

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

FSIS DIRECTIVE	5020.2	10/24/17
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THE NEW TECHNOLOGY REVIEW PROCESS

I. PURPOSE

A. This directive provides procedures that FSIS headquarters personnel are to follow when an establishment, egg products plant, or company submits a notification to inform the Agency of its intent to use a new technology, a new technology protocol for Agency review before implementation, a new technology protocol requesting to conduct an in-plant trial, or a validation protocol for Agency review before in-plant validation. New technology includes the use of substances in FSIS regulated products as well as technologies that require a waiver.

B. This directive also facilitates improved coordination and uniformity among the following program areas involved in the review of new technology:

1. Office of Policy and Program Development (OPPD);
2. Office of Field Operations (OFO), District Offices (DO) and inspection program personnel (IPP);
3. Office of Public Health Science (OPHS);
4. Office of Management (OM), Labor and Employee Relations Division (LERD);
5. OM, Employee, Safety, Health and Wellness Staff (ESHWS);
6. Office of Data Integration and Food Protection (ODIFP); and
7. Other FSIS program personnel as assigned.

II. BACKGROUND

A. On February 11, 2003, FSIS published the *Federal Register* notice, "[FSIS Procedures for Notification of New Technology](#)" (68 FR 6873) outlining new submission procedures for all official establishments (meat, poultry, and egg products) and companies that manufacture and sell technology to official establishments. As FSIS explained in that notice, 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.

B. The *Federal Register* notice advised that notifications should describe the intended use, operation, and purpose of a new technology in official meat and poultry establishments or egg product plants and establishments. The notice also explained that the notification may also include a protocol. A protocol is a written document that describes in detail the standardized methods by which the proposed new technology will be tested, implemented, and evaluated.

C. The [FSIS Compliance Guideline: Procedures for New Technology Notifications and Protocols](#) provides compliance guidance to industry concerning the procedures for preparing and submitting new technology notifications and protocols to the Agency. FSIS reviews these submissions to determine whether the new technology could affect product safety, FSIS regulations, inspection procedures, and the safety of Federal IPP.

D. [FSIS Directive 5020.1 Verification Activities For The Use of New Technology In Meat and Poultry Establishments and Egg Product Plants](#) provides instructions to IPP on how they are to verify that a meat or poultry establishment or egg products plant is following the procedures outlined in its protocols for new technology or the procedures agreed to as a condition of a waiver of regulatory requirements.

E. The [Memorandum of Understanding \(MOU\) 225-00-2000 Amendment 1](#) establishes the working relationship followed by FSIS and the Food and Drug Administration (FDA) in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by FDA and intended for use in the production of meat, poultry, and egg products regulated by FSIS.

III. NEW TECHNOLOGY OVERVIEW

A. A notification may contain protocols for:

1. New ingredients or antimicrobials (including new uses or new use levels for currently approved ingredients or antimicrobials);
2. New processes or procedures;
3. On-line or off-line reprocessing systems; and
4. Alternative procedures for in-plant trials or waived regulations.

B. FSIS defines a “new technology” as a new application of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or the processing of meat, poultry, or egg products. The Risk Innovations and Management Staff (RIMS) in the OPPD works closely with other program areas in the Agency to review new technology protocols to determine whether the new technology:

1. Is deemed suitable for use in meat, poultry or egg products;
2. Affects product safety;
3. Violates FSIS regulations;
4. Interferes with inspection procedures; or
5. Jeopardizes the safety of IPP.

C. New technology also includes alternative procedures in lieu of waived regulations. This includes waivers for establishments that participate in the *Salmonella* Initiative Program (SIP). Under [9 CFR 303.1\(h\)](#), [9 CFR 381.3\(b\)](#), and [9 CFR 590.10](#), the FSIS Administrator may, in specific cases, waive any provisions of the regulations for limited periods to permit experimentation (in-plant trial) so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. Waivers of regulations may be granted, provided that the alternative procedures are not in conflict with the

purposes or provisions of the Federal Meat Inspection Act (FMIA) (21 USC 601), Poultry Products Inspection Act (PPIA) (21 USC 451), or Egg Products Inspection Acts (EPIA) (21 USC 1031). At the completion of the in-plant trial, or when the submitter has sufficient scientific justification, the submitter is to petition the agency to amend or repeal the regulation waived.

D. New technology also includes new substances or new applications of substances ([FSIS Procedures for Notification of New Technology](#) (68 FR 6873)). FSIS defines ingredients as any substances added to food, the intended use of which results or may reasonably be expected to result in it becoming a component, directly or indirectly, or otherwise affecting the characteristics of food. These include substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, including any source of radiation intended for any such use.

E. Substances recognized as safe and suitable under the conditions of their intended use, such as those listed in [9 CFR 424.21\(c\)](#) are not subject to this notification process. Substances that have gone through the new technology review process and are recognized as safe and suitable under the conditions of their intended use, are listed in [FSIS Directive 7120.1](#), *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Product*. [FSIS Directive 7120.1](#) provides an up-to-date list of substances that may be used in the production of meat, poultry, and egg products. It also lists the approved On-Line Reprocessing (OLR) and Off-Line Reprocessing (OFLR) Antimicrobial Intervention Systems. However, new uses of previously approved substances, including changes in concentration or application methods, are to be reviewed for safety and suitability by FDA and FSIS per [MOU 225-00-2000 Amendment 1](#), as described in the Background section above.

F. If, after review, the Agency does not object to the proposed use of a new technology, RIMS sends the submitter a no objection letter (NOL) for the use of the technology. The NOL describes the technology, intended use, and limitations on the conditions of use.

G. The OFO receives copies of the NOL. For in-plant trials or in-plant validation, the NOL includes instructions for the establishment to notify RIMS and IPP two weeks prior to the implementation date. Upon notification, the Inspector-in-Charge may request RIMS to arrange orientation of the in-plant trial or validation procedures with the manufacturer or establishment prior to implementation. For other technologies (including ingredients), establishments are to reassess the adequacy of the HACCP plan in accordance with [9 CFR 417.4\(a\)\(3\)](#).

IV. NOTIFICATION RECEIVED BY RIMS

A. When RIMS receives a notification from an establishment or company intending to employ a new technology an electronic file is established and the notification receives a log number for tracking. Then it is assigned to a Project Manager (PM) and a notice, providing the project manager's contact information and the log number, is sent to the submitter acknowledging receipt of the submission.

B. The PM is the primary contact with the submitter and coordinates the following activities of the Technical Review Team (TRT) throughout the review process:

1. Prepares the review plan with the team;
2. Monitors the status of review activities;
3. Maintains up-to-date information in the electronic file; and
4. Facilitates actions to solve problems.

V. NOTIFICATION REVIEW PROCESS

- A. The PM reviews the notification to determine whether the submission meets the definition of new technology.
- B. The PM reviews the notification for completeness. The notification is to include a detailed description of what the technology is intended to accomplish as well as the beneficial or adverse effects that the technology is expected to have on products.
- C. The PM reviews the notification to ensure it includes all relevant scientific and technical support. The PM is to be aware that supporting documentation may include theoretical principles, expert advice from processing authorities, scientific or technical data, product safety data sheets (SDS), peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that the proposed use can perform as expected to achieve the intended objective. Documentation may also include approvals, if applicable, by other Federal agencies.
- D. If the notification does not have sufficient supporting documentation or scientific or technical support, the PM will send written notices or emails requesting additional information or clarification to the submitter until sufficient information is received.
- E. The PM is to serve as the conduit between the TRT, Agency, and the submitter. If the TRT or Agency requests additional information or needs clarification, the PM is to contact the submitter.
- F. When the notification is complete, the PM is to determine the scientific and technical expertise needed for an adequate review. Section VI: Primary Review Functions of the Technical Review Team lists each of the program areas that may serve on the TRT and its primary review function for a new technology submission.

VI. PRIMARY REVIEW FUNCTIONS OF THE TECHNICAL REVIEW TEAM

- A. Once notified, the TRT members are to review the submission and provide comments or concurrence within two weeks. Each team member uses their expertise to determine if the new technology:
1. Adversely affects the safety of the product and is it suitable for use in meat, poultry, and egg product;
 2. Jeopardizes the safety of Federal IPP;
 3. Interferes with inspection procedures; or
 4. Requires a waiver of any Agency regulation.
- B. The TRT members are to work collaboratively to determine whether the submission includes a method to document the performance of the new technology so the resulting data can be monitored and analyzed. The TRTs consist of members from the following program areas:
1. ODIFP reviews applicable notifications and protocols for supporting documentation to determine whether:
 - a. The statistical methods to be used to analyze the data are included;
 - b. The sampling plan is statistically valid; and

- c. The sampling characteristics are described, (e.g., sample size and adequacy, for the hypothesis under investigation, and whether the selection of samples is conducted appropriately (i.e., to be representative of the population of interest)).
2. OFO reviews submissions for new processes or procedures that may interfere with inspection activities. OFO may also consult with OM to determine if the technology impinges on the Labor Management Agreement.
3. OPHS-Science Staff (Microbiologists, Chemists, and Toxicologists) assess the adequacy of the scientific information, the proposed study or protocols, and methods used. The Science Staff will analyze the microbiological, chemical, and toxicological data to ensure the conclusions drawn are appropriate from the studies conducted.
4. OPPD establishes the data analysis plan for establishments operating under a waiver. The data generated during the in-plant trial is used to support their petition to amend or repeal the waived regulation ([9 CFR 392](#)). For all other new technology submissions, including those with waivers, OPPD determines if the technology meets the regulatory requirements, including whether the technology:
 - a. Results in an adulterated product or one that misleads consumers;
 - b. Requires a waiver of the provisions of the regulations;
 - c. Prompts the Agency to conduct a cost benefits analysis;
 - d. Meets labeling requirements;
 - e. Is consistent with food standards of identity; or
 - f. Impacts FSIS inspection procedures.
5. OM ensures safe and healthy working conditions as a part of the overall inspection process. They provide technical advice and support in identifying, assessing and minimizing workplace hazards that can cause illness, impaired health, or significant discomfort as a result of exposure to chemical, physical, and biological agents. OM also reviews to determine if the technology impinges on the Labor Management Agreement.
6. FDA is authorized to determine the safety of substances (including Generally Recognized as Safe (GRAS) substances, food additives, and color additives), as well as prescribing safe conditions of use. However, while FDA has the responsibility for determining the safety of substances, FSIS still retains, under the tenets of the FMIA, PPIA, and EPIA, the authority to determine if new substances and new uses of previously approved substances are suitable for use in meat and poultry products. Suitability relates to the effectiveness of the substance in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers.

VII. REVIEW OUTCOMES

A. No Objection Letter (NOL): The RIMS Director will send a letter stating that FSIS has no objection to the use of the technology (provided that implementation is according to all parameters set forth by the protocol), if the TRT determines after the review, that the technology will not adversely affect product, personnel safety, inspection procedures, or be inconsistent with any Agency regulation. In the case of ingredients, on-line reprocessing or off-line reprocessing submissions, the technology is listed in [FSIS Directive 7120.1](#).

B. Grant Permission Letter: The Agency issues letters granting permission to gather scientific support through in-plant trials when a technology is not established in literature or is applied in an unusual way (modifying critical operating parameters from the literature). In-plant trials are experiments conducted to test protocols during commercial conditions. The experiments may take place in an official establishment according to the provisions of the grant permission letter.

C. Waiver Letter: If the in-plant trial is associated with a waiver, RIMS issues an NOL granting approval of the waiver until the regulation is amended.

D. Temporary Suspension: RIMS may put a submission on a temporary hold, permitting the submitter time to gather additional scientific support (e.g., time to conduct experiments in a lab or test facility).

E. Withdrawn: A submitter may request to withdraw their submission from the RIMS review process. If withdrawn, a submitter may resubmit to the Agency at any time.

F. Letter to File (Memo To File): RIMS may create a letter to file when the Agency amends [FSIS Directive 7120.1](#) for corrections, discovers new ingredients or new uses of the existing ingredients during literature reviews.

G. Not a New Technology: If after the initial RIMS review, RIMS determines that the technology is not a new technology, or if it is not a new use of an existing technology, the RIMS Director sends a written notice to the submitter stating that the proposed technology is not considered a new technology and the technology may be used in accordance with FSIS regulations listed in the letter.

VIII. FSIS WEBSITE

The Agency posts brief descriptions of all new technologies in the [New Technology Table](#) on the FSIS Website. IPP can find a summary of the verification activities, including the conditions of use, for each new technology and waivers, on [Inside FSIS](#) (level 2-E-Authentication is required to access this site). Once a safe and suitable determination is made for the use of a substance in meat, poultry or egg products, it is added to [FSIS Directive 7120.1](#). On-line and off-line reprocessing systems are also listed in [FSIS Directive 7120.1](#).

IX. QUESTIONS

Refer questions regarding a specific submission to the project manager from RIMS to which it was assigned. Refer general questions regarding this directive to RIMS through [askFSIS](#). When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided.

Subject Field: Enter **Directive 5020.2**

Question Field: **Enter your question with as much detail as possible.**

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select an item under **New Technology** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



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