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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2011-0008]

Compliance Guide for Residue Prevention and Agency Testing Policy for Residues

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of a compliance guide for the prevention of violative residues in livestock slaughter establishments. FSIS has posted this compliance guide on its Web page and it may be used immediately. FSIS also welcomes comments on this compliance guide, which will be revised as needed. This notice also discusses changes to the FSIS Residue Repeat Violator List and announces the Agency's intention to subject to increased testing animals from producers who are under an injunction obtained by the Food and Drug Administration because of drug use practices that have led to residue violations.

DATES: Submit written comments by [INSERT 60 DAYS FROM DATE OF PUBLICATION].

ADDRESSES: FSIS invites interested persons to submit comments on this notice and the compliance guide, which can be accessed at

<http://www.fsis.usda.gov/Regulations & Policies/Compliance Guide>

[s Index/index.asp](#). 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>. 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.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2011-0008. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Ph.D., Assistant Administrator for Office of Policy and Program

Development, FSIS, U.S. Department of Agriculture, Room 349-E, Jamie Whitten Building, 14th and Independence, SW, Washington DC 20250-3700; telephone (202) 205-0495, fax (202) 720-2025; [daniel.engeljohn@fsis.usda.gov](mailto:daniel.engeljohn@fsis.usda.gov).

SUPPLEMENTARY INFORMATION:

Background

The U.S. National Residue Program (NRP) is administered by FSIS to collect data on chemical residues in domestic and imported meat, poultry, and egg products and to keep products that are adulterated because of illegal residues out of commerce. 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. With the implementation of the Hazard Analysis and Critical Control Points (HACCP) inspection system, another important component of the NRP is to provide verification of residue control in HACCP systems. As part of the HACCP regulation under 9 CFR 417, establishments are required to conduct a hazard analysis and to consider the food safety hazards that can be expected to arise from drug and other chemical residues.

The USDA Office of Inspector General (OIG) report of January 29, 2010, reflecting its review of the NRP with regard to cattle, identified as a contributing factor to violative

residue problems the practice of slaughter establishments continuing to purchase livestock from repeat residue violators. OIG also noted that there is often insufficient information at slaughter establishments to identify the producers responsible for the violative residues. The OIG review also underscored the fact that there are two slaughter classes of livestock, dairy cows and bob veal, that account for 90 percent of the residues found in animals presented for slaughter, pointing to the need for the Agency to continue to focus compliance efforts on cull dairy cows and bob veal.

This Compliance Guide emphasizes that establishments, especially those that slaughter dairy cows and bob veal calves, should apply five basic measures to reduce or prevent the occurrence of violative residues. The guide recommends that establishments should: 1) confirm producer history; 2) buy animals from producers who have a history of providing residue-free animals and have effective residue prevention programs; 3) ensure that animals are adequately identified to enable traceback; 4) supply information to FSIS at ante-mortem inspection showing that animals in the lot did not come from repeat violators; and 5) notify producers in writing if their animals are found to have either violative residues or detectable levels that do not exceed the tolerance levels established by FDA and FSIS. Persistent non-violative levels

residues may indicate a pattern of usage that could result in a violation at some point.

The Compliance Guide discusses the Agency's revised [Residue Repeat Violator List](#), which has been streamlined for greater ease of use. The List now includes only producers who have provided more than one animal with a violative residue during the past 12 months. The List is also now presented in two differing forms. "Part I" is intended for use by Agency inspection personnel and contains comprehensive information on the individual residue findings (e.g., tissue identified with the violation, chemical compound identified, concentration), organized alphabetically by state and firm name. "Part II" is intended for use by industry and lists producers that have been the source of multiple animals with residue violations and does not provide the technical information contained in Part I. The Agency invites comments on these recent revisions to the List, especially comments related to the List's utility and ease of use. Should the Agency be providing additional information on producers who supply animals with violative residues?

The Compliance Guide explains that 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. 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.

FSIS has also been asked recently whether producers could be removed from the Residue Repeat Violator List in less than 12 months in certain circumstances, e.g., if a producer goes three consecutive months without any new violations. The Agency is evaluating this issue and invites comments on it.

FSIS recently increased testing for residues of carcasses in establishments with violations associated with the same producer or at establishments that fail to apply the residue control measures described in the Compliance Guide. The notices with instructions to FSIS personnel concerning increased testing for residues are available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/21-11.pdf> and <http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/12-11.pdf>.

In addition, FSIS intends to increase its testing for residues in animals from producers who are under an injunction obtained by the Food and Drug Administration because of drug use practices that have led to residue violations. This action is consistent with FSIS's policy of increasing testing of carcasses at slaughter establishments that are attributable to producers with multiple residue violations.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at

<http://www.fsis.usda.gov/regulations & policies/2010 Notices Index/index.asp>.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized

access to selected food safety news and information. This service is available at [http://www.fsis.usda.gov/news\\_and\\_events/email\\_subscription/](http://www.fsis.usda.gov/news_and_events/email_subscription/). Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on April 18, 2012

Alfred V. Almanza,

Administrator.

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