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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 98-004N]

Ground Beef Processing Guidance Material

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of its revised guidance document intended to assist processors of ground beef, especially small processors, in developing procedures to minimize the risk of *Escherichia coli* O157:H7 (*E. coli* O157:H7) and other pathogens in ground beef products produced in their establishments. This is an updated version of the guide that FSIS made available to the public in March 1998 and presented in a public meeting on April 22, 1998.

ADDRESSES: Single copies of the guidance document are available from the FSIS Docket Clerk in Room 102, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250-3700 from 8:30 a.m. to 4:30 p.m., Monday through Friday. An electronic version of the revised guidance document is available on line through the FSIS web page located at <http://www.fsis.usda.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. William J. Hudnall, Assistant Deputy Administrator, Office of Policy, Program Development, and Evaluation, at (202) 205-0495.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 20, 1998 (63 FR 13618), FSIS announced that, as a result of recent product recalls involving *E. coli* O157:H7, the Agency had prepared guidance material to help beef grinding operators minimize the risk of, and potential effects associated with, *E. coli* O157:H7 and other microbial pathogens in raw ground beef.

FSIS also intended that this guidance help grinding operators, especially small and very small establishments prepare for the development and implementation of Hazard Analysis and Critical Control Point (HACCP) systems. The guidance included recommendations for development of purchase specifications to ensure receipt of safe and wholesome raw materials; storage, handling, and transport of raw products; the grinding process, including rework and risk-based product separation; packaging, cooling, and storage; shipping, handling, and distribution; recordkeeping, product coding systems, and recall plans; and food safety education.

Comments

FSIS received several comments on the guidance in response to the March 20, 1998 **Federal Register** Notice. Overall, the comments were in support of the recommendations in the guidance. Comments and suggestions were directed at microbial sampling, purchase requirements, rework, distribution, traceback and recordkeeping, and education.

1. Several comments were directed at the recommendation to test for *E. coli* O157:H7. One commenter stated that testing for *E. coli* O157:H7 provides an indication to grinders that HACCP systems do not provide the most effective method of minimizing the risk in commercial circumstances from microbiological hazards of gastrointestinal origin.

HACCP is designed to prevent, eliminate, or reduce to an acceptable level, the presence of hazards in food. However, implementation of HACCP will not eliminate all risks. *E. coli* O157:H7 has been linked to or found in ground beef that caused foodborne illness. Thus, the guidance recommends that grinding operators test for *E. coli* O157:H7 as one means of minimizing the risk of illness from the consumption of ground beef. If grinders find a positive sample, they can divert the product to further processing that will make it safe.

2. A commenter questioned the need to test for *E. coli* O157:H7 because testing only provides limited assurance that the pathogen is present, and a negative result will not guarantee that the pathogen is absent.

We agree that the pathogen is often present at low levels, and that the number of samples taken may not be adequate to find it.

However, regular testing at an appropriate frequency will enhance chances of detection if the pathogen is present.

The use of process interventions capable of reducing the number of *E. coli* O157:H7 is recommended. Incorporating these process interventions, and microbial testing at an appropriate frequency, as part of the establishment's HACCP system will provide an increased level of public health protection.

3. One commenter questioned why testing for *E. coli* O157:H7 was not instituted as part of the HACCP rule.

One objective of the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) rule was pathogen reduction. FSIS selected *Salmonella* as the target pathogen to be tested for in meat and poultry products to attain this objective. *Salmonella* is an appropriate target pathogen for measuring success in achieving this objective, because (1) it is prevalent in raw beef, pork, and poultry; (2) at the time of the PR-HACCP final rule, it was the most common bacterial cause of foodborne disease in humans; (3) enumeration procedures for this pathogen are reliable and affordable; and (4) intervention strategies aimed at reducing fecal contamination and other sources of *Salmonella* on raw product should be effective against other pathogens, including *E. coli* O157:H7.

Testing for *E. coli* O157:H7 has a much narrower purpose—to help ensure that ground beef in the market place is safe. FSIS started the Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef in 1994 and issued a directive on the testing program in 1998 (Directive # 10,010.1).

4. A commenter stated that any imposition by U.S. grinders of an *E. coli* O157:H7 testing regime on overseas suppliers of frozen, boneless boxed manufacturing meat would pose additional logistic difficulties for exporting country packers. According to the commenter, these difficulties arise partly because the ultimate fate of the product (i.e. for grinding or for manufacturing purposes involving validated lethality steps) is not necessarily known at the time of packing or shipping.

U.S. grinders may impose an *E. coli* O157:H7 testing regime on overseas suppliers of frozen, boneless boxed manufacturing meat through purchase specifications. Use of such specifications would be consistent with the establishment's obligation to control its source materials. On the other hand, some purchasers may only require documentation from the supplier that its

raw material was produced under a HACCP-based system, or that intervention methods were used, and that the raw material does not pose a risk.

5. One commenter suggested that FSIS consider *E. coli* O157:H7 found on any meat as an adulterant.

No changes are being made to the guidance document as a result of this comment. However, FSIS regularly assesses the public health implications of this pathogen for products other than ground beef and will take this comment into consideration in connection with this process. To date, FSIS has only stated that *E. coli* O157:H7 is an adulterant in ground beef. The Agency is publishing in this issue of the **Federal Register** its policy on this matter.

6. A commenter stated that guidelines do not have the force of law, are not binding, and are only recommendations.

The Agency agrees. The guidance for beef grinders is intended to illustrate how grinders can avail themselves of opportunities to minimize food safety hazards associated with their products. The guidance may be used in conjunction with the Agency's draft generic HACCP model for raw ground meat and poultry products. The HACCP system of process control is mandatory now for large plants and will become mandatory in small and very small plants in January 1999 and January 2000, respectively.

7. A commenter suggested that lots or batches be limited to raw materials from a single slaughterhouse.

Limiting lots or batches of raw materials to a single slaughterhouse represents one means of controlling the quality and safety of the raw materials. However, demand will dictate whether a grinding plant can secure all the raw materials that it needs from a single slaughterhouse. The guidance recommends control of source materials by establishing purchase requirements and demanding appropriate records from the suppliers. It is up to individual plants to decide whether they want to get their source materials from one or several slaughterhouses.

8. One commenter suggested that FSIS should require identification of the farm of origin, slaughterhouse, and subsequent processors on the consumer package.

The guidance recommends that grinding plants require suppliers to maintain records that facilitate traceback to the farm or animal source. Furthermore, the guidance recommends that grinding plants develop and institute codes on retail-ready packages of ground beef to facilitate traceback and trace-forward. However, at this time, FSIS is not proposing to adopt these recommendations as requirements. FSIS believes that the guidance is adequate to assist processors of ground beef to minimize the risk of *E. coli* O157:H7.

9. A commenter stated that there is a higher probability of handling mistakes,

such as temperature abuse, when there are numerous intermediate distributors compared to just one.

The Agency agrees with the point made in the comment; however, the current food production and distribution system is complex, often involving lengthy distances, multiple distribution points, and numerous handlers. For this reason, the guidance recommends that intermediate distributors, in addition to the ultimate retailer, be included in the recordkeeping to facilitate trace-forward in case there is a need to do so. The guidance also recommends the use of tamper-proof time-temperature indicators on boxes of finished products to disclose temperature abuse.

10. One commenter asked what FSIS can do, aside from education, to achieve the recommendation that grinders structure their operations to take into account the handling and preparation of meat by consumers after it leaves the store.

In addition to educating consumers by training and educational programs, FSIS requires that important consumer information be included on labels of meat and poultry products. Food labels inform consumers about whether the product is ready-to-eat or needs to be cooked, and about how to store the product. Non-ready-to-eat meat and poultry products are required to include safe handling instructions, which instruct consumers about handling, storing, and cooking the product. In addition, cooking instructions may be included on labels of non-ready-to-eat products.

11. A commenter stated that the guidance did not stress food handler education.

The Agency disagrees with this comment. The guidance recommends training and education of employees, *food handlers*, distributors, and consumers on the risks of foodborne illness associated with ground beef and suggests measures to prevent foodborne illness. In addition, the plant's Sanitation Standard Operating Procedures may include training and education of employees and food handlers. The Agency does agree, however, with the suggestion from the commenter that training food handlers in their native language will make the training more effective and meaningful. In response to this comment, FSIS revised the education section of the guidance by recommending that establishments provide training to food handlers and other employees in their native language, if necessary.

12. There was a suggestion from a commenter to spell out sanitation of the carrier in the subsection on transport of raw materials.

In the original guidance document, the subsection on transport of raw materials included examination of conditions of transport, such as temperature inside transport vehicles, and of meat itself, as well as duration of transport. In response to this

comment, FSIS expanded the subsection on transport of raw materials to add sanitation of the carrier and details on the different conditions of transport, such as presence of cracks, debris, foreign material or off-odors, condition of the insulation and of the door seals.

Revised Guidance Document

In addition to the changes noted above in response to the comments and suggestions, the Agency has incorporated details on rework and product recall plans that were derived from the guidance material provided by the National Meat Association and the American Meat Institute. As a result, the section on the grinding process has been expanded, especially the subsection on lotting, rework, unprocessed raw material and outside trimmings. The shipping, handling and distribution section has also been expanded to include more details on transport, secondary distributors, inventory control and in-house recall plans.

FSIS intends to update the guidance regularly and to make it available through the FSIS web page. Recommendations for improving this guidance material are welcome at any time.

Done in Washington, DC on December 21, 1998.

Thomas J. Billy,
Administrator.

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DEPARTMENT OF AGRICULTURE

Forest Service

Supplement to the Final Environmental Impact Statement for the Mt. Ashland Ski Area, Rogue River National Forest, Jackson County, Oregon

ACTION: Notice of intent to supplement a final environmental impact statement.

SUMMARY: The USDA, Forest Service will prepare a supplement to the final environmental impact statement (SEIS) for the Mt. Ashland Ski Area (MASA) on the Rogue River National Forest. The final EIS and Record of Decision (ROD) for the MASA were released in July 1991. This decision established a programmatic Master Plan for future ski area expansion. In March, 1998, the Mt. Ashland Association (MAA) submitted a proposal to the Forest Service (based, on the Master Plan) to implement a variety of ski area facility improvements within the MASA. The Association leases the operation from the City of Ashland, holder of a Forest Service Special Use Permit for the MASA. As identified in