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

# FSIS NOTICE	03-18	1/8/18

PROFILE UPDATES AT ESTABLISHMENTS THAT APPLY HIGH PRESSURE PROCESSING OR IRRADIATION

I. PURPOSE

A. This notice introduces a new intended use option to be utilized in the Public Health Information System (PHIS) profiles of establishments which apply high pressure processing (HPP) or irradiation (IR) to products originally produced by other establishments.

B. This notice provides instructions to inspection program personnel (IPP) assigned to these HPP and IR establishments on how to utilize this new intended use option in PHIS: "Not sampled at HPP or IR establishment because returned to producer or shelf life extension applied." As explained in this notice, IPP are to update these establishments' PHIS profile to indicate when product groups produced by other establishments are to be excluded from microbiological sampling eligibility at HPP or IR establishments.

C. This PHIS profile update and new intended use are needed to exclude certain product groups or portions of product groups from routine FSIS microbiological verification sampling eligibility at establishments which apply HPP or IR to Ready-to-Eat (RTE) or raw meat and poultry products (all species and product groups) that were originally produced by other establishments when they can be sampled at those original producing establishments.

II. BACKGROUND

A. Establishments are being constructed for the sole purpose of providing HPP or IR services to producing establishments. These services may be a third party contract establishment or an establishment within a corporate structure. These processes are applied either to reduce or eliminate foodborne pathogens or are applied for quality purposes alone, such as to extend shelf life by targeting spoilage organisms.

B. The concept of a third party establishment, typically at a different geographical location, completing a HACCP process for a producing establishment poses a challenge to the traditional way FSIS has performed verification sampling. FSIS policy is to sample products after all validated pathogen reduction interventions have been applied. In the past, these interventions have all typically been applied at the producing establishment. However, producing establishments are now sending packaged products to other establishments where processes such as HPP or IR are applied as an intervention. Sometimes these products are returned to the producing establishment prior to release into commerce and sometimes they are released directly into commerce from the HPP or IR establishment without being returned to the producing establishment. This development changes

where FSIS must perform microbiological verification sampling in order to do so after all pathogen interventions have been applied.

C. The intended use options that are currently used to enter product groups in establishment profiles in PHIS vary by commodity and purpose. This notice adds one new additional intended use option in PHIS, "Not sampled at HPP or IR establishment because returned to producer or shelf life extension applied," which is only applicable to the profiles of establishments that apply processes such as HPP or IR to products produced by other establishments. This new intended use does not apply to producing establishments that send products to another establishment for the application of HPP or IR.

D. For FSIS verification activities related to HPP, IPP are to refer to FSIS Directive 6120.2, *High Pressure Processing (HPP) and Inspection Program Personnel (IPP) Verification Responsibilities*. For FSIS verification activities related to IR, IPP are to refer to FSIS Directive 7700.1, *Irradiation of Meat and Poultry Products*.

III. HOW TO DETERMINE WHEN THE NEW INTENDED USE APPLIES

A. The new intended use option, "Not sampled at HPP or IR establishment because returned or shelf life extension applied" should only be utilized in the PHIS profiles of establishments which apply processes such as HPP or IR to products originally produced by other establishments. It should not be utilized in the profiles of producing establishments.

B. This new intended use option could possibly apply to all species and product categories in the profiles of HPP or IR establishments, subject to the limitations described below. It is to be used to exclude product groups or portions of product groups from microbiological sampling eligibility at HPP or IR establishments when these products can be sampled at the producing establishment. Checking the new intended use option will exclude a product group from sampling eligibility at the HPP/IR establishment.

C. If an HPP or IR establishment is both producing meat and poultry products as well as applying HPP or IR to both its own products and to the products produced by other establishments, the new intended use applies only to that portion of products or product groups originally produced by other establishments. When products are produced by an HPP/IR establishment, they can also be sampled at that location. This new intended use is not applicable in this case.

D. With these limitations in mind, there are currently two situations in which IPP stationed at establishments applying processes such as HPP or IR are to use this new intended use option. In both of these situations, products can be sampled for microbiological analyses at the original producing establishment rather than at the HPP or IR establishment. The new intended use should be utilized:

1. When an HPP or IR establishment applies a pathogen reduction treatment(PRT) to a product group produced by another establishment which is also returned to the producer before being released into commerce; or

2. When HPP or IR is applied for quality purposes alone, not as a PRT. In this case, it does not matter if the product is returned or not because the product is eligible for FSIS sampling at the producing establishment before application of HPP or IR for quality purposes.

IV. IPP RESPONSIBILITIES AT OFFICIAL ESTABLISHMENTS THAT APPLY PROCESSES SUCH AS HPP AND IR

A. IPP are to review and update the establishments' PHIS profiles to ensure product groups are accurate and to include the new intended use, when applicable.

B. When necessary, IPP are to add or delete product groups one group at a time, as described in FSIS Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System*. When portions of product groups have more than one intended use, IPP are to make more than one entry for that product group. IPP are to complete the instructions in this notice by **Friday, March 9, 2018.**

C. FSIS policy is to sample products after all validated pathogen reduction interventions have been applied. To correctly apply this new intended use option, IPP assigned to HPP or IR establishments are to first review records to determine whether HPP or IR is being utilized as an intervention to reduce or eliminate pathogens or if it is only being applied for quality purposes, such as a shelf life extension, as per FSIS Directive 6120.2 for HPP and FSIS Directive 7700.1 for IR. There may also be a variety of other documents that IPP in HPP or IR establishments may use to help make this determination. This information could typically be obtained from the hazard analysis, as that reflects the appropriate decision making documentation and scientific support. There also may be communication in the form of a contractual agreement that indicates the purpose of the process being applied. This might include the validation documentation for a post-lethality treatment (PLT) or PRT. There may also be additional documents available that indicate the purpose of the treatment being applied.

NOTE: A PLT is also considered a PRT because its purpose is to reduce or eliminate pathogens. All levels of pathogen reduction apply when determining whether HPP or IR is being utilized as a PRT.

D. IPP assigned to HPP or IR establishments are then to determine which product groups or portions of product groups are returned to the producing establishment following application of HPP or IR as a PRT.

E. The following two situations will require IPP to revise the PHIS product groups in the HPP or IR establishments' PHIS profiles:

1. If any portion of a product group produced by other establishments is receiving a process such as HPP or IR for quality purposes only (e.g., targeted against spoilage organisms or to extend the shelf life), IPP are to revise these product groups to exclude them from sampling eligibility at the HPP or IR establishment by checking the new intended use; or

2. If any portion of a product group produced by other establishments is receiving HPP or IR as a PRT which is then returned to the producer before it enters commerce, IPP are to revise the product groups to exclude these product groups from sampling at the HPP or IR establishment by checking the new intended use.

APPLICABILITY OF THE NEW INTENDED USE CHECK BOX

What is the purpose of the process such as HPP or IR?	Is the production lot returned to the producing establishment before being released into commerce?	Where are FSIS verification samples to be collected?	Should the new intended use button be selected/checked*?
For quality purposes, e.g. shelf life extension.	The above question is not applicable when HPP or IR is applied only for quality purposes.	At the producing establishment before shipment to the HPP or IR establishment.	Yes.
As a PRT.	Yes.	At the producer, after application of the PRT and before being released into commerce.	Yes.
As a PRT.	No.	At the establishment which applies HPP or IR after application of the PRT.	No.
The above 2 questions are not applicable when products are produced by same establishment which is applying HPP or IR because these samples can be collected at that producer.		At the producing establishment which is also applying HPP or IR.	No.

*Checking the new intended use will exclude the corresponding production volumes from sampling scheduling algorithms at the HPP or IR establishment.

F. If an entire product group is being treated in the same manner, then only one product group entry will be needed. If this is the case, IPP at HPP or IR establishments are to check the new intended use for applicable product groups that are eligible for FSIS sampling at the original producer, as per the table above. For any product groups which are to be sampled by FSIS at the HPP or IR establishment, as is indicated in the above table, this new intended use does not apply and an update may not be necessary. In this case, IPP at HPP or IR establishments are to follow the guidance in FSIS Directive 5300.1 for completing product group information.

G. In some cases, it may be necessary to create two entries for a PHIS product group, one with the new intended use checked as per this notice and an additional entry using the most appropriate intended use following the guidance provided in FSIS Directive 5300.1. For example:

Situation 1: An HPP establishment receives raw ground turkey from multiple offsite producing establishments. HPP is applied as a PRT to one portion, while HPP is being applied only to extend shelf life to another portion. Both are released directly into commerce from the HPP or IR establishment.

Response 1: Two raw ground poultry product groups will be needed. The production volume of the portion of this product group where HPP is applied only for quality purposes is to be reflected in a raw poultry product group with the new intended use checked because this portion is eligible for FSIS sampling at the producing establishments before being shipped to the HPP establishment. This new intended use is not to be utilized for the portion of the production volume that is receiving HPP or IR as a PRT and is released directly into commerce because these products are to be sampled at the HPP or IR establishment and the purpose of this intended use is to exclude products from microbiological sampling at these HPP or IR establishments.. The product group information for this entry, including intended use, should be completed as per the guidance found in FSIS Directive 5300.1.

Situation 2: An HPP establishment receives RTE products from multiple offsite producing establishments. HPP is being applied to all of the RTE products as a PRT. One portion of the RTE product group is returned to the producer following application of the PRT but before entering into commerce and another portion of the RTE product group is released directly into commerce from the HPP establishment after application of the PRT.

Response 2: Two RTE product groups will be needed. The production volume of the portion that is being returned to the producer after application of the PLT but before being released into commerce is to be reflected in a RTE product group with the new intended use box checked because these products are eligible for sampling at the producing establishments after being returned. This new intended use is not to be utilized for the portion of the product group that is receiving HPP or IR as a PRT and is being released directly into commerce because these products are to be sampled at the HPP or IR establishment after all interventions have been applied, but before entering commerce. The product group information for this entry, including intended use, should be completed as per the guidance found in FSIS Directive 5300.1.

H. In cases where more than one entry is needed for a product group, IPP are to do their best to estimate the total weight for each portion using information from all offsite producing establishments within the given product group for the previous calendar month. If this is highly variable from month to month, IPP may make an estimate by using the average production volume over the previous 3 months.

I. For more detailed guidance on entering product groups in PHIS per this notice, including how to make two entries for a product group, each with a different intended use and different production volumes, IPP are to refer to updating HPP or IR establishment profiles in *IPP Help*.

IX. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Staff through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field:	Enter **Notice 03-18**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Sampling - General** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**

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

Assistant Administrator
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