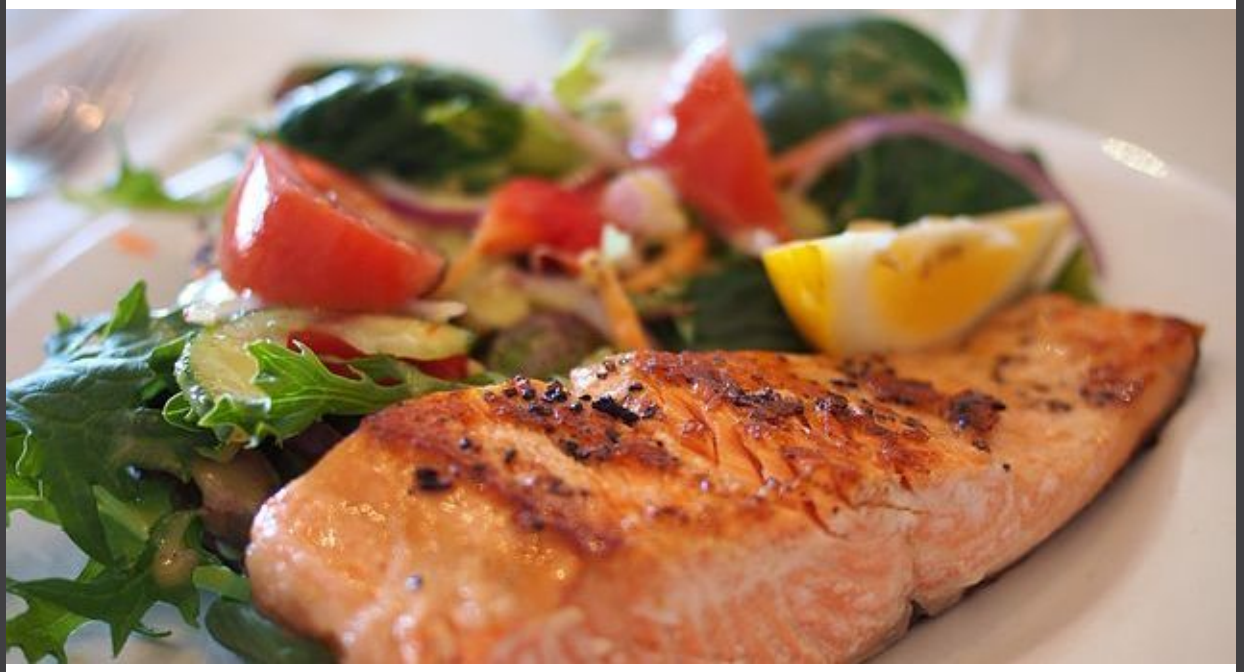
HACCP Consulting Group, L.L.C®

Excellence in Food Safety Management

March Newsletter



In this edition...

-When to Report Concerns to FDA / USDA
-Training Opportunities
-FDA Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry
-FSIS Guideline for Industry Response to Customer Complaints
-FDA Strategy for the Safety of Imported Food

When to Report Concerns to FDA / USDA

The food industry can learn from other industries when considering how and when to report concerns. Laws for reporting medical device malfunctions require reporting to the FDA if a malfunction is "likely" to cause serious injury or death upon recurrence. Unfortunately, "likely" is not defined and there is no settled, legal definition for the term. Those subject to the law, must essentially guess at the meaning of "likely" and how to or when to comply with the reporting requirement.

FDA has indicated through Guidance that "likely" means "not remote" and having not occurred within the previous two years. However, in an FDA Warning Letter written later, a company was advised that this two-year expiration was not acceptable.

This leaves the meaning of "likely" to potentially mean any single event regardless of the sample

set. It may be 1 event per 10, or 1 event per one million uses per year. In fact, the implication is that *any* probability of reoccurrence above zero may equate to a requirement to report a medical device malfunction.

A similar ambiguity exists for food manufacturers required to report to the FDA when potentially unsafe products have entered commerce. Read more...

Training Opportunities

Basic HACCP

- April 8-9, Philadelphia, PA
- April 23-24, Ontario, CA
- June 25-26, San Diego, CA

Developing & Implementing SQF Systems

- April 10-11, Philadelphia, PA

Basic HACCP + Preventive Controls (combined)

- May 8-10, Dayton, OH
- May 14-16, College Park, MD

FSPCA Preventive Controls for Human Food (PCQI)

- March 27-29, Fayetteville, AR
- May 6-8, Dallas, TX

FSPCA Foreign Supplier Verification Programs (FSVP)

- May 9-10, Dallas, TX

Register Now!

Do you need On-Site Training? No problem.

Please contact us to schedule a time that works for you...
email: **info@haccpcg.com**
or check out our website **www.haccpcg.com**

FDA Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry

The purpose of this guidance (attached) is to help facilities develop and implement a food defense plan (FDP) in accordance with the Intentional Adulteration rule's requirements. Specifically, this provides guidance on understanding:

- the components of an FDP and the importance of each component
- how to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps
- how to identify and implement mitigation strategies for the actionable process steps associated with a facility's processes
- how to identify and apply the mitigation strategies management components (i.e., food defense monitoring, food defense corrective actions, and food defense verification)
- the reanalysis requirements associated with the FDP
- the education, training, and/or experience required for individuals who perform certain activities; and
- the record-keeping requirements associated with the FDP and implementation of the FDP

HCG reminds our readers that FDA's guidance documents do not establish legally enforceable responsibilities. They they describe FDA's current thinking and should be viewed primarily as recommendations.

While this guidance is specific for FDA regulated facilities, facilities regulated by FSIS should also take note of the recommendations as compared to their Food Defense Programs.

If establishments need further advice or guidance in the review or development of its FDP please contact HCG.

FSIS Guideline for Industry Response to Customer Complaints

This FSIS guideline (attached) provides industry with reference material on best practices for responding to customer complaints of adulterated and misbranded meat and poultry products. FSIS developed it in response to an increase in the number of recalls due to foreign materials. In many cases, the recalling establishments received multiple customer complaints prior to these recalls. FSIS specifically developed this document to address foreign material customer complaints, but establishments can apply the information to other customer complaints of adulterated or misbranded products in commerce. This guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date.

Importantly, the guideline identifies notification requirements under 9 CFR 418.2 as:

§418.2 Notification. Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

The FSIS guidelines further discuss best practices for handling and documenting customer complaints and the importance of developing a program to handle such incidents.

If companies need assistance in developing a comprehensive customer complaint program or an assessment of an existing program please contact HCG.

FDA Strategy for the Safety of Imported Food

In conjunction with FDA's effort to address the safety of imported food and following the publication of the Foreign Supplier Verification Program (FSVP) regulations and Industry Guidance: Foreign Supplier Verification for Imports of Food for Human and Animals, FDA has now published its overall strategy for the safety of imported food (attached).

FDA's imported food safety goals fall into three categories: (1) preventing food safety problems in the foreign supply chain prior to entry into the United States, (2) effectively detecting and refusing entry of unsafe foods at the border, and (3) rapidly responding when FDA learns of unsafe imported foods. An overarching fourth goal is to create an effective and efficient food import program. FDA's strategy outlines several methods the agency plans to use to accomplish these goals including strategies for each objective.

Companies relying on imported ingredients and foods, as necessary components of its finished products, should have assurance that their foreign suppliers and the importers of record are in compliance with all applicable FDA import regulations. Failure to comply can cause serious disruptions in the production of foods at your domestic establishment.

HCG has worked in over 70 different countries . We can assist your importer-of-record and/or the foreign supplier to ensure compliance. Please contact us at any time.

Best Wishes,

Cathy M. Crawford, President

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STAY CONNECTED