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Remote Regulatory Assessments of Human Food Facilities

The global COVID-19 pandemic significantly impacted the ability of the U.S. Food and Drug Administration (FDA) to conduct traditional on-site inspections of human food facilities. Although mission-critical inspections have continued throughout the public health emergency (PHE), the agency resumed surveillance inspections in July 2020 following a temporary postponement in March of the same year.

In response to the challenges to on-site inspections presented during the global pandemic, and in preparation for future such emergencies, FDA's Office of Human and Animal Foods Operations (OHAFO) introduced a new study for selected human food (HF) facilities to voluntarily participate in Remote Regulatory Assessments (RRA) of their records. An RRA is a request for a remote review of records that a firm is required to maintain for FDA's review under normal circumstances.

The data from this voluntary study showed that RRAs benefit both the human food industry and FDA by helping to reduce on-site inspection time, to keep FDA and facility personnel safer during the COVID-19 pandemic, and, in the future, to more efficiently use on-site inspection time. FDA's overall RRA study was created to explore alternate ways to protect public health while continuing to provide regulatory oversight beyond traditional on-site inspections during the COVID-19 pandemic.

Objectives of the RRA study for human foods

1. Determine whether requesting and reviewing records remotely influences FDA's on-site inspections through more efficient use of inspectional resources.
2. Identify whether records requested through RRAs are useful in determining the timing of a firm's planned follow-up inspection or whether this approach can negate the need for a follow-up inspection.
3. Obtain sufficient information to recommend whether or not to expand the use of current records-request authority to a broader set of inspections.

Key facts about RRAs for human food facilities

- RRAs are strictly voluntary for human food facilities.
- FDA reaches out to selected individual facilities with a good compliance history to request their voluntary participation.
- There is no penalty for opting out of the RRA. Firms may decline to participate at any time.
- Human food RRAs help the FDA assess a firm's compliance with requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act and human food safety regulations.
- The RRA includes a review of firms' records and an interview via phone or video call with firms about their records.
- A close-out meeting with the firm's management is conducted during which any issues are discussed.
- FDA discusses any concerns with firms, which gives them an opportunity to correct concerns prior to a future on-site inspection.

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Benefits of an RRA

For human food facilities:

- Potentially decreases future on-site inspection time in a firm because a portion of the record review will already have been completed.
- Assesses facilities' compliance with certain regulations by FDA outside of an inspection, which allows facilities to make corrective actions prior to their next on-site FDA inspection.

For FDA:

- Helps FDA continue to provide oversight of the human food industry while protecting both industry employees and FDA staff during the COVID-19 pandemic by limiting in-person contact.
- Initial reviews of the RRA study may be used to develop a future program that would allow use of RRAs as part of future inspection procedures. This approach may be a more efficient use of resources because it may reduce FDA on-site inspection time.
- Allows FDA to document that previously promised corrective actions have been implemented.

Is an RRA considered an inspection?

- No – RRAs are not considered FDA inspections under the FD&C Act.
- No FDA-482 Notice of Inspection will be issued.
- No FDA-483 Inspectional Observations will be issued.
- Firms who do not wish to voluntary participate may opt out without penalty.

How does FDA select firms for an RRA?

The FDA selects firms with a good compliance history who, after previous inspections, had promised corrective actions that the agency has determined can be verified through a remote review of records documenting that those corrective actions have been implemented.

What can a human food facility expect during an RRA?

- A letter, sent via email, is provided to the facility requesting voluntary participation in RRA.
- If a facility voluntarily agrees to participate, the facility selects a designee to work with FDA staff to provide the requested information.
- FDA staff sets up a meeting via audio or video call with the firm's designee to explain the process.
- Information, including a facility's required records, is shared electronically and securely.
- FDA staff reviews information in the firm's records that help the FDA assess current compliance with applicable regulatory requirements; FDA staff also interviews the firm via audio or video call, if necessary, to clarify information on the records.
- If a firm wishes to provide context about the records provided to the agency, FDA is willing to meet with the firm via audio or video call upon receipt of the firm's records.
- FDA staff and the facility's most responsible person or designee hold a close-out meeting to verbally explain any concerns.
- RRAs do not result in an Establishment Inspection Report (EIR) or 483; written documentation will not be provided to the firm during the close-out meeting.

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Types of records that are reviewed during a human food RRA

- FDA's initial RRA for human food focuses on compliance with requirements under regulations.
- FDA focuses on required records for the initial human food RRAs because human food facilities are required to keep specific records that can be reviewed outside of an on-site inspection to assess a facility's general compliance with FDA requirements.
- The specific records requested for review are communicated to the human food facility once the facility has voluntarily agreed to participate in the RRA.
- FDA evaluates the success of the initial human food RRA and determines whether to expand the study to other FDA human food safety regulations.

Is FDA conducting RRA for other FDA-regulated products?

Yes – FDA is also exploring the use of RRAs for animal foods and other FDA-regulated products.

Whom can I contact if I have questions about the RRA process?

This fact sheet was designed specifically to provide information on the RRA study for human food.

If you have any questions after being invited to participate, please reach out to the FDA point of contact listed in the letter you received.

About the Office of Human and Animal Food Operations

The Office of Human and Animal Food Operations (OHAFO), a program within the Office of Regulatory Affairs (ORA), oversees all field inspection and compliance operations related to human and animal food and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). OHAFO collaborates with CFSAN, CVM, and the agency's Office of Food Policy and Response (OFPR) on all FDA-regulated food products.

OHAFO also provides advice and counsel to ORA and FDA leaders regarding human and animal food products, field operations, and emergency response activities. As part of FDA's implementation of the FDA Food Safety Modernization Act, ORA, OFPR, CFSAN, and CVM partner to develop annual work plans and strategic priorities for inspections, compliance, analysis, and import operations.

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