MSA DIRECTIVE	11,000.2	5/6/15

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

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) on how they are to verify that an establishment is following the procedures outlined in its new technology protocol.

KEY POINTS:

- *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 FSIS posts brief descriptions of all new technology in the New Technology Table on the Agencies Web site*
- *The conditions of use, including operating parameters, for each new technology are made available to IPP on Inside FSIS*

II. BACKGROUND

A. In a *Federal Register* notice titled "FSIS Procedures for Notification of New Technology" (68 FR 6873, Feb. 18, 2003), FSIS advised that all official establishments (meat, poultry, and egg products) and companies that manufacture and sell technology to official establishments should submit to FSIS notification regarding the use of a new technology.

B. IPP are to be aware that the Federal Register notice also advised that notifications should describe the intended use, operation, and purpose of a new technology in official meat and poultry establishments or egg products plants. The notification may also include a protocol describing the methods by which the proposed technology will be tested, implemented, and evaluated.

C. FSIS defines a "new technology" as new, or new application of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or the processing of meat, poultry, or egg products. The Agency reviews new technology protocols to determine whether the new technology could affect product safety; violate regulations; interfere with inspection procedures; or jeopardize the safety of IPP.

D. "New technology" also includes alternative procedures in lieu of waived regulations. Under 9 CFR 303.1(h), 9 CFR 381.3(b), and 9 CFR 590.10, the FSIS Administrator may, in specific classes of cases, waive any provisions of the regulations for limited periods to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements,

provided that such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Federal Meat Inspection Act, Poultry Products Inspection Act, or Egg Products Inspection Acts.

E. The Risk Innovations and Management Staff (RIMS) in the FSIS Office of Policy and Program Development (OPPD) reviews industry submissions on the use of new technologies to determine whether they interfere with the inspection activities of FSIS personnel; create a risk to the health or safety of IPP; create a food safety concern; or are inconsistent with FSIS's 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. If applicable, the letter may permit in-plant trials and waive specified provisions of the regulations. The NOL describes the conditions of use, including any appropriate alternative procedures and protocols under which the establishment receiving the waiver or permission to conduct in-plant trials can operate. The letters instruct the submitter to notify IPP prior to implementing the new technology or an in-plant trial.

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

NOTE: Substances recognized as safe and suitable under the conditions of their intended use, such as those listed in 9 CFR 424.21(c) and those that are listed in FSIS Directive 7120.1, *"Safe and Suitable Ingredients in Meat, Poultry, and Egg Products,"* are not subject to the new technology notification process.

III. IPP RESPONSIBILITIES AT THE WEEKLY MEETING

A. When IPP receive a copy of a Salmonella Initiative Program (SIP) Letter with an attached SIP Protocol, they are to maintain a copy in the MSA file and follow the instructions in MSA Directive 5020.1 *Verification of Salmonella Initiative Program*.

B. When IPP receive a copy of the new technology NOL or when the establishment informs them that it plans to implement a new technology, they are to discuss the technology with establishment management at the next weekly meeting, in accordance with MSA Directive *5000.1, Verifying an Establishment's Food Safety System*, Ch. 1., VII Weekly Meeting. IPP are to maintain a copy of the NOL in the FSIS file and at the weekly meeting, they are to discuss the following with the establishment:

1. When applicable, the specific provisions of the regulations that are waived and the alternative procedures that the establishment is employing. NOLs may or may not include regulatory waivers.

NOTE: The agency may waive specific provisions of a regulation. IPP are to review the NOL for the waived provisions and the use of alternative procedures. Alternative procedures are those that an establishment will use in place of certain provisions of the regulation.

2. The written protocol and scientific or technical support containing critical operating parameters and monitoring procedures to ensure that the technology is functioning as intended.

3. The location in the establishment's food safety system where the establishment has elected to include the new technology or alternative procedures. Establishments can elect to include all new technology procedures and the associated protocols in the Hazard Analysis Critical Control Point (HACCP) plan or in the Standard Operating Procedure (Sanitation SOP) or in another prerequisite

program. Alternatively, establishments can elect to incorporate new technology procedures in any combination of the HACCP plan or Sanitation SOP or other prerequisite program.

4. When establishment management intends to begin to employ the technology in the establishment, including in-plant validation and on-going verification.

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

A. IPP are to verify the proper execution of an establishment's HACCP plans and Sanitation SOP and other prerequisite programs as set out in FSIS Directive 5000.1. IPP are to conduct verification procedures according to which of these programs the establishment has chosen to place the new technology procedures.

B. Using the appropriate HACCP verification task, following the instructions in FSIS Directive 5000.1, IPP are to verify that the establishment is adhering to the critical operating parameters in the new technology protocol. IPP are to be aware that the protocol typically would include operational procedures, alternative procedures (if applicable), 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 the new technology protocol:

1. If the establishment's protocol is part of the HACCP plan, IPP are to perform, as available, a HACCP Verification task to verify that the alternative procedures or protocol is implemented in accordance with their HACCP plan.

2. If the establishment's protocol is part of the Sanitation SOP, IPP are to perform as available, an operational Sanitation SOP observation.

3. If the establishment's protocol is part of a prerequisite program, then IPP are to perform, as available, a HACCP Verification task to verify that the protocol is implemented as written. If IPP have questions regarding verification activities or supporting documentation in the hazard analysis, they are to consult with the Frontline Supervisor (FLS) or contact the Policy Development Staff (PDS) for regulatory and technical questions, or RIMS for questions on specific new technology (refer to Section XIII below for instructions on submitting a question).

C. When documenting the task performed, 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 when verifying whether the establishment is adequately following alternative procedures in place of certain provisions of the regulations (regulatory waivers).

V. FSIS VERIFICATION OF NEW TECHNOLOGY WHEN THE ESTABLISHMENT DOES NOT HAVE AN NOL FOR THE USE OF A NEW TECHNOLOGY

A. When IPP discover that the establishment implemented a new technology, and the establishment does not have an NOL, they are to schedule a directed Hazard Analysis Verification (HAV) task and to follow the instructions in FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task*. 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. IPP are to submit questions they may have to askFSIS regarding the establishment's supporting documentation for the new technology.

B. IPP can find a summary of the verification activities, including the conditions of use, for each new technology on Inside FSIS.

C. IPP are to take appropriate action, as instructed in FSIS Directive 5000.1, Ch. V. Documentation and Enforcement, if the establishment is operating under alternative procedures in lieu of regulations and does not have an NOL waiving the regulations.

NOTE: An establishment must have an NOL to operate under alternative procedures in lieu of waived regulations to show that FSIS has waived the regulatory requirements for that establishment.

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

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

B. IPP are to take appropriate enforcement action when they observe the establishment using an ingredient for purposes other than its intended use as listed 9 CFR 424.21(c) or as approved by the Administrator (9 CFR 424.21(c)) as listed FSIS Directive 7120.1, *Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products.*

NOTE: Prior approved substances are listed in 9 CFR 424.21(c). The *Table of Safe and Suitable Ingredients* and *FSIS Directive 7120.1* list food grade substances that have been approved in 21 Code of Federal Regulations (CFR) for use in meat, poultry, and egg products as food additives or generally recognized as safe (GRAS) substances, or that have been the subject of pre-market notifications of acceptability determinations.

C. The manner in which the establishment has addressed the new technology within its food safety system will affect how IPP document any noncompliance found. IPP are to follow the instructions below, including also citing 9 CFR 381.3(b) in poultry establishments or 9 CFR 303.1(h) in livestock establishments, when documenting noncompliance with alternative procedures used in place of certain provisions of the regulations (regulatory waivers):

1. When the establishment has incorporated new technology in its HACCP plan as a CCP or as an ongoing verification activity, and the establishment has failed to implement those procedures as addressed its protocol or HACCP plan, IPP are to document the noncompliance. IPP are to cite 9 CFR 417.2(c) if noncompliance is related to the CCP or 9 CFR 417.4(a) if noncompliance is related to ongoing verification activities.

2. When the establishment has incorporated a new technology in its Sanitation SOP, and the establishment has failed to implement these procedures as addressed its protocol or in the Sanitation SOP, IPP are to document noncompliance. IPP are to cite 9 CFR 416.13 if noncompliance is related to implementation or 9 CFR 416.16 if the noncompliance is related to recordkeeping requirements.

3. When the establishment has incorporated new technology in a prerequisite program, and the establishment has failed to implement the prerequisite program as addressed its protocol or in the hazard analysis, IPP are to determine whether the observed failure to implement the alternative procedure and new technology protocol affect the establishment's ability to support decisions in its hazard analysis. If IPP have questions regarding supporting documentation in the hazard analysis they should consult with the FLS or contact PDS for technical and regulatory questions or RIMS for questions on specific new technology protocols (refer to Section XIII below for instructions on submitting a question). If the decisions in the hazard analysis are no longer supported, IPP are to document noncompliance citing 9 CFR 417.5(a)(2).

D. IPP are to report through supervisory channels if they observe a clear trend of repetitive NRs related to alternative procedures or new technology protocol. The FSIS Administrator may revoke waivers when repeated NRs documenting failure of an establishment to maintain its alternative procedures occur.

VII. QUESTIONS

Questions regarding this Directive shall be directed to the MSA Central Office through the supervisory chain-of-command.

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