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

FSIS DIRECTIVE

5020.2
Rev 1

7/29/22

THE TECHNICAL REVIEW PROCESS

I. PURPOSE

A. This directive provides procedures that FSIS headquarters personnel are to follow when an establishment or company submits a request for the Agency to review or evaluate a new technology (including new ingredients and antimicrobials), an on-line reprocessing (OLR) or off-line reprocessing (OFLR) system, a regulatory waiver request, a protocol requesting to conduct an in-plant trial, or a validation protocol for Agency review before in-plant validation. This revision updates and clarifies the procedural responsibilities of the program offices that participate in the technical review process.

B. This directive also facilitates improved coordination and uniformity among the following program areas involved in the Technical Review Team (TRT):

1. Office of Policy and Program Development (OPPD);
2. Office of Field Operations (OFO);
3. Office of Public Health Science (OPHS);
4. Office of Management (OM);
5. Office of Planning, Analysis and Risk Management (OPARM); and
6. Other FSIS program personnel as assigned.

KEY POINTS:

- *Describes the types of submissions evaluated by the Technical Review Process.*
- *Provides a summary of the roles and responsibilities of all FSIS headquarters personnel participating in the Technical Review Process.*
- *Describes the joint review agreement between the FSIS and the U.S. Food and Drug Administration (FDA) established by* Memorandum of Understanding (MOU) 225-00-2000 Amendment 1 *(MOU 225-00-2000 Amendment 1).*
- *Describes the steps and outcomes of the Technical Review Process.*
- *Provides instructions on how the Project Manager (PM) and TRT members are to document their assessment of support associated with requests and those that require a waiver from regulatory requirements.*

II. CANCELLATION

FSIS Directive 5020.2, *The New Technology Review Process*, 10/24/17

III. BACKGROUND

A. FSIS regulations (specifically 9 CFR 303.1(h), 9 CFR 381.3(b), and 9 CFR 590.10) authorize the Administrator to waive, for limited periods, any provisions of the regulations 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 (21 U.S.C. 601 *et seq.*), Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

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

C. The FSIS Guideline: *Procedures for New Technology Notifications and Protocols* provides guidance to industry concerning the procedures for preparing and submitting new ingredient requests, waiver requests, and protocols to the Agency. FSIS reviews these submissions to determine whether product safety, FSIS regulations, inspection procedures, and the safety of Federal Inspection Program Personnel (IPP) could be affected.

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 to verify that meat and poultry establishments and egg products plants are following procedures for the implementation of a new technology (including new ingredients), an in-plant trial, or a regulatory waiver.

E. Memorandum of Understanding (MOU) 225-00-2000 Amendment 1 establishes the process that FSIS and the FDA use to respond to requests for sanctioning 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. FDA is authorized to determine the safety of substances (including Generally Recognized as Safe, 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 has the authority to determine if new substances and new uses of previously approved substances are suitable for use in meat and poultry products. FSIS defines ingredients as any substances added to food with an intended use that results in it being a component, 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.

IV. TECHNICAL REVIEW PROCESS OVERVIEW

A. FSIS uses the technical review process to evaluate:

1. New ingredients or antimicrobials (including new uses or new use levels for currently approved ingredients or antimicrobials);

2. OLR or OFLR systems;

3. In-plant trials or regulatory waivers, including waivers for establishments that participate in the Salmonella Initiative Program; and

4. Validation protocols.

B. The technical review process is managed by the OPPD, Risk Management and Innovations Staff (RMIS). When a request is received, an electronic record with a log number for tracking is created and assigned a PM. The PM receives notification, all associated files, and the submitter's contact information. A notice is also sent to the submitter acknowledging receipt of the request, providing the log number and the PM's contact information.

C. The PM is the primary contact with the submitter and coordinates the following activities of the 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 and documents the TRT members' assessments of criteria for all submission types in the electronic file;

4. Facilitates actions to resolve correspondence between the submitter and the TRT;

5. Drafts and clears the final decision and communicates the outcome of the review.

D. The RMIS works closely with other program areas in the Agency to review submissions and determine whether the proposed new technology, OLR or OFLR system, regulatory waiver, in-plant trial protocol, or validation protocol:

1. Affects product safety;

2. Violates FSIS regulations;

3. Interferes with inspection procedures;

4. Jeopardizes the safety of IPP; or

5. Is deemed suitable for use in meat, poultry, or egg products.

E. 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.

1. 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 technical review process. The latest substances that have gone through the technical 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 Products.*

2. 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 OLR and 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. A complete listing of approved substances and OLR and OFLR Antimicrobial Intervention Systems may be found on the FSIS website.

F. FSIS will make every effort to review the submission and respond within 60 calendar days for new technology (including new ingredients and antimicrobials), OLR and OFLR system, in-plant trial, and validation protocol requests, or 90 calendar days for regulatory waiver requests.

G. If, after review, the Agency does not object to the proposed new technology, protocol for in-plant trial, regulatory waiver, or validation protocol request, RMIS issues the submitter a letter describing its determination.

V. PRIMARY FUNCTIONS OF THE PROJECT MANAGER

A. The PM reviews the submission to determine whether the submission requires technical review. If it does not, the PM drafts a letter describing the determination.

B. If the submission requires technical review, the PM reviews the submission for completeness by verifying the submission includes all relevant written Hazard Analysis and Critical Control Point (HACCP) system programs and scientific and technical support. Supporting documentation may include theoretical principles, expert advice from processing authorities, scientific or technical data, product safety data sheets, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that the proposed use or alternative procedures can perform as expected to achieve the intended objective. Documentation may also include approvals, if applicable, by other Federal agencies.

C. If the submission does not have sufficient supporting documentation as well as scientific or technical support, the PM coordinates with the submitter until all questions and concerns are adequately addressed with sufficient information needed to conduct a technical review with a TRT.

D. Once the submission is complete, the PM determines the scientific and technical expertise needed for a comprehensive review and serves as the conduit between the TRT and the submitter. If additional information is requested or clarification is needed, the PM coordinates with the submitter.

E. During the review process, the PM prepares and clears correspondence. The PM ensures that the electronic record is updated regularly, and that all correspondence and additional documentation is uploaded when the submission is closed.

F. After RMIS management clearance, the PM sends the correspondence to the submitter, uploads it to the electronic file, and closes out the submission using the appropriate resolution.

G. In circumstances requiring revocation of a regulatory waiver, the PM assembles all documentation supporting the basis for revocation and reconvenes the TRT. An establishment may lose its ability to operate under waived regulatory requirements when it has demonstrated an inability or unwillingness to implement and maintain compliance with alternative procedures used *in lieu of* regulatory requirements granted under 9 CFR 303.1(h), 9 CFR 381.3(b), or 9 CFR 590.10 (temporary waiver of regulatory requirements). This may include repetitive non-compliance with regulatory waiver requirements, loss of process control, or failure to comply with the non-regulatory terms of the regulatory waiver letter. The TRT reviews the supporting documentation and together decides whether to take an action of revocation and rescind the establishment's privilege to operate under the regulatory waiver. If the TRT makes a determination to terminate the waiver, the PM:

1. Drafts the letter of revocation and clears it with the TRT, RMIS management, the OPPD Assistant Administrator, and the Office of the Administrator;

2. Updates the original electronic record associated with the waiver with all revocation documents and distributes the revocation letter to the establishment and original cc list; and

3. Facilitates any meetings with the plant management and updates the Public Health Information System waiver record to show the date on which the waiver was revoked.

H. At the conclusion of an in-plant trial, the PM reconvenes the TRT to review the results provided by the submitter in accordance with Section VI. After the TRT makes a determination, the PM drafts the final No Objection Letter (NOL), clears it with the TRT and RMIS management, and updates the original electronic record associated with the in-plant trial.

I. If the submission contains worker safety information, the PM will ensure through RMIS management that the information is shared with Department of Labor's Occupational Safety and Health Administration and Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health, as appropriate.

VI. PRIMARY FUNCTIONS OF THE TECHINCAL REVIEW TEAM

A. TRT members review the submission and provide comments, concurrence, or nonconcurrence within 2 weeks. In addition, to document their self-assessment, each TRT member provides a written rationale in support of their determination, which includes support considered and any analysis performed. Each team member uses their expertise to evaluate the submission for the criteria in Section IV: Technical Review Process Overview.

B. The TRT works collaboratively to review the submission and consists of members from the following program areas: *Note: For in-plant trials and requests involving the waiving of regulations, the TRT is to include members from the OFO headquarters, the respective OFO district, and the OPARM.

1. OPARM reviews applicable submissions 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 to assess whether new processes or procedures interfere with inspection activities and recommends inspection verification activities of alternative procedures and processes.

3. OPHS assesses the adequacy of the scientific information, the proposed study or protocols, and methods used. The OPHS subject matter experts will analyze the microbiological, chemical, and toxicological data to ensure the conclusions drawn from the studies conducted are appropriate.

4. OPPD establishes the data analysis plan for establishments operating under a waiver. The data generated during the waiver period is used to evaluate whether changes to the waived regulation(s) are supported (9 CFR 392). For all submissions, including those requiring 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-benefit analysis;

d. Meets labeling requirements;

e. Is consistent with food standards of identity; and

f. Impacts FSIS inspection procedures.

5. OM ensures safe and healthy working conditions for FSIS personnel 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 or results in a change to conditions of employment.

VII. REVIEW OUTCOMES

A. NOL: The RMIS Director issues a letter to the submitter stating that FSIS has no objection to the use of the technology (provided that implementation is according to all parameters set forth by the submission), and the OFO also receives copies of the NOL. This happens once the TRT determines, that the technology will not adversely affect the product, personnel safety, inspection procedures, or be inconsistent with any Agency regulation. In the case of ingredients, OLR, and OFLR 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 has not been 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. For in-plant trials, the NOL includes instructions for the establishment to notify RMIS and IPP 2 weeks prior to the implementation date. In addition to the letter, a summary of the verification activities, including the conditions of use for the technology, are sent to the OFO District Office and disseminated to the appropriate IPP prior to implementation. Upon notification, the OFO may request RMIS to arrange orientation of the in-plant trial or validation procedures with the manufacturer or establishment prior to implementation.

C. Waiver Letter: If a submission for a regulatory waiver request is approved, the RMIS Director issues a letter granting approval of the use of an alternative procedure *in lieu of* a regulatory requirement. In addition to the letter, a summary of the verification activities including the conditions of use for the waiver, are sent to the OFO District Office and disseminated to the appropriate IPP prior to implementation. Upon notification, the OFO may request RMIS to arrange orientation of the waiver procedures with the establishment prior to implementation. If a waiver request is not granted, a written notice outlining the basis of the decision is issued to the submitter. In the case of a waiver revocation, see Section V.

D. Temporary Submission Suspension: RMIS 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). Submissions may also be suspended if submitters are unresponsive (longer than 14 days) during the technical review process.

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

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

G. Not a New Technology: If it is determined that the submission does not fit under new technology, the RMIS 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 current FSIS regulations, as listed in the letter.

VIII. FSIS WEBSITE

The Agency posts brief descriptions of the recent new technologies in the New Technology Table on the FSIS website. 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. An additional list of substances recognized as safe and suitable is also provided in 9 CFR 424.21(c). OLR and OFLR are listed in FSIS Directive 7120.1. A complete listing of approved substances and OLR and OFLR Antimicrobial Intervention Systems may be found on the FSIS website.

IX. QUESTIONS

Refer questions regarding a specific submission to the project manager from RMIS to which it was assigned. Refer general questions regarding this directive as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select **New Technology**, Innovations for the inquiry type.

NOTE: Refer to FSIS Directive 5,620.1, *Using askFSIS*, for additional information on submitting questions.

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