

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES
MEAT SAFETY ASSURANCE
AUSTIN, TX**

MSA DIRECTIVE	5020.1 Revision 1	10/6/16
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**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 a meat or poultry establishment 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. MSA has rewritten this directive to provide verification instructions for IPP at establishments with waivers 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*

- *Explains waivers of regulatory requirements and procedures for IPP verification of such waivers*

II. CANCELLATION

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

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 or poultry products. The implementation of new technologies may involve a waiver of one or more specific regulations. MSA grants waivers of certain regulations that allow establishments to test new procedures, equipment, and processing techniques that otherwise would be in violation of current regulations.

B. To implement new technologies that are not consistent with 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. MSA Regulations 9 CFR 303.1(h) and 9 CFR 381.3(b) allow any provisions of the meat and poultry products regulatory requirements to

be waived for a limited period of time to permit experimentation.

C. The Central Office (CO) leads the review of industry submissions on the use of new technologies. The CO reviews new technology submissions to determine whether the use of the new technology will: (1) interfere with MSA inspection activities; (2) pose a risk to the health or safety of IPP; (3) create a food safety concern; or (4) be inconsistent with MSA regulations. If, after review, the Agency does not object to the proposed use of a new technology, the CO sends the submitter a No Objection Letter (NOL) for the use of the technology. NOLs indicate that MSA 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. The CO 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).

D. 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. The CO notifies the Circuit Manager (CM) 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 CM

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

A. 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. 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.

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, they are to instruct the establishments to send their requests for information to the CO.

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

A. IPP are to follow the instructions in MSA 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 MSA Directive 5000.1 and MSA 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;
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, 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 MSA.

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 MSA Directive 5000.1.

E. When IPP determine that an establishment implemented a new technology that is not associated with a waiver or that the establishment did not incorporate the new technology into its food safety system, they are to schedule a directed 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.

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.

B. IPP are to follow the instructions in MSA 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. 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.

E. As described in MSA 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.

F. 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 the CO through their IPP. CO will review the changes and if acceptable, CO will notify the IIC and CM and reissue a NOL to the submitter. The establishment is not to implement the change until it receives the updated NOL from CO. 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 MSA Directive 5000.1, if the establishment is not properly executing its protocol for new technology in its food safety system.

B. 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 MSA Directive 7120.1.

C. 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 CO through their CM. 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

MSA 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 CO through supervisory channels. The CO 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 MSA regulations. The CO and establishment are to work together to determine a suitable date to resume operations as per MSA regulations should revocation of the waiver occur.

IX. QUESTIONS

Refer questions through supervisory channels.



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