

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://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