FSIS Guideline for Residue Prevention

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USDA Food Safety and Inspection Service

This guideline provides information to establishments that:

- Slaughter livestock and poultry. This guidance explains how industry can meet FSIS requirements regarding violative residue prevention.

Preface

This is a revised version of the *FSIS Compliance Guide for Residue Prevention, 2013.* It has been updated in response to askFSIS questions received since the previous version. The guideline has also been revised to provide updates based on up-to-date science to:

- incorporate new information on purchase specifications and documentation that can be used to support that violative residues are not reasonably likely to occur; and
- address Food Safety and Inspection Service (FSIS) policy for establishments that perform residue testing.

Additionally, this guideline has been updated to clarify how residues influence New Swine Inspection System (NSIS) sorting procedures and FSIS Kidney Inhibition Swab (KIS™) testing procedures. The guideline also includes changes to improve its readability.

This guideline represents FSIS' current thinking on these topics and should be considered effective as of its issuance.

The information in this guideline is provided to assist livestock and poultry slaughter establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations.

- For guidance on controlling residues in egg products, please refer to the FSIS Egg Products Hazards and Controls Guide and the FSIS Food Safety Guideline for Egg Products; and

- For guidance on controlling residues in fish of the order Siluriformes, please refer to the FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products.

While all meat and poultry establishments may apply the recommendations in this guideline, it is focused on small and very small establishments in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazards Analysis and Critical Control Point (HACCP) systems. Although large establishments can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Purpose

This guideline contains information to assist meat and poultry establishments in preventing violative chemical residues in their products. This guideline includes information on:

- Addressing chemical hazards in the establishment food safety system; and
- Supporting documentation establishments can use when designing controls for violative residues.

Establishments can always seek guidance from the HACCP Coordinators and meat science and extension service resources listed on "Helpful Web Sites" under the "Resources" button on the FSIS HACCP Validation web page on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements.

How to Effectively Use the Guideline

This guideline is organized to provide users with the current science and recommendations. To use this guideline, FSIS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically and are also provided to bring you to other complementary documents.

How to Comment on the Guideline

FSIS is seeking public comment 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. The comment period will be 60 days from publication of the Federal Register notice and, as appropriate, the Agency may update this guideline in response to comments.

Comments may be submitted by either of the following methods:

- Federal eRulemaking Portal Online submission at *regulations.gov*. This website provides a way to type short comments directly into the comment field on the webpage or attach a file to submit lengthier comments. Follow the online instructions at that site to submit comments.
- Mail and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Washington, D.C. 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, document title, and docket number: FSIS-2022-0032, FSIS Guideline for Residue Prevention**.** Comments received will be made available for public inspection and posted without change, including any personal information, on https://www.regulations.gov.

Questions Regarding Topics in this Guideline

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select **Residue** as the Inquiry Type or by telephone at 1-800-233-3935.

Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

FSIS Guideline for Residue Prevention

Background

FSIS-regulated products may be adulterated because they bear or contain residues of drugs, pesticides, and other chemicals used in animal production or present in the animals' environment (see 21 U.S.C. 453(g)(1), (g)(2), and (g)(3) and 601(m)(1), (m)(2), and (m)(3)). FSIS tests for residues under the National Residue Program. Through this testing, FSIS verifies that a product does not contain prohibited levels of residues.

The Food and Drug Administration (FDA) is responsible for administering and enforcing the Federal Food, Drug and Cosmetic Act (FFDCA). Under this Act, FDA is responsible for ensuring that human foods and animal feeds are safe and, among other things, do not contain illegal residues of drugs, pesticides, or environmental contaminants. FDA also approves drugs used for food producing animals, establishes tolerances for drug residues and may establish action levels for unavoidable contaminants that may adulterate food.

> *The United States National Residue Program for meat, poultry, and egg products is an interagency program designed to identify, prioritize, and analyze chemical residues and contaminants in meat, poultry, and egg products. The USDA FSIS administers this program.*

The Environmental Protection Agency (EPA) is responsible for administering and enforcing the Federal Insecticide, Fungicide and Rodenticide Act. Under this Act, EPA has the authority to protect humans and their environment from unreasonable adverse effects of pesticide chemicals by regulating the sale and use of pesticide products. EPA is responsible under the FFDCA for establishing tolerances for residues of pesticides in food and has the authority to monitor the effectiveness of surveillance and enforcement. Under the Toxic Substances Control Act, EPA also regulates other chemical substances (e.g., industrial chemicals) that can adulterate food.

Regulatory Requirements and Federal Register Notice

Under the HACCP system regulations, a food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption (9 CFR 417.1). The possible sources from which food safety hazards might be expected to arise specifically include chemical contamination, pesticides, and drug residues (9 CFR 417.2(a)(3)(iii), (a)(3)(iv), and (a)(3)(v)). Establishments are required, under 9 CFR 417.2(a), to conduct a hazard analysis and consider the food safety hazards that might be expected to arise from residues. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5(a)(1).

Establishments are required to verify the ongoing effectiveness of their residue programs under HACCP per 9 CFR 417.4(a). Establishments that determine in their hazard analysis that the food safety hazard "violative residues" is a hazard not reasonably likely to occur are required under 9 CFR 417.3(b)(4) to reassess their HACCP plan each time a violative drug residue is found by FSIS. With repeated violations it becomes increasingly difficult for establishments to support the decision that drug residues are not reasonably likely to occur.

The Federal Register Notice Residue Control in a HACCP Environment describes how FSIS adapted its approach to the control of chemical residues in or on meat and poultry products in light of the implementation of the regulation in the Agency's Pathogen Reduction-Hazard Analysis and Critical Control Point Systems final rule. Here, FSIS listed four practices available to slaughter establishments to avoid slaughtering animals that contain illegal residues:

1. Ensure that all animals brought into an establishment for slaughter are identified, so that they can be traced back to the producers as required by 9 CFR 310.2, 9 CFR 320.1, and 9 CFR 381.175;

2. Notify animal producers in writing of both violative and non-violative residue findings, with such notification including a discussion of the issues involved, the company's (slaughter establishment's) future expectations, and an indication that repeat violators will not be future suppliers;

3. Explore the possibilities for the establishment to require purchase specifications including voluntary residue avoidance programs; and

4. Explore live animal testing.

Key Point

Slaughter and processing establishments are required to identify all chemical residue hazards that are reasonably likely to occur and develop systems to guard against them.

Recommendations for Livestock and Poultry Slaughter Establishments

FSIS is specifically emphasizing in this guide that livestock slaughter establishments should apply five basic measures, which expand upon and further clarify the four practices listed in the Federal Register Notice, to prevent the occurrence of violative residues:

1. Confirm producer history. An establishment with an effective residue control program considers the historical residue violation information associated with producers. Establishments can access the FSIS Residue Repeat Violators List (RRVL) prior to purchasing livestock or presenting them for ante-mortem inspection. An establishment that does not use the information in the RRVL, either

directly or through a letter or certification, would not be taking advantage of a tool for identifying livestock from known repeat violators. Thus, the establishment would not be taking advantage of a means of controlling a hazard that is foreseeable.

2. Purchase animals that are free of violative residues. An establishment should purchase animals from producers that have a history of providing residue-free animals, that employ an effective residue prevention program, and that use drugs judiciously by avoiding unnecessary or inappropriate use.

3. Ensure animals are adequately identified. FSIS regulations 9 CFR 320.1, and 9 CFR 381.175 require slaughter establishments to maintain records of their suppliers. Livestock slaughter establishments should purchase animals with sufficient identification, such as tattoos, ear tags, or back tags, to trace back to the producer and should not purchase livestock that do not have identification that would allow them to be traced back to the farm of their origin. Livestock and poultry slaughter establishments may also apply their own tags, tattoos, or other devices to further maintain animal identification until post-mortem inspection is completed. Maintaining proper identification and supplier records enables accurate trace back to the producer that can be upheld in a court of law if necessary.

4. Supply the producer information to FSIS at ante-mortem inspection. When producer information or other assurances are not available at ante-mortem, or when livestock are purchased from a producer listed on the RRVL, FSIS is likely to screen test the livestock at a higher rate. Inspection Program Personnel (IPP) are instructed in FSIS Directive 10800.1, *Residue Sampling, Testing and Other Verification Procedures Under the National Residue Program for Meat and Poultry Products*, to document a noncompliance report when an establishment fails to provide producer information upon reporting of a violative residue on FSIS testing.

5. Notify producers of animals with detected residues. Slaughter establishments should notify animal producers in writing if their animals are found either with violative or high, but non-violative levels of a drug residue. Such notification should include a discussion of the issues involved, the company's future expectations, and an indication that repeat violators will not be future suppliers. Residue results below the Minimum Level of Applicability (MLA), the lowest level at which a method has been successfully validated for a residue in reach matrix, are reported as "Not detected". If the results are above the MLA during screening, then the result is recorded as detected and is a "Presumptive positive." The Field Service Laboratories conduct additional testing to confirm and/or quantitate the presence of the residue, and a violation occurs if a chemical residue exceeds the established level. In situations involving quantitation, if the result is above the MLA but below the tolerance, the result is reported as "Detected, non-violative." However, if the result is above the tolerance, then the result is reported as "Detected, violation."

Recommendations for HACCP System Controls at Establishments Handling Livestock or Poultry that have had Historic Violative Residues

FSIS has told establishments, in the Federal Register Notice Residue Control in a HACCP Environment, that if their HACCP plans include residue controls that constitute the best available preventive practices for slaughter establishments, if they implement those controls effectively, and if they supply FSIS with information about violators, then the Agency will not treat violative residue findings by the establishment that are followed by appropriate corrective actions as noncompliance (see 9 CFR 417.3(a)).

Establishments are not prohibited from purchasing animals from producers or markets on the RRVL or from producers or markets with historic violations. However, when establishments purchase animals from producers or markets on the RRVL, and as part of implementing best practices, FSIS recommends establishments:

1. Have supporting documentation showing why the hazard that has historically occurred is still not reasonably likely to occur; 9 CFR 417.5(a)(1). Examples of supporting documentation an establishment could use to support this not reasonably likely to occur decision include:

    a. Requiring participation in food safety certification programs that are verified by a third party;

    b. Documentation from third party audits;

    c. Individual or herd animal treatment records; or

    d. Written attestations from the producer or their veterinarian verifying that slaughter withholding times have been strictly adhered to.

2. Have a critical control point that controls the hazard. Under HACCP, a Critical Control Point (CCP) could be used to control a chemical residue hazard that has historically occurred. Examples of a CCP include:

    a. Ante- or post-mortem residue tests conducted by the establishment;

    b. Ante- or post-mortem residue testing conducted by a reference laboratory; or,

    c. The review of documentation attesting to certifications, animal treatment controls, the observance of withdrawal times, or other documentation that shows the hazard was controlled prior to marketing the animals.

Recommendations for Establishments that Slaughter Show Animals

When show animals appear otherwise healthy, the FSIS veterinarian or IPP, under the direction of the FSIS veterinarian, based on their direct knowledge of the establishment

history, show history, and professional judgement, are to select a determined number of healthy show animals from the entire lot of show animals for inspector generated residue testing. FSIS recommends that establishments that purchase show animals for slaughter consider whether the show animals exhibit conditions that may indicate the animals may have violative residues. Examples include:

1. Abnormal muscling or size for the age and breed of animal that may indicate misuse of growth promotants;

2. Abnormal temperament (agitated or depressed) that may indicate misuse of stimulants, tranquilizers, or analgesics; or,

3. Any other condition based on the FSIS Veterinarian's professional judgement.

FSIS recommends that establishments not purchase show animals if the animal history or ante-mortem conditions indicate the show animals may have violative residues. For example, some shows perform residue tests on winning animals, or a random sampling of animals exhibited. Establishments can consider negative test results when making show animal purchasing decisions and when supporting HACCP decisions that violative residues are not reasonably likely to occur. FSIS recommends establishments not purchase show animals with positive show test results.

Considerations for Establishments that Conduct Residue Testing

As stated in the Federal Register, FSIS encourages all livestock slaughter establishments to consider implementing residue testing procedures:

1. As a critical control point when violative residues are reasonably likely to occur; or,

2. As a prerequisite program to support that violative residues are not reasonably likely to occur.

The establishment must have initial scientific support the method will control the hazard as expected by the HACCP plan, and that the method continually be supported by initial validation and ongoing verification data generated by the establishment. Establishments may choose a residue testing method that works best for their specific operations. Establishments may also choose to have a reference laboratory conduct residue testing on a fee -for- service basis. Residue testing can be conducted on live animals, using blood, urine, tissue, or milk. Residue testing can also be conducted post-mortem. FSIS recommends establishments consider the following criteria when identifying supportable residue testing methods and the frequency of testing:

1. The spectrum of compounds detected and the sensitivity of the test. For example, some residue tests analyze for a limited number of medications, whereas others may detect a wide variety of medications used on food animals.

The establishment may be able to support a simple, limited test when historic data shows the test detects residues historically found at the establishment;

2. The frequency of testing;

3. The skills of the employees conducting the test, and the complexity of the equipment needed, to support that test results are accurate; and

4. The amount of time required before reading the test results.

For additional assistance, establishments can always seek guidance from the HACCP Coordinators and meat science and extension service resources listed on "Helpful Web Sites" under the "Resources" button on the FSIS HACCP Validation web page on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements.

Special Considerations for NSIS Establishments

Establishments that operate under the NSIS inspection system are required by 9 CFR 310.26(b) to develop, implement, and maintain sorting procedures in their food safety system to remove food safety hazards associated with slaughter. Violative residues are a food safety hazard that an NSIS establishment may address in their sorting procedures.

Examples of sorting procedures for violative residues may include:

1. Ante- or post-mortem residue screening or testing; and

2. Disposing of diseased livestock or livestock suspected of having a violative residue prior to presenting live animals or carcasses for FSIS inspection. Examples include:

    a. Febrile livestock;

    b. Livestock exhibiting generalized, acute pathology during post-mortem; and

    c. Fresh injection site lesions.

As is explained in FSIS Directive 6600.1, FSIS only conducts KIS™ testing on carcasses retained by IPP and subject to veterinary disposition in NSIS establishments. Carcasses disposed of by an establishment's sorting procedures are not sampled by FSIS for violative residues because they have been removed from the human food supply.

Livestock slaughter establishments (other than those operating under NSIS) that are interested in incorporating residue sorting procedures into their food safety system may contact the FSIS Risk Management and Innovations Staff using askFSIS, and selecting "New Technology, Innovations" under the "Inquiry Type" drop down menu.

https://www.fsis.usda.gov/contact-us/askfsis

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