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

FSIS DIRECTIVE	6120.1	5/23/12

HIGH PRESSURE PROCESSING (HPP) AND INSPECTION PROGRAM PERSONNEL (IPP) VERIFICATION RESPONSIBILITIES

I. PURPOSE

High Pressure Processing (HPP) is an antimicrobial treatment for use on meat, poultry, and processed egg products without prior-approval from FSIS. HPP is capable of either reducing or eliminating biological food safety hazards in these foods, depending upon the intended use of the treatment by the establishment. This directive provides inspection program personnel (IPP) with instructions for verifying an establishment's intended use of the treatment. In addition, this directive instructs IPP to perform HACCP Verification tasks in official establishments that apply the HPP antimicrobial treatment as a process step.

NOTE: PHIS sample collection and submission instructions will be provided in a separate issuance.

II. [RESERVED]

III. [RESERVED]

IV. BACKGROUND

When this process is used by the establishment as an antimicrobial treatment, IPP are to verify that it is included in the establishment's flow chart in accordance with 9 CFR 417.2(a)(2).

V. HPP PROCESS

A. HPP subjects food to elevated pressures, with or without the addition of heat, to inactivate microorganisms and extend microbiological shelf life. Product processed with HPP is placed in a sealed flexible container. The flexible container is placed in a basket or barrel and moved to a high-pressure chamber filled with a pressure-transmitting fluid, usually water that does not contact product. The chamber is equipped with pumping and decompression systems. The action of the high pressure causes the microorganism cell walls to rupture resulting in injury or death. Depending upon length of time the product is

subjected to pressure, some or all of the microorganisms might be affected. In addition, changes in the product could occur such as distortion of the shape of the product, as well as reduction in its capacity to retain moisture (purge) because of the rupture of the cell walls.

B. Anticipated uses of HPP within food safety systems include:

1. Reducing *Lm* post-lethality in post-lethality exposed RTE meat and poultry products to qualify for Alternative 1 or Alternative 2, Choice 1 status in accordance with 9 CFR 430.4(b); and

2. Addressing the control of pathogens in the food safety system, such as *E. coli* O157:H7 in beef manufacturing trimmings.

VI. IPP VERIFICATION OF ESTABLISHMENT ACTIVITIES

A. When an official establishment uses HPP as an antimicrobial treatment, IPP are to verify that the hazard analysis supports the use of the HPP treatment in controlling pathogens in the product. IPP are to perform a HACCP Verification task to verify compliance with 9 CFR 417.2(a)(1) and 417.2(a)(2). Does the establishment:

1. Include the HPP process in the flow chart and the intended use

B. When an official establishment uses HPP as support for decisions in the hazard analysis, IPP are to perform a HACCP Verification task to verify compliance with 9 CFR 417.5(a)(1) and 417.4(a)(1). Does the establishment:

1. Maintain supporting documentation to demonstrate that the HPP process can adequately address the identified hazards, depending on the purpose of the treatment. The documentation may consist of journal articles from published literature, challenge studies, in-plant data, or other types of scientific support.

2. Provide scientific supporting documentation to show the log reduction achieved for the specific pathogen identified in the hazard analysis and the critical operational parameters (e.g., pressure, time, temperature) necessary for the process to achieve the stated log reduction. The composition of the products and the critical operational parameters used in the scientific supporting documentation should reflect the establishment's actual process. The critical operational parameters will become a part of the critical limit within the HACCP plan, incorporated into the Sanitation SOP, or other prerequisite program.

3. Consider certain scientific criteria when validating the effectiveness of its HPP process in eliminating or reducing a specific biological food safety hazard to an acceptable level. Critical operational parameters the establishment may consider for the process include:

a. Process pressure;

b. Process hold time at pressure;

c. Initial temperature;

d. Time to achieve pressure;
(1) Long come-up times will add considerably to the total process time and influence the product (quality) characteristics uniformly, but these periods will also affect microbial inactivation rates; therefore, consistency and awareness of these times are important in the development of HPP conditions.

e. Decompression time;

f. Treatment temperature; and

g. The absence or presence of added CO_2

4. Define a process for every type of food treated. Given the variety and combinations of critical operational parameters, establishments may evaluate factors such as pH, water activity, composition, and preservatives to determine if these are critical factors for a specific food.

   a. For example, an establishment may shorten a HPP process for RTE chicken breast by a minute if the same product is breaded.
   b. HPP's inactivation rate is the most effective when the water activity is increased.
   c. pH has a marked effect on inactivation rates of *E.coli O*157:H7. As pH is lowered, most microorganisms become more susceptible to HPP inactivation.

5. Consider the pressure resistance of the pathogen. In general, Gram-positive bacteria (*Lm*) are more pressure resistant than Gram-negative bacteria. Additionally, a wide range of pressure sensitivity exists among the pathogenic Gram-negative bacteria. Some strains of *Salmonella* and *E. coli* O157:H7 have demonstrated relatively high levels of pressure resistance.

C. When an official establishment uses HPP to achieve food quality characteristics and does not include HPP in its food safety system, IPP are to verify that the establishment:

1. Maintains decision-making documents to support the exclusion of the antimicrobial treatment from its hazard analysis and food safety system.

NOTE: Extension of product shelf life or tenderization (quality characteristics) are outcomes that economically benefit the manufacturer. Even if these quality

characteristics are provided as the sole purpose of the HPP treatment, IPP are still to verify that the establishment includes the antimicrobial treatment in the food safety system through supporting documentation.

D. When an establishment sends product to another official establishment that performs the HPP treatment and ships the product into commerce, IPP are to verify that originating establishment's flow chart, hazard analysis, and HACCP plan includes the HPP process step and all supporting documentation.

NOTE: In this situation, the originating establishment cannot complete preshipment review until it receives documentation back from the establishment that performs the HPP treatment. At the completion of the process, the originating establishment maintains control of the product and verifies the critical limits and critical operational parameters are met as specified in their food safety system.

E. If an establishment follows reprocessing criteria, in order to eliminate an adulterant, it is important that good manufacturing practices (GMPs) are followed to minimize further cross-contamination and additional growth of pathogens (e.g., temperature abuse). IPP are to verify the establishment has supporting documentation to achieve the specified log reductions. Unless the establishment has data to justify other reductions, the following are minimum expected lethalities:

1. **For reprocessing *Lm*-adulterated RTE product**, an HPP process that achieves a 5-log *Lm* reduction should be sufficient for product produced under good manufacturing practices.

2. **For reprocessing *Salmonella*-adulterated RTE product**, an HPP process that achieves a 5-log ***Salmonella*** reduction for meat products and a 7-log reduction in poultry products should be sufficient for product produced under good manufacturing practices.

3. **For reprocessing *E. coli* O157:H7-adulterated raw or RTE product**, an HPP process that achieves a 5-log ***E. coli* O157:H7** reduction should be sufficient for product produced under good manufacturing practices.

VII. DOCUMENTATION AND ENFORCEMENT

A. When performing a HACCP Verification task for the appropriate HACCP processing category**,** IPP are to verify that establishments include HPP as a process step in their flow chart and address biological food safety hazards at the HPP process step in their hazard analysis. This applies to both the official establishment performing the HPP treatment and the manufacturing establishment contracting with it to perform the process.

B. If either establishment fails to include the HPP process step in its flow chart, or to conduct a hazard analysis to address biological food safety hazards at the HPP process step, IPP are to document noncompliance under the appropriate HACCP Verification task

code. Document noncompliance with 417.2 (a)(2), and 417.2(a)(1) as the relevant regulations, respectively, as set out in FSIS PHIS Directive 5000.1.

C. When performing a HACCP Verification task for the appropriate HACCP processing category or Hazard Analysis Verification (HAV) procedure, IPP are to verify the establishment provides documentation to support decisions made in its hazard analysis and food safety system. This applies to both the establishment performing the HPP treatment the establishment that manufactures the product, if different.

D. 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 code, with 417.5(a)(1) as the relevant regulation cited. This support may include antimicrobial reduction achieved based upon specific critical operational parameters.

VIII. DATA ANALYSIS

On an annual basis, the Data Analysis and Integration Group (DAIG) within the Office of Data Integration and Food Protection (ODIFP) is to review Public Health Information System (PHIS) data on verification activities for the use of HPP in the hazard analysis for potential trends in noncompliances, specifically for compliance with 417.2(a) (2) and 417.5(a)(1). Results from these analyses are to be shared with the Office of Field Operations (OFO) and the Office of Policy and Program Development (OPPD); Risk, Innovations and Management Division, to determine whether the findings suggest potential improvements in verification procedures or guidance to IPP.

Refer questions regarding this directive to the Policy Development Division (PDD) through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935. Direct questions regarding the adequacy of an establishment's scientific supporting documentation for its HPP process to the Risk, Innovations, and Management Division through *ask*F*SIS*.

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