
FDA Oversight of Food Products Covered by Systems Recognition Arrangements:

Guidance for Food and Drug Administration Staff

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs (ORA)
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JULY 2021

TABLE OF CONTENTS

I. INTRODUCTION.....	1
II. BACKGROUND.....	2
III. POLICY.....	3

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I. INTRODUCTION

The document provides guidance related to the FDA’s regulatory oversight activities for food products¹ covered by a Systems Recognition Arrangement (SRA)² between another country’s food safety authority and FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

¹ Existing Systems Recognition Arrangements (SRAs) define “food products” for the purposes of each SRA. Under the existing SRAs, the term “food products” 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 products 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>

² 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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31 The FDA Food Safety Modernization Act (FSMA) transformed FDA’s approach to food safety.
32 Among other things, FSMA recognizes the role of the food safety regulatory system in exporting
33 countries to assure compliance with FDA food safety standards for a given food. Systems
34 recognition is consistent with FSMA because it takes a risk-based approach to the safety of
35 imported food. To the extent practicable, FDA will leverage the work done by foreign
36 competent authorities to help ensure the safety of imported foods.

37
38 One way FDA is leveraging the efforts of some foreign competent authorities is through an SRA,
39 which establishes a regulatory partnership between FDA and the agency’s regulatory
40 counterpart. Systems recognition takes into account whether (1) another country’s food safety
41 system provides a similar, though not necessarily identical, system of protections as the U.S.
42 food safety system under FDA’s jurisdiction; and (2) the country’s food safety authority or
43 authorities provide similar oversight and monitoring activities for food produced under its
44 jurisdiction as FDA provides. Systems recognition is based on the conclusion that food safety
45 systems with similar elements and similar levels of oversight lead to similar food safety
46 outcomes.

47
48 FDA recognizes that food safety issues and outbreaks associated with inadequate food safety
49 practices can arise in all countries, and systems recognition accounts for this reality. FDA’s
50 systems recognition assessments, therefore, focus not only on the ability of food safety systems
51 to help prevent food safety problems, but also on the ability of food safety authorities to identify,
52 address, and contain food safety issues and outbreaks when they do occur, as well as to learn
53 from past events and strengthen the system over time.

54
55 SR is a reciprocal process. If FDA’s systems recognition assessment concludes that the foreign
56 food safety system operates a comparable regulatory program that yields similar food safety
57 outcomes as the FDA food safety system, and the foreign competent authority reaches the same
58 conclusion about the U.S. food safety system under FDA’s oversight, FDA and the foreign
59 competent authority may enter into a regulatory partnership, which is memorialized in an SRA.
60 Under an SRA, FDA intends to rely on the food safety oversight of the foreign competent
61 authority, which then helps FDA refine its risk-based decisions about the scope and frequency of
62 its oversight activities related to imported products, including foreign facility inspections, import
63 field exams, and import sampling.

64
65 Systems recognition is one tool among many that allows FDA to acknowledge and leverage the
66 reliable food safety oversight of a foreign competent authority in risk-based decision-making
67 regarding inspections, verification programs (e.g., importer verification programs under FDA’s
68 Foreign Supplier Verification Program (FSVP) and seafood and juice Hazard Analysis and
69 Critical Control Point (HACCP) regulations), import admissibility, and follow-up when food
70 safety incidents occur. In addition, FDA may rely on a foreign competent authority’s
71 implementation of science-based food safety regulatory programs to take regulatory action based
72 on information provided by those authorities, when appropriate. Systems recognition allows
73 FDA to better leverage and plan its oversight of foods because it allows FDA to rely on
74 regulators in other parts of the world that provide a similar system of food safety protection.
75 This is one tool that FDA has to ensure that consumers have confidence that their food is safe,
76 whether produced in the United States or elsewhere. This level of regulatory partnership and

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77 leveraging of work requires a rigorous assessment process to ensure that FDA is justified in
78 recognizing a foreign food safety system and relying on the work of foreign governments in
79 making regulatory decisions about food imported into the United States.
80

81 **III. POLICY**

82
83 Systems recognition allows FDA to avoid duplicating certain food safety-related work in
84 countries with an SRA. Accordingly, for food products covered by an SRA and imported from a
85 country with an active SRA, FDA intends to adjust its regulatory oversight activities as follows:
86

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

- 88
89 1. FDA does not intend to prioritize foreign establishment inspections in countries with
90 an SRA. Therefore, FDA's routine inspections of foreign food establishments for
91 food products covered by an SRA will be rare, allowing FDA to allocate its risk-
92 based foreign inspection resources more efficiently and effectively.
93 2. Nevertheless, FDA intends to continue to conduct inspections in countries with SRAs
94 in certain situations, that include, but are not limited to:
95 a. To inspect establishments engaged in manufacturing/processing, packing, or
96 holding FDA-regulated food products not covered by the SRA;
97 b. On a for-cause basis, where appropriate, to address a public health concern or
98 specific food safety issues; and
99 c. For any establishment, in response to a request by the foreign competent
100 authority.
101

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

- 103
104 1. FDA intends to adjust its risk-based screening and targeting criteria for import entries
105 of food products covered by an SRA to reflect FDA's determination of the
106 comparability of the regulatory system covered by an SRA, and to allow for more
107 efficient and effective use of FDA's import investigation and screening resources.
108 Risk-based screening and review for food products imported from a country with an
109 SRA, but that are not covered by the SRA, will remain unchanged.
110 2. Import Alert (IA) and Detention Without Physical Examination (DWPE)
111 a. Existing IA's
112 i. The existence of an SRA with a foreign competent authority does not
113 automatically affect whether there appears to be a violation of FDA
114 requirements. Therefore, food products and establishments subject to
115 DWPE under an existing IA will not be automatically removed from the IA
116 when an SRA is signed.
117 ii. FDA will communicate with the foreign competent authority regarding
118 information about the conditions that gave rise to the appearance of the
119 violation, as appropriate. Establishments and food products may be
120 removed from DWPE when the conditions that gave rise to the appearance
121 of the violation have been resolved.

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- 122 iii. FDA will consider evidence provided by the foreign competent authority
123 regarding corrective actions taken by the establishment when assessing
124 potential removal from an IA, as appropriate.
125 b. Future IA's
126 i. As appropriate FDA may recommend an establishment or food product from
127 a food safety system covered by an SRA for DWPE.
128 ii. FDA will ensure prompt notification, when appropriate (e.g., class I recalls),
129 of a food safety concern to the foreign competent authority.
130 iii. When a foreign competent authority has evidence that is relevant to FDA's
131 decision about whether it is appropriate to list a food product or
132 establishment on an IA, FDA may consider such evidence, as appropriate.
133

C. Examination and Sampling of Imported Food

- 134
135
136 1. Generally, FDA will not prioritize import samples and field examinations of food
137 products covered by an SRA. This will be reflected in FDA's annual field work plan.
138 However, there are some situations where FDA will prioritize sampling a shipment of
139 food products from a country with an SRA, including:
140 a. Food that FDA is targeting for sampling on a surveillance basis (e.g., a
141 particular commodity for which FDA is targeting both domestic and import
142 samples);
143 b. Food exported from a country whose food safety system is covered by an
144 SRA but the specific type of food is not covered by the SRA; and
145 c. On a for-cause basis for food products covered by an SRA, where appropriate
146 to address a specific food safety issue or other potential violations.
147

D. Relevance of Importer Verification Programs

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149
150 1. In accordance with FDA's risk-based approach to inspections, when verifying an
151 importer's compliance with importer verification requirements, FDA will make risk-
152 based decisions about which foods to target. Therefore:
153 a. FDA does not intend to prioritize inspections of importers for FSVP³
154 compliance or compliance with juice and seafood HACCP importer
155 requirements⁴ with respect to imported foods covered by an SRA.

³ "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).

⁴ "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 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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- 156 b. However, FDA may periodically verify that importers of food products
157 covered by an SRA are in compliance with FSVP and HACCP importer
158 requirements.
159 c. In addition, for importers of food products both from countries with SRAs and
160 from countries that do not have SRAs, FDA will continue to prioritize FSVP
161 and HACCP inspections for those products imported from food safety systems
162 that FDA has not recognized.
163 2. FDA’s inspections of imported, non-covered products will remain unchanged.
164

165 **E. Regulatory Compliance Actions**

- 166
167 1. FDA may pursue regulatory actions, such as issuing warning letters, adding
168 establishments or food products to DWPE, and refusing products offered for import,
169 as appropriate:
170 a. This applies to food products and establishments not covered by an SRA; and
171 b. When food covered by an SRA that appears violative is offered for import in
172 the United States and/or is intended for use in the United States.
173 2. FDA has confidence in the countries’ food safety programs for which we have SRAs.
174 This facilitates FDA’s ability to consider information provided by the regulatory
175 authorities, as appropriate, when FDA considers regulatory action.