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Inside

Retail customer. *(USDA Photo)*

Getting to Know the Retail Rule and Its Implications for You

By Michael Califa

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) has added a significant new safeguard for consumers and businesses, aptly titled the "retail rule." If your establishment is involved in a class one recall, the retail rule applies. In short, this rule allows FSIS to publish a list of retailers who received the recalled product if there is a class one recall that involves meat or poultry products.

From the onset, the rule seems to favor consumers. This, however, is not necessarily true. The rule can benefit you too. How? It will allow consumers to see if the recalled product is carried by their local retail store. This helps you because a consumer will have more information and can more easily identify a product, thereby significantly limiting your liability. That's right, if consumers don't eat the recalled product, then they don't get sick, and if they don't get sick, you have a smaller chance of getting sued.

The rule was proposed on March 7, 2006, and the Agency received over 6,000 comments about it. Of those comments, only nine were not in favor of the rule. FSIS reviewed the comments and weighed its options for nearly 2 years. In April 2008, FSIS submitted the draft final rule to the U.S. Office of Management and Budget. The final rule was published in the *Federal Register* on July 17, 2008, and became effective on August 18,

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Food Safety Resources

By Sally Fernandez

The Interactive Knowledge Exchange (IKE) is a valuable Web-based tool for FSIS' inspection force to help them stay current and correlated on regulatory requirements, directives, notices, Hazard Analysis Critical Control Point System, Sanitation Standard Operating Procedures, and agency sampling programs. IKEs can also be a very helpful tool for you and are readily available for your review.

Here's how they work. A scenario about an inspection-related subject is presented with a section on "what would you do?" or "what is the correct action to take?" Although suggested solutions are included, the greatest benefit is gained from discussions of the scenarios and questions at weekly meetings with your inspection team. If questions are not resolved, they can be submitted to *Ike@fsis.usda.gov*. Questions are then evaluated, researched, and answered by specialists.

IKEs cover a wide range of topics. Two examples are IKE Scenario 01-07: *Citing Relevant Regulation When Documenting Specified Risk Material Noncompliance* and IKE Scenario 01-08: FSIS *Verification* of 9 Code of Federal Regulations (CFR). 416.2 (d) *Regarding Frozen Condensate in Product Freezers*.

IKEs can be accessed online at *www.fsis.usda.gov/FSIS_Employees/IKE/index.asp* or simply type IKE in the search box of FSIS' home page at *www.fsis.usda.gov*.

Commonly Asked Questions & Answers

Q. *Can an official establishment send heads with specified risk materials (SRM) from cattle 30 months of age or older to another official establishment for further processing and removal of the SRM under its control or USDA seal?*

A. No. Heads from cattle 30 months of age and older are ineligible to bear the mark of inspection because SRMs (i.e., brain, skull, eyes, trigeminal ganglia) are located throughout the head. Because high-risk tissues are an integral part of the head of cattle 30 months of age and older, unmarked heads with SRMs from cattle 30 months of age or older may not be transported under company control or USDA seal. FSIS is unaware of methods or procedures an establishment could use to address the potential risk for the edible product (head meat, cheek meat, and/or tongue) to be contaminated with SRMs in cattle 30 months of age or older during transportation to another official establishment.

Q. *Can an official establishment send heads from cattle younger than 30 months that contain SRMs (i.e., tonsils) to another official establishment for further processing if both establishments have controls in place to ensure that the tonsils are removed and excluded for human food, similar to the controls required for vertebral column in cattle 30 months of age or older as provided in* 9 CFR 310.22(g).

A. No. FSIS inspection personnel will not allow the mark of inspection to be applied to the heads of cattle younger than 30 months unless the tonsils have been removed and disposed of as inedible. Therefore, an official establishment may only transport heads from cattle younger than 30 months that contain SRMs (i.e., tonsils) to another official establishment for removal of the tonsils and further processing of inspected and passed edible parts under official USDA seal as provided under 9 CFR 316.8 and 325.5, using FSIS Form 7350-1 *Request and Notice of Shipment of Sealed Meat and Poultry* for further processing and removal of the SRMs. Both the shipping and receiving establishments are required to address the removal, segregation, and disposition of SRMs, and the contamination of edible materials with SRMs before, during, and after entry into the official establishment (9 CFR 310.22(e)).

Understanding the Full Scope of the National Residue Program and How it Impacts You

By Penny Zervos

You've seen FSIS inspectors take samples from your plant many times and have anxiously awaited the results. Besides testing for pathogens, what else is FSIS looking for and why?

FSIS personnel also analyze the samples taken from your plant at its laboratories for chemical residues of veterinary drugs, pesticides, and environmental contaminants. This collection and testing authority is provided under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. The Agency's regulations are found in Title 9 of the Code of Federal Regulations, Chapter III.

However, FSIS does not work alone when it comes to residue testing. If FSIS laboratories find samples with residues that exceed established tolerances and action levels, the Agency will share these findings with the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA). EPA and FDA have statutory authority for establishing residue tolerances or action levels. FSIS, through the National Residue Program, analyzes animal tissues and processed egg products to prevent chemically adulterated products from entering the food supply.

Since 1967, FSIS has administered the National Residue Program to collect data on chemical residues in domestic and imported meat, poultry, and processed egg products. This program is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory followup of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

Due to the implementation of the Hazard Analysis and Critical Point System (HACCP), another important component of the National Residue Program is to provide verification of residue control in HACCP systems. As part of the HACCP regulation, your plant is required to identify all chemical residue hazards that are reasonably likely to occur and develop a system to guard against them. A vigilant chemical residue prevention program is essential to foster the prudent use of veterinary drugs and pesticides in food animals. In 1999, the program was modified to make residue evaluation more consistent with risk analysis principles.

The National Residue Program consists of two sampling plans: domestic and import. The domestic sampling plan includes scheduled sampling and inspector-generated sampling, and the import reinspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling.

Under the scheduled sampling plans, random tissue samples are collected from animals that appear to be healthy. Scheduled sampling plans are generated from FSIS Headquarters.

Inspector-generated sampling is conducted by FSIS' in-plant Public Health Veterinarians (PHVs). Most of the National Residue Sampling will be conducted by PHVs. This occurs when the in-plant PHV suspects that an animal may have violative levels of chemical residues. Inspector-generated sampling targets individual suspect animals and suspect populations of animals.

When an inspector-generated sample is collected, the carcass is held at your plant pending the results of laboratory testing. If a carcass is found to contain violative levels of residues, the carcass is condemned. FSIS will notify FDA of the violation and assist that Agency in obtaining the names of producers and, in the case of food animal products, other parties involved in offering the animals for sale.

FSIS also posts a Repeat Violator List on its Web site at *www.fsis.usda.gov/PDF/Residue_Violators_List.pdf*, listing the names and addresses of parties whom FDA has determined are responsible for more than one veterinary drug, pesticide, or other chemical residue violation in a 12-month period. This list is a useful source for small plant owners and operators to check to avoid getting sources of animal products that have illegal levels of residues.

Imported meat, poultry, and processed egg products are sampled at U.S. ports of entry to detect chemical residues. Port-of-entry reinspection is a monitoring program conducted to verify the equivalence of inspection systems in exporting countries. The chemical residue sampling program is one of several types of inspection conducted during FSIS reinspection of imported products. All imported products are subject to reinspection, and one or more types of inspection are conducted on every lot of product before it enters the United States. The following are the three levels of chemical residue reinspection:

- Normal sampling is defined as random sampling from a lot;
- Increased sampling is defined as above the normal sampling as the result of an Agency management decision; and
- Intensified sampling is defined as occurring when a previous sample for a type of inspection failed to meet U.S. requirements.

The data gathered in the national residue program are used to verify the safety of meat, poultry, and processed egg products in the United States. The program helps FSIS, FDA, and EPA enforce Federal laws and regulations and assists in the design of programs to enhance the Nation's residue control programs.

For a more indepth look at the National Residue Program sampling programs and data, as well as the Repeat Violator List, go to the chemistry section of FSIS' Web site at *www.fsis.usda.gov/Science/Chemistry/index.asp*. Here you'll find links for the 2008 *FSIS National Residue Program Scheduled Sampling Plans* publication, otherwise known as the "Blue Book;" the *National Residue Program Data* publication, known as the "Red Book;" and the Repeat Violator List.

If you have further questions and comments on the National Residue Program, contact FSIS' Risk Assessment and Residue Division at (202) 690-6409.

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The Agency carefully deliberated on when the rule should apply. It was decided that the rule should only apply to class one recalls. "A class one recall is one involving a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death," said Lisa Volk, director of FSIS' Recall Management Staff.

Additionally, the Agency decided that only "retailers" would be listed. Retailers include supermarkets, grocery stores, convenience stores, meat markets, wholesale clubs, and supercenters that have received the recalled product. Intermediate distributors such as food service or institutional distributors are not included in the definition of a "retailer" and therefore are not listed. Furthermore, only recalls involving meat or poultry products trigger the retail rule.

Let's say hypothetically that your plant has to recall product that has gone out to retail distribution. Here's how it works.

During the recall process, FSIS will request that you provide the Agency with a list of the consignees to whom the recalled meat or poultry products were distributed. FSIS will use this information to verify and ensure that the consignees have been notified of the recall and are removing the products from the market and returning them to your establishment. FSIS also obtains lists from the consignees of all entities to which they distributed the product and contacts those entities to ensure that they were notified. The Agency then obtains those consignees' distribution lists and thereby traces the product forward to the retail level.

Because this process takes time, the retail list won't be available until 3 to 10 business days after the date of the recall. For each retail location, the name of the retailer, the street location, city, and State will be listed. If new information becomes available, FSIS will update the list. In the event that there is a large volume recall with an extensive distribution area, the Agency may use general geographic locations, e.g., "products subject to recall were distributed in all *XYZ* company locations west of the Mississippi." The recall lists are posted on the FSIS Web site. Go to *www.fsis.usda.gov/Fsis_Recalls/index.asp*.

FSIS firmly believes that this additional safeguard will not only save lives but also limit your liability. The list also helps consumers clearly identify the recalled product. Proper identification reduces the amount of product that may be mistakenly returned to retail locations.

In addition to limiting exposure during a recall, FSIS also recommends that you take the extra steps to prevent recalls from happening in the first place to reduce your liability risk even further (see *Small Plant News*, March 2008, "How You Can Prevent Recalls").

For questions or additional information about the retail rule, contact either FSIS' Congressional and Public Affairs Office at (202) 720-9113 or Recall Management Division at (202) 690-6389.

Briefs

By Sheila Johnson

Podcasting

Don't forget to check out the latest educational podcasts related to various food safety and consumer education issues. If you haven't signed up yet for a free subscription, visit www.fsis.usda.gov. For assistance or details concerning FSIS podcasts, send an email to *podcast@fsis.usda.gov* or call FSIS' Congressional and Public Affairs Office at (202) 720-9113.

Public Meetings on Animal Raising Claims and Addressing Sampling and Testing Methodologies, Compliance Guidelines and N-60 Sampling

On October 14, 2008, FSIS and USDA's Agricultural Marketing Service held a public meeting on animal raising claims. This meeting initiated a public process to review USDA's policies on the use of animal raising claims in the labeling of meat and poultry products.

FSIS also held a public meeting on October 14-15 to focus on *E. coli* O157:H7 sampling and testing procedures. The purpose of the meeting was to discuss and solicit comments on issues associated with the uniformity and consistency of sampling and testing methods for *E. coli* O157:H7 by the Agency and industry. FSIS also presented draft compliance guidelines for *E. coli* O157:H7 sampling for beef trimmings as well as draft guidance on the use of labels bearing voluntary *E. coli* O157:H7 testing claims. Presentations on training for FSIS personnel on *E. coli* O157:H7 sampling and for industry N-60 sampling procedures were also provided at the meeting.

Transcripts from both of these meetings are available at *www.fsis.usda.gov/News_&_Events/Past_Events/index.asp.* If you need copies of the materials presented at the meetings, feel free to contact FSIS' Congressional and Public Affairs Office at (202) 720-9113.