# Compliance Guide
# For Residue Prevention
# 2013

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.

This information is provided as guidance to assist slaughter establishments and is not legally binding. It was developed with appropriate review and public participation, to be accessible and transparent to the public.

## Table of Contents

## I. Purpose

FSIS is issuing this final guidance to assist livestock slaughter establishments in preventing violative chemical residues in their products.

## II. 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. An effective 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 percent 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.

Furthermore, on July 6, 2012, FSIS announced changes to the NRP (77 FR 39895). Most significantly, FSIS began analyzing fewer samples but by using multi-residue methods. FSIS now uses multi-residue techniques to quantify a larger number of analytes with greater precision and accuracy. Such methods can often be performed with faster throughput and at lower cost to the Agency than conventional single residue methods.

## III. 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, an establishment should consider whether the producer of the animals it is considering for 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 an establishment to purchase livestock with adequate identification to trace back to the producer. This information will enable the establishment to determine whether the producer appears on the most recent Residue Repeat Violator List for Establishments and Livestock Auctions (Residue Repeat Violator List). The Residue Repeat Violator List is composed of suppliers who have had

more than one residue violation in the preceding 12 months. FSIS began compiling and publishing the Residue Repeat Violator List in August 2009 in response to an industry request. FSIS updates the listing 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.

If an establishment regularly purchases animals from a particular livestock market, it may obtain a general certification from the market stating that market personnel check all animals sold at that market 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. As an alternative to a general certification, particularly if the establishment purchases cattle from a livestock market, establishments should obtain a letter or some other type of credible 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.

A person or firm that is on the Residue Repeat Violator List remains eligible to market its livestock for slaughter. An establishment may present for slaughter animals from producers on the FSIS Repeat Residue Violator List, but it 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. An establishment that receives a certification from the seller that the animal is not from a producer with a history of residue violations should keep the certification in its HACCP records, but they should ensure each time it intends to purchase animals from the market that the market has performed an appropriate review of the list. Without producer information or appropriate certification, it is not possible for an establishment 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.

## IV. 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

An establishment should have an effective residue control program that includes measures that takes 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. The establishment can access the Residue Repeat Violator List to obtain the list of repeat violator producers prior to purchasing the cattle. 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 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.

An establishment that does 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

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 from 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. In addition, an establishment should require documentation from the producer that the animals are "free from violative residues." 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.

FSIS acknowledges that incidental loss of back tags does occur while livestock are in transport and holding areas. If back tags do not work in certain situations, other means of identification like producer ear tags, feedlot identification tags, tattoos, and calf-hood tags ("bangs") should be considered.

Without adequate identification, neither the establishment nor FSIS can utilize herd history to determine 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. If someone has attempted to obscure the origin of the cattle, FSIS would be concerned about a possible higher risk that these animals contain violative residues.

Because of this risk, FSIS Notice 44-12 instructs inspection program personnel to perform in-plant screening tests at an increased frequency if an establishment is not able to demonstrate that it has put in place measures designed to prevent or reduce the possibility that it will receive animals for slaughter with a violative residue. Thus, 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 on 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, 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 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.

**5. 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.

## V. Comments and Responses

In April 2012, FSIS announced the availability of a compliance guide for residue prevention (77 FR 24671) and requested comment on the guide. FSIS received a total of 12 comment letters in response to the April 2012 notice from professional veterinary associations, national trade organizations, private citizens, and an animal welfare advocacy organization. In response to the comments it received, FSIS has updated the compliance guide by substituting "residue free" and "drug free" with the phrase "free from violative residues." In addition, FSIS has included a discussion of means of livestock identification other than those discussed in the initial guidance that should be considered by livestock slaughter establishments when back tags are lost and prove ineffective in maintaining the identity of the animals. Following is a summary of the comments and FSIS's responses.

Comment: Several comments stated that only a small percentage of livestock receiving a back tag at the livestock market or sale barn actually retain those tags all the way to slaughter. One comment estimated that 80 percent of back tags placed on swine

fall off before the animals are presented for slaughter. Several comments conjectured that if processors refuse to purchase animals without identification as recommended by FSIS, owners of animals that unwittingly lose their back tags while in transit or holding pens will be denied market access. As an alternative to back tags, two comments requested that FSIS mandate the use of permanent ear identification tags in swine.

Response: FSIS acknowledges that incidental loss of back tags does occur while livestock are in transport and holding areas. However, FSIS believes, in some cases, back tags prove to be an acceptable form of identification. If back tags do not work in certain situations, FSIS recommends that establishments use other means of identification, like producer ear tags, feedlot identification tags, tattoos, and calf-hood tags ("bangs"). FSIS amended the guide to address animal identification options for establishments to consider when incidental loss of back tags occurs.

FSIS has limited authority to mandate the use of specific identification devices, permanent or otherwise, on livestock presented for slaughter. Therefore, FSIS does not intend to propose changes to its regulations to require specific identification devices at this time.

Comment: Several comments opposed FSIS's recommendation that slaughter establishments notify animal producers if their animals are found to have non-violative levels of a drug residue because the information will likely confuse producers.

Response: On November 28, 2000, FSIS informed establishments that if their HACCP plans included residue controls that incorporate 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 (65 FR 70809). The *Federal Register* notice went on to recommend that slaughter establishments notify animal producers in writing of both violative and non-violative residue findings as one of several "best preventive practices." As reaffirmed in the compliance guide, FSIS believes that such an approach will result in a decrease in violative residue findings because evidence of non-violative residues is an indication of lack of care in drug use by that producer.

Comment: Several comments requested that FSIS resume publishing the Residue Violator List in addition to the revised Residue Repeat Violator List. According to the comments, information contained within the discontinued Residue Violator List was used by certain trade organizations to target outreach on residue avoidance to reduce the probability that a repeat violation would occur.

Response: In 2011, to avoid confusion, FSIS stopped publishing the monthly Residue Violator (Alert) List that included the names of any producer, including first-time offenders, with a residue violation in the previous 12-months. FSIS replaced that list with the Residue Repeat Violator List. Published weekly, the Residue Repeat Violator List identifies producers who repeatedly (i.e., on more than one occasion) within a 12-month period have sold animals for slaughter whose carcasses were found by FSIS to contain a violative level of a chemical residue.

FSIS recognizes that posting the name of a livestock producer to a publicly-available list of residue violators may potentially result in significant economic harm to that producer. Moreover, the incentive of removal of the producer's name from the Residue Repeat Violator List, which motivates repeat violators to improve their operations to prevent violative residues, will be weakened if producers with only one violation are listed on the web site. Finally, FSIS notes that many first-time residue violators do not go on to become repeat violators within the designated 12-month period. Therefore, FSIS does not intend to resume publishing names of producers with a single violation within a 12-month period.

Comment: Because producers or suppliers can sell livestock to multiple Federal establishments, one comment suggested FSIS consolidate residue test results from the supplier or producer and set an acceptance level of non-violative samples that would trigger removal of a producer from the Residue Repeat Violator List rather than use a hard 12-month timeframe.

Response: FSIS would need to evaluate existing data to set a level of acceptable non-violative residue sample results that would trigger removal of a producer from the Residue Repeat Violator List. Given the time and resources that it would take to perform this evaluation, FSIS finds that the passage of time without a violation remains the appropriate criterion for removal from the list and is not making any changes to the Residue Repeat Violator list at this time.

Comment: Two comments requested that FSIS amend the compliance guide by substituting "residue-free" and "drug residue free" with the phrase "free from violative residues".

Response: FSIS agrees with the suggested changes and has modified the compliance guide accordingly.

Comment: Two comments expressed various concerns about drug residues in horses destined to be slaughtered for human consumption.

Response: In January 2010, the USDA Office of Inspector General determined in its review of the FSIS National Residue Program for Cattle that cull dairy cows and bob veal account for 90 percent of the residues found in animals presented for slaughter. Therefore, the guide focuses primarily on establishments that slaughter these livestock. However, this guide will be useful to any establishments that slaughter horses under Federal inspection in the future. By following the recommendations in the guidance, horse slaughter establishments would employ practices that help them avoid receiving horses with residues

## 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 2010 (June 2012)

FSIS National Residue Program Scheduled Sampling Plans "Blue Book" for 2012