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

FSIS DIRECTIVE

10,700.1, Revision 1

6/24/2003

Procedures for New Technology and Experimental Protocols for In-Plant Trials

I. PURPOSE

The purpose of this directive is to inform inspection program personnel about the procedures that the Technology Program Development Staff (TPDS) will follow to notify the field about official meat and poultry establishments and egg products plants that will use new technologies or that will conduct in-plant trials of a new technology.

II. CANCELLATION

10,700.1, dated 4/11/95

III. REFERENCES

9 CFR Parts 317, 318, 381, 590.

IV. REASON FOR REISSUANCE

This directive has been revised in its entirety to inform inspection program personnel about the TPDS staff's procedures for notifying the field about an establishment's use of a new technology or the need for an in-plant trial.

V. BACKGROUND

A. FSIS published new procedures regarding new technology in a Federal Register notice, "FSIS Procedures for Notification of New Technology" (68 FR 6873; 2/18/03) (Attached). The new procedures state that all official establishments (meat, poultry, and egg products) and companies that manufacture and sell technology to official establishments, are to notify FSIS about the use of a new technology.

B. FSIS defines “new technology” as “new, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products”. This definition should not be interpreted to mean that all equipment used in official establishments now has to be approved. This definition does not include new equipment or new models of equipment that performs the same function in essentially the same manner as that routinely used in processing facilities. The definition does include new equipment or new models of equipment if it is used in a novel manner. This directive should not be applied to routine changes in HACCP procedures resulting from reassessment or in response to corrective actions. Additionally, the routine use of common sanitizers or chemicals covered by the Sanitation Performance Standards would not be considered as new technology.

C. Establishments or companies interested in using or selling a new technology should submit documentation to TPDS describing the operation and purpose of the new technology. Within 60 calendar days, TPDS will make every effort to review the document and issue a letter to the establishment or company, with cc:’s to Technical Service Center (TSC) and the appropriate District Office (DO), Front-line Supervisor, and Inspector-in-Charge (IIC), stating either:

1. TPDS does not object to the use of the new technology and the establishment or company may proceed to use or sell the new technology, or

2. TPDS has determined that the use of the new technology could adversely affect product safety, interfere with FSIS inspection procedures, jeopardize the safety of inspection program personnel, or require a waiver of a regulation. In such cases, the letter will inform the establishment or company that a pre-use test is necessary, and that the establishment or company is to send TPDS a pre-use test protocol.

VI. FIELD NOTIFICATION BY TPDS

A. TPDS will issue a weekly new technology report by e-mail to the DOs; Deputy Administrator and Associate Administrator for Field Operations (FO); TSC Director; Front-line Supervisors; Deputy Administrator for Program Evaluation, Enforcement, and Review; and other program employees that details the requests received and pending, the issued no objection letters, protocols required, and protocols approved.

B. If in-plant test protocols are needed, TPDS sends correspondence approving the protocol to the establishment or company, with cc’s to the TSC and the appropriate DO, Front-line Supervisor, and IIC. TPDS also will send e-mails to the appropriate DO, Front-line Supervisor, and IIC advising them of the date of the trial two weeks before it is to begin. In the approval letter, TPDS informs the establishment that the protocol submitter will provide the affected inspection program personnel with training materials and conduct a pre-in-plant trial training session. Representatives from FO and the National Joint Council are to be invited to the pre-in-plant trial training session.

VII. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

As specified in FSIS Directive 5000.1, Revision 1, the Rules of Practice (9 CFR 500), and 9 CFR Part 590, inspection program personnel are to take appropriate action if the use of the new technology leads to insanitary conditions or to the adulteration of product.

Direct questions to the Technical Service Center.

/s/ Philip S. Derfler

Assistant Administrator
Office of Policy and Program Development

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00-011N]

FSIS Procedures for Notification of New Technology

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing new procedures for meat and poultry official establishments, egg products official plants, and companies that manufacture and sell technology to official establishments and plants, to notify the Agency of any new technology intended for use in official establishments and plants, so that the Agency has an opportunity to decide whether the new technology requires a pre-use review. If a new technology could affect product safety, FSIS regulations, inspection procedures, or the safety of Federal inspection program personnel, FSIS will advise the firm that a pre-use review is necessary. The Agency will cancel FSIS Directive 10,700.1, "Guidelines For Preparing and Submitting Experimental Protocols for In-Plant Trials of New Technologies and Procedures." "Guidelines For Preparing Experimental Protocols for In-plant Trials of New Technologies and Procedures," and issue a revised directive. FSIS is requesting comments on these new procedures. The Agency believes that facilitation of the use of new technology represents an important means of improving the safety of meat, poultry, and egg products.

DATES: This notice is effective February 11, 2003. The Agency must receive comments by April 14, 2003.

ADDRESSES: Submit one original and two copies of written comments within the scope of the rulemaking to the FSIS Docket Room, Docket 00-011N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250-3700. All comments submitted in response to this proposal will be available for public inspection in the Docket Room Office between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Guidance material for completing protocols will be available on the Internet at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.usda.gov and in the Docket Room.

FOR FURTHER INFORMATION: For further information contact Charles Edwards, Director, Technology Program Development Staff, Office of Policy, Program Development, and Evaluation, FSIS, U.S. Department of Agriculture, Room 112, Cotton Annex Building, 300 12th Street, SW., Washington, DC 20250-3700; telephone (202) 205-0675, fax (202) 205-0080.

SUPPLEMENTARY INFORMATION:

Background

On May 25, 1995, FSIS published a notice in the Federal Register, "Guidelines for Preparing and Submitting Experimental Protocols for In-Plant Trials of New Technologies and Procedures"(60 FR 27714). This notice stated that the Agency is encouraging industry technological innovation in the meat and poultry industry. At the same time, FSIS established a single entry point for in-plant research protocols.

With the issuance of the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) System final rule (61 FR 38806) on July 25, 1996, the Agency shifted away from a command and control approach to one that gives industry greater flexibility to innovate in order to meet food safety requirements.

On October 20, 1999, FSIS published the Sanitation Requirements final rule (64 FR 56400), which was intended to make sanitation requirements less prescriptive and to allow for more innovation on the part of industry.

New technologies have resulted in significant improvements in the safety of meat and poultry in recent years. Steam vacuums, steam pasteurization, and antimicrobials are all examples of advances in food safety technology that have occurred in recent years. The Agency is desirous of seeing these kinds of advances continue.

Therefore, in the spirit of providing an opportunity for further technological advances and innovations, FSIS is establishing new, flexible procedures to actively encourage the development and use of new technologies in meat and poultry establishments and egg products plants. These new procedures provide for a central location in the Agency to handle new technology, instead of having program inspection personnel address individual instances and questions as they arise in establishments and plants. In addition, these procedures are designed to eliminate unnecessary delays and to establish uniform acceptance criteria to facilitate the application of new technology. By screening the initial notifications of new technology, FSIS will eliminate unnecessary submissions of protocols for pre-use review. Consequently, the Agency is announcing its procedures for submitting notifications of new technologies by the meat, poultry, and egg products industries. FSIS will also cancel FSIS Directive 10,700.1, "Guidelines For Preparing Experimental Protocols for In-plant Trials of New Technologies and Procedures," and issue a revised directive to explain these new procedures to inspection program personnel.

FSIS defines "new technology" as new, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products. The Agency has a regulatory interest in a new technology if the new technology could affect product safety, inspection procedures, or inspection program personnel safety, or if it would require a waiver of a regulation. Substances used as new technology must also meet the requirements for safety and suitability under the Agency's food ingredient approval process. While FDA has the responsibility for determining the safety of food ingredients and additives, as well as prescribing safe conditions of use, FSIS has the authority to determine that new ingredients and new uses of ingredients are suitable for use in meat and poultry products.

Notification

It is important that establishments and plants that are interested in introducing new technology into their operations pursue the introduction in an appropriate manner. Failure to do so is likely to create delays in the introduction of the new technology and interruption in establishment or plant operations. Consequently, firms that are interested in using or selling a new technology should submit documentation to the FSIS Technology Program Development Staff (see address above), describing the operation and purpose of the new technology. The document should explain whether why the new technology will not:

adversely affect the safety of the product,

jeopardize the safety of Federal inspection program personnel, or

interfere with inspection procedures.

The notification also should state whether the technology will require a waiver of any Agency regulation and, if it will, identify the regulation and explain why a waiver would be appropriate.

FSIS will make every effort to review the document and notify the firm within 60 calendar days as to whether the Agency needs to review the new technology, or whether the establishment, plant, or company may proceed to use or sell it. If FSIS determines that the new technology will not have any of the effects listed above, the Agency will issue a letter of no objection to the use of the new technology to the firm.

If the establishment or plant proceeds with the use of the new technology before the 60 day period has expired or without receiving a no objection notice from FSIS, then the Agency will take appropriate action the product processed using the new technology could be deemed to be adulterated (see, e.g., 21 U.S.C. 453(g)(4); 601(m)(4); and 1033(a)(4)).

If FSIS determines that the proposed use of the new technology could adversely affect product safety, interfere with FSIS inspection procedures, jeopardize the safety of inspection program personnel, or require a waiver of a regulation, then the Agency will so inform the firm. Following are two examples of new technologies that could adversely affect product safety, inspection procedures, inspection program personnel safety, or Agency regulations: A new technology that changed the line speeds for poultry would require a waiver to the regulations for a limited time to test the new technology (see 9 CFR 381.67 and 381.68). Devices capable of detecting and sorting contaminated carcasses might also alter the method of carcass presentation to inspection program personnel and thus probably require changes to current inspection procedures.

FSIS will advise the establishment, plant, or company of the information that it needs for full pre-use review of the new technology, including whether a pre-use review of the new technology, including an in-plant trial of the new technology is necessary. An in-plant trial is necessary when the Agency needs data to perform a more informed review of the new technology. If an in-plant trial is necessary, FSIS will request that the firm submit a protocol that is designed to collect relevant data to support the use of the new

technology.

Firms that recognize that the use of their new technologyy will likely raise questions about its effects on could affect product safety, the safety of inspection program personnel, or inspection procedures, or that recognize that their new technology is not consistent with FSIS the regulations, may simply contact FSIS about developing information that the Agency will need to make an informed judgment on the new technology a protocol instead of first submitting a notification.

Pre-Use Review and Protocol

The protocol should contain , as applicable, the following information:

A descriptive title and statement of purpose for the in-plant trial.

The name of the sponsor and the name and address of the facility at which the trial is to be conducted.

A description of the experimental design, including the methods for control of bias.

Identification of the test subjects and control articles.

The type and frequency of tests, analyses, and measurements to be made.

The records to be maintained.

A statement of the proposed statistical methods to be used to analyze the data that are to be generated in the study.

A time period for the in-plant trial.

Any applicable research data.

Any prior approvals from other Federal agencies.

All changes in, or revisions of, an approved protocol must be approved by FSIS and be documented and maintained with the protocol.

If the in-plant trial requires a waiver of any provision of FSIS'' regulations, the submitter must request and obtain the waiver receive written permission from the Agency before proceeding. FSIS regulations (specifically 9 CFR 303.1(h), 381.3(b), and 590.10) authorize the Administrator to waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. No waiver can be granted if the new technology 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, based on the in-plant trial, the submitter plans to petition FSIS for a change in the Agency's regulations to permit the use of the new technology, then the submitter should collect information that will assist the Agency in performing rulemaking analyses required by law and executive orders, such as Executive Order 12866 and the Regulatory

Flexibility Act.

FSIS will expect the submitter to provide data throughout the duration of the in-plant trial for the Agency to examine. Data may take several forms: laboratory results, weekly or monthly summary production reports, and or evaluations from inspection program personnel. If, at any time, the Agency determines that the in-plant trial results in product being produced that presents an increased risk to food safety or to the safety of inspection program personnel safety, the trial will be suspended or ended.

If requested by FSIS, the submitter should provide an orientation session for employees of the establishment on each shift before the start of each in-plant trial. The Agency reserves the right to review all data collected and to conduct on-site observations during an in-plant trial.

At the conclusion of the in-plant trial, the establishment or plant will is expected to submit a final report to the Agency and, if applicable, a petition requesting rulemaking to change the pertinent provisions of the regulations. See FSIS Notice, ``FSIS Petition Submission and Review Procedures'' (58 FR 63570), published December 2, 1993. The Agency may extend the in-plant trial period pending action on the petition.

FSIS will review the final report on the in-plant trial. The Agency's evaluation of the final report could result in a decision to initiate rulemaking in response to a petition, a recommendation of additional in-plant trials, or either acceptance or rejection by FSIS of the use of the new technology.

If the Agency rejects the use of the new technology, the establishment or plant would have the option to submit a revised protocol to address any problems areas identified by FSIS. The Agency will then begin a new review of the revised protocol.

FSIS is requesting comment on these procedures.

Paperwork Analysis

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this notice in accordance with the Paperwork Reduction Act and submitted an information collection request to the Office of Management Budget for emergency clearance. FSIS is publishing procedures for meat and poultry official establishments, egg products plants, and companies that manufacture and sell technology to official establishments to notify the Agency of new technology that they propose to use in meat and poultry establishments or egg products plants.

If the new technology could affect FSIS regulations, product safety, inspection procedures, or the safety of Federal inspection program personnel, then the establishment or plant would need to submit a written protocol to the Agency. As part of this process, the submitter will have be expected to conduct in-plant trials of the new technology. The submitter will need to provide data to FSIS throughout the duration of the in-plant trial for the Agency to examine. Data may take several forms: laboratory results, weekly or monthly summary production reports, and evaluations from inspection program personnel.

Estimate of Burden: FSIS estimates that it will take 8 hours for establishments to answer all of FSIS'' questions for the notification

of intent to use new technologies. If the notification involves the submission of a protocol for FSIS approval, FSIS estimates that this will take an additional 80 hours for the submitter to develop. For in-plant trials, FSIS estimates that the data collection and recordkeeping involved will take establishments 10 hours per week over an average of an 8-week (2-month) period.

Respondents: Meat, Poultry and Egg Products establishments, equipment manufacturers.
Estimated Number of Respondents: 250 requests for new technologies. 40 requests for new technologies that require a protocol.
Estimated Number of Responses per Respondent: 1.
Estimated Total Annual Burden on Respondents: 5,440.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Specialist, Food Safety and Inspection Service, USDA, Room 109 Cotton Annex, Washington, DC 20250-3700.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the method and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond; including through use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to John O'Connell, see the address above, and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) Washington, DC 20253.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and make copies of this Federal Register publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the Internet at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fsis.usda.gov.

The update is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information contact the Congressional and Public Affairs Office, at (202) 720-9113. To be added to the free e-mail subscription service (Listserv) go to the "Constituent Update" page on the Internet at http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fsis.usda.gov/ oa/update/update.htm. Click on the "Subscribe to the Constituent Update Listserv" link, then fill out and submit the form.

Done at Washington, DC, on: February 6, 2003.
Garry L. McKee,
Administrator.