FSIS RECALLS — A Legal Perspective

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A. Legal Authority for a Recall

FSIS's Recall Directive defines a recall as a "firm's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded." The key word in this definition is "voluntary." FSIS currently lacks the statutory authority to order a recall.

However, if a company refuses to conduct a recall, the agency has other options. Distribution of an adulterated meat or poultry product is a felony, even if the adulteration itself was unintentional. If a company refuses to conduct a recall, the agency may exercise its prosecutorial discretion to initiate a criminal action against the company. Beyond prosecution, FSIS has the statutory right to obtain shipment records, detain product at customer locations, and seek a mandatory injunction. Perhaps FSIS's most important authority is that it has the power of the press at its command. It is bad customer relations to have FSIS announce on the six-o'clock news that the company was uncooperative.

B. Factors in Making the Recall Decision

If a company discovers that it has distributed meat or poultry products in commerce that are adulterated or misbranded, it should seriously consider conducting a recall. There is a great tendency in dealing with recalls to focus exclusively on the regulatory implications of the recall (e.g., criminal prosecution or the issuance of a press release). However, companies should not lose sight of the fact that recalls generally involve potentially hazardous products. If a company wishes to "run the risk" and not inform the agency, there still remains the chance that a consumer will be injured. If the company knew of the problem and did nothing, the potential product liability concerns are huge. Companies should operate under the assumption that if a defective product is shipped out, it will be found.

Companies also should remember the definitions of a "market withdrawal" or "stock recovery." If a company removes product from commerce that "involves a minor infraction, or involves no violation of the FMIA or the PPIA, or no health hazard," the action will be deemed a market withdrawal, not a recall. If a company removes product that is adulterated or misbranded, but has not been "marketed or that has not left the direct control of the company," the action will be deemed a stock recovery. Market withdrawals or stock recoveries are preferable to recalls because FSIS generally will not take a significant role or issue press releases in such actions.

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C. Contacting the Agency Regarding a Recall

Strictly speaking, there is no legal obligation to inform the agency when a company decides to initiate a recall. However, if a company does not inform the agency and the agency subsequently discovers the recall, the agency may exercise its discretion to initiate judicial proceedings or make "suggestions" as to how the recall should be modified and exercise its authorities if the company refuses the modifications. FSIS's Recall Directive states that companies conducting recalls should contact FSIS's Emergency Response Division (ERD) "as soon as possible" (generally within 24 hours).

Prior to contacting the ERD, the company should confirm the facts and write them down (using the FSIS Recall Worksheet). Specifically, the company should document:

a. The defect and its likely recall classification — FSIS is the ultimate decisionmaker on recall classifications, but the company should have arguments in support of its classification ready, including the agency's previous classifications of the same or similar defects found on the FSIS website. The FSIS Recall Directive classifies the health risk and appropriate recall class as follows:
   Class I — "reasonable probability that the use of the product will cause serious, adverse health consequences or death."
   Class II — "remote probability of adverse health consequences."
   Class III — "will not cause adverse health consequences."
b. The scope of the product involved or "recall window" — A company should not start a recall unless it has conclusively locked the window in. The questions are when did the defect occur and what products are implicated. Just because one code date has been identified in a consumer complaint or a laboratory test does not necessarily mean that it will be the only implicated date. Issues such as carryover product, e.g., rework or work in process, must be considered. Additionally, raw

materials may be important. In the case of *E. coli* O157:H7, we believe FSIS will look at whether there was a unit of raw material (carcass, combo bin or box) used on different days. Even if a company has determined what dates are implicated, it is also necessary to determine what specific products are implicated on those dates. When it comes to pathogens, the general rule is that all products under a HACCP plan between clean-up and clean-up are implicated. However, the scope of the recall may be expanded or narrowed depending on the circumstances.

c. The identity of the products and the amount of production involved — brand name, product name, package type, size, codes, production dates, amount produced, etc.
d. The consignees that received the product — the company should generate a list of consignees and check it twice, because the agency certainly will. In identifying the consignees, the company should ascertain whether the consignees distributed product downstream. If so, the consignees will have to assist the company in retrieving product.
e. The likely cause of the defect and what the company will do to prevent recurrence — if adulterated product was produced or shipped, the agency will expect the company to determine the likely cause of the defect and to implement effective corrective and preventive actions pursuant to 9 C.F.R. § 417.3. This may involve a reassessment of the company's HACCP plan.

The company should begin preparing for media inquiries prior to contacting the ERD. FSIS recently announced in its revised Recall Directive that it will issue a written press release and post a Recall Notification Report (RNR) on its website for all recalls, including Class III recalls. Although FSIS will not permit the company to review the press release prior to issuance, the agency generally will allow the company to review the RNR. Companies should make sure that all of the information on the RNR is correct, since that information will be used for the press release. We also recommend that companies prepare their own draft press release and, depending on the particular circumstances, hire a public relations firm to assist in addressing the media.

Once the company contacts the ERD, the ERD will schedule a conference call with the company and other FSIS officials to discuss the specifics of the recall, including the recall class and scope. Please note that FSIS must concur with the company's decisions prior to the company initiating the recall. If a company disagrees with the agency's determinations on the recall, failure to comply with the agency's recommendations could expose the company to the sanctions discussed above.

D. Implementing the Recall

Assuming the company agrees with the agency's recall class and level, the next step is implementation. The company should contact customers by phone to notify them of the recall and follow up the telephone call with a letter (preferably by fax). The letter should identify: the product (by name, brand, code, package size and type, and establishment number); that a recall is being conducted; what the customer should do with the product; and that the customer in turn should contact its downstream customers.

FSIS will conduct effectiveness checks to ensure that all consignees have been contacted. Therefore, we strongly advise that the company maintain a recall log identifying: the name of the customer; the contact person/phone number; the time and day the contact was made; how much product is on hand; whether a letter was sent; and how much product was ultimately retrieved. Moreover, it is advisable to let the customer know that they could be contacted by an agency official verifying that the notice was received and that the customer followed the instructions. FSIS's Recall Directive states that "if the firm does not take prompt action to contact the consignees with recall instructions, or the consignees fail to act on the product as requested by the firm, District Enforcement personnel may initiate other enforcement actions."

In addition to contacting the customer, it appears FSIS also will go to the company and thoroughly review the records to determine that the company selected the right recall window. During this review, the agency may ask to review certain documents to which it is not otherwise entitled (such as non-mandatory micro-test results). From a strict legal perspective, a company does not have to provide such documents. However, from a practical perspective, failure to cooperate raises risk of adverse agency action.

If the company decides to share the records with FSIS, it should take certain measures to ensure the confidentiality of the documents. The company can ask that no copies be made of the records or that any documents provided be returned to the company or shredded once the recall is terminated. The company also should stamp all documents "Trade Secret and/or Confidential Commercial Information."

When the product is returned, inspected companies should notify the Inspector-in-Charge so that the product can be retained. If meat or poultry products are to be destroyed, the destruction must be done under FSIS compliance supervision. Once the company believes that there is no more product left in commerce, it should contact the agency and request termination of the recall. Once the agency sends the termination letter, the recall is over.

One final point in dealing with the agencies on recalls: honesty is always the best policy. Do not be "cutesy" or evasive. Half-truths have a tendency to come back to bite a company. If the company discovers an error in what it has said: (1) let the agency know and (2) document the correction.