UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5000.15 | 8/2/21

VERIFICATION ACTIVITIES FOR HIGH PRESSURE PROCESSING, IRRADIATION AND MICROWAVE TEMPERING

I. PURPOSE

This directive provides instructions for inspection program personnel (IPP) to verify that official establishments meet regulatory requirements when they treat products with high pressure processing (HPP) or irradiation and send product to another official establishment for treatment with HPP or irradiation. This directive also provides IPP with verification instructions on microwave tempering.

KEY POINTS:

- *Combines and cancels FSIS Directive 7700.1, Irradiation of Meat and Poultry Products, and FSIS Directive 6120.2, High Pressure Processing (HPP) and Inspection Program Personnel (IPP) Verification Responsibilities because the verification procedures are essentially the same for irradiation and HPP processes*
- *Clarifies instruction for verifying regulatory compliance based on how HPP or irradiation is included in the Hazard Analysis and Critical Control Point (HACCP) system*
- *Provides instruction for verifying certain regulatory requirements specific to establishments that use irradiation*
- *Provides instructions for verifying microwave tempering*

II. CANCELLATION

FSIS Directive 7700.1, Revision 1, *Irradiation of Meat and Poultry Products*, 4/13/05

FSIS Directive 6120.2, *High Pressure Processing (HPP) and Inspection Program Personnel (IPP) Verification Responsibilities*, 5/23/12

III. BACKGROUND

A. HPP is an antimicrobial treatment that does not require prior approval from FSIS for use on meat, poultry, and processed egg products. HPP subjects food to elevated pressures to inactivate microorganisms for food safety or quality purposes. HPP can be performed on both raw and ready-to-eat (RTE) products.

B. Irradiation is a treatment that exposes food to ionizing radiation at levels necessary to achieve a desired microbial reduction as well as penetrates deeply into food without significantly raising its temperature. The FDA regulates food irradiation as a food additive under the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act and 21 CFR, part 179. However, these regulations do not exempt foods regulated by other authorities. FSIS permits the use of irradiation for treating refrigerated or

frozen uncooked meat, meat by-products, and certain other meat and poultry products to reduce levels of pathogens and to extend the shelf life of these products (9 CFR 424.22(c)). Irradiation is not allowed for RTE products. There are additional regulatory requirements for the use of irradiation included in 9 CFR 424.22(c), such as dosimetry and labeling, which are not applicable to HPP.

C. In addition to FSIS regulatory requirements, meat and poultry establishments using irradiation must meet other regulatory 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. State governments often regulate machine sources of radiation.

D. Some producing establishments send packaged products to other official establishments where the products are treated with HPP or irradiation as an intervention to control pathogens or for quality purposes alone, such as to extend the shelf life.

E. HPP, irradiation, and microwave tempering are considered preparation or processing of meat or poultry products as defined in 9 CFR 301.2 or 9 CFR 381.1, and, thus, are subject to the inspection requirements of the Federal Meat Inspection Act or Poultry Products Inspection Act. Therefore, FSIS inspection is required at all facilities that perform HPP, irradiation, and microwave tempering on amenable meat or poultry products, regardless of whether the process is being used for food safety or food quality purposes.

IV. VERIFICATION WHEN AN ESTABLISHMENT USES MICROWAVE TEMPERING IN THEIR PROCESS

A. IPP are to be aware that when done as intended, microwave tempering is a way to take hard-frozen product and make it less frozen (e.g., take it from 0 degrees up to 30-35 degrees) before it's moved into processing. Because microwaving can result in uneven heating, the process could raise parts of the tempered product into microbial growth temperature range, potentially allowing growth of any pathogens present. Therefore, when an official establishment uses microwave tempering, IPP are to verify that the establishment includes it in their flow chart as a step in their process and in the hazard analysis.

B. As per 9 CFR 417.2(a), each establishment must have a flow chart describing the steps of each process and the product flow and must determine if there are any food safety hazards associated with the process.

V. VERIFICATION WHEN AN ESTABLISHMENT USES HPP OR IRRADIATION AS A CRITICAL CONTROL POINT (CCP)

A. If an establishment is using HPP or irradiation to control a hazard that is reasonably likely to occur, then IPP are to verify that the HPP or irradiation process is included in the HACCP plan as a CCP. Examples include situations when:

1. An establishment uses HPP as a CCP to control biological hazards, such as *Salmonella* or *Campylobacter,* in comminuted poultry product;

2. An establishment uses HPP as a post-lethality treatment to control *Listeria monocytogenes* (*Lm*) in an RTE product; or

3. An establishment uses irradiation to reduce biological hazards in comminuted beef product.

NOTE: Irradiation is not allowed for RTE products.

B. When HPP or irradiation is included as a CCP in that establishment's HACCP plan, IPP are to verify that the establishment meets the regulatory requirements in 9 CFR 417. IPP are to verify that its hazard

analysis supports the use of the HPP or irradiation treatment to control pathogens in product by performing the HACCP Verification task and the Hazard Analysis Verification (HAV) task, as assigned in PHIS.

C. If the producing establishment sends product to another establishment for HPP or irradiation treatment as a CCP, IPP are to verify that the producing establishment has processes in place to meet the monitoring, verification, and corrective action recordkeeping requirements for a CCP found in 9 CFR 417.5(a)(3) and 417.5(b).

NOTE: A producing establishment is an FSIS establishment that produces FSIS products. This term is used in this directive to distinguish establishments which produce FSIS products from HPP establishments which only apply HPP to these products produced by other FSIS establishments.

D. When reviewing the producing establishment's hazard analysis and HACCP plan, IPP are to follow the instructions in FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, and FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task*, when a HAV task has been assigned.

1. IPP are to verify that the establishment has included HPP or irradiation in the flow chart and hazard analysis (9 CFR 417.2(a)).

NOTE: In establishments that apply HPP or irradiation to product from another establishment, the flow chart, hazard analysis, and HACCP plan are to reflect the steps in the overall process of the establishment applying HPP or irradiation, not those of the producing establishment's process.

2. IPP are to verify that when an establishment includes HPP or irradiation as a CCP in their HACCP plan, the establishment maintains supporting documentation to demonstrate that the HPP or irradiation process can adequately address the hazards identified in their hazard analysis (9 CFR 417.2(a)(1) and 9 CFR 417.2(a)(2)). The supporting documentation:

    a. Can include journal articles, challenge studies, in-plant data, or other types of scientific support;

    b. Must show the log reduction achieved for the specific pathogens being addressed by the CCP;

    c. Must address the critical operational parameters (e.g., pressure, irradiation dosage, time, temperature) necessary for the process to achieve the stated log reduction; and

    d. Must reflect the composition of the product and the establishment's actual process.

3. Because of the variety of critical operational parameters and products under which HPP or irradiation can be applied, IPP are to verify that establishments evaluate factors such as pH, water activity, composition, packaging, or preservatives to determine critical operational parameters for each product type. IPP are to verify that there is a defined process for every type of product treated. Various intrinsic properties can affect the critical operational parameters of the HPP and irradiation processes. For example:

    a. An HPP process for RTE chicken breast may be shorter when the same product is breaded;

    b. HPP is generally more effective in reducing microbial pathogens when the water activity of a product is increased;

c. As pH is lowered, most microorganisms become more susceptible to HPP treatment; and

d. The effectiveness of irradiation in reducing microbial pathogens can be affected by the temperature of the irradiated food.

4. IPP are to verify that the HPP or irradiation process follows critical operational parameters identified in the supporting documentation for the specific pathogen and product types being treated.

E. Critical operational parameters for an HPP process may include:

1. Process pressure;

2. Process hold time at pressure;

3. Time to achieve pressure;

4. Initial product temperature;

5. Treatment temperature; or

6. Decompression time.

F. Critical operating parameters for an irradiation process may include:

1. Total irradiation time;

2. Dose (the amount of ionizing energy absorbed per unit mass);

3. Beam energy; or

4. Conveyer speed.

G. IPP are to verify that, if the product is shipped offsite for the application of HPP or irradiation to control a hazard or as a CCP, the producing establishment has procedures in place for maintaining control of product, such as the use of company seals, until pre-shipment review is completed (9 CFR 417.5(c)).

H. When HPP or irradiation is applied as a CCP as documented in the HACCP system and hazard analysis, IPP are to verify that the original producing establishment does not complete pre-shipment review until it receives documentation back from the establishment that performed the HPP or irradiation treatment and has verified that the critical limits and critical operational parameters were met (9 CFR 417.5(c)).

I. When a product lot is sampled for one or more adulterants (e.g., *Lm or shiga-toxin producing Eschericia coli (STEC))* by either FSIS or an establishment, IPP are to verify that the sampled lot is held and that the pre-shipment review is not completed until negative test results for all the adulterants have been received.

VI. VERIFICATION WHEN AN ESTABLISHMENT USES HPP OR IRRADIATION AS A PREREQUISITE PROGRAM

A. An establishment can include HPP or irradiation in the HACCP system as part of a prerequisite program that it uses to support a decision in the hazard analysis that a potential hazard is not reasonably likely to occur (NRLTO).

NOTE: Irradiation is not allowed for RTE products.

B. When an official establishment uses HPP or irradiation in its hazard analysis to support that a hazard is NRLTO, IPP are to perform the HACCP verification tasks and the HAV tasks, as assigned in PHIS and as described in FSIS Directive 5000.1 and FSIS Directive 5000.6, to verify compliance with 9 CFR 417.5(a)(1) and 417.2(a), including verifying that the establishment:

1. Includes HPP or irradiation in its flow chart and hazard analysis (9 CFR 417.2(a));

2. Maintains supporting documentation to demonstrate that decisions made in the hazard analysis are supportable (9 CFR 417.5(a)(1)); and

NOTE: The regulations in 9 CFR 417 do not include specific requirements (e.g., monitoring, recordkeeping, or corrective actions) for prerequisite programs. However, 9 CFR 430.4(c)(6) states that if the measures to control Lm are included in a prerequisite program, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5. In any case, if the establishment does not maintain documentation that demonstrates that the prerequisite program has been implemented effectively and serves its intended purpose, the prerequisite program may not support a decision that a food safety hazard is NRLTO to comply with the requirements of 9 CFR 417.5(a)(1).

3. Implements the prerequisite program in a manner that supports the relevant hazard analysis decisions.

C. When a product lot is sampled for one or more adulterants (e.g., *Lm or STEC)* by either FSIS or an establishment, IPP are to verify that the sampled lot is held and that the pre-shipment review is not completed until negative test results for all adulterants have been received.

VII. VERIFICATION WHEN AN ESTABLISHMENT USES HPP OR IRRADIATION STRICTLY FOR QUALITY OR SHELF LIFE

A. When an official producing establishment uses HPP or irradiation to achieve food quality characteristics or to extend product shelf life and not as support for decisions made in their HACCP system, IPP are to verify that the producing establishment includes HPP or irradiation in their flow chart as a step in their process.

1. As per 9 CFR 417.2(a), each establishment must have a flow chart describing the steps of each process and product flow and must determine if there are any food safety hazards associated with the process. Therefore, even if food quality characteristics are provided as the sole purpose of the HPP or irradiation treatment, IPP are still to verify that the establishment includes the step in their flow chart; and

2. If the treatment is used for only quality purposes and not as a pathogen intervention, then FSIS verification sampling can be performed before application of the quality treatment.

VIII. VERIFICATION WHEN AN ESTABLISHMENT USES HPP OR IRRADIATION TO RE-PROCESS ADULTERATED PRODUCT

A. If an establishment applies HPP or irradiation to product to eliminate an adulterant, IPP are to verify that the establishment has supporting documentation demonstrating that the treatment achieves a

sufficient log reduction to eliminate the adulterant of concern. The following are the minimum levels of lethality to be achieved in the product to eliminate adulterants:

1. Using HPP for reprocessing *Lm*-adulterated RTE product, a 5-log reduction of *Lm*;

2. Using HPP for reprocessing *Salmonella*-adulterated RTE product, a 5-log reduction of *Salmonella* for meat products and a 7-log reduction of *Salmonella* in poultry products; and

3. Using irradiation for reprocessing STEC adulterated raw or RTE product, a 5-log reduction of STEC.

NOTE: Irradiation is not allowed for RTE products.

IX. REQUIREMENTS SPECIFIC TO IRRADIATION ESTABLISHMENTS

A. The regulations at 9 CFR 424.22(c)(2) provide the regulatory requirements regarding dosimetry (i.e., the measurement of the amount of radiation absorbed by a substance or living organism) in an establishment that irradiates meat and poultry products. IPP are to verify that the establishment:

1. Maintains the laboratory operation procedures it uses to determine the dose value from the dosimeter (9 CFR 424.22(c)(2)(i));

2. Maintains calibration criteria for verifying the accuracy and consistency of its measurements, including time clocks and weight scales (9 CFR 424.22(c)(2)(ii));

3. Maintains traceability and accuracy of dosimeters and documentation that dosimeters are calibrated every 12 months (9 CFR 424.22(c)(2)(iii)). To confirm traceability, the establishment must relate, through documentation, the end point measurement of a dosimeter to recognized standards;

4. Maintains procedures to ensure that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and that such regions are consistent from one product unit to another of like product (9 CFR 424.22(c)(2)(iv));

    a. The establishment's documentation must support that the minimum dose is sufficient to accomplish the specified purpose of the irradiation treatment; and

    b. The establishment's documentation must support that the maximum dose is within the limits specified in 21 CFR 179.26 for meat or poultry products.

5. Maintains procedures that account for the total absorbed dose received by a product unit (9 CFR 424.22(c)(2)(v));

6. Destroys any product that receives a dose higher than the maximum dosage allowed. If any part of a product receives a higher than the maximum dosage allowed, the product is adulterated and cannot be brought into compliance;

7. Maintains procedures for determining the number and placement of dosimeters to ensure each production lot receives the total absorbed dose. The establishment must either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region that is verified to represent such) on at least the first, middle, and last product unit in each production lot or use a statistically-based validation and dose mapping procedure to determine the number and placement of dosimeters in each production lot (9 CFR 424.22(c)(2)(vi));

8. Determines the relationship of the absorbed dose (as measured by the dosimeter) and the time exposure of the product unit to the radiation source (9 CFR 424.22(c)(2)(vii)); and

9. Makes the necessary adjustments to dosimetry procedures if the radiation source is altered, modified, replenished or adjusted (9 CFR 424.22(c)(2)(viii)).

B. IPP are required to wear individual dosimetry badges to record any occupational radiation dose received when working in an irradiation facility.

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

2. RSS maintains radiation exposure records for IPP.

C. IPP are to perform a General Labeling task to review records or observe labels to verify that the establishment has met general labeling requirements including those found in 9 CFR 424.22(c)(4). IPP are to:

1. Verify that the required radura logo is present on the product label for products irradiated in their entirety. If the product name does not include "irradiated," IPP are to verify that a statement such as "treated with radiation" or "treated by irradiation" is present and is placed in conjunction with the radura logo (9 CFR 424.22(c)(4)(i));

2. Verify products irradiated in their entirety but not sold in consumer packages have the logo 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," IPP are to verify that a statement such as "treated with radiation" or "treated by irradiation" is present (9 CFR 424.22(c)(4)(ii)); and

3. Verify that for multi-ingredient products containing irradiated meat or poultry product as an ingredient, the irradiated meat or poultry product is listed as being irradiated (e.g., irradiated beef) in the ingredient statement (9 CFR 424.22(c)(4)(iii).

NOTE: If food treated by irradiation is used in another product as an ingredient, it is not required to be labeled as “irradiated” except irradiated meat and poultry product ingredients which must be listed as irradiated in the ingredients listing. For example, previously irradiated beef used as an ingredient must be included in the list of ingredients as “irradiated beef”, but spices or other Food and Drug Administration ingredients that have been irradiated do not need to be listed as irradiated. However, when the final, multi-ingredient product has not been irradiated in its entirety, the radura logo or any additional type of statement about irradiation is not required.

4. Review the supporting documentation for labels bearing claims regarding a reduction of pathogens to verify that the Office of Policy and Program Development's (OPPD) Labeling and Program Delivery Staff (LPDS) has approved the sketch label bearing the claim. IPP are to verify that the claim being made has been validated in the product's HACCP plan. IPP are to verify that statements that attest to a specific reduction of pathogens are substantiated by processing documentation (9 CFR 424.22(c)(4)(iv)); and

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

5. Verify, when a producing establishment sends product that has been already packaged and labeled to another establishment for irradiation treatment, that both the sending (producing) and receiving establishments have controls in place to ensure all product labeled as irradiated receives the irradiation treatment.

D. IPP are to verify that establishments that irradiate meat or poultry products meet the documentation regulatory requirements in 9 CFR 424.22(c)(3). IPP are to:

1. Review, when IPP enter the establishment for the first time, all required certificates and documentation to verify the establishment and all operators have met regulatory requirements to operate;

2. Periodically check renewable records, such as licenses, to verify they are current; and

3. Verify the establishment maintains the following:

    a. Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered with the NRC or the appropriate State government acting under authority granted by the NRC;

    b. Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable;

    c. Documentation that a worker safety program addressing Occupational Safety and Health Administation (OSHA) regulations (29 CFR chapter XVII) is in place;

    d. Citations or other documents, if applicable, that relate to incidences in which the establishment was found not in compliance with Federal or State agency requirements for irradiation facilities;

    e. Certification by the operator that the irradiation facility personnel are only to operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities;

    f. 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; and

    g. Guarantees from the suppliers that all food contact packaging materials that are subject to irradiation comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the specific requirements found in 21 CFR 179.

X. DOCUMENTATION AND ENFORCEMENT

A. If an establishment fails to include the HPP, irradiation, or microwave tempering process step in its flow chart or fails to conduct a hazard analysis to determine if there are any food safety hazards at the HPP, irradiation, or microwave tempering process step, IPP are to document noncompliance with 9 CFR 417.2(a)(2), and 417.2(a)(1), respectively, following the instructions in FSIS Directive 5000.1.

B. If the establishment fails to provide supporting documentation for decisions in the hazard analysis, IPP are to document noncompliance under the HACCP Verification task or HAV task with 9 CFR 417.5(a)(1), following the instruction in FSIS Directive 5000.1.

C. If IPP determine that product did not receive the HPP or irradiation treatment as specified in the establishment's HACCP system, IPP are to verify the establishment is in control of the product and that it has not entered commerce. If the product has entered commerce, IPP are to contact their supervisor or the DO to determine if further action is warranted.

D. If IPP determine product that is labeled as irradiated enters commerce without undergoing irradiation treatment, IPP are to contact their supervisor to determine further actions to take.

E. If an establishment has irradiated product not yet put into commerce that does not comply with the labeling provisions, IPP are to document the noncompliance with the appropriate regulation in a noncompliance record under the General Labeling task and tag the product. If clarification is needed about whether further action is warranted, a question should be submitted to the FSIS LPDS through askFSIS.

XI. QUESTIONS

Refer questions regarding this directive to your supervisor or if needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select HACCP Deviation and HACCP validation for the Inquiry Type.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development