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October 22, 2002

Dr. Garry McKee
Administrator, FSIS
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Room 331E
Washington, D.C. 20250

Dear Dr. McKee:

The purpose of this letter is to respond to the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service's (FSIS's) October 15, 2002 announcement requesting comment on the notice entitled, "FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli* (E. coli) O157:H7 Positive Raw Ground Beef Product" (hereinafter "the draft Notice").[1] The draft Notice explains the steps that FSIS will take in conjunction with sampling raw ground beef products for the presence of *E. coli* O157:H7 at federally inspected establishments as well as retail facilities.

FMI supports the draft Notice, provided that the critical modifications discussed below are made before the Notice is finalized. Specifically, and for the reasons set forth below, retailers should be afforded the same prior notice regarding sample collection that FSIS intends to provide to federally inspected establishments and import establishments. In addition, FSIS should explain the relationship between the Notice and FSIS Directive 10,010.1, 2-1-98, Microbiological Testing Programs for *Escherichia coli* O157:H7 in Raw Ground Beef.

[1] Food Marketing Institute (FMI) conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

PRE-NOTIFICATION

As described in Paragraph I, both federal plants (I.A.1.) and import establishments (I.C.) are notified before a sample is collected and provided enough time to hold the sampled product voluntarily. Retailers should be given this same opportunity.

Rationale

Federal and import establishments are given prior notice of a sample collection so that they can hold product pending the test results. These test-and-hold programs serve a dual purpose: one, they better protect the public health by preventing contaminated product from entering commerce and, second, they can prevent recalls of product that has already been distributed or sold. Retailers grind and sell beef in a continuous process so that a given sample will represent product that is both being ground at the time and product that has already been sold to consumers. A review of the FSIS Microbiological Results of Raw Ground Beef Products Analyzed for *Escherichia coli (E. coli)* O157:H7 for calendar year 2002 (updated October 16, 2002) shows that the test-and-hold advantage is given to federal plants but not to retailers. Specifically, for federal plants, positive test results led to recalls only 13 out of 37 times (35%), which means that, for the remaining 65% of the samples taken, the product had been held from distribution until the results had been obtained, thereby preventing the need to recall the product from the distribution chain. In contrast, according to the same report, positive test results from samples collected at retail resulted in a recall 11 out of 11 times (100%).

Benefits

First, if retailers were given notification of the intent to collect a sample at least 24 hours prior to collection, all product represented by the sample in that store could be put on hold. In some cases, retailers may even be able to hold all or a portion of the same source material from further distribution pending test results. Second, retailers can provide more accurate information on source material, including production date and lot number, if given prior notice. Third, if retailers have prior notice of sampling, they may be able to implement preventive practices such as using a dedicated grinder for the sampled lot or conducting a clean and sanitize procedure after the sample is collected, thereby minimizing or preventing cross-contamination of other product. Finally, if FSIS notifies retailers when they will be in the store to collect a sample, the retailer can also be instructed to make certain that beef is being ground at the time of the visit, thereby making more efficient use of the compliance officer's time and avoiding repeat trips to the store.

REASON FOR SAMPLE COLLETION

Paragraph I.A.2. lists examples of reasons why a sample may be collected at a federal plant. Although the same reasons for a sample collection apply at retail, there are only two reasons cited for why a sample would be collected at retail in I.B.2. Retailers should be fully informed about the reason for sample collection and Part I.B.2 should be the same as Part I.A.2.

INFORMATION COLLECTED AT TIME OF RETAIL SAMPLE

In most cases, retailers will be able to provide the information requested in Part I.B.3. at the time of sample collection, especially if the source material is coarse ground beef. It is less likely that an individual store can provide information on the source of store- generated trim under the program as outlined in the Notice. Prior notice will help to facilitate the retailer's ability to provide the information FSIS requests. Records indicating specific lot number and production dates are not required in the FMIA nor in the regulations. (See 9 CFR § 320.1.) Retailers have always, and will continue, to give FSIS personnel full access to records as required by statute or regulation. However, such records may be kept at a headquarters location or centralized in a data base where information can be more accurately maintained, retrieved and archived. As stated previously, information on supplier and source will be more readily available, accurate and reliable if the retailer is given at least 24 hours prior notice of sample collection.

SAMPLED LOT

It is unclear if the reference to a "lot of ground beef being sampled" in Part I.B.3. of the Notice is consistent with the terminology of a "sampled lot" in FSIS Directive 10,010.1, Section V. Individual retail stores may not be able to provide the information requested in Part I.B.3. of the Notice if a lot is defined as per Directive 10,010.1 because some retailers do not track all the meat sources that may have been used previously in the day or throughout the day.

PRESUMPTIVE POSITIVES: RETAILERS MUST ALSO BE NOTIFIED

Section II of the draft Notice does not indicate how a retailer will be notified of a presumptive positive and should be amended to indicate the persons responsible for notifying the retailer, when the retailer will be notified and the means by which the retailer will be given the necessary information. As written, the draft Notice implies that the supplier plant will have information about presumptive positive test results on samples collected at retail without the retailer having the same information.

CONFIRMED POSTIVE SAMPLES

Similarly, Section III of the draft Notice does not indicate how a retailer will be notified of a confirmed positive. Section III should be revised to indicate the persons responsible for notifying the retailer, the time period in which the retailer must be notified and the means by which the information will be given to the retailer. As written, it seems that all parties other than the retailer will have information about confirmed positive test results on samples collected at retail. Furthermore, the Notice should explain the action that FSIS will take at retail following a confirmed positive result.

SUMMARY

The foregoing concerns should be fully addressed before the Notice is finalized and implemented. Retailers should receive prior notification of sampling in the interest of public health and to assure equal treatment. Questions regarding the definition of a sampled lot, notification to retailers of preliminary and final test results, and records requirements should all be resolved before this Notice is finalized.

We are also concerned about actions being taken at retail by FSIS compliance officers, consistent with this Notice but prior to it being finalized and implemented. Retailers are at a disadvantage if they are expected to comply with requirements that have not been finalized and shared with them.

We look forward to discussing these issues at our October 22, 2002 meeting.

Sincerely,

Jill Hollingsworth
Vice President
Food Safety Programs