

# **FDA Oversight of Food Covered by Systems Recognition Arrangements: Guidance for Food and Drug Administration Staff**

You may submit written or electronic comments regarding this guidance at any time. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number FDA-2019-D-1997 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance or additional copies, contact the Office of Regulatory Affairs (ORA) Office of Strategic Planning and Operational Policy (OSPOP) at [ORAPolicyStaffs@fda.hhs.gov](mailto:ORAPolicyStaffs@fda.hhs.gov).

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs (ORA)  
Center for Food Safety and Applied Nutrition (CFSAN)**

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# **FDA Oversight of Food Covered by Systems Recognition Arrangements:**

## **Guidance for Food and Drug Administration Staff**

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### **I. INTRODUCTION**

The document provides guidance related to the FDA’s regulatory oversight activities for food<sup>1</sup> covered by a Systems Recognition Arrangement (SRA)<sup>2</sup> between another country’s food safety authority and FDA.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

### **II. BACKGROUND**

The FDA Food Safety Modernization Act (FSMA) transformed FDA’s approach to food safety. Among other things, FSMA recognizes the role of the food safety regulatory system in exporting countries to assure compliance with FDA food safety standards for a given food. Systems

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<sup>1</sup> Existing Systems Recognition Arrangements (SRAs) define “food” for the purposes of each SRA. Under the existing SRAs, the term “food” includes (1) any article used as food or drink for humans, (2) chewing gum, and (3) any article used for components of any such article. However, the SRAs also exclude certain types of food from the scope of the arrangements. Excluded items may vary with each SRA. For additional information on individual SRAs, including excluded products, please reference the specific arrangements at: <https://www.fda.gov/food/international-cooperation-food-safety/systems-recognition-food>.

<sup>2</sup> For more general information about Systems Recognition, please see: <https://www.fda.gov/food/international-cooperation-food-safety/systems-recognition-food>.

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Recognition (SR) is consistent with FSMA because it takes a risk-based approach to the safety of imported food. To the extent practicable, FDA will leverage the work done by foreign competent authorities to help ensure the safety of imported foods.

One way FDA is leveraging the efforts of some foreign competent authorities is through an SRA, which establishes a regulatory partnership between FDA and the Agency's regulatory counterpart. SR takes into account whether (1) another country's food safety system provides a similar, though not necessarily identical, system of protections as the U.S. food safety system under FDA's jurisdiction; and (2) another country's food safety authority or authorities provide similar oversight and monitoring activities for food produced under their jurisdiction as FDA provides. SR is based on the conclusion that food safety systems with similar elements and similar levels of oversight lead to similar food safety outcomes.

FDA recognizes that food safety issues and outbreaks associated with inadequate food safety practices can arise in all countries, and SR accounts for this reality. FDA's SR assessments, therefore, focus not only on the ability of food safety systems to help prevent food safety problems, but also on the ability of food safety authorities to identify, address, and contain food safety issues and outbreaks when they do occur, as well as to learn from past events and strengthen the system over time.

SR is a reciprocal process. If FDA's SR assessment concludes that the foreign competent authority operates a comparable regulatory program that yields similar food safety outcomes as the FDA food safety system, and the foreign competent authority reaches the same conclusion about the U.S. food safety system under FDA's oversight, then FDA and the foreign competent authority may enter into a regulatory partnership that is memorialized in an SRA. Under an SRA, FDA intends to rely on the food safety oversight of the foreign competent authority, which then helps FDA refine its risk-based decisions about the scope and frequency of its oversight activities related to imported products, including foreign facility inspections, import field exams, and import sampling.

SR is one tool among many that allows FDA to acknowledge and leverage the reliable food safety oversight of a foreign competent authority in risk-based decision-making regarding inspections, verification programs (e.g., importer verification programs under FDA's Foreign Supplier Verification Programs (FSVP) and seafood and juice Hazard Analysis and Critical Control Point (HACCP) regulations), import admissibility, and follow-up when food safety incidents occur. In addition, FDA may rely on a foreign competent authority's implementation of science-based food safety regulatory programs to take regulatory action based on information provided by those authorities, when appropriate. SR allows FDA to better leverage and plan its oversight of foods because it allows FDA to rely on regulators in other parts of the world that provide a similar system of food safety protection. This is one tool that FDA has to ensure that consumers have confidence that their food is safe, whether produced in the United States or elsewhere. This level of regulatory partnership and leveraging of work requires a rigorous assessment process to ensure that FDA is justified in recognizing a foreign food safety system and relying on the work of foreign governments in making regulatory decisions about food imported into the United States.

### **III. POLICY**

SR allows FDA to avoid duplicating certain food safety-related work in countries with an SRA. Accordingly, for food covered by an SRA and imported from a country with an active SRA, FDA intends to adjust its regulatory oversight activities as follows:

#### **A. In-country Food Establishment Inspections**

1. In general, FDA does not intend to prioritize foreign food establishment inspections in countries with an SRA. Therefore, FDA's routine inspections of foreign food establishments for food covered by an SRA will be rare, allowing FDA to allocate its risk-based foreign inspection resources more efficiently and effectively.
2. Nevertheless, FDA intends to continue to conduct inspections in countries with SRAs in certain situations, that include, but are not limited to:
  - a. To inspect establishments engaged in manufacturing/processing, packing, or holding FDA-regulated food not covered by the SRA;
  - b. On a for-cause basis, where appropriate, to address a public health concern or specific food safety issues; and
  - c. For any establishment, in response to a request by the foreign competent authority.

#### **B. Automated Screening and Risk Targeting and Review of Imported Food**

1. FDA intends to adjust its risk-based screening and targeting criteria for import entries of food covered by an SRA to reflect FDA's determination of the comparability of the regulatory system covered by an SRA, and to allow for more efficient and effective use of FDA's import investigation and screening resources. Risk-based screening and review for foods imported from a country with an SRA, but that are not covered by the SRA, will remain unchanged.
2. Import Alert (IA) and Detention Without Physical Examination (DWPE)
  - a. Existing IAs
    - i. The existence of an SRA with a foreign competent authority does not necessarily affect whether there appears to be a violation of FDA requirements. Therefore, food and establishments subject to DWPE under an existing IA will not be automatically removed from the IA when an SRA is signed.
    - ii. FDA will communicate with the foreign competent authority regarding information about the conditions that gave rise to the appearance of the violation, as appropriate. Establishments and food may be removed from DWPE when the conditions that gave rise to the appearance of the violation have been resolved.
    - iii. FDA will consider evidence provided by the foreign competent authority regarding corrective actions taken by the establishment when assessing potential removal from an IA, as appropriate.
  - b. Future IAs

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- i. As appropriate, FDA may recommend for DWPE an establishment or food from a food safety system covered by an SRA.
- ii. FDA will ensure prompt notification, when appropriate (e.g., class I recalls), of a food safety concern to the foreign competent authority.
- iii. When a foreign competent authority has evidence that is relevant to FDA's decision about whether it is appropriate to list a food or establishment on an IA, FDA may consider such evidence, as appropriate.

#### **C. Examination and Sampling of Imported Food**

1. Generally, FDA will not prioritize import samples and field examinations of food covered by an SRA. This will be reflected in FDA's annual field work plan. However, there are some situations where FDA will prioritize examination and sampling a shipment of food from a country with an SRA, including:
  - a. Food that FDA is targeting for examination and sampling on a surveillance basis (e.g., a particular commodity for which FDA is targeting both domestic and import samples);
  - b. Food exported from a country whose food safety system is covered by an SRA but the specific type of food is not covered by the SRA; and
  - c. On a for-cause basis for food covered by an SRA, where appropriate to address a specific food safety issue or other potential violations.

#### **D. Relevance of Importer Verification Programs**

1. In accordance with FDA's risk-based approach to inspections, when verifying an importer's compliance with importer verification requirements, FDA will make risk-based decisions about which foods to target. Therefore, in general:
  - a. With respect to imported foods covered by an SRA, FDA does not intend to prioritize inspections of importers for FSVP<sup>3</sup> compliance or compliance with juice and seafood HACCP importer requirements.<sup>4</sup>
  - b. However, FDA may periodically verify that importers of food covered by an SRA are in compliance with FSVP and HACCP importer requirements.
  - c. In addition, for importers of food both from countries with SRAs and from countries that do not have SRAs, FDA will continue to prioritize FSVP and

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<sup>3</sup> "FSVP" refers to the Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (21 CFR part 1 subpart L). Under the FSVP rule, importers are required to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. The FSVP rule provides for modified requirements for certain foods from a foreign supplier in a country whose food safety system has been recognized as comparable or determined to be the equivalent of the United States' system (21 CFR 1.513).

<sup>4</sup> "Juice and seafood HACCP importer requirements" refers to the requirements that apply to importers under two rules: HACCP Procedures for the Safe and Sanitary Processing and Importing of Juice (21 CFR part 120) and Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (21 CFR part 123). Under 21 CFR 120.14 and 123.12 of those regulations, importers of juice, fish, and fishery products subject to the HACCP regulation are generally required to implement affirmative steps to ensure that products being offered for entry into the United States were processed under controls that meet the requirements of the relevant HACCP regulations, among other requirements.

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HACCP inspections for those products imported from food safety systems that FDA has not recognized.

2. FDA's inspections of imported, non-covered products will remain unchanged.

**E. Regulatory Compliance Actions**

1. FDA may pursue regulatory actions, such as issuing warning letters, adding establishments or food to DWPE, and refusing products offered for import, as appropriate. This applies to food and establishments regardless of whether they are covered by an SRA.
2. The existence of an SRA facilitates FDA's ability to consider information provided by the regulatory authorities, as appropriate, when FDA considers regulatory action.