Compliance Guide
For Residue Prevention
2012

This is the first edition of the Compliance Guide for Residue Prevention. Future editions will reflect feedback received from all stakeholders.

This Compliance Guide articulates how industry can meet FSIS expectations regarding residue prevention. It is important to note that this Guide represents FSIS's current thinking on this topic and should be considered usable as of this issuance. Guide will be continually updated to reflect the most current information available to FSIS and stakeholders.

This information is provided as guidance to assist slaughter establishments and is not legally binding. It is being developed with appropriate review and public participation, to be accessible and transparent to the public. In order to make this guide as useful as possible, FSIS encourages all persons interested to submit for review their comments and concerns regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. All submissions will be posted to the Agency's Web site.

The Compliance Guide will be updated in response to comments and FSIS encourages establishments to begin following the guide.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site 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 floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to U.S. Department of Agriculture (USDA), FSIS, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW, Room 8-163A, Mailstop 3782, Washington, DC 20250-3700.

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I. Summary of Guidance Material

This is the first edition of the Compliance Guide for Residue Prevention.

II. Purpose

FSIS is issuing this Compliance Guide for Residue Prevention to assist livestock slaughter establishments in preventing violative chemical residues in their products.

III. Background

The National Residue Program (NRP) has been administered by the Food Safety and Inspection Service (FSIS) since 1967 to collect data on chemical residues in domestic and imported meat, poultry, and egg products. The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

FSIS collects samples of meat, poultry, and egg products at federally inspected establishments and analyzes the samples at FSIS laboratories for chemical residues of veterinary drugs, pesticides, and environmental contaminants. Laboratory findings that exceed established tolerances or action levels are shared respectively with FDA and EPA. This authority is provided under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS regulations are published in Title 9 of the Code of Federal Regulations (9 CFR), chapter III.

The National Residue Program (NRP) consists of two sampling plans: domestic and import. These plans are further divided to facilitate the management of chemical residues such as veterinary drugs, pesticides, and environmental contaminants in meat, poultry, and egg products. The domestic sampling plan includes scheduled sampling and inspector-generated sampling. The import reinspection sampling plan is separated into normal sampling, increased sampling, and intensified sampling.

With the implementation of the Hazard Analysis and Critical Control Points (HACCP) system, another important component of the NRP is to provide verification of residue control in HACCP systems. As part of the HACCP regulation, slaughter and production establishments are required to identify all chemical residue hazards that are reasonably likely to occur and develop systems to guard against them. A vigilant chemical residue prevention program is essential to foster the prudent use of veterinary drugs and pesticides in food animals. In 1999, the NRP was modified to make residue evaluation more consistent with risk assessment principles.

The USDA Office of Inspector General (OIG) determined in its review of the FSIS National Residue Program for Cattle, dated January 29, 2010, that the FSIS National Residue Program for Cattle is not meeting its objective of preventing residues from entering the food supply. The OIG report identified slaughter establishments that continue to purchase livestock from repeat violator producers as one issue contributing to the residue problem. Another issue identified as a problem is the lack of cattle identification available at slaughter that can be associated to the producer. The review further determined there are two slaughter classes of livestock (dairy cows and bob veal) that contribute 90% of the residues found in animals presented for slaughter. For this reason, this Compliance Guide is primarily focused on cull dairy cows and bob veal.

IV. Regulatory Requirements

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 drug 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). FSIS expects, as it has since HACCP was implemented, that establishments will 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 "drug residues" is not a hazard 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.

As a part of an effective HACCP system, establishments should consider whether the producer of the animals they are considering to purchase has a history of residue violations. Because it is not possible to know for sure whether an animal contains a drug residue that would cause FSIS to condemn the carcass, an establishment's best indicator of whether the animal may have such a residue is past practice by the producer. A producer who has had more than one residue violation in the preceding 12 months may be more likely than other producers to be selling additional animals with violative residues.

Therefore, it is prudent for establishments to purchase livestock with adequate identification to trace back to the producer. This information will enable establishments to determine whether the producer appears on the most recent Residue Repeat Violator List for Use by Livestock Markets and Establishments. This document lists the suppliers who have had more than one residue violation in the preceding 12 months. Alternatively, particularly if the establishment purchases cattle from a livestock market, it should obtain a letter or some type of certification from the seller or livestock market or auction that states that the animals in question either are or are not from a supplier who

has had more than one residue violation in the last 12 months. If an establishment regularly purchases animals from a particular livestock market, it may obtain a general certification from the market that it (the market) will check all animals that it sells against the Residue Repeat Violator List and notify potential buyers of animals from producers whose names appear on that list. This certification may also identify those animals from a producer known to be on the Residue Repeat Violator List.

A firm or person that is on the Residue Repeat Violator List remains eligible to market its livestock for slaughter. Establishments may present for slaughter animals from producers on the FSIS Repeat Residue Violator List, but they must have effective controls in place to ensure that any carcasses with violative residues are not allowed into commerce. An official establishment would need to be aware of when it receives livestock from a person or firm on the Residue Repeat Violator List in order for it to be able to design and implement its food safety program to address the potential hazard of an illegal residue. Establishments that receive a certification from the seller that the animal is not from a producer with a history of residue violations should keep it in their HACCP records, but they should ensure each time they intend to purchase animals from the market that it (the market) has performed an appropriate review of the list. Without producer information or appropriate certification, it is not possible for establishments to institute effective preventive measures. If an establishment does not follow this guide and FSIS finds violative residues, the establishment's HACCP system may be inadequate under 9 CFR 417.6.

V. Residue Prevention Recommendations

In a Federal Register Notice entitled "Residue Control in a HACCP Environment" (70 FR 70809, November 28, 2000), FSIS listed four practices available to slaughter establishments to avoid slaughtering animals that contain illegal residues: ensure that all animals brought into an establishment for slaughter are identified, so that they can be traced back to the producers; notify animal producers in writing of both violative and high, though not 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; explore the possibilities for the establishment to require purchase specifications including voluntary residue avoidance programs; and explore live animal testing. These four preventive practices are still relevant to prudent establishments and are entailed and reaffirmed in this Guide.

FSIS is specifically emphasizing in this Guide that establishments, especially those that slaughter dairy cows and bob veal calves, 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

Establishments should have effective residue control programs that include measures that take into account the historical residue violation information associated with producers. A livestock producer is the individual, farm, dairy, ranch, feed yard or other firm from which the animal originates. Establishments can access the Residue Repeat Violator List for Use by Livestock Markets and Establishments to obtain the list of repeat violator producers prior to purchasing the cattle. FSIS began compiling and publishing the Residue Repeat Violator List for Use by Livestock Markets and Establishments in August 2009 as a result of an industry request. This listing is updated weekly and when properly used, this information can be a valuable tool for assisting slaughter establishments in avoiding illegal residues in animals they slaughter by identifying livestock from known producers of repeat violator animals. FSIS has determined that a letter or certification from the seller, livestock market, or auction on a lot by lot basis demonstrating that the person issuing the letter or certification has reviewed the most recently posted Residue Repeat Violator List for Use by Livestock Markets and Establishments and determined that none of the animals in the lot came from suppliers with more than one violation in the last 12 months is a way that slaughter establishments can protect themselves. In addition, as discussed above, if an establishment regularly purchases livestock from a market, instead of getting a certification for each lot, it may decide to obtain a general certification that the market will check the list for each lot, although the establishment should regularly ensure that the market is adhering to this certification. In addition, this documentation may also identify those animals from a producer known to be on the Residue Repeat Violator List.

Establishments that do not use the information in the Residue Repeat Violator List, either directly or through a letter or certification, would not be taking advantage of a tool to identify livestock from known repeat violators. Thus, they would not be taking advantage of a means of controlling a hazard that is foreseeable.

2. Buy residue-free animals

Buy 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. In addition, require documentation from the producer that the animals are “Drug Residue Free.” The Food and Drug Administration recommends in guidance on Judicious Use of Medically Important Drugs that producers

limit use in food-producing animals of medically-important antimicrobial drugs to cases when such use is necessary to ensure animal health and then only with veterinary oversight or consultation.

3. Ensure animals are adequately identified

FSIS encourages slaughter establishments to purchase animals with sufficient identification, such as ear tags or back tags, to trace back to the producer and not to purchase any cattle that do not have identification that would allow them to be traced back to the farm of their origin. Cattle should be consistently identified with ear tags or back tags, and that identification has to be maintained with the cattle through the slaughter process until post-mortem inspection is complete. Maintaining proper identification of cattle enables accurate trace back to the producer that can be upheld in a court of law if necessary.

Without adequate identification, neither the establishment nor FSIS can utilize herd history to assess how likely cattle are to have violative levels of chemicals. Cattle that do not have animal identification may have had the identification intentionally removed in an effort to obscure their origin, leading to an FSIS concern about a higher risk that these animals contain violative residues.

Given this risk and the facts supporting it, FSIS advises cattle slaughter establishments that its inspection personnel will be less likely to test livestock presented for ante-mortem inspection that are properly identified with respect to the producer, or for which the establishment has an appropriate certification from the seller, livestock market, or auction. When cattle are not identified to the producer at ante-mortem inspection, given the Agency's experience with such livestock, FSIS is likely to test such animals at a more frequent basis (up to 100 percent).

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 the cattle are purchased from a producer listed on the Residue Repeat Violator List for Use by Livestock Markets and Establishments , FSIS is likely to screen test the cattle at a higher rate and may test up to 100 percent. If FSIS is presented with producer information or a letter or certification from the seller, livestock market, or auction, on a lot by lot or other appropriate basis, demonstrating that the person issuing the letter or certification reviewed the most recently posted Residue Repeat Violator List for Use by Livestock Markets and Establishments and determined that none of the animals in the lot came from suppliers with more than one violation in the last 12 months, FSIS is likely to screen test the cattle at a lower rate.

Notify Producers of Violative Animals

Slaughter establishments are notified through the FSIS Public Health Information System (PHIS) of both violative residues and of residues that are detectable but that do not exceed the tolerance levels established by FDA and EPA. Slaughter establishments should notify animal producers in writing if their animals are found either with violative or non-violative levels of a drug residue. Persistent non-violative residues may indicate a pattern of usage that could result in violations at some point. 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.

VI. References

Federal Meat Inspection Act (FMIA),

Poultry Products Inspection Act (PPIA),

Egg Products Inspection Act (EPIA),

9 CFR 310.2(a) and generally 9 CFR 300 to end, 417.3(a) and (b);

Residue Repeat Violator List for Use by Livestock Markets and Establishments

FSIS National Residue Program "Red Book" for 2008

FSIS National Residue Program Scheduled Sampling Plans "Blue Book" for 2010