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FDA Issues New Draft Guidance on Imported Food

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FDA Releases Draft Guidance on Oversight of Food Products Covered by Systems Recognition Arrangements

- On July 12, 2021, the U.S. Food and Drug Administration (FDA) published notice of a new draft guidance document for industry: FDA Oversight of Food Products Covered by Systems Recognition Arrangements. A Systems Recognition Arrangement (SRA) establishes a regulatory partnership between FDA and another food safety authority in countries with systems FDA has concluded have similar elements and similar levels of oversight that lead to similar food safety outcomes.

- The new draft guidance details adjustments to FDA's regulatory oversight activities for food products covered by an SRA and imported from a country with an active SRA. The draft guidance does not impact activities for food exported from a country whose food safety system is covered by an SRA but the specific type of food is not covered by the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 or "for-cause" activities concerning food products covered by an SRA. Otherwise, regulatory adjustments include:

    - In-country food establishment inspections will be rare in countries with an SRA (currently Australia, Canada, and New Zealand);

    - Automated screening and risk-targeting and review of imported food will be adjusted, although foods subject to Detention Without Physical Examination (DWPE) under an existing Import Alert (IA) will not be automatically removed from the IA when an SRA is signed;

    - Imported food covered by an SRA will generally not be prioritized for examination and sampling unless it is a commodity subject to routine surveillance sampling that targets both domestic and import samples;

    - FDA does not intend to prioritize inspections of importers for Foreign Supplier Verification Program (FSVP) compliance or compliance with juice and seafood Hazard Analysis Critical Control Point (HACCP) importer requirements with respect to imported foods covered by an SRA; and

- With respect to regulatory compliance actions, FDA may issue warning letters, add establishments or food products to DWPE, refuse products offered for import, or take other regulatory actions as appropriate when food covered by an SRA that appears violative is offered for import and/or is intended for use in the United States.

- Stakeholders are invited to submit comments on the new draft guidance by September 10, 2021 to ensure consideration before FDA begins work on the final version of the guidance.

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