When to Report Concerns to FDA / USDA

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An article by Jeffrey Shapiro was posted 9/9/13 regarding the challenges of understanding FDA medical device malfunction reporting laws. This law currently requires a malfunction to be reported to the FDA if it is "likely" to cause serious injury or death upon recurrence. Mr. Shapiro questions the constitutionality of this requirement partially because "likely" is not defined and there is no settled, legal definition for the term. It requires, those subject to the law, to essentially guess at the meaning of "likely" and how to or when to comply with the reporting requirement.

Around 1987, FDA indicated through Guidance that likely meant "not remote" and having not occurred within the previous two years. However later, in an FDA Warning Letter, a company was advised that this two-year expiration is no longer 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* probably 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. Which foods are to be reported? According to the FDA, a reportable food is defined as any food product that has a "reasonable probability" of causing serious health problems or death in humans or animals. There is wide room for debate on the meaning of "reasonable" and "serious". FDA provided examples of reasons a food may be reportable such as bacterial contamination, allergen mislabeling or elevated levels of inappropriate chemical components.

For foods under FSIS jurisdiction, the reporting function a bit clearer. The FSIS Directive 8080.1 was updated 9/9/13 and requires reports within 24 hours after a company becomes aware of product that is in commerce and is adulterated or misbranded. Fortunately, both 'adulterated' and 'misbranded' are defined in the law. In this case, unlike the FDA requirements, the requirement seems to apply regardless of the potential for risk to the consumer.

Recently, FSIS published "FSIS Guidelines for Industry Response to Customer Complaints", which makes it even clearer when companies must report incidents of foreign material contamination (i.e., either a food safety hazard or otherwise adulterated) that results in product being adulterated or misbranded. The guidance document sites Section 9 CFR 418.2-Notification which states: "*Each official establishment must promptly notify the local FSIS District Office with 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 products."

When an establishment **receives** adulterated or misbranded product and the product has been shipped in commerce, the receiving establishment must notify FSIS is accordance with 9 CFR 418.2. The receiving establishment may notify the District Office directly or may elect to notify Inspection Program Personnel (IPP) instead of the District office. If the receiving establishment elects to notify the IPP then the IPP will complete FSIS Form 8140-1 to notify the IPP at the shipping/producing establishment and the applicable District Office.

When the producing establishment is notified directly by the receiving establishment that it produced adulterated or misbranded product and the producing establishment has not been notified by the local IPP that FSIS Form 8140-1 was received from the District Office, or when the producing establishment is notified of adulterated or misbranded product by a customer, the producing establishment must notify its District Office within 24 hours of learning that adulterated or misbranded product has entered commerce. When the producing establishment receives a customer complaint from a location other than an official establishment (e.g., state inspected, retail, restaurant, household consumer) that indicates adulterated or misbranded product has entered commerce, then the producing establishment is solely responsible for the notification of the District Office.

In the end, it is up to the manufacturer or distributor of FDA or USDA regulated items to practice judgment in making reporting decisions. Often, those who initiate a message have the best opportunity to ensure that message is accurate and the response appropriate. If uncertain, consider the consequences of not reporting. If there is a potential for illness or injury, damage to the company image or brand, or damage to the company's trust from regulators or consumers, it is advisable to report.

Companies that understand risk management and ensure proactive systems should be prepared to manage incidents calmly and factually. FSIS recommends, but does not require, that an establishment develop a program to receive and process customer complaints. The Program should be comprehensive and teams trained to identify concerns through internal auditing. Results of those audits should be managed to reduce risk through corrective actions.

If the concept of reporting a potentially unsafe food product or an adulterated or misbranded product in commerce keeps you awake at night, contact the HACCP Consulting Group. Our team can assist in development of management systems and incident management plans to add confidence.