

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 technology 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 be 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