
FSIS DIRECTIVE

7700.1

4/13/2005

Revision 1

IRRADIATION OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides inspection program personnel with information and instructions regarding the irradiation of meat and poultry products in official establishments.

II. CANCELLATION

This directive cancels FSIS Directive 7700.1 dated 2/22/00.

III. REASON FOR REISSUANCE

This directive is being reissued in its entirety to provide clarification regarding the off-site irradiation of product as it relates to the Hazard Analysis and Critical Control Point (HACCP) requirements.

IV. REFERENCES

9 CFR 317, 320, 381, 417 and 424

21 CFR 179.26

FSIS Directives 5000.1, Rev. 1, 5400.5, 8080.1, Rev. 4, and 8410.1, Rev. 2

V. BACKGROUND

On December 23, 1999, the Food Safety and Inspection Service (FSIS) published the final rule, [Irradiation of Meat Food Products](#), 64 FR 72150. This rule permits the use of ionizing radiation for treating refrigerated or frozen/uncooked meat, meat by-products, and certain other meat food products to reduce levels of foodborne pathogens and to extend the shelf-life of these products. The final rule also revised the regulations governing the irradiation of poultry products so that they are more consistent with the regulations for the irradiation of meat food products.

Irradiation is a process of exposing food to high levels of radiant energy. Irradiation penetrates deeply into food, killing micro-organisms without raising the temperature of the food significantly. Scientific data indicate that ionizing radiation can significantly reduce levels of many of the pathogenic micro-organisms of concern in meat food products, including *Salmonella*; *Escherichia coli* O157:H7; *Staphylococcus aureus*; *Listeria monocytogenes*; *Campylobacter Jejuni*; and the protozoan parasite, *Toxoplasma gondi*. Irradiation is just of the many treatments that can be used with a HACCP system to reduce the level of pathogens in meat and poultry.

If official establishments choose to irradiate meat food and poultry products, they must do so in accordance with the HACCP system requirements in part 417 of the regulations and the regulations specific to irradiation in section 424. Any facility that irradiates meat food products or poultry products is designated as an official establishment and, therefore, is not permitted to operate under another establishment's HACCP plan. Each official establishment must develop and implement its own HACCP plan.

Meat and poultry establishments using irradiation also must meet other Federal regulatory safety requirements. The Nuclear Regulatory Commission (NRC), or a State government acting under the NRC's authority, has regulations applicable to the possession and use of radioactive materials, as well as other safety requirements. The Food and Drug Administration has use requirements, and States enforce the Occupational Safety and Health Administration (OSHA) regulations for possession of radioactive materials.

VI. GENERAL REQUIREMENTS

A. What are the regulatory requirements for irradiation use?

Section 424.22(c)(1) states;

"1. General requirements. Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section."

B. What is an establishment expected to have in its HACCP plan?

In meeting the requirements of 9 CFR 417.2, all establishments irradiating product will address the use of irradiation in their hazard analysis. If an establishment determines that irradiation will be used to control a food safety hazard that is reasonably likely to occur (i.e., they are using it as an antimicrobial to eliminate or reduce the level of pathogenic organisms), the establishment will need to modify its HACCP plan. These establishments would likely designate irradiation as a critical control point (CCP) and possibly have other CCPs that would address such practices as holding the product at a certain temperature. Critical limits could be the absorbed dosage, as measured by dosimetry, temperature of the product, or other processing parameters that reflect the efficacy of irradiation.

Some establishments may send product off-site for the irradiation treatment and elect to have the irradiation facility ship the product into commerce. If an establishment sends its product off-site, inspection program personnel are to verify that the establishment addresses, in its HACCP system (9 CFR part 417), the control of the product (e.g., company seals) while it is in transit to the irradiation facility. Inspection program personnel also are to verify that the establishment's HACCP system incorporates procedures for the receipt of notification from the irradiation facility that the product received the appropriate irradiation treatment. The establishment cannot complete its pre-shipment review (9 CFR 417.5(c)) until it documents that the product received the appropriate irradiation treatment. **Note:** Inspection program personnel should not collect any samples from product to be irradiated (e.g., sampling for Salmonella performance standards) if the establishment's HACCP plan states that the product will be irradiated offsite. Inspection program personnel should only collect samples after the irradiation treatment.

If an establishment claims that irradiation is being used solely for the purpose of extending shelf life, it is conceivable, although highly unlikely, that the establishment could disregard any amount of pathogen reduction achieved by the irradiation and, therefore, not list irradiation as a CCP in its HACCP plan. These establishments are to have documentation, such as validated research studies or published journal articles, to support their hazard analysis as to why irradiation is not addressed in their HACCP system in order to meet the requirements in 424.22(c)(1). These establishments still must meet the regulatory requirements for dosimetry, documentation, and labeling.

C. What are inspection program personnel responsibilities?

For irradiation incorporated into HACCP (under the appropriate 03 ISP code), review the establishment's hazard analysis and HACCP plan to verify that documentation, as required in section 417.5(a) of the HACCP regulations, is present. Inspection program personnel may directly observe procedures related to irradiation or recordkeeping on an ongoing basis.

For irradiation not incorporated into HACCP, (under ISP code 04B04), inspection program personnel may directly observe procedures related to irradiation or recordkeeping on an ongoing basis.

VII. DOSIMETRY

A. What are the regulatory requirements for dosimetry?

Section 424.22(c)(2) states:

“(2) Dosimetry. Official establishments that irradiate meat food and poultry products must have the following procedures in place:

(i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (e.g., time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(iv) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(vi) Procedures for verifying routine dosimetry, i.e., assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit in each production lot or use statistically

based validation and dose mapping to determine the number and placement of dosimeters in each production lot.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.”

B. What are inspection program personnel responsibilities?

For irradiation incorporated into HACCP (under the appropriate 03 ISP code) or for irradiation not incorporated into HACCP (under ISP code 04B04),

1. Observe laboratory operation procedures used to determine the dose value from the dosimeter.

2. Ask about the calibration criteria used for verifying the accuracy and consistency of any means of measurement.

3. Review documentation that addresses the end point measurement of a dosimeter.

4. Observe dose mapping procedures.

5. Check how the establishment accounts for the total absorbed dose. If product received higher than the maximum dosage allowed, the product is considered to be adulterated. (Note: The product cannot be brought into compliance. The product must be destroyed for human food purposes.) Verify that the establishment has destroyed product that has received higher than the maximum dosage allowed.

6. Ask how the establishment determined the number and placement of dosimeters.

7. Observe how the establishment determines the relationship of the absorbed dose, as measured by the dosimeter, to time exposure of the product unit to the radiation source.

8. Check that the establishment makes the necessary adjustments to dosimetry procedures if the radiation source is altered, modified, replenished, or adjusted.

VIII. DOCUMENTATION

A. What are the regulatory requirements for documentation?

Section 424.22(c)(3) states:

“(3) Documentation. Official establishments that irradiate meat food or poultry products must have the following documentation on premises, available to FSIS:

(i) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate

State government acting under authority granted by the NRC.

(ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).”

B. What are inspection program personnel responsibilities?

Under the plant profile:

The first time you enter an establishment that is using irradiation, review all required certificates and documentation to verify that the establishment and all operators have met regulatory requirements to operate.

After the initial review of records, periodically check renewable records, such as licenses, to verify that they are current.

IX. LABELING

A. What are the regulatory requirements for labeling?

Section 424.22(c)(4) states:

“(4) Labeling. (i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph (c)(4)(i). Unless the word "Irradiated" is part of the product name, labels also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under Section 317.2(c)(2). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4 of this chapter or subparts M and N of part 381.



(ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word "Irradiated" is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used.

(iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation."

Note: The processing documentation could be the supporting documentation included in the establishment's HACCP system, e.g., validation documentation.

B. What are inspection program personnel responsibilities?

Using ISP code 04B04, review records or observe labels to verify that the establishment has met the regulatory requirements and that the labels comply with the regulations. Review records to verify that the Labeling and Consumer Protection Staff approved the label sketch and that the establishment maintains records in accordance with 9 CFR 317.4(a). The following are examples of labeling scenarios:

MEAT FOOD AND POULTRY PRODUCTS IRRADIATED IN THEIR ENTIRETY

Check the product label to see if the required logo is present. If the product name does not include "irradiated," check to see if a statement such as "treated with radiation" or "treated by irradiation" is present and is placed in conjunction with the logo.

MEAT FOOD AND POULTRY PRODUCTS IRRADIATED IN THEIR ENTIRETY BUT NOT SOLD IN CONSUMER PACKAGES

Verify that the logo is displayed to the purchaser by way of the label on the bulk container or another appropriate device showing that the product has been treated with radiation. If the product name does not include "irradiated," check to see if statements such as "treated with radiation" or "treated by irradiation" are present.

MULTI-INGREDIENT MEAT FOOD AND POULTRY PRODUCTS CONTAINING IRRADIATED PRODUCT AS AN INGREDIENT

Verify that the irradiated product is listed as being irradiated, (e.g., irradiated beef), in the ingredient statement. **Note:** The logo or any other type of statement about irradiation does not need to be on the label in the case of products formulated with previously irradiated ingredients.

OPTIONAL LABELING STATEMENTS REGARDING REDUCTION IN MICROBIAL PATHOGENS

Review documentation to verify that the Labeling and Consumer Protection Staff has approved the sketch label bearing the claim. Verify that the claim being made has been validated in the product's HACCP plan.

C. Can an establishment ship product that has already been packaged and labeled to an irradiation facility for treatment?

Yes. FSIS expects both the shipping and receiving establishment to have controls in place to ensure that all product labeled as irradiated receives the irradiation treatment. Inspection program personnel should verify the establishment's controls. See paragraph VI. B.

D. What are the requirements for an establishment that irradiates raw, nonintact beef product known to contain *E. coli* O157:H7?

Establishments that irradiate product must address the elimination of *E. coli* O157:H7 in raw, nonintact beef products in their HACCP plan.

X. INSPECTION PROGRAM PERSONNEL SAFETY

A. Are inspection program personnel required to wear dosimetry badges?

Yes. Inspection program personnel are required to wear individual dosimetry badges when working in an irradiation facility to record any occupational dosage received.

B. Where do inspection program personnel receive the personal dosimetry badge?

The USDA Radiation Safety Staff (RSS) supplies thermoluminescent dosimetry badges to FSIS through a private contractor. The FSIS field safety and health specialists will initiate badge service when requested by their assigned District Office (DO). At the end of each monitoring period, all badges should be returned to the DO so they can be given to the RSS contractor.

C. Who maintains inspection program personnel exposure records?

RSS keeps radiation exposure records for inspection program personnel.

XI. ENFORCEMENT ACTIONS

Establishment addressing irradiation in its HACCP plan

If an establishment has not complied with the irradiation provisions in 9 CFR 424.22, inspection program personnel will follow the instructions found in FSIS Directive 5000.1, Revision 1. Use the appropriate 03 ISP code when documenting a noncompliance on the FSIS Form 5400-5, Noncompliance Record.

Establishment not addressing irradiation in its HACCP plan

If an establishment has not complied with the irradiation provisions in 9 CFR 424.22, inspection program personnel will follow the instructions found in FSIS Directive 5400.5. Use ISP code 04B04 when documenting a noncompliance on the FSIS Form 5400-5, Noncompliance Record.

All establishments

If an establishment has not complied with the labeling provisions in 9 CFR 317.4, or 381.132, document the noncompliance on an NR under ISP activity code 04B04.

If product that is labeled as irradiated enters commerce without undergoing the irradiation treatment, FSIS will request a voluntary recall, as set out in FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products. If such product is not recalled, Program Investigators and Enforcement Investigations and Analysis Officers are to detain the product as set out in FSIS Directive 8410.1, Revision 2, Detention and Seizure.

XII. GUIDANCE

For technical guidance, contact the Technical Service Center. For guidance related to regulatory activities, refer questions through supervisory channels.

/s/ Philip S. Derfler

Assistant Administrator
Office of Policy, Program, and Employee Development