HACCP Consulting Group, LLC

September 2022 Newsletter

FDA Moving Towards Remote Regulatory Assessments

As recently announced, FDA is developing a new system for Remote Regulatory Assessments (RRAs). To expand on FDA plans, the Food Safety Magazine is offering a webinar series, one of which addresses Advanced Strategies for Smarter Food Safety. Topics discussed during this webinar were held on September 20, 2022 and included:

- How RRAs (Remote Regulatory Assessments) are tied into other aspects of FSMA and the New Era of Smarter Food Safety.
- How and why RRAs were developed, and how they are being deployed to oversee foreign facilities that FDA was not previously able to reach.
- How RRAs can be useful in both the domestic and foreign arenas.
- What an RRA entails, and the steps that foreign and domestic facilities need to take to prepare for the assessment.
- The advantages to domestic companies that are invited to participate in the RRA program
- How FDA will inform industry and the public about RRAs and give them an opportunity to provide input.

The Webinar can be found at Food-Safety.com and a FDA Draft Guidance Document on RRAs is **HERE**.

Tracing High-Risk Food: New Details Required in November

In early November, a new food traceability rule will be in place requiring detailed records of the origins and movements of certain "high risk" foods through production, processing, and shipping. There are 16 foods recognized by FDA as high-risk foods.

In this FDA rule, Key Data Elements (KDEs) and Critical Tracking Events (CTEs) require maintaining and communicating certain data depending on a site's role in the food chain. The rule addresses growing, receiving, transforming, creation and shipping of high-risk foods. Typically required data includes items such as location description and identifier, Lot Code information, and business contact details.

For a summary of requirements: **HERE**

Prepare for Registration Season

U.S. and foreign human and animal food facilities that are required to register with the FDA must renew their registration this year between October 1 and December 31, 2022.

For more information, watch this Webinar on Food Facility Registration (FFR), Biennial Renewal, and Unique Facility Identifiers (UFI). **LINK HERE**

Foreign Supplier Verification Programs (FSVP) – FDA Warning Letters

FDA continues to issue Warning Letters to importers in violation of the FSVP regulations. Violations most notably are for not having *all* imported products addressed in the FSVP Program and/or having an inadequate hazard analysis as required by the FSVP regulations.
The FSVP regulations, in Subpart L – FSVP for Food Imports, Section 1.504, requires that:

Except as specified in paragraph (d) of this section, you must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food you import to determine whether there are any hazards requiring a control. Your hazard analysis must be written regardless of its outcome.

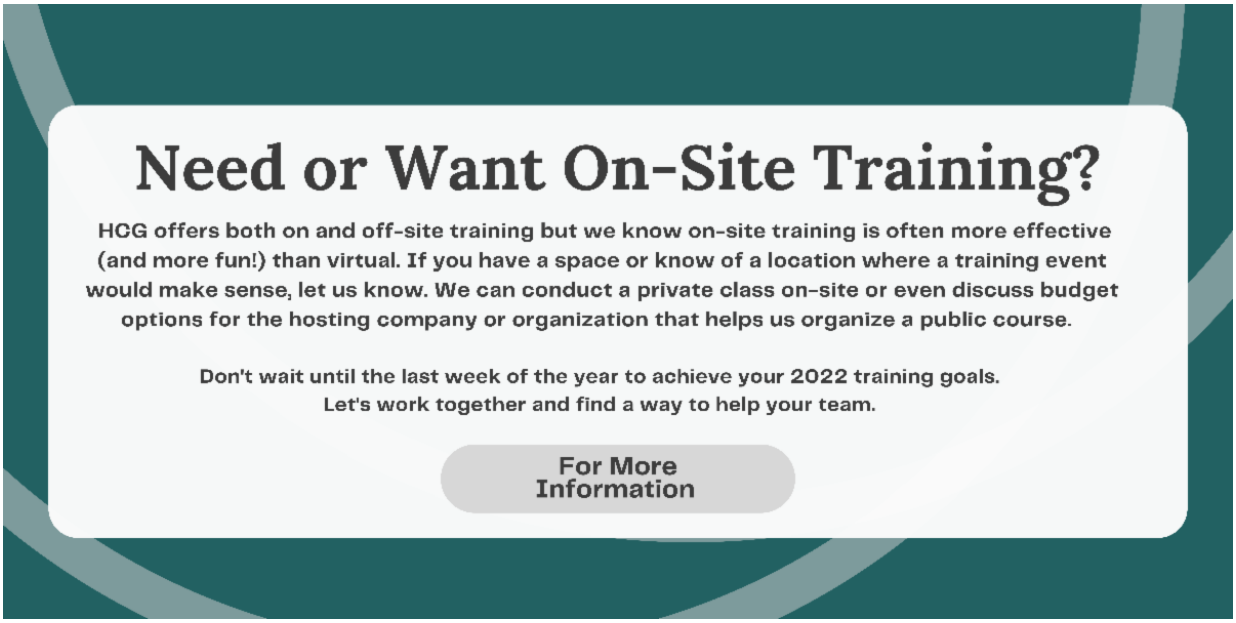
The regulations also require that if the importer has another entity conduct a hazard analysis, the importer must document it was conducted by a "Qualified Individual" and the importer must document their review and assessment of the hazard analysis. Also, when conducting or reviewing a hazard analysis, the Qualified Individual should ensure a two-step process: hazards are to be identified and evaluated per 21CFR504(c)(1). When potential hazards are identified, the hazard analysis should include evidence or documentation that the evaluation addresses both the likelihood and severity of those hazards in the absence of control. This should be part of a hazard analysis table or written into the FSVP procedure manual.The additional effort to demonstrate how risk and severity have been considered is an important step. While not often seen in Warning Letters or point-loss on third-party audits, it is a requirement that encourages better evidence of thoughtful Food Safety Plans.

Failure to comply with the above requirements can and has resulted in an FDA Warning Letters giving the importer 15 days to comply and can result in further action including preventing the importation of the food material into the Unites States.

In addition to impacting importers, FDA Warning Letters can have serious consequences for the domestic facility that uses imported materials in their production. While the importer ensures its FSVP follows FDA regulations, the domestic facility must also ensure through Supply Chain Verification Program, that imported ingredients are from FSVP-compliant importers.

HCG Members have collectively worked with food and food safety systems in over 70 countries. With over 26 years' experience in food safety (HACCP) training, assisting food facilities develop and implement food safety programs, HCG can help you find options that work best for you to document a thorough evaluation of hazards.

For more information, please contact HCG at **info@haccpcg.com**



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VIRTUAL TRAINING EVENTS

Basic HACCP
October 20-21
November 17-18; Spanish
December 6-7

FSPCA Preventive Controls + HACCP
December 7-9

FSPCA Preventive Controls for Animal Food
October 19-21

Implementing SQF Systems
October 13-14; Spanish
December 8-9

FOR MORE INFORMATION OR TO REGISTER: WWW.HACCPCG.COM

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