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

FSIS DIRECTIVE

5020.1
Revision 1

10/6/16

VERIFICATION ACTIVITIES FOR THE USE OF NEW TECHNOLOGY IN MEAT AND POULTRY ESTABLISHMENTS AND EGG PRODUCTS PLANTS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) on how they are to verify that a meat or poultry establishment or egg products plant is following the procedures outlined in its protocol(s) for new technology or the procedures agreed to as a condition of a waiver of regulatory requirements. FSIS has rewritten this directive to provide verification instructions for IPP at establishments with waivers, including those participating in *Salmonella* Initiative Program (SIP) and at establishments following protocols for new technology. It also includes new instructions for documenting tasks performed in the Public Health Information System (PHIS).

KEY POINTS:

- *Defines new technologies and protocols*
- *Provides instructions for IPP at establishments participating in SIP*
- *Explains waivers of regulatory requirements and procedures for IPP verification of such waivers*

II. CANCELLATION

FSIS Directive 11,000.2, *Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plants*, 5/6/15

FSIS Directive 5020.1, *Verification of Salmonella Initiative Program*, 8/12/11

III. BACKGROUND

A. New technologies are new or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or the processing of meat, poultry, or egg products. The implementation of new technologies may involve a waiver of one or more specific regulations. FSIS grants waivers of certain regulations that allow establishments to test new procedures, equipment, and processing techniques that otherwise would be in violation of current FSIS regulations.

B. A Federal Register (FR) notice titled "*FSIS Procedures for Notification of New Technology*" (68 FR 6873, Feb. 18, 2003) explained that to implement new technologies that are not consistent with FSIS regulations but that show a measurable improvement in the operation of an establishment, an establishment is to petition the Agency with sufficient scientific research or data validating the new technology. FSIS regulations 9 CFR 303.1(h), 9 CFR 381.3(b), and 9 CFR 590.10 allow any provisions of the meat, poultry, and egg products regulatory requirements to be waived for a limited period of time to permit experimentation.

C. A second FR notice titled *Salmonella Verification Program: Response to Comments on New Agency Policies and Clarification of Timeline for the Salmonella Initiative Program (SIP)*, (FR 76. Vol. 134 July 13, 2011), announced several policy changes regarding SIP. SIP is a voluntary program for meat and poultry slaughter establishments that agree to share internal food safety data with FSIS in order to receive waivers of regulatory requirements. New technology requests that do not fit under this FR notice fall under the FR notice titled "*FSIS Procedures for Notification of New Technology*" (68 FR 6873, Feb. 18, 2003).

D. The Risk Innovations and Management Staff (RIMS) in the FSIS Office of Policy and Program Development leads the review of industry submissions on the use of new technologies by forming a Technical Review Team (TRT) composed of staff from multiple program areas. The TRT reviews new technology submissions to determine whether the use of the new technology will: (1) interfere with FSIS inspection activities; (2) pose a risk to the health or safety of IPP; (3) create a food safety concern; or (4) be inconsistent with FSIS regulations. If, after review, the Agency does not object to the proposed use of a new technology, RIMS sends the submitter a No Objection Letter (NOL) for the use of the technology. NOLs indicate that FSIS has received and reviewed a new technology submission and has no objection to the use of such technology in official establishments. The Agency also issues NOLs granting permission to conduct in-plant trials in official establishments. In-plant trials are experiments conducted to test protocols during commercial conditions. In-plant trials may or may not be associated with a waiver of regulatory requirements. RIMS may issue a NOL at the end of an in-plant trial. If the in-plant trial was conducted to support a waiver of regulatory requirements, the Agency may grant an establishment a continuous waiver until the regulation is amended. For any new technology, establishments are to reassess their food safety system in accordance with 9 CFR 417.4(3)(i).

E. The NOL describes the new technology and conditions of use. If the NOL includes a waiver of regulatory requirements, it needs to document the alternative procedures to be conducted in lieu of the waived regulations. NOLs associated with in-plant trials and waivers are issued directly to an official establishment. RIMS notifies the District Office (DO) and Inspector-In-Charge (IIC) of the new technology and provides them with a copy of the letter. The NOLs that do not involve a waiver or in-plant trial are issued to the requesting firm and a copy of the letter is provided to the DO

F. The Agency posts brief descriptions of all new technology in the New Technology Table on the FSIS Website. IPP can find a summary of the verification activities, including the conditions of use, for each new technology, including waivers, on Inside FSIS.

G. The Food and Drug Administration (FDA) and FSIS coordinate during the review of the approval process involving the safe and suitability determination for uses of substances in meat, poultry and egg products. Once a safe and suitable determination is made for the use of a substance in meat, poultry or egg products, it is added to FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products,* (originally, safe and suitable substances were added to 9 CFR 424.21(c)). Substances recognized as safe and suitable under the conditions of their intended use, such as those listed in 9 CFR 424.21(c) and FSIS Directive 7120.1, have already been subjected to the new technology notification process. A NOL is not needed when the substance is recognized and listed in 9 CFR 424.21(c) or FSIS Directive 7120.1.

IV. IPP RESPONSIBILITIES AT THE WEEKLY MEETING IN MEAT AND POULTRY ESTABLISHMENTS

A. When IPP receive a copy of a NOL, they are to maintain it in the government file. When IPP become aware of an establishment's new technology; rotate into an establishment and need to determine whether a plant is operating under a protocol for new technology; or discover what they believe to be the use of a new technology, they are to discuss the technology with establishment management at the next weekly meeting, in accordance with FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System.* More specifically, IPP are to seek the answers to the following questions:

1. Does the establishment have scientific or technical support for the use of the new technology?

2. What are the critical operating parameters and monitoring procedures to ensure that the new technology is functioning as intended?

3. In what part of the establishment's Hazard Analysis Critical Control Point (HACCP) system is the new technology addressed? Establishments can elect to address their use of new technology in the HACCP Plan, Sanitation Standard Operating Procedure (Sanitation SOP), or in another prerequisite program. Alternatively, establishments can elect to address its use of new technology in any combination of the HACCP Plan, Sanitation SOP or other prerequisite program. For example, a SIP establishment with two waived regulatory requirements may elect to include the alternative procedures for one of its waived requirements in its HACCP plan and the alternative procedures for another waived regulatory requirement in a prerequisite program.

4. When applicable, what are the specific provisions of the regulations that are waived and what are the alternative procedures that the establishment is employing?

5. When applicable, what are the establishment's sampling and testing procedures? For example, what are the written sampling procedures, who is designated to collect samples, where will sampling and testing be conducted, how is sampling randomness achieved to cover all lines and shifts, how will samples be handled to ensure sample integrity, and what is the frequency of microbial sampling and testing?

6. When does establishment management intend to begin employing the new technology in the establishment, including in-plant validation and on-going verification?

7. Did the establishment reassess their food safety system according to 9 CFR 417.4(a)(3)(i)?

B. If IPP are contacted by establishments interested in implementing the use of a new technology or joining the SIP program, they are to instruct the establishments to send their requests for information to askFSIS and follow the guidance for waivers, notifications and protocols posted on the FSIS Web site at: FSIS Compliance Guideline for New Technology Notification and Protocols.

V. FSIS VERIFICATION OF NEW TECHNOLOGY IN MEAT AND POULTRY ESTABLISHMENTS

A. IPP are to follow the instructions in FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task,* to verify compliance with the regulatory requirements in 9 CFR 417.4(a)(3)(i) and all other regulatory requirements of 9 CFR Part 417.

B. The establishment may elect to address the use of new technology as part of its HACCP Plan, Sanitation SOP or prerequisite programs. For ongoing verification, IPP are to use the appropriate verification task, and follow the instructions in FSIS Directive 5000.1 and FSIS Directive 5000.2 *Review of Establishment Testing Data by Inspection Program Personnel,* to verify that the establishment is adhering to the critical operating parameters in its protocol for new technology

or supporting documentation. IPP are to be aware that the protocol for new technology will typically include operational parameters, alternative procedures (if associated with a waiver), and scientific or technical supporting documentation. IPP are to use the appropriate verification task, as described below, to verify that the establishment is operating in a manner that is consistent with its protocol for new technology:

1. Once per week, IPP are to verify one or more parts of the establishment's protocol for new technology;

2. If the establishment's protocol for new technology is included as part of its HACCP Plan or prerequisite program, IPP are to schedule and perform a HACCP verification task to verify that the alternative procedures as defined in the protocol are implemented in accordance with the establishment's HACCP Plan or prerequisite program;

NOTE: IPP should schedule and perform the applicable HACCP verification task as a routine task, if available. In instances when the routine task is not available, IPP should schedule and perform the applicable HACCP verification task as a directed task and provide as the justification "as instructed in the policy issuance".

3. If IPP have questions about verification activities or supporting documentation in the hazard analysis relative to a new technology, they are to consult with their supervisor or RIMS through askFSIS;

4. If the establishment's protocol for new technology is addressed as part of its Sanitation SOP, IPP are to perform an Operational Sanitation SOP verification task, as available; and

5. If the establishment's protocol for new technology includes approved alternative procedures in place of certain provisions of the regulations (including SIP procedures), IPP are to verify implementation of these alternative procedures. This may include, but is not limited to:

    a. Identification of the provisions of the regulations that are to be waived;

    b. Alternative procedures that are to be used in place of any waived provisions of the regulations;

    c. Description of the microbiological sampling and testing procedures that the establishment will implement; and

    d. Agreement to share microbiological and other data with FSIS.

C. When documenting the task performed, including verifying whether the establishment is adequately following alternative procedures in place of certain provisions of the regulations (i.e. waivers), IPP are to follow the instructions above and record 9 CFR 381.3(b) for poultry establishments or 9 CFR 303.1(h) for livestock establishments, as appropriate.

D. An establishment must have a NOL that includes an approval to operate under alternative procedures in lieu of waived regulatory requirements. If IPP determine that the establishment is implementing a new technology that would require a waiver of regulatory requirements and it does not have a NOL, they are to take appropriate action, as instructed in FSIS Directive 5000.1.

E. When IPP determine that an establishment implemented a new technology that is not associated with a waiver (including SIP) or that the establishment did not incorporate the new technology into its food safety system, they are to schedule a directed HAV task and follow the instructions in FSIS Directive

5000.6. IPP are to verify whether the establishment meets the requirements in 9 CFR 417.4(a)(3)(i) and all other regulatory requirements of 9 CFR Part 417.

VI. SPECIAL CONSIDERATIONS FOR MEAT AND POULTRY ESTABLISHMENTS OPERATING UNDER REGULATORY WAIVERS OR CONDUCTING IN-PLANT TRIALS

A. New technology requests are reviewed on a case-by-case basis. For requests that involve granting a waiver from regulatory requirements or conducting an in-plant trial, special considerations are given to those establishments that agree to share internal food safety data as a condition of the waiver or in order to conduct the in-plant trial. For example, waivers granted as part of the SIP represent a new technology request in which the establishment has agreed to share internal food safety data. SIP examples are used in this directive, as they are the most commonly encountered special circumstance. Questions similar to those included in section D. below would apply in special circumstances other than SIP.

B. IPP are to follow the instructions in FSIS Directive 5000.2, when verifying an establishment's microbial sampling and testing procedures and that the establishment is meeting established sampling frequencies as specified in its protocol for new technology. IPP should note that positive test results do not automatically mean there is noncompliance. Noncompliance occurs when the establishment is not implementing its sampling and testing procedures as identified in its new technology protocol.

C. IPP are to verify that the establishment is recording test results and responding to those results in a manner consistent with its protocol for new technology that includes, in part, critical operating parameters and monitoring procedures. This will ensure that the new technology is functioning as intended.

D. Questions that IPP are to consider when verifying the testing results in SIP establishments include, but are not limited to, the following:

1. Is the establishment recording *Salmonella* test results?

2. Is the establishment using a moving window approach (evaluation of a number of sequential events) to evaluate its most current test results and *Salmonella* process control? This approach should be specified in the establishment's protocol for new technology; and

3. If the establishment demonstrates a lack of *Salmonella* process control by exceeding the acceptable number of positives in a sample moving window for the current *Salmonella* standard specified in the establishment's protocol for new technology, consider the following:

    a. Does the establishment increase the frequency of its sampling for *Salmonella* until at least two consecutive monthly window results have demonstrated process control?

NOTE: The frequency of testing may be increased to demonstrate process control.

    b. Does the establishment investigate whether the provisions in its protocol for new technology or other conditions in the establishment's process contributed to, or caused, the lack of process control?

    c. Does the establishment document its findings and corrective and preventive actions taken to return to the current *Salmonella* standard of process control?

    d. Has the establishment reduced line speed to an appropriate level, if applicable, until *Salmonella* process control is restored?

    e. Has the establishment maintained records in the same manner and for the same

duration as HACCP records (9 CFR 417.5)?

E. If the establishment's testing results indicate a loss of process control, IPP are also to utilize inspection verification procedures to investigate the potential cause of the positive results. For example, IPP may conduct a sanitary dressing verification task to observe sanitary conditions during slaughter and to observe the application and concentration of any antimicrobial interventions utilized in the slaughter process.

F. As described in FSIS Directive 5000.1, IPP are to discuss any issues or questions related to the establishment's new technology at weekly meetings. After at least one *Salmonella (or other indicator organism),* completed moving window has been collected, analyzed and the results recorded, IPP are to discuss the following:

1. Whether the establishments' *Salmonella* sampling results indicate that the establishment is maintaining the current standard of process control as specified in its protocol for new technology. If daily *Salmonella* testing results show the establishment is not maintaining process control, IPP are to ask establishment management what contributed to, or caused, the lack of process control and what corrective actions have or will be taken; and

2. Identified or observed noncompliance related to the use of new technology and developing trends that could lead to recurring noncompliances. The objective is to prevent trends and repetitive NRs that may result in a revocation of a waiver.

G. If an establishment wants to change a procedure or parameter and is operating under a waiver or is conducting in-plant trials, it must first notify RIMS through askFSIS. RIMS will review the changes and if acceptable, RIMS will notify the IIC and DO and reissue a NOL to the submitter. The establishment is not to implement the change until it receives the updated NOL from RIMS. When IPP receive an updated copy of the NOL, they are to follow the procedures listed in sections IV. and V.

VII. INSPECTION, DOCUMENTATION, AND ENFORCEMENT IN MEAT AND POULTRY ESTABLISHMENTS

A. IPP are to take appropriate action, as instructed in FSIS Directive 5000.1, Chapter V Documentation and Enforcement, if the establishment is not properly executing its protocol for new technology in its food safety system.

B. IPP are not to document a noncompliance if a SIP establishment exceeds the number of acceptable positives necessary to meet the current *Salmonella* standard but complies with all other requirements in its protocol for new technology, such as recording, evaluating and responding to test results and taking corrective actions.

C. IPP are to take appropriate regulatory control action when they observe an establishment using a substance (new ingredient or processing aid) for purposes other than its intended use as listed in 9 CFR 424.21(c) or FSIS Directive 7120.1.

D. The manner in which the establishment has addressed its new technology within its food safety system will affect how IPP document noncompliance. IPP are to follow the instructions below for documenting noncompliance. If the noncompliance involves a waiver, IPP are to also cite 9 CFR 381.3(b) in poultry establishments or 9 CFR 303.1(h) in livestock establishments when documenting noncompliance.

1. When an establishment incorporates its protocol for new technology in its HACCP Plan as a Critical Control Point (CCP) or as ongoing verification activities and the establishment fails to follow associated procedures or to meet the CCP, IPP are to document noncompliance. IPP

are to cite 9 CFR 417.2(c) if the noncompliance is related to the CCP or 9 CFR 417.4(a) if the noncompliance is related to ongoing verification activities;

2. When the establishment incorporates its protocol for new technology in its Sanitation SOP, and the establishment fails to implement associated procedures in the Sanitation SOP, IPP are to document noncompliance. IPP are to cite 9 CFR 416.13 if the noncompliance is related to implementation or 9 CFR 416.16 if the noncompliance is related to recordkeeping requirements; or

3. When the establishment incorporates its protocol for new technology in a prerequisite program, and the establishment fails to implement the associated procedures in its prerequisite program, IPP are to determine whether the observed failure to implement the prerequisite program affects the establishment's ability to support decisions in its hazard analysis. If IPP have, questions regarding the impact to the establishments hazard analysis, they should consult with their supervisor, and if additional information is needed, contact RIMS through askFSIS. If the decisions in the hazard analysis are no longer supported, IPP are to document noncompliance citing 9 CFR 417.5(a)(1).

VIII. ESTABLISHMENTS OPERATING UNDER A WAIVER

FSIS may revoke a waiver of regulatory requirements when an establishment fails to maintain or follow its alternative procedures associated with the waiver. If IPP find that an establishment fails to follow the alternative procedures associated with its waiver of regulatory requirements, they are to notify the DO through supervisory channels. The DO will determine whether the establishment can resume the use of the alternative procedures associated with the waiver of regulatory requirements or whether the waiver needs to be revoked; if the waiver is revoked, the establishment is required to resume operations that comply with FSIS regulations. The DO and establishment are to work together to determine a suitable date to resume operations as per FSIS regulations should revocation of the waiver occur. The DO is to notify RIMS of these situations.

IX. IPP RESPONSIBILITIES IN EGG PRODUCTS PLANTS

A. When IPP receive a copy of a NOL, they are to maintain it in the government file. When IPP: become aware of a plant's new technology; rotate into a plant and they need to determine whether it is operating under a protocol for new technology; or discover what they think is a new technology, they are to discuss the technology with plant management at the next weekly meeting. IPP are to follow the procedures in Section IV. of this document and the instructions as described in FSIS Directive 5030.1, *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants*.

B. Using the appropriate PHIS verification task, IPP are to review alternative procedures and any new technology protocols to verify that egg product plants are meeting the regulatory requirements of 9 CFR 590. IPP are to perform verification activities in accordance with FSIS Directive 5030.1. When verifying whether the establishment is adequately following alternative procedures in place of certain provisions of the regulations (i.e. waivers) and documenting the task performed, IPP are to follow the instructions in Section V. above (as appropriate) and record as per 9 CFR 590.10.

X. INSPECTION, DOCUMENTATION, AND ENFORCEMENT IN EGG PRODUCTS PLANTS

A. IPP are to document noncompliance as instructed in FSIS Directive 5030.1.

B. IPP are to follow the instructions in FSIS Directive 5030.1, including also citing 9 CFR 590.10 in egg products plants, when documenting noncompliance with alternative procedures used in place of certain provisions of the regulations (waivers of regulatory requirements).

C. FSIS may revoke an egg products plant's waiver as set out in section VIII. above.

XI. DATA ANALYSIS

RIMS will analyze *ask*FSIS questions received pertaining to new technologies. Specifically, the analysis will assess whether the number and type of questions warrant a revision or clarification of this directive.

XII. QUESTIONS

A. Refer to the "IPP Help" button for new technology frequently asked questions (FAQs). Select the menu item "Waivers and New Technology Protocols FAQs" to view the list of questions. Once you select a question, a brief, narrated video opens and answers the FAQ. (Speakers need to be on to hear the video.) Click Go Back to return to the FAQ list.

B. Refer questions regarding this directive to RIMS through askFSIS. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 5020.1.**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select an item under **New Technology** 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
Office of Policy and Program Development