TFA levels) or fully hydrogenated (and thus not containing significant amounts of TFA). Therefore, it is important to check whether companies are required to specify on nutrient lists whether oil is partially hydrogenated, and that labels comply with this requirement.
- Note that the amount of TFA that is generated from high-temperature cooking and repeated use of frying oil is not considered significant. According to WHO, "[t]he amount of trans fat generated during heating and frying is low when compared with the amount of trans fat in partially hydrogenated oils (PHO). On average, trans fat concentrations in PHOs are 25-45% of the oil, where heating and frying only increases trans fat concentrations by approximately 3%."[vii] From a regulatory perspective, it is more efficient to focus higher up the food supply chain and focus on large actors, such as PHO producers.

Once you have gathered your information:

Assess your information in order to determine the primary source of TFA in your country's food supply. Then, use the following options to guide your choice of measure.

If **domestic production** is the primary source of TFA in your country's food supply, consider implementing a **PHO ban**.

- In some countries, domestic PHO production is the primary source of TFA. If you can trace the sources of PHO to the top of the national food supply chain (for example, you can identify that the majority of PHO is produced by a few large manufacturers), then a PHO ban may be a good fit for your country. For example, in **Thailand**, three PHO producers accounted for the majority of TFA in the country, making a PHO ban a good fit because it could easily be implemented, monitored, and enforced; regulators could focus on these three PHO producers.
- If most TFA in the food supply comes from domestic prepackaged foods – and you have mandatory and reliable ingredients lists on food labels – then a PHO ban may be a good fit. This is because such labels can be used for efficient monitoring and enforcement efforts, particularly when prepackaged products are domestically produced. The **United States** took this approach, banning PHO after already requiring ingredients lists and TFA levels on prepackaged products. This approach was fitting for the United States, because it determined that most TFA in its food

supply was from domestic products, and it considers domestic food labels to be reliable.

If **imported products** are the primary source of TFA in your country's food supply, consider implementing a **2% TFA limit.**

- If imported products are a significant source of TFA, then a 2% TFA limit will likely be a better fit than a PHO ban. This is because you can test the TFA level in products, but there is no test for identifying PHO. To know whether PHO is present in prepackaged products, you need to trace them back through the food supply chain to the site of production to learn if PHO was used as an ingredient. If you test a product for TFA and find that its levels exceed what is possible from ruminant and other sources, then you may know that PHO was used; however, learning this information requires testing levels of TFA – not PHO.
  Ingredients lists can be helpful for enforcing a PHO ban, such as in the context of domestic production. However, labeling may be less reliable for imported products, since the site of production is further removed than for domestic products. Further, many countries do not require PHOs to be listed as an ingredient on a product label. Where such labeling is available, it may be inadequate for enforcing a PHO ban if there are inconsistencies in terminology for describing PHO, as noted above in the domestic production section.
- Note that high-TFA imports may increase in countries lacking TFA measures, as more countries regulate TFA. In response to the shifting global landscape on TFA regulation, companies may be looking for new markets. This happened in **Slovenia**; as neighboring countries enacted TFA measures, companies began exporting more high-TFA products to Slovenia. To prevent this from continuing, Slovenia enacted a mandatory 2% TFA limit.

If it is **not possible to answer** this question, or there are **multiple domestic producers and importers**, consider implementing a **hybrid 2% TFA limit** and a **PHO ban**.

- In some cases, it may be most appropriate to include both a 2% TFA limit and a PHO ban in the measure. This may be the case where there are a few major domestic PHO producers, as well as a significant number of importers, or where it is difficult to determine where the majority of the TFA originates.
- This option allows for enforcement to occur at each level in the food supply chain: banning PHO production at the top, down to testing and regulating the products containing TFA at the retail level. It also allows for specific enforcement mechanisms to be developed later, as more data about the sources of TFA becomes available.

If **poor refining of vegetable oils** is a primary source of TFA in your country's food supply, consider a **2% TFA limit or a hybrid measure.**

- The process of refining vegetable oils can create TFA. Commonly, the amount of TFA resulting from this process is minimal and considered too low to be worth regulating. However, if poor refining processes are used, then dangerous amounts of TFA can be created in (non-PHO) vegetable oils. In such instances, a PHO ban would not prevent this source of TFA from entering the food supply, so a 2% TFA limit or a hybrid measure should be considered. This varies across countries, so it will be useful to know whether poor refining of vegetable oils in your country may generate a significant amount of TFA.

Drafting Tip #3: Responsibility for compliance

- **Regardless of the type of measure you choose**, consider placing the burden of providing proof of products' compliance on industry, such as the manufacturer or importer, especially for large industry players. This can be particularly useful for imported products, since regulators lack access to their site of production. Check if this type of compliance system already exists for other requirements, such as whether a regulatory agency already mandates proof of compliance for a specific list of products. **Thailand** uses this approach to enforce its PHO ban, which helps reduce the regulatory burden of monitoring compliance.
- Once you are ready to design a TFA measure, make sure that it will apply to domestic and imported products consistently. If your country imports significant quantities of PHO or other high-TFA products, be especially careful about **complying with international trade laws**. In particular, ensure the measure applies equally to all products regardless of their origin, and that foreign products or companies are not more heavily burdened than domestic companies in complying with the measure. Carefully document the public health justification for any unavoidable distinctions between domestic and imported products. This is a complex area of law; **contact GHAI for further support** if needed.

If **informal producers and markets** are the primary source of TFA in your country's food supply, consider the need for **monitoring and enforcement** of the informal sector to be included in the measure.

- Depending on the structure of the supply chain, it is not always easy to identify all informal sources of TFA – such as PHO produced by small manufacturers, or products sold by unauthorized retailers or street-food vendors – particularly when a measure is first being implemented.
- If good monitoring systems are included in the measure, then regulators may gather useful data as they begin implementation. Learning how TFA moves through informal channels can help regulators gain a more complete understanding of food supply chains, which can lead to more refined monitoring and enforcement efforts.

Drafting Tip #4: Include monitoring and enforcement provisions

If TFA moves through the food supply via informal markets, then it is particularly important to set up monitoring and enforcement at all relevant levels of the food supply chain. It is generally more burdensome and challenging to monitor and enforce measures farther down the supply chain, where there are more actors to regulate. However, creating legal capacity to implement the measure from the top to the bottom of the supply chain provides regulators with options that can be helpful for future implementation and enforcement.

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QUESTION THREE

Are there disparities in TFA consumption across the population?

In many countries, some sub-populations consume much more TFA than the national average. Knowing if there are disparities in TFA consumption across the population can help you advocate for a TFA measure's passage, as well as craft the language of the measure.

This question is Important because:

- Some groups may consume higher amounts of TFA than the population at large; this can be obscured by national averages of TFA consumption.
- A TFA measure should be designed to ensure that all groups are protected.
- Protecting vulnerable populations and ensuring equity can be a powerful argument for moving forward with a measure, even if there is low TFA consumption in the general population.

How to gather information to answer this question:

- Review existing national data about population fat consumption.
- Contact relevant ministries, such as the ministry of health, about existing population dietary intake surveys or food audits.
- If dietary intake surveys or food audits are not available, consider conducting research to gather data.
- If you do not have information about TFA consumption levels, it can help to look at total fat consumption rates. (If some sub-populations have higher rates of total fat consumption, they may be more prone to increased levels of TFA intake.)

Once you have gathered your information:

What kinds of patterns are evident in your findings on TFA consumption across the population?

If you find high TFA or total fat consumption among sub-groups:

- National averages of TFA consumption may not reflect the risk that TFA poses for some groups that have disproportionately high rates of TFA consumption. For example, this could occur where some groups consume more than the 2,000 calorie diet that forms the basis of the WHO 2% limit. In **Denmark**, national TFA consumptions levels obscured the high TFA levels consumed by some sub-populations. These communities' vulnerabilities helped to persuade the Danish government to pass the world's first mandatory 2% TFA limit.
- If some groups have very high rates of TFA or total fat consumption, then a PHO ban might be a good fit for your country. This is because WHO based its 2% TFA limit recommendation on a standardized 2,000 calorie diet. Thus, a 2% TFA limit may not adequately protect groups with particularly high-TFA diets, since they may consume a large number of products that contain up to 2% TFA. In such circumstances, eliminating PHO from the food supply may offer greater protection. **Canada** began with a (voluntary)TFA limit but shifted to a mandatory PHO ban in part because some sub-populations continued to consume excess amounts of TFA, despite many companies having reformulated to meet the TFA limit.
- Some countries have used the disparate levels of TFA intake as the basis for an equity argument, which in turn can inspire governments to regulate TFA. If you find that TFA consumption is not high across your national population, it may be important to explain how a TFA measure can ensure that no populations are left vulnerable. As noted above, disparities in TFA consumption in **Denmark** helped to persuade government to pass the world's first mandatory 2% TFA limit.

If you have a lack of population consumption data on TFA or total fat:

- In some contexts, population consumption data for TFA may not be available. In such circumstances, it can be helpful to identify whether any populations consume much higher levels of total fat, as this may indicate high TFA consumption.
- If no data on fat consumption are available, consider conducting research to begin generating data. If that is not possible, design a TFA measure in a way that accounts for this information gap; for example, incorporate specific monitoring mechanisms for population fat or TFA consumption. Another option is to write into the measure broad authority for a regulatory agency to amend the measure to make it more protective, such as to lower the TFA limit or add a ban on PHO.
- Alternatively, if you are considering a 2% TFA limit but identify some sub-populations that may still be at risk of consuming dangerous levels of TFA, a hybrid measure may be a good option.

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QUESTION FOUR

Are there existing measures regarding TFA or PHO?

When regulating public health issues, there are often lessons that can be learned from existing measures on related topics. Many countries already have some measures related to TFA or PHO, such as labeling requirements. Learning how these measures are structured, and whether they are working well, can inform what type of TFA measure may be a good fit for your country. It can also help you craft the measure in a way that works well in the context of your country's regulatory system.

This question is important because:

- Many countries already regulate TFA in some way, such as requiring TFA to be included on nutrition labels.
- Analyzing existing measures related to TFA and their effectiveness can help you determine what type of TFA measure may be a good fit for your country, based on what is working well or needs improvement within existing regulatory systems.
- This information can also help you design a measure that is as effective as possible.

How to gather information to answer this question:

- Work with a lawyer in your country to determine whether there are any existing measures that relate to TFA and PHO. The lawyer can also assess what government agencies or ministries are responsible for implementing these measures.
- Reach out to relevant government agencies or ministries to learn more about the implementation of existing TFA measures. Examine if and how these measures are monitored and enforced, and whether companies are complying.
- If you learn that any existing TFA measures are not effective, it may be helpful to work with a lawyer to determine why this is the case. For example, were appropriate powers accorded to the correct agencies? This information can help you avoid such issues in a new TFA measure.

Once you have gathered your information:

Efficacy of existing measures:

- Some countries may have existing TFA measures e.g. in the context of food labeling, or voluntary TFA limits. Understanding how well existing measures related to TFA are working can avoid you repeating mistakes. For example, if you determine that such measures are not being enforced, you can assess whether this is due to factors like resource constraints, equipment and personnel gaps, or a lack of inter-agency cooperation.
- An assessment and evaluation of existing measures can also allow you to build upon current systems, if they are working well.

TFA labeling measures:

- Some countries already require TFA on nutrition labels, or PHO on products' ingredient lists. Yet relevant agencies do not always enforce these labeling requirements. It is important to assess if product labels are reliable in your country. If such labels are mandatory and reliable, then they can be a useful tool for monitoring a TFA measure. For example, the **United States** relies on existing labeling requirements to monitor its PHO ban. The United States uses this method of monitoring because it determined that its labels are sufficiently accurate. In **Chile**, regulators periodically test some products to ensure that labels are accurate.
- Labeling as a tool for monitoring and enforcement does not account for unpackaged products. Therefore, while potentially helpful, relying on labels alone is often insufficient. For example, **Argentina** has primarily used labels for monitoring and enforcing its TFA measure, yet unpackaged baked goods are a significant source of TFA in the country. Since such products are unpackaged, they do not have nutrition and ingredient labels. As a result, the country's monitoring and enforcement system did not account for these products, which resulted in a significant gap in coverage and many products with high levels of TFA remaining on the market.
- It is important to set up monitoring and enforcement capacity at all levels of the food supply chain. Relying on labeling will likely focus at the bottom the food supply chain, as raw materials and ingredients may not be labelled. Therefore, it is often important to utilize additional monitoring and enforcement efforts that are appropriate at other points in the supply chain. The "E" module of WHO's REPLACE action package discusses various monitoring and enforcement techniques.

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QUESTION FIVE

Is there TFA testing capacity?

Around the world, many countries either lack or have limited capacity to test for TFA. WHO provides guidance on developing TFA testing capacity in the "A" module of its REPLACE action package. Knowing whether testing is possible will help you determine what type of TFA measure may be best suited for your country. Also, if testing is limited, there are steps that governments may be able to take to fill this gap, such as working with laboratories in the region that have previously carried out testing for WHO, or accrediting private laboratories government may commission to test TFA levels.

This question is Important because:

- The answer to this question will help you determine the type of TFA measure that will be easiest to implement, and will work most effectively, in your country.
- It can also help you determine what types of authority or power the measure should grant to relevant government agencies or ministries.
- It can help you determine whether your country should seek out alternative testing options, such as accrediting non-governmental or regional laboratories.

How to gather information to answer this question:

- Contact government ministries or agencies tasked with food safety or food regulation.
- If there is no government capacity for TFA testing, consider whether government can partner with private or regional laboratories. Assess whether the current regulatory system allows for testing in private laboratories and outside of the country.

Once you have gathered your information:

What do your data suggest about existing testing capacity?

If you find you have **limited or no testing capacity**, consider a **PHO ban** along with **mandatory labeling**.

- Some countries have little or no capacity to test TFA levels in food, due to lack of equipment, trained personnel, or resources. It is important to assess whether building testing capacity is possible.
- If your country cannot readily develop testing capacity, then a PHO ban might be a better option – particularly if the main source of TFA in the food supply is domestically produced PHO. This is because a PHO ban targets the top of the food supply chain. Monitoring and enforcement efforts can focus on the site of production. Rather than test for the presence of TFA, regulators can check that manufacturers are not using the process of partial hydrogenation. This may be challenging if there are many PHO producers, including small and informal production sites. Also, imported products are more challenging to regulate without testing TFA levels since regulators cannot inspect the site where such products are produced.
- If government laboratories lack TFA testing capacity, you can assess whether private or regional labs have such capacity and may be used for monitoring and enforcement purposes. Regulatory agencies may have rules related to lab accreditation, which should be analyzed to determine if the use of non-government labs is possible.
- If no testing capacity is possible, reliable and mandatory TFA labeling can be a useful – albeit imperfect – substitute. However, in this scenario, at least limited testing capacity is likely necessary to determine that labeling is and remains reliable. The **United States** decided to rely on its existing labeling requirements for monitoring its TFA measure because it determined that such labels are reliable.

Available laboratories may not meet WHO standards:

- WHO has published standards for laboratory testing of TFA levels. Yet many laboratories do not currently have the capacity to meet the WHO standards. Providing governments and laboratories with information about the WHO standards can help them identify ways in which the laboratories are currently deficient. You may help to provide or identify support – such as needed equipment and training – so that the laboratories can meet global best practices.

Potential role of civil society in monitoring and enforcement:

- If funding for monitoring and enforcement – potentially including TFA testing – is limited, consider whether it is possible for the government to collaborate with civil society. For example, government can set up complaint mechanisms in which citizens and organizations can flag potential violations for regulators. Including civil society can help to reduce the regulatory burden of implementing a TFA measure. **Thailand** uses this approach; the Thai FDA has invited civil society to help monitor its TFA measure.

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QUESTION SIX

What are likely replacements for PHO?

When advocating for a TFA measure, you will likely encounter this question from various actors, from government officials to members of the food industry and public health advocates. Countries around the world have found cost-effective and healthier alternatives to PHO. Available fats and oils and their primary uses vary, so it is important to assess what options may be best for your country's local context.

This question is Important because:

- This is often one of the first questions raised by governments when considering a TFA measure. For example, governments may want to assess how reformulating products may impact the food supply and costs for consumers. This question may also be prompted by industry, particularly related to taste, consistency, shelf life, and manufacturing costs.
- TFA measures are designed to improve public health, so you want to make sure that PHO will be replaced with healthy alternatives.
- In some settings, other unhealthy fats, such as palm oil and other products high in saturated fats, are prevalent in the food supply – or could easily become prevalent. It is important to account for this possibility when designing a TFA measure to ensure the measure's potential public health benefits are not undermined by an industry promoting other unhealthy fats as an alternative.

How to gather information to answer this question:

- Contact government ministries working on food safety and commerce to learn about what oils are produced, imported, and sold in your country.
- Refer to Food and Agriculture Organization (FAO) country statistics.
- Commission research to determine healthy alternatives to PHO that may be available in your country. Evaluate existing policies, such as trade agreements and incentive programs that may already be in place and consider how these can be adapted to support the use of healthy alternatives.
- Review the "P" module of WHO's REPLACE action package for information about determining the best replacement oils, technology options and interventions to promote their use.

- Conduct focus groups or engage industry bodies to understand questions and concerns.

Once you have gathered your information:

Consider which of the following scenarios may be relevant to your country:

The need to address reformulation:

- Government and industry will likely want to know how foods can be reformulated to comply with a TFA measure. In some countries, governments have provided industry with technical assistance to help them reformulate products, particularly small and midsize enterprises. For example, **Saudi Arabia**'s FDA is working to support small and midsize food manufacturers in implementing the country's TFA measures, and helping them learn lessons from larger multinational companies.
- From an advocacy perspective, it is helpful to identify viable healthier alternatives. This will help you defend TFA measures against potential opposition, such as claims that reformulation will be unduly expensive.
- Information about potential PHO replacements is provided in the "P" module of WHO's REPLACE action package. It provides a guide for determining the best replacement oils and technological solutions for replacing PHO, and interventions to promote their use.
- Suitable alternatives to PHO vary by country based on what fats and oils are accessible. Countries around the world have found viable solutions, demonstrating that replacing PHO with healthier and affordable alternatives is feasible.

Unhealthy fats or oils are often suggested as PHO replacements:

- In some countries, unhealthy fats or oils may be well-positioned to replace PHO. For example, tropical oils (e.g. palm oil and coconut oil) – which are high in saturated fat – may already be prevalent in the food supply or easily accessible for import. This could mean it is a likely PHO replacement unless government incentivizes the use of healthier alternatives.
- When passing a TFA measure, complementary measures can minimize the risk that the food industry will use unhealthy PHO replacements. Such measures can focus on disincentivizing the use of unhealthy alternatives as well as incentivizing the use of better options.
- Complementary measures that disincentivize the use of unhealthy alternatives include mandating front-of-package labels (FOPL) for products high in saturated fat and banning the use of "TFA-free" claims on products. FOPL provide consumers with easily accessible information about unhealthy nutrients in foods. Limiting

"TFA-free" claims prevents the food industry from potentially leading consumers to think a product is healthy when, in reality, it might have high levels of other unhealthy fats. **Thailand** utilized this approach; along with enacting a PHO ban, it prohibited the use of "TFA-free" claims to prevent a health "halo" effect on foods that may contain high levels of other unhealthy fats.

- Incentives for healthier fats and oils can include complementary agricultural, import, and tax measures. More information about these options is available in the "P" module of WHO's REPLACE action package.

Lack of industry pushback:

- If you find little or no industry opposition to a proposed TFA measure, you may want to investigate whether industry has something to gain from a regulatory focus on TFA. In some circumstances, industry might be prepared to use other unhealthy oils instead of PHO, such as palm oil.
- If corporations are already planning to increase the use of other unhealthy fats, then they might support a TFA measure. In such contexts, it is particularly important to build protections against financial conflicts of interest in the policymaking process.
- In these circumstances, the complementary policies described above may be particularly important.

Protecting against conflicts of interest:

- If industry has any role in developing a TFA measure, it should be narrow and clearly defined. At times, governments may want to consult with industry on targeted questions. For example, governments may want information from the food industry about product reformulation options, so the government can support efforts by small and midsize enterprises to comply with the measure. It is critical that such consultations are specific and that industry does not receive a seat at the policymaking table.
- Protections against conflicts of interest are important throughout the process of developing a TFA measure and implementing it. **Argentina** provides a useful example; the country was a pioneer in regulating TFA, but government consulted with industry when designing its measure. Ultimately, the country's TFA regulation included loopholes that undermined its effectiveness; government has since been making efforts to strengthen TFA regulations. More information about this example is available in a Global Health Advocacy Incubator webinar hosted by LINKS.

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Appendix: Country examples

Information in this Appendix is from a range of sources, including primary legal texts, meetings with government officials and civil society organizations, seminars and workshops on TFA regulation, and publications from WHO, the NCD Alliance and others.

TFA limits

Denmark

- Limits TFA to 2% of total fat in all fats, oils, and foods sold directly to consumers
- First mandatory TFA measure in the world
- Conducted rigorous research and data collection for a decade before the measure was enacted
- High levels of TFA were identified in some popular foods, such as Danishes
- Identified significant disparities in TFA consumption across the population
    - National average TFA consumption rates masked the high levels consumed by some sub-groups; high rates of TFA consumption among such groups helped to persuade the government to take action and set a mandatory TFA limit

South Africa

- Limits TFA to 2% of total fat in fats, oils, and foods
- Department of Health originally issued a draft regulation on TFA labeling, but decided to set TFA limit instead
- No baseline data were generated; this created challenges for monitoring and determining the impact of the measure
- Compliance is thought to be lowest among small domestic manufacturers and importers
- Government enforcement of food measures typically focuses on food safety; when designing the TFA measure, enforcement needs may not have been adequately considered

Slovenia

- Limits TFA to 2% in all fats, oils, and foods
- As nearby countries implemented TFA measures, TFA levels in imported products increased
    - Exporters had fewer regional markets for high-TFA goods
- Some domestic producers voluntary reformulated, but imports and unpackaged foods (particularly baked goods) continued to have high TFA levels
- Government sought to protect vulnerable populations with high-TFA diets

- When designing sanctions for non-compliance with the TFA measure, Slovenia included product recalls, which it determined can be particularly impactful – especially for larger food companies

Chile

- Limits TFA to 2% limit for all fats, oils, and foods
- Country mandated TFA labels before establishing the 2% TFA limit
- Food industry initially pushed back against the TFA limit
- Regulators periodically inspect production facilities and test some products to ensure that labels are accurate

Argentina

- Limits TFA to 2% of total fat in fats and oils, and 5% in foods (this is not considered a best-practice measure due to the 5% limit in foods) modelled on the PAHO regional strategy (2008) and Canada's policy at that time
- Before 2021, the 2% limit in fats and oils only applied to products intended for direct consumption; regulators interpreted the measure as excluding raw materials, some of which continued to have high levels of TFA
- Additional enforcement issues include: labels are not always reliable, yet regulators rely on them for monitoring and enforcement; many unpackaged foods – such as foods sold in bakeries – continue to have high levels of TFA

PHO bans

Thailand

- 3 domestic PHO manufacturers were identified as the main source of TFA in the food supply
- Country already had a certification process for importers of certain types of products, so it could add PHO to this process
- TFA was not a major issue in Thailand and government wanted to prevent it from becoming one, so it approved a PHO ban mainly as a preventative measure
- Government wanted to disincentivize the replacement of TFA with other unhealthy fats like saturated fat, which pose a health challenge in Thailand
    - Government banned the use of "TFA-free" labels to prevent a health "halo" effect on products that may be high in other unhealthy nutrients
- The Thai FDA is collaborating with civil society on monitoring and enforcement

United States

- Choosing a PHO ban was convenient from a regulatory perspective because the government has an existing list of products that are "generally recognized as safe"; it could remove PHO from this list
- Much of the TFA in the food supply was from domestic products, rather than imports
- Government could trace much of the TFA in the food supply to PHO at the top of the food supply chain
- Government relies on mandatory and reliable TFA labeling for monitoring and enforcement; it considers food labels to be sufficiently accurate for this function

Canada

- Before enacting a mandatory PHO ban, the country had a voluntary 2% TFA limit in fats and oils, and a 5% limit in foods
- In part, it switched to a PHO ban because some sub-populations continued to consume excess amounts of TFA, despite many companies having reformulated to meet the voluntary TFA limits
    - Government noted that some sub-populations could be at risk of consuming dangerous amounts of TFA even if there was a mandatory 2% limit for all products
- Industry had already identified feasible and healthier alternatives to PHO, so implementing a PHO ban could be efficient

Hybrid approaches

Saudi Arabia

- Limits TFA to 2% in fats and oils, and 5% in food; bans PHO
    - The country first implemented mandatory TFA labeling and TFA limits
- It enacted the PHO ban to align with global best practice, since the 2% and 5% TFA limit is not a best-practice measure
    - Major food companies had already ceased using PHO in order to comply with the TFA limits, so the PHO ban was not seen as a significant burden
- Regulators are working to support small and midsize food manufacturers as they implement the TFA measures, including by helping them learn lessons from larger multinational companies
- Testing compliance for the PHO ban is expected to be a challenge, since a test for PHO does not exist; the government is planning to seek guidance from the United States and Canada

Global Health Advocacy Incubator

About GHAI

The Global Health Advocacy Incubator (GHAI) supports civil society organizations who advocate for public health policies that reduce death and disease. We bring a proven advocacy approach and a global network of local partners, built on a 20-year track record of success across multiple issues in more than 60 countries.

End notes

[i] Information on country examples throughout this document are from a range of sources, including primary legal texts, meetings with government officials and civil-society organizations, seminars and workshops on TFA regulation, and publications including from the WHO and the NCD Alliance.

[ii] World Health Organization, REPLACE: An Action Package to Eliminate Industrially Produced Trans-Fatty Acids, WHO/NMH/NHD/18.4 (2019).

[iii] Due to TFA's harmful and unnecessary contribution to death and disease, the WHO included TFA elimination as a key target in its 13th General Programme of Work, which guides the organization's work in 2019-2023. WHO/PRP/18.1 (2019).

[iv] World Health Organization, REPLACE: An Action Package to Eliminate Industrially Produced Trans-Fatty Acids, WHO/NMH/NHD/18.4 (2019).

[v] World Health Organization, Countdown to 2023: WHO Report on Global Trans Fat Elimination 2019, ISBN 978-92-4-151644-0 (2019). See also: Downs, S. M., Bloem, M. Z., Zheng, M., Catterall, E., Thomas, B., Veerman, L., and Wu, J. H. Y. (2017). The Impact of Policies to Reduce Trans Fat Consumption: A Systematic Review of the Evidence. Current Developments in Nutrition 1 (12), doi 10.3945/cdn.117.000778.

[vi] Global Health Advocacy Incubator, Partially Hydrogenated Oil (PHO) Market Mapping: Identifying Sources of Industrially Produced Trans-Fatty Acids in the Food Supply (2021).

[vii] World Health Organization, REPLACE: Frequently Asked Questions, WHO/NMH/NHD/18.7 (2018).