FSIS Compliance Guideline Procedures for New Technology Notifications and Protocols

April 2015

This guideline is designed to help manufacturers and users of new technology in FSIS-regulated establishments:

- Understand how FSIS defines New Technology
- Develop a New Technology notification
- Develop a New Technology protocol

USDA-FSIS

Preface

What is the purpose of this Compliance Guideline?

The purpose of this document is to provide guidance concerning the procedures for preparing and submitting a new technology notification and protocol to the Agency. New technology notification provides FSIS an opportunity to determine whether new technology could affect product safety, FSIS regulations, inspection procedures, or the safety of Federal inspection program personal (IPP). This document replaces previous versions of the Guidance Procedures for Notification and Protocol Submission of New Technology.

It is important to note that this Guideline represents FSIS's current thinking on this topic, and FSIS encourages manufacturers and users of new technology in FSIS regulated establishments to make use of it.

Who is this guideline designed for?

This guidance is designed for all manufacturers and users of new technology in FSIS regulated establishments.

In this document, the term ***submitters*** refers to all meat and poultry official establishments, egg products plants, and companies that notify the Agency of new technology or submit to FSIS protocols for the use of new technology in the production of FSIS regulated products.

How can I comment on this guideline?

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at regulations.gov: This Website provides the ability to type short comments directly into the comment field on this Web-page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: *FSIS Compliance Guidance Procedures for New Technology Notifications and Protocols*. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter FSIS Compliance Guidance Procedures for New Technology
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **New Technology** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

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What is New Technology?

New technology, as defined in the Federal Register notice *FSIS Procedures for Notification of New Technology* (68 FR 6873;February 11, 2003), is 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.

Key Point

High Pressure Processing, steam vacuums, steam pasteurization, and antimicrobials are all examples of new technologies that have advanced in food safety technology in recent years. FSIS encourages continued improvement and innovation in food safety technologies. To view the most recent advances in technology visit the FSIS New Technology Information Table.

Are food ingredients considered a new technology?

Yes, new technology is also new 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, directly or indirectly, in its becoming 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.

KEY DEFINITION

Food Ingredient refers to any substances added to food, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food.

Substances recognized as safe and suitable under the conditions of its intended use, such as those listed in 9 CFR 424.21(c) and those that are listed in FSIS Directive 7120.1, "*Safe and Suitable Ingredients in Meat, Poultry, and Egg Products*," are not subject to this notification process. However, establishments or companies that manufacture new substances or desire new uses of previously approved substances, including changes in concentration or application methods, are to submit a notification to the Food and Drug Administration (FDA).

Key Terms

Acceptability Determination: The process by which a new ingredient or substance or a new use of an ingredient or substance is deemed safe and suitable in the production of meat, poultry, and egg products.

Alternative Procedures: Alternative procedures are those an establishment will use in place of certain provisions of the regulations waived by FSIS.

Egg Products: Per 9 CFR 590.5, egg product means any dried, frozen, or liquid eggs, with or without added ingredients, except products that contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and that may be exempted by the Secretary under such conditions as he may prescribe to ensure that the egg ingredients are not adulterated and such products are not represented as egg products.

Food Ingredient: For the purpose of this document, the term "food ingredient" includes any and all substances listed below:

- Food Additive: Defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s)) as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.[1]

- Food Contact Substance: Defined in section 409(h)(6) of the FD&C Act as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

- GRAS Substance: Defined in section 201(s) of the FD&C Act as a substance, generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

[1] The definition of a food additive does not include: (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to the FD&C Act, Federal Meat Inspection Act (FMIA), or the Poultry Products Inspection Act (PPIA); or (5) a new animal drug; or (6) an ingredient in or intended for use in a dietary supplement.

- Prior-sanctioned Substance: A substance with an explicit approval granted for its use in food prior to September 6, 1958, by FDA or USDA.

- Color Additive: Defined in section 201(t) of the FD&C Act (21 U.S.C. § 321(t)) as a material which (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.

HACCP System Validation: Hazard Analysis and Critical Control Point (HACCP) System validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product (9 CFR 417.4).

In-Plant Trial: An experiment conducted in a federally inspected establishment to test a protocol during commercial conditions to confirm that the use of new technology does not 1) affect product safety, 2) jeopardize the safety of Federal inspection program personnel, 3) interfere with inspection procedures, or 4) require a change in the Agency's regulations.

Meat: Per 9 CFR 301.2, the part of the muscle of any cattle, sheep, swine, or goats that is skeletal or that is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels that normally accompany the muscle tissue and that are not separated from it in the process of dressing.

New Technology: New or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock or poultry or processing of meat, poultry, or egg products.

No Objection Letter (NOL): A letter indicating that FSIS has received and reviewed a new technology submission and has no objection to the use of such technology in FSIS regulated establishments under the conditions described in the NOL.

Notification: A submission addressed to FSIS describing the intended use, operation, and purpose of a new technology in official meat and poultry establishments or egg products plants. The notification may also include a protocol describing the methods by which the proposed technology will be tested, implemented, and evaluated. Per the Federal Register notice *FSIS Procedures for Notification of New Technology* (68 FR 6873), the document should also 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 needs a waiver of any Agency regulation and, if it does, identify the regulation and explain why a waiver would be appropriate.

Poultry: Per 9 CFR 381.1, "Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs, also termed young pigeons from one to about thirty days of age), whether live or dead.

Processing Aid: Processing aids are defined in the Food and Drug Administration's (FDA) regulation 21 CFR 101.100(a)(3)(ii) as substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form. Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in food. Substances that are added to a food for their momentary technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food during the shelf life of the product.

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.

Scientific Support: Scientific support is the theoretical principles, expert advice from processing authorities, scientific data, peer reviewed journal articles, regulatory requirements, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately address specific hazards.

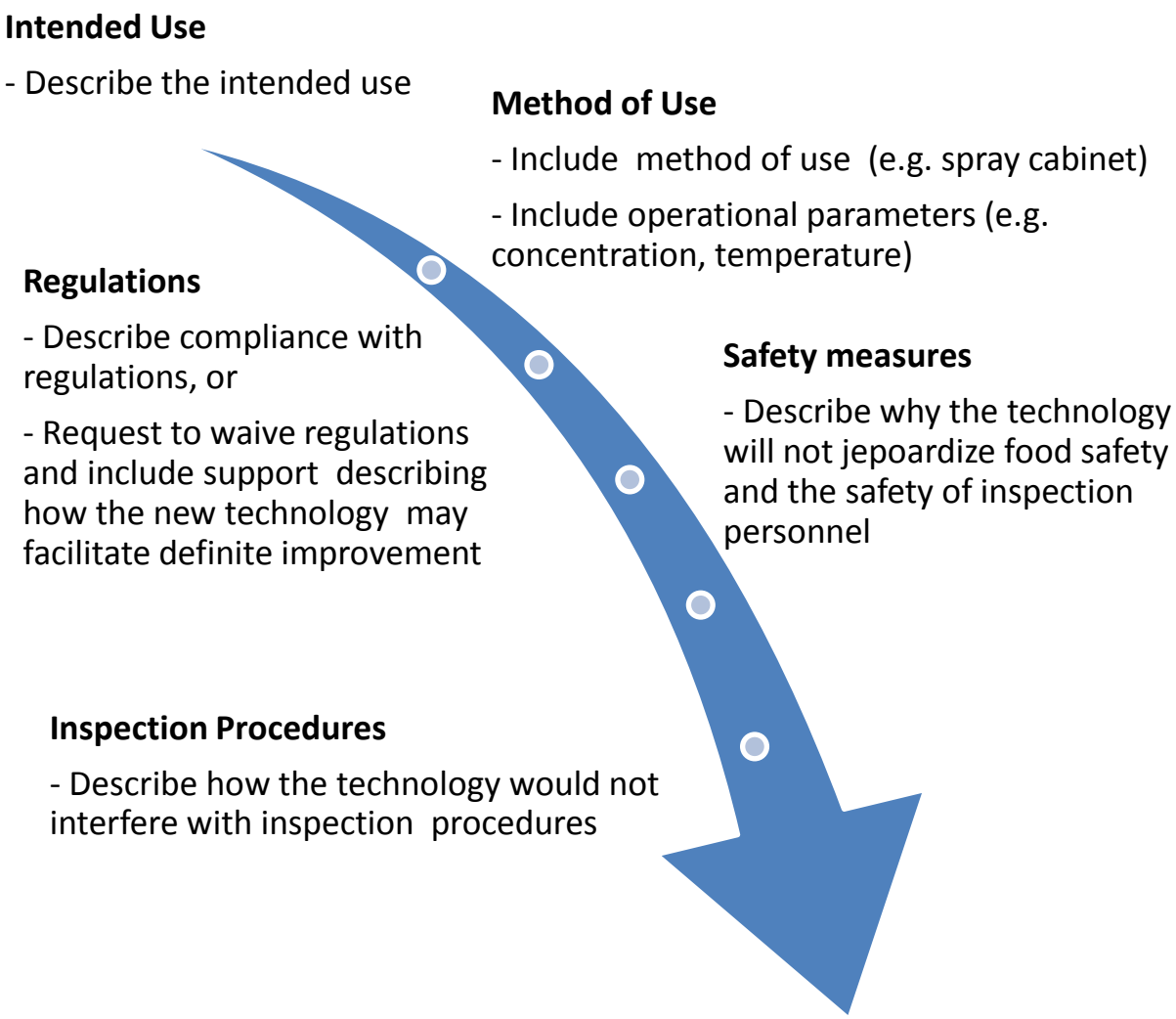
Suitability: Suitability relates to the effectiveness of the ingredient or substance in performing the intended purpose of use, and the assurance that the conditions of use in a FSIS regulated establishment will not result in an adulterated product or one that misleads consumers.

Waiver: FSIS regulations 9 CFR 303.1(h), 9 CFR 381.3(b), and 9 CFR 590.10 allow meat, poultry, and egg product regulatory requirements to be waived for a limited period of time to permit experimentation. Waivers are granted in order to test new procedures, equipment, and processing techniques that otherwise would be in violation with current FSIS policies and regulations.

Overview

Figure one is an overview of what to include in a new technology submission.

Figure 1: Overview of Notification Process



Submit Notification to:

United States Department of Agriculture
Food Safety Inspection Service
Risk, Innovations, and Management Staff
Patriot's Plaza III Mail Stop 3782
1400 Independence Ave. SW
Washington, DC 20250
Fax: 301-254-4703

What should be included in a New Technology notification?

The notification should 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. It should also include, but not be limited to, the following:

- ✓ Describe how the technology will be used including the method of application and operational parameters where applicable.
- ✓ Describe why the new technology will not jeopardize the safety of inspection program personnel (IPP). For example, it may include a description of safety measures taken to ensure IPP safety such as installation of shields, ventilation, new construction to isolate the technology, or personal protective equipment.
- ✓ Describe why the technology will not interfere with inspection procedures.

KEY DEFINITION

Notification is a written notice addressed to the Agency describing the intended use, operation, and purpose of a new technology intended for use in official meat and poultry establishments or egg products plants.

- ✓ List applicable regulatory authority under which use of the technology is allowed, or an explanation of why the technology does not violate any existing regulatory requirements. If the technology facilitates definite improvement, but its use does not comply with provisions of the regulations, include a request for a waiver and provide supporting documentation.
  - o FSIS regulations 9 CFR 303.1(h), 9 CFR 381.3(b), and 9 CFR 590.10 allow meat, poultry, and egg product regulatory requirements to be waived for a limited period of time to permit experimentation. For more information, refer to the *section How do I obtain a waiver of a regulation?*

- ✓ Describe why the new technology will not adversely affect the safety of the product and provide scientific support.
  - o If the technology is a substance;
    - ▪ include suitability data to support that neither the intended use nor the substance would adversely affect the wholesomeness of the product,

KEY DEFINITION

Suitability: Suitability relates to the effectiveness of the ingredient or substance in performing the intended purpose of use, and the assurance that the conditions of use in a FSIS regulated establishment will not result in an adulterated product or one that misleads consumers.

- state whether the substance's use will be declared on the labeling of any resultant product. If not, explain why not declaring the substance is consistent with FDA's definition of a processing aid per 21 CFR 101.100(a)(3)(ii).

Additional Guidance: Labeling

For more information, visit the FSIS Label Approval web site

- include the Food and Drug Administration's (FDA) safety determination, generally recognized as safe (GRAS) notice or food contact notification (FCN) for use of the substance in the meat, poultry or egg products, and
- describe any prior approvals, if applicable, by other Federal agencies, for example, Environmental Protection Agency (EPA), or Occupational Safety and Health Administration (OSHA), of the equipment, methods, processes, procedures, or substances.

Additional Guidance

To learn more about the FSIS-FDA working relationship, review the Memorandum of Understanding (MOU) between both agencies regarding the listing or approval of food ingredients and sources of radiation used in the production of meat, poultry and egg products.

What types of documents are acceptable as scientific support?

✓ There are several types of documents that can be used to support the use of new technology in a food safety system, these include:

- o Published processing guidelines that achieve a stated reduction of a pathogen.
- o Peer-reviewed scientific data/information that describes a process and the results of the process.
  - Challenge or inoculated pack studies designed to determine the lethality or stabilization of a process.
    - Base challenge studies on a sound statistical design and employ positive and negative controls. As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the number of samples for analysis, initially and at each time interval during processing or storage, should be at a minimum of two; however, analysis of three or more samples is preferred.
    - Conduct at least three replicates. Replicates are independent trials using different batches of product and inoculum to account for

variations in product, inoculum, and other factors. Increase the number of samples and replicates in situations of higher variability or uncertainty.

- A pathogen modeling program (PMP), based on such factors as growth, lethality, and survival in culture broth and food products, estimates the growth or decline of a foodborne microbe in food samples in production. USDA's Agricultural Research Service (ARS) makes a PMP available for download. ARS's PMP is a predictive microbiology application that was designed as a research and instructional tool for estimating the effects of multiple variables on the growth, inactivation, or survival of foodborne pathogens.

Key Point

Changes in, or revisions of, an approved protocol must be approved by FSIS and maintained with the protocol. Additionally, any changes to substances must be determined to be safe and suitable before they can be used in the production of meat, poultry and egg products.

- Data gathered by the establishment as part of a research study or other study. This data gathering is typically done if establishments are not able to implement the process as documented in the literature within its processing environment.

What should be included in the protocol?

There are three elements to a protocol: experimentation, implementation, and evaluation. The experiment phase specifies the rationale, goals, and objectives of the proposed research or trial. The experiment may take place in a lab, a test facility, or an official establishment as an in-plant trial.

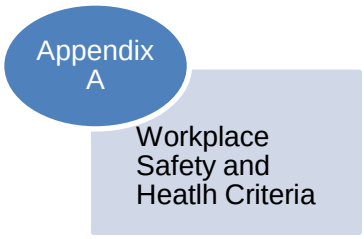
When an establishment implements a new technology in its food safety system, it should maintain the scientific supporting documentation for the duration of the use of the technology and implement the technology within the same ranges and operational parameters listed in their documentation (e.g. research or experimental protocols.) The establishment should demonstrate the technology is achieving the intended result and may do so by documenting in-plant observations, measurements, microbiological test results, or other information demonstrating the adequacy of the new technology in its own processing environment.

Lastly, evaluation of the technology consists of on-going verification and record keeping ensuring that it is operating as intended.

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

✓ **A descriptive title and date.**

- ✓ **A statement of purpose for the experiment or in-plant trial.** The statement of purpose specifies the rationale, goals, and objectives of the proposed research or trial. If enhanced food safety is the purpose, the statement of purpose should identify the particular area of concern: e.g., pathogenic microorganisms in raw beef. In all cases, the practical outcome to be measured must be clearly defined.
    - o The statement of purpose should set forth the scope and any pertinent limitations of the study, such as species or production class.
    - o The statement of purpose should define the specific application to be measured and the standard of measure employed: e.g., a hot water wash at a certain temperature, pressure, and time to reduce quantities of certain pathogens.
- ✓ **The name of the sponsor and the name and address of the testing facility.** In addition, include the name of the lead researcher for any submitted proposal that will act as principal spokesperson and contact with FSIS.
- ✓ **A description of the experimental design, including the methods for control of bias.** The general approach should be detailed: e.g., nature of the treatments, how they are to be applied, number and names of participating establishments, and time frame of the study.



✓ **A description of how the use of this technology will not adversely affect the safety of FSIS inspectors**. Workplace safety and health hazards include inhalation, direct skin contact (skin, eyes, mouth), and fire/explosion caused by exposure to the product, its working solution or dry mixture and potential by-products formed and/or off-gassed during the application process. Refer to Appendix A for the Workplace Safety and Health Criteria.

- ✓ **Identification of the hypotheses test subjects and control articles.** Include the statistical hypotheses, control, and experimental groups and clearly define the number of independent replications of the experimental procedure.
- ✓ **The type and frequency of tests, analyses, and measurements.**
    - o Describe sample set characteristics: e.g., sample size and adequacy for the question under investigation (including power against alternative hypotheses), sample selection procedures, and effects of any rejected samples.
- ✓ **A description of the sample collection methods to ensure mitigation of antimicrobial agent carryover.** Interventions used immediately prior to sample collection, such as chiller or post-chill dips and sprays may reduce the recovery of *Salmonella* or any other indicator organism on the sampled product. For example, describe the drip time or neutralization process used when sampling poultry carcasses after the chill step.
- ✓ **A description of sample handling:** e.g., visual scoring or laboratory sample preparation, kind and number of laboratory analyses to be performed, and analytical methods to be used.
- ✓ **A description of records maintenance.** The protocol should describe the records that will be maintained during the experiment, implementation, and evaluation phases. The records should document the performance of the technology throughout an experiment and be adequate to verify that food products produced during the experiment are not

adulterated and that safety precautions are followed. Some examples include but are not limited to:

1. microbial tests results,
2. air monitoring results,
3. chemical concentrations (e.g. ppm, pH),
4. organoleptic evaluations (consumer acceptability),and
5. monitoring or verification activities

Additional Guidance: FDA, EPA and OSHA

- FDA's Food Contact Substance Notification Program
- EPA's Pesticide Registration process
- OSHA's Hazard Communication Standard (HCS)

✓ **Availability of records.** When conducting in-plant trials in official establishments maintain records onsite for FSIS verification. Whether conducting an experiment as an in-plant trail or an experiment under other conditions such as a lab or test facility, provide an analysis of the data from each trial in addition to the raw data for the Agency to examine. Additionally, records generated during the implementation and evaluation phases should be made available for FSIS verification to ensure that the technology is operating as intended.

✓ **A statement of the proposed statistical methods used to analyze the data generated in the study.** Describe data processing and analysis techniques. Where appropriate, descriptions of analytical methods may be abbreviated if appropriate citations are provided. A description of why the chosen statistical tests are appropriate, or of planned evaluations that the tests are appropriate (i.e., the assumptions of the test are met) should be included.

✓ **Any applicable research or regulatory data.**

- o A literature review/bibliography should describe the current scientific status of the question addressed by the proposed research and highlight key previous work.
- o A literature review/bibliography should be concise, representative, and balanced, with full and consistent citations. Data on pertinent preliminary experimentation should be included in this section.
- o Any chemical reagents (substances) or other materials to be used in the project must have been approved by FDA, or the applicant must submit written FDA approval with the protocol. The proposed project must not violate any Federal law or regulation.

✓ **Any prior approvals from other Federal Agencies.** Ensuring the safety of inspection personnel is a key responsibility of FSIS. In order to safeguard its employees, FSIS will evaluate the protocol for impact on employee safety. Where pertinent, the protocol should contain written approval, appropriate regulatory citations, or safety documentation from EPA or OSHA.

- o The Federal Food, Drug and Cosmetic Act (FFDCA) requires EPA to set pesticide tolerances for all pesticides used in or on food or in a manner that will result in a residue in or on food or animal feed. A tolerance is the maximum permissible level for pesticide residues allowed in or on human food and animal feed. Pesticide registrations from EPA will need to be in the protocol to demonstrate environmental safety.

- OSHA's Hazard Communication Standard (HCS) requires chemical manufacturers, distributors, or importers to provide Safety Data Sheets (SDS) to communicate the hazards of hazardous chemical products.

✓ **Data and time frame of the experiment.** If the experiment is conducted in an official establishment (in-plant trial)**,** provide data throughout the duration of the in-plant trial for examination.

- Include the frequency of data submission. Data may take several forms including: laboratory results, weekly or monthly summary of production reports, or personnel safety reports.

At the conclusion of an experiment conducted as an in-plant trial, submit a final report, with the data as an electronic file (e.g., Microsoft Excel), to the Agency and, if applicable, a petition requesting rulemaking to change the pertinent provisions of the regulations.

FSIS will review the final report on the in-plant trial. The 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 acceptance or rejection by FSIS.

If rulemaking occurs in response to a petition, FSIS may grant an extension for the in-plant trial. FSIS expects the submitter to provide data to the Agency until the provisions of the regulation can be amended.

Checklist	Key information to include in Notification/Protocol
✓	Title and date
✓	Intended use of technology and purpose of the experiment
✓	Method of use & operating parameters
✓	Name of the sponsor and the name and address of the testing facility
✓	Experimental design, including the methods for control of bias
✓	A description of how the use of this technology will not adversely affect the safety of FSIS inspectors
✓	Identification of the hypotheses, test subjects, and control articles
✓	Type and frequency of tests, analyses, and measurements
✓	Sample collection methods and handling techniques
✓	Records maintenance
✓	Records availability
✓	Statistical methods used to analyze the data generated in the study or operation
✓	Applicable research or regulatory data
✓	Prior approvals from other Federal Agencies such as FDA, EPA, or OSHA

Do I have to conduct an in-plant trial?

FSIS may request scientific support if the technology does not have sufficient scientific research or data validating the new technology. Additional experiments may be warranted to

gather additional data for support. Experiments may take place in a lab, test facility, or an official establishment as an in-plant trial.

An in-plant trial is the examination of a protocol during commercial conditions to confirm that the use of new technology does not 1) affect product safety, 2) jeopardize the safety of Federal inspection program personnel, 3) interfere with inspection procedures, or 4) require a change in the Agency's regulations. If the intended use of the new technology could affect any of the four areas that are of interest to FSIS, the submitter will need to submit to the Agency a protocol requesting an in-plant trial to gather data on the effects of the use of the new technology.

KEY DEFINITION

Waiver: FSIS regulations 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

When use of the new technology would not be possible without a change in the Agency's regulations, the submitter needs to request a waiver prior to conducting the in-plant trial.

It is important to note that FSIS does not recommend in-plant trials where researchers artificially contaminate carcasses with fecal material that may contain human pathogens. An alternative would be to treat product with a special sterile medium to which are added food-grade microorganisms that approximate the growth or spread of pathogens of interest. In such cases, trimming of treated areas followed by an antimicrobial wash is required before product can move into commerce. Testing for human pathogens present in normal processing is acceptable.

Do I have to obtain a waiver for a regulation?

When use of the new technology would not be possible without a change in the Agency's regulations, the submitter needs to request a waiver and obtain from FSIS a letter waiving provisions of the regulations. FSIS regulations 9 CFR 303.1 (h), 381.3 (b), and 590.10 allow meat, poultry, and egg product regulatory requirements to be waived for a limited period of time to permit experimentation.

The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, or processing techniques may be tested to facilitate definite improvements. However, under these regulations, a waiver cannot be granted if the Administrator determines that a waiver would conflict 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.).

When a protocol includes a request for a waiver or when an in-plant trial requires a waiver of any provision of FSIS' regulations, a written request is submitted to the Risk & Innovations Management Staff (RIMS) with data that demonstrates that:

- the in-plant trial is scientifically sound;
- the alternative procedure, equipment, or processing technique will facilitate definite improvements; or
- there is a public health emergency; and
- issuance of the waiver will not conflict with the provisions of the relevant Act.

Additional Guidance

- Information on filing procedures for petitions for rulemaking is located in title 9 CFR Part 392
- For additional information visit Petitions

Data that justify a waiver would include:

1. validated laboratory results;
2. peer-reviewed journal articles; or
3. prototype production results.

At the completion of the in-plant trial, or when the submitter has sufficient scientific justification, the submitter must petition the agency to amend or repeal the regulation waived.

Where do I submit my notification or protocol?

Submit new technology notifications and protocols in one of the following ways:

Mail:

United States Department of Agriculture
Food Safety and Inspection Service
Risk, Innovations, and Management Staff
Patriots Plaza III, Mail Stop 3782
1400 Independence Ave., SW
Washington, DC 20250
Fax: 301-245-4703
Email: http://askfsis.custhelp.com

What happens after I submit my documents for Agency Review?

The Risk, Innovations, and Management Staff (RIMS) reviews the information for general acceptability and completeness. If complete, a technical review team (TRT) is established. The TRT is comprised of members from pertinent disciplines and program areas, within the Agency, including staff members from the Employee Safety, Health & Wellness Staff, Labor and Employee Relations Division, Science Staff, Data Analysis & Integration Staff, Labeling and Program Delivery Staff, and the Policy Development Staff. If the technology is a substance, FSIS works closely with FDA to assess its safety, suitability, and intended function of use.

The TRT reviews the submission to determine:

- ✓ Whether the technology adversely affects the safety of the product,
- ✓ Whether to waive requested provisions of the regulations for a limited period of time for the in-plant trial (9 CFR 303.1 (h), 381.3, and 590.10),
- ✓ Whether inspection can be appropriately maintained,
- ✓ Whether the safety of inspection personnel will be affected,
- ✓ Whether it complies with the Agency's humane slaughter regulations, and
- ✓ Whether the technology is scientifically sound.

If, after review, the Agency does not object to the proposed use of a new technology, the submitter receives a letter of no objection for the use of the technology and, if applicable, permission to conduct in-plant trials.

Should establishments validate new technology?

Yes, protocols contain scientific technical support and describe in detail the implementation process for new technologies. The intent is so that others could obtain the same results when they execute the technology in their establishments. Validation provides an opportunity for the user to confirm the adequacy of the new technology in the establishment's processing environment.

KEY DEFINITION

HACCP System Validation: Hazard Analysis and Critical Control Point (HACCP) System validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product.

Validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product.

Validation of a HACCP system involves two separate elements 1) design and 2) execution. Under 9 CFR 417.4(a)(1), establishments are required to assemble two types of supporting documentation to demonstrate these elements are met:

1. The scientific or technical support for the HACCP system design (design) - that is the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other

information demonstrating that particular process control measures can adequately address specific hazards; and

2. The in-plant validation data (execution) - that is the in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective.

To help establishments ensure that their HACCP systems are properly validated, FSIS developed FSIS Compliance Guideline HACCP Systems Validation for assistance in meeting validation requirements in 9 CFR 417.4.

Official Establishments

When implementing new technology that could affect an establishment's hazard analysis, or when an establishment alters its HACCP plan as a result of a new technology, the establishment is required to reassess its food safety system (9 CFR 417.4 (a)(3)). Where appropriate based on the decisions made in the hazard analysis, establishments may incorporate the new technology into a HACCP plan, written Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite program. Establishments are to validate the technology under in-plant conditions (9 CFR 417.4 (a)(1)) and verify it on an on-going basis for effectiveness (9 CFR 417.4 (a)(2)).

Key Point

Letters of no objection are not to be considered as validation that a new, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock or poultry or processing of meat, poultry, or egg products are effective in any particular official establishment or plant. Establishments implementing new technology should maintain scientific support as part of their validation, or they may conduct experiments to gather additional support that the technology will be effective for its intended purpose.

Official Egg Products Plants

Although official egg products plants are not required to operate under the HACCP system, FSIS recommends plants validate their new technology under in-plant conditions. Refer to FSIS Compliance Guideline HACCP Systems Validation.

APPENDIX A: Workplace Safety and Health Criteria

Workplace Safety and Health Criteria

New Technology notifications and protocols are to include how technology can be used without adversely affecting the health and safety of FSIS inspection program personnel (IPP). Workplace safety and health hazards include adverse effects caused by inhalation, direct contact (skin, eye, and mouth), or fire/explosion as a result of exposure to the product, its working solution/mixture (at all use concentrations), and any by-products. Exposure includes splashes, mists, particulates/dusts, gases and vapors generated in IPP work areas during preparation, application, disposal, or storage of the product. When assessing personnel safety, address each of the following areas:

Product Safety and Health Hazard Information

Provide a Safety Data Sheet (SDS) (formerly known as Material Safety Data Sheets or MSDS) for the product as a pure concentrate and if possible, for the actual working solution (the diluted use concentration) or dry mixture, indicating any potential intermediate chemicals formed or off-gassed by its use.

OSHA's Hazard Communication Standard (HCS) requires chemical manufacturers, distributors, or importers to provide SDSs to communicate the hazards of hazardous chemical products

If the SDS does not contain the following information at all use concentrations, include it separately:

SDSs assist employees in determining chemical hazards and protective measures and in consultation with physicians

- A description of the odors of the pure product, the working solution, and the working solution/mixture in contact with carcasses.
- The pH of the pure product, the working solution, and the working solution/mixture in contact with carcasses.
- Whether the pure product, any substance in the product or the working solution is a respiratory, eye, or skin irritant, is corrosive, or can cause dermatitis. For example, if IPP are splashed with solution from the application system or drips from carcasses or are exposed to contact with airborne aqueous mists, what health effects may occur?
- Whether the pure product, any ingredient in the product, or the working solution is a carcinogen or suspect carcinogen (including airborne mists of the product).
- Occupational exposure limits (OEL) including OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLV), and, if no PEL or TLV, any other recognized or recommended OEL.
- The results of any studies or testing that support a claim that the product, any substance in the product, or the working solution/mixture is not an occupational health hazard.

Describe the potential air contaminants or by-products that could be formed or off-gassed from the working solution or dry product based on contact or mixing with the following chemicals ("contact" includes mixing in floor drains):

- chlorine containing compounds (sodium hypochlorite, calcium hypochlorite, chlorine gas)
- ammonia-containing compounds
- organic acids
- inorganic acids
- ozone or other oxidizers
- typical cleaning agents used (including caustics)
- source waters containing inorganic chloramines
- low pH and high pH materials or solutions

Employee Exposure Monitoring

Describe the air sampling methods/equipment and sampling strategy that should be used to determine potential workplace inhalation exposures to FSIS inspectors during the use of this product. Provide methods for evaluating occupational exposure to all airborne forms of the product present in the workplace including gas, vapor, mist, liquid and dust.

Describe plans for any air monitoring that will be conducted during the in-plant trial or any air monitoring that has been conducted during previous in-plant testing. (Please submit any air sampling reports that are available.)

Describe any conditions under which this product has been used where an OEL was exceeded.

If this product does not present an inhalation hazard because of its physical or chemical properties, or if air monitoring is not considered necessary, please provide rationale on which these decisions are based.

Engineering Controls

Describe the engineering controls that will be used to reduce safety and health hazards from inhalation, direct contact during product use, and fire/explosion where applicable. Address each of the following:

- Local ventilation on the application system (e.g. cabinet, tank, booth), including air volume and flow rate/capture velocity
- General plant ventilation (air changes per hour or velocity in feet per minute)
- Containment and shielding for sprays, splashes, mists, gases, vapors, and particulates/dusts
- Emergency shut-offs, interlocks, safety release valves, visible and audible alarms (e.g., emergency shut-offs or alarms to ensure chemical concentration is in proper range, ventilation system is working properly, and access to cabinet/booth is controlled to prevent exposure to a hazardous environment).

- The need for dedicated drain lines from application point to floor trenches and within floor trenches to a remote discharge point to prevent airborne exposures and control the potential for chemical mixing.
- The need for special control measures (e.g., explosion proof equipment, static eliminators, avoidance of dust formation) to prevent a dust explosion.

Safety Practices/Personal Protective Equipment

In order to work safely with, or in the vicinity of, the working solution, identify what personal protective equipment (PPE) IPP should use to prevent inhalation and direct contact. Please address PPE for eyes, face, hand, skin, and inhalation. Provide specific type of glove material (e.g. neoprene), respirator type, and cartridges (if applicable). Indicate whether emergency eyewash/shower equipment is needed in areas where product application occurs.

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