RE: Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries (Docket No. FDA-2011-N-0135)

The Center for Science in the Public Interest (CSPI)\(^1\) appreciates the opportunity to comment on the proposal to use comparability assessments of foreign food safety systems to assist the Food and Drug Administration (FDA) in ensuring the safety of imported foods and feeds (Docket No. FDA-2011-N-0135). CSPI supports the agency’s efforts to better protect consumers from foodborne hazards in imported foods, and offers the following comments regarding implementation of comparability assessments.

Comparability assessment is a new initiative that holds promise for improving risk-based inspection of imported food. FDA defines a comparability assessment as a complete assessment to determine if a foreign country has a food safety system that is similar, though not identical; is comprised of analogous elements; and provides the same level of public health protection as the U.S. food safety system.

The standard under international trade law is not comparability but determining equivalency for imported foods. While the elements of a comparability assessment appear to mirror an equivalency determination, there are distinct differences between the two. Equivalency is an established, and trade compliant, system for protecting the public from hazards posed by high-risk foods. Not only does it require imported food to achieve the appropriate level of protection demanded by U.S. consumers, it would permit the U.S. to prohibit imports from countries that cannot meet the standards set in the equivalence process. Meanwhile, there is no indication that FDA would prohibit imports from a country that failed a comparability assessment or that current trade rules would allow FDA to ban products based on the source country having failed a comparability assessment. We encourage FDA to require an equivalency determination for high-risk foods, while looking to initiatives like comparability only as a way to improve its ability to target border inspection resources.

\(^{1}\) The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its Nutrition Action HealthLetter and by foundation grants. We accept no government or industry funding.
Comparability is likely to be used when an exporting country may not have domestic standards that meet the standards required of an importing nation. However, it should not be used for stovepiping the safest products out of a country, and thus not providing the advantage of safer products to the domestic consumers. For example, the Federal Register notice indicates FDA is using comparability as a component in the equivalency assessment of the U.S. and European Union (EU) shellfish programs to address the fact that the EU has banned some U.S. oyster products.\(^2\) The choice of using comparability in negotiating an agreement on shellfish is troubling given the woefully inadequate U.S. system. The U.S. National Shellfish Sanitation Program imposes few controls on the Gulf Coast oyster industry, exposing the public to an unreasonable risk of severe injury or death from *Vibrio vulnificus*.

Trade actions that highlight the weakness in a domestic program can be important to development of national food safety systems. The ban on U.S. oysters, for example, protects the citizens of the EU, while also creating an incentive for improvement in the exporting country, in this case, the U.S. FDA’s use of a comparability component in discussions with the EU is troubling because it suggests that comparability may be used to facilitate U.S. exports while protecting the ability of domestic industries to continue unsafe practices.

Our concern about the relationship between equivalency and comparability does not mean we oppose FDA’s initiative. Comparability may be a positive approach for assisting the agency in targeting inspection resources for imported foods. The FDA Food Safety Modernization Act (FSMA) provides a number of tools for ensuring the safety of imported foods and feeds. Section 303 of FSMA provides authority to assess a foreign country to determine if food from that country needs to be certified as meeting U.S. standards. Section 305 of FSMA encourages FDA to conduct assessments of foreign food safety systems and reach agreements that ensure the safety of imported foods. These provisions open the door to using comparability as a system for improving oversight of imports. CSPI encourages FDA to continue development of the comparability assessment program, and recommends FDA adopt a clear statement of purpose, indicating which provisions of the FSMA that it will implement using the approach (e.g. assessing foreign systems for the purpose of certification; targeting border inspections).

FDA should also set certain additional limits with regard to the use of a comparability determination.

1. FDA should not allow importers to rely on a comparability determination to satisfy the requirements under the Foreign Supplier Verification Program (FSVP). The FSVP provides a mechanism for cross-checking the quality of foreign food safety systems. By holding the importer accountable for problems, the FSVP assures that an importer will practice due diligence in assuring that a foreign supplier is compliant with U.S. practices and standards. That cross-checking would not be present if the importer could simply rely on a comparability determination.

2. Comparability determinations should not be used to permit countries to forego certifying the safety of high-risk foods. Under section 303 of FSMA, FDA is to consider the risk posed by the food without regard to its source as one of the four

factors on which it can base a certification requirement. In this context, a comparability assessment would be useful in assuring FDA that the country’s food safety authority is competent to issue a certification. Where FDA cannot find the country’s system comparable, and does not believe the government to be a reliable partner for certifying safety, it should require accredited third-party certifications.

In conclusion, comparability may be an effective way to inform the agency’s risk-based decisions on import inspections and certification, but it is not a substitute for requiring equivalency.

CSPI thanks the agency for taking these comments into consideration as it moves forward with its programs for assuring the safety of the U.S. food supply. We encourage the agency to continue making progress on implementing its new authority under FSMA by making public health and safety the primary objective of new programs under its expanded authority.

Sincerely,

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