NEW TECHNOLOGY STAFF
STANDARD OPERATING PROCEDURES FOR NOTIFICATION AND PROTOCOL SUBMISSION OF NEW TECHNOLOGIES

I. Introduction

This document sets out the standard operating procedures (SOPs) of the Food Safety and Inspection Service's (FSIS) New Technology Staff (NTS) when an official meat, poultry, or egg product establishment, or company that manufactures technology for use in official establishments:

- Submits a notification to the Agency of its intent to use a new technology[1], or
- Submits a protocol to the Agency for an in-plant trail of a new technology.

II. Notification

When the NTS receives a notification of intent to use a new technology, the following is to take place:

- The NTS Program Analyst assigns a tracking number to the notification.
- The NTS Director sends a letter acknowledging date of receipt of the notification to the submitting establishment or company.
- The NTS Director assigns the notification to an NTS Project Manager (PM).
- The PM may convene a Technical Review Team (TRT) to assist in the review process.

III. Technical Review Team

The Technical Review Team may include representatives from the:

- Office of Public Health Science (OPHS)
  - Microbiology Division (MD)
  - Zoonotic Diseases & Residue Surveillance Division – Residue Branch (ZDRSD, RB)

- Office of Policy, Program, and Employee Development (OPPED)
  - Inspection and Enforcement Initiatives Staff (IEIS)
  - Labeling and Consumer Protection Staff (LCPS)
  - Program Analysis Staff (PAS)
  - Technical Analysis Correlation Staff (TAC)

- Office of Management (OM)
  - Administrative Services Division - Environmental, Health and Safety Branch (ASD, EHSB)
  - Labor and Employee Relations Division (LERD)

- Office of Field Operations (OFO)

IV. Notification Review Process

The PM, with the help of the TRT as necessary, reviews the notification:

- If the technology is not a new technology,[1] or if it is not a new use of an existing technology, the NTS Director issues a letter stating that notification to NTS is not necessary.

- If the technology is a new technology, or if it is a new use of an existing technology, the PM, in consultation with the TRT as necessary, will review and fully assess all facets of the notification to determine whether the use of the new technology raises one or more of four concerns; that is, that it will:

    1. adversely affect the safety of product,
    2. jeopardize the safety of Federal inspection program personnel,
    3. interfere with inspection procedures, or
    4. be inconsistent with an Agency regulation.

- If the notification does not establish that none of the concerns are raised, the NTS Director will send a written notice to the submitter requesting additional information or clarification.

- If the PM determines that the new technology does not raise any of the four concerns, the NTS Director issues a no objection letter to the submitter. The NTS director also sends copies to: the Technical Service Center (TSC), the Office of Field Operations (OFO) headquarters, the appropriate District Office (DO), the Frontline Supervisor (FLS), and the Inspector-in-charge (IIC). The no objection letter will be sent through facsimile and first-class mail to the submitter. A copy of the no objection letter will also be sent to any members of the TRT who reviewed the notification.

- If the PM decides that the issuance of a no objection letter is appropriate, before issuing the letter, he/she will review all of the information associated with the use of the new technology to determine whether there is a need to issue or revise a FSIS directive or compliance guide. If it is necessary to issue or revise a FSIS directive because there is information on verification in conjunction with the new technology of which in-plant personnel need to be aware, the NTS Director will contact the Director of the Directives and Economic Analysis Staff (DEAS) and setup a development team. NTS will lead the team assigned to develop the directive. The directive should provide inspection program personnel with any insights into the use or operation of the technology or other information necessary to effectively verify compliance with regulatory requirements in establishments using the new technology. The NTS Director may also be aware that a compliance guide

[1] For the purpose of FSIS, **new technology** is defined as new, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock or poultry or processing of meat, poultry, or egg products.

that the Agency has issued needs to be revised to reflect the availability of the new technology. In such a case, the NTS Director contacts the Technical Analysis Staff (TAS) Director about changes to the compliance guide.

- If the new technology does raise one or more of the four concerns, the NTS Director issues a letter to the submitter stating that a protocol for an in-plant trial is necessary to address the matter about which concerns have been raised by the review. If the in-plant trial requires a waiver of any provision of FSIS' regulations, the submitter would need to request and obtain a waiver from the Agency before proceeding (see section VII. Regulation Waiver).

V. Protocol

When a protocol is received by NTS,

The NTS Program Analyst assigns it a tracking number.

- The NTS Director sends a letter of acknowledgment of receipt of the protocol to the submitter.

- The NTS Director assigns the protocol to an NTS Project Manager. It is the responsibility of the PM to fully understand all facets of the protocol.

VI. Protocol Review Process

The PM and TRT review the protocol using the following questions:

- Does the protocol include
    - a descriptive title and a statement of purpose for the in-plant trial?
    - what is being tested?
    - identified control factors?
    - the name of the sponsor and the name and address of the facility at which the trial will be conducted?
    - a description of the experimental design, including the methods to control bias?
    - the type and frequency of tests, analyses, and measurements to be made?
    - a statement of the statistical methods to be used to analyze the data that is to be generated in the study?
    - an estimate of the amount of time that it will take to conduct the in-plant trial?
    - any applicable research data, such as a literature review?
    - a commitment to make periodic reports on the progress of the investigation, including a commitment to supply data developed to FSIS?
    - the records that will be created during the study?
    - any prior approvals from other Federal agencies?
    - an expected start date and projected completion date?

- Is the protocol inconsistent with any provision of the FSIS regulations? If it is inconsistent with a regulation, see the Section VII. Regulation Waiver.

If the protocol does not include all of the pertinent information, the PM contacts the submitter requesting the missing information.

If the PM determines that the submission is complete, he/she sends the protocol to the appropriate TRT members for review and comment. These members are to be selected based on the scientific and technical expertise needed to address issues raised by the protocol. Comments from the TRT normally are expected within two weeks.

- If the TRT comments identify the need for additional information from the submitter, the PM will prepare and send a letter requesting that information.

- If the PM and the TRT determine that the protocol contains appropriate information, and that the concerns at issue will be addressed by the trial described in the protocol, the PM will recommend that the NTS Director issue a letter advising the submitter that it may proceed with an in-plant trial. Before the NTS Director issues the letter, however, if he/she determines that there is information that would help inspection program personnel to understand the technology or perform their verification function during the course of the trial, he/she will work with the Director of the Directives and Economic Analysis Staff (DEAS) to ensure that such a notice is prepared, issued, and in the hands of relevant inspection program personnel before the in-plant trial starts. This FSIS notice will supply background information on, and verification procedures for, the new technology to the inspection program personnel. The PM will advise the submitter to provide the affected inspection program personnel with training materials and to conduct a pre-in-plant trial training session. The NTS Director's letter will advise the submitter that it should notify the NTS at least two weeks before the in-plant trial is to start to allow NTS to notify all appropriate personnel in FSIS of the beginning of the in-plant trial and to ensure that the FSIS personnel are appropriately prepared to perform their function.

- When the submitter notifies the PM of the planned date for the in-plant trial, the NTS Director issues a letter to the TSC, OFO headquarters, the appropriate DO, the FLS, the IIC, and individuals who served on the TRT. Representatives from OFO headquarters and the NJC are invited by LERD to the pre-in-plant trial training and orientation session.

- If there is not adequate time for FSIS to prepare for the trial before the planned start date, the PM will work with the plant and the FLS and IIC to adjust the start date.

- If the in-plant trial requires a waiver of any provision of FSIS regulations, the trial may not begin until the submitter obtains the waiver. If the in-plant trial does not begin within 90 calendar days, the PM will contact the submitter for information on the status of the in-plant trial. If the submitter responds that it intends to begin the in-plant trial within the next 30 calendar days, then NTS will take no action. If the submitter responds that it has no plans to begin the in-plant trial within 30 days from contact, in the absence of special circumstances, the NTS Director will advise the submitter that permission to proceed with the protocol is revoked, without prejudice.

VII. Regulation Waiver

A. Regulation: Under 9 CFR 303.1(h), 381.3 (b), and 590.10, the Administrator may waive, for limited periods, any provisions of the regulations because there is a public health emergency, or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. However, under these regulations, a waiver cannot be granted if the Administrator determines that the waiver would conflict with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031, et seq.).

B. Waiver: If a waiver is requested, the PM reviews the request to determine whether:

- there is a public health emergency; or

- the request is for experimentation that involves new procedures, equipment, or processing techniques that offer the possibility of facilitating definite improvements. The PM will assess whether the claim that the waiver will result in an improvement has a credible basis.

Moreover, the PM will need to determine whether a waiver will create a situation that is inconsistent with the Agency's humane slaughter regulations; or that conflicts with the provisions of the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031, et seq.).

If the waiver is granted, the PM, in consultation with other OPPED staffs or with the TRT, as appropriate, will review the data that is developed in the trial to verify that the purpose of the waiver is being met.

When the PM completes his/her review and determines that there is an appropriate basis for issuing a waiver, the PM will prepare a waiver letter that states the Agency will waive specific regulations for a limited period of time. The PM will send the waiver letter through the clearance process to the FSIS Administrator for signature.

If the Administrator decides to issue a waiver, a letter granting the waiver will be returned to the PM who will send it to the submitter. The letter will be sent by facsimile and first-class mail to the submitter.

VIII. Verification Process

- The PM should receive from the submitter data throughout the in-plant trial for the Agency to examine and review. Data may take several forms: accredited laboratory results, weekly or monthly summary production reports, ongoing monitoring and verification observations, or the establishment's evaluation reports. If the PM does not receive data, then he/she will contact the submitter to determine why NTS is not receiving data and to determine whether the trial should be suspended or terminated.

- If at any time the PM receives information from inspection program personnel that the in-plant trial is resulting in products that present an increased food safety risk, that the process presents a risk to the safety of inspection program personnel, or that establishment personnel are not following the conditions of the protocol, then the Director of NTS will suspend or terminate the trial.

- During the in-plant trial, the NTS Director may decide to make on-site observations of the new technology in operation. The NTS Director may decide to send an individual or a team to observe the technology.

IX. Evaluation Process

At the conclusion of the in-plant trial, the NTS Project Manager will request a report on the trial from the submitter.

The PM and TRT evaluate the final report to assess whether the relevant concerns about the new technology were conclusively addressed. While this review is being conducted, use of the technology may continue.

After the PM evaluates the final report, the PM will either:

- Recommend additional in-plant trials.

- Recommend the issuance of a "no objection" letter by the NTS Director for the use of the new technology in all FSIS-regulated establishments and explain the basis for such action.

- Recommend the issuance of a conditional "no objection" letter by the Administrator predicated on the submitter submitting a petition for rulemaking to change the regulation or regulations that had been waived to allow the trial to proceed. See Federal Register Notice, **"FSIS Petition Submission and Review Procedures" (58 FR 63570)** published December 2, 1993. The Agency may extend the in-plant trial period while the petition is pending if the Administrator determines that doing so will result in substantial benefit to public health.

X. Petition Received for Change of FSIS Regulations

PM will forward the petition to the FSIS, OPPED, Regulations and Petitions Policy Staff (RPPS). The NTS Director will issue a letter informing the petitioner that the petition has been forwarded to RPPS.

Abbreviations used in this SOP Document:

Directives and Economic Analysis Staff (DEAS)

District Office (DO)

Food Safety and Inspection Service (FSIS)

Frontline Supervisor (FLS)

Inspector-in-charge (IIC)

New Technology Staff (NTS)

Office of Field Operations (OFO)

Office of Policy, Program, and Employee Development (OPPED)

Office of Public Health Science (OPHS)

Program Analysis Staff (PAF)

Project Manager (PM)

Regulations and Petitions Policy Staff (RPPS)

Standard Operating Procedures (SOPs)

Technical Analysis Staff (TAS)

Technical Review Team (TRT)

Technical Service Center (TSC)