DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00–026N]

Residue Policy; Response to Comments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is implementing the modified approach to the testing of meat carcasses for the presence of violative new animal drug residues, and disposition of product thereafter, as was announced in an August 6, 2001, **Federal Register** notice (66 FR 40964). This action will make FSIS' testing and disposition procedures consistent with the target tissue/marker residue policy of the Food and Drug Administration (FDA). FSIS is modifying its approach to ensure that meat containing unsafe levels of animal drug residues is not released into commerce.

DATES: *Effective Date:* June 7, 2004.

FOR FURTHER INFORMATION CONTACT: Carole Thomas, Technical Analysis Staff, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 405, Cotton Annex, Washington, DC 20250–3700, (202) 205–0210.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Food, Drug, and Cosmetic Act, FDA determines whether new animal drugs proposed for use in food producing animals are safe for those animals, and establishes tolerances for residues of such drugs that remain in the edible tissues of treated animals. The term ''new animal drug'' is defined in FDA's regulation in Title 21 of the Code of Federal Regulations (21 CFR 510.3(g). For new animal drugs approved prior to 1976, FDA established residue tolerances for each edible tissue of food producing animals. Since 1976, however, FDA has been establishing tolerances for new animal drugs using a marker residue. In a guideline published by FDA's Center for Veterinary Medicine (CVM), ''General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals'' (CVM Guideline #3, *http://www.fda.gov/cvm/guidance/guideline3toc.html*), the term ''marker residue'' is defined as the residue selected for assay whose concentration is in a known relationship to the total residue of toxicological concern in the last tissue to deplete to its permitted concentration.

Marker residues serve as sentinels for levels of residues of toxicological concern associated with a drug (parent and metabolites) in edible tissues of a food producing animal. In more general terms, a marker residue is the residue that reflects the depletion of animal drug residues in edible tissues. A target tissue (typically the liver or kidney or, more rarely, the muscle or fat) is the edible tissue from which residues deplete most slowly, and the tissue used for regulatory surveillance. When the concentration of the marker residue in the target tissue is equal to or less than the target tissue tolerance, the residue concentration reached in each edible tissue will be at a safe concentration.

If FSIS inspection personnel identify an animal as suspect for any condition where animal drug misuse is possible, and a suitable in-plant test is available, an initial screen test is performed at the federal establishment to determine whether the animal drug is present. If the screen test is positive, the target tissue of the animal is analyzed in a FSIS laboratory to verify that the drug is present, as well as to quantify the amount of the drug that is present. If the target tissue contains violative levels of the animal drug, FSIS tests the muscle tissue of the animal to determine whether it also contains a violative residue level. If the target tissue is found to contain a violative residue level, but the muscle tissue is not found to contain a violative residue level, FSIS condemns only the target tissue and releases the muscle tissue for human consumption. Likewise, if the target tissue does not contain violative levels of residue, but the muscle tissue does, only the muscle tissue is condemned.

On August 6, 2001, FSIS issued a **Federal Register** notice (66 FR 40964) that announced its intent to harmonize its procedures with those of FDA with respect to applying FDA's target tissue/marker residue policy regarding the testing of meat carcasses for residues of new animal drugs and disposition of tissues thereafter. In the notice, FSIS stated that it had reviewed its approach regarding the testing of meat carcasses for new animal drug residues and the disposition of meat carcasses containing violative residues and had determined that it was not consistent with FDA's approach. FSIS is now implementing the approach discussed in its August 2001 notice.

For the new animal drugs for which FDA has established a marker residue tolerance in a specific target tissue without also establishing a tolerance for a residue in muscle tissue or an official analytical method for muscle residues, FSIS will only test the target tissue that is identified in FDA's regulations (21 CFR Part 556 Subpart B—Specific Tolerances for Residues of New Animal Drugs). If the residue concentration in the target tissue exceeds the FDA's established tolerance, FSIS will consider the entire carcass to be adulterated, and condemn it, and not allow it to be distributed for human food purposes. If, however, FDA has established an animal drug residue tolerance in muscle tissue and an official analytical method for detecting muscle residues, FSIS will test the muscle tissue using the official analytical method to determine whether the concentration of residue in the muscle is at or below the established muscle tolerance. If the residue concentration in the muscle does not exceed the tolerance, FSIS will release the muscle tissue and allow it to be distributed in commerce for human consumption.

For the new animal drugs where tolerances have been established for all edible tissues, but for which a target tissue has not been identified, FSIS will continue to collect and monitor multiple edible tissues and allow those that have animal drug residue levels equal to or less than the established tolerances to be distributed in commerce for human consumption.

FSIS received several comments about the intended change that it announced on August 6, 2001. FSIS has carefully considered the comments and is now responding to them.

Several commenters asked whether the intended change had a scientific rationale. They stated that it was important that the change be based on public health concerns, and that FSIS not discard safe tissues or place unnecessary burdens on producers and processors. Others stated that the change would not enhance public health.

FDA's Center for Veterinary Medicine (CVM) has the primary responsibility for establishing and codifying tolerances for new animal drugs. In establishing tolerances, FDA relies on human food safety studies, including analysis of toxicological, total residue depletion, and metabolic data submitted by individual new animal drug sponsors. In a letter from the Office of New Animal Drug Evaluation (NADE), Center for Veterinary Medicine, CVM states that a tolerance represents the concentration of an indicator (marker residue) of the total residues in all edible tissue below which FDA has a reasonable certainty that no harm will

occur to a consumer through daily exposure to the residues in food over a lifetime. Thus, all of the animal drug tolerances established in 21 CFR part 556 are based on human safety considerations. When the tolerance in the target tissue is exceeded, FDA considers the entire carcass to be adulterated because the residue in the target tissue is imputed to the rest of the animal.[1]

FSIS does not establish animal drug tolerances. However, it does have authority over a food animal once it is presented for slaughter at an official federal establishment. FSIS conducts ante-mortem inspections of animals. The ante-mortem inspections screen for visible diseases and pathological conditions in an animal that could pose a public health risk if the meat from the animal entered the food supply. FSIS also conducts post-mortem inspection of animals. On post-mortem inspection, FSIS inspectors check an animal carcass for indications of animal drug use, including examining the carcass for injection sites, septicemia, endocarditis, mastitis, pneumonia, or other conditions that may indicate the animal was medicated. If such conditions are identified, the carcass and parts of the animal are retained, and appropriate tissue samples are submitted to a FSIS Food Service Laboratory for further testing. FSIS believes that these procedures, and the modifications it is now implementing, will ensure that meat containing unsafe levels of chemical residues are not being released into commerce.

Many commenters asked why FSIS does not use the ''maximum residue limit'' (MRL) established by CODEX for the drugs that do not have established tolerances for muscle tissue. They stated that FSIS should harmonize its procedures with CODEX.

FDA has the authority to regulate veterinary drugs and to establish and codify animal drug tolerance levels. FDA has determined that its method for establishing tolerance levels for muscle tissue is more reflective of consumption patterns in the U.S. than the MRLs established by CODEX. FSIS does not establish or codify animal drug tolerance levels. FSIS enforces the tolerances established by FDA and relies upon FDA's determination of what are appropriate tolerance levels.

One commenter stated that it is important that FSIS develop beef muscle residue testing methods since the European Union is requiring testing of beef for violative residues before entry into the European beef market.

FSIS does not itself develop residue testing methods. The Agency does not believe that it needs to develop them itself since there are validated methods available for its use. The tests for beef muscle residues that are used by FSIS are based on the testing methods developed by drug sponsors as part of the FDA approval process. These methods are used for tissue residue determinations once the FDA method trial has validated their use for this purpose.

A commenter stated that imported beef should be subjected to a limited amount of residue testing to verify that the beef is free of violative residues.

Through its National Residue Program (NRP), FSIS tests meat and poultry products imported into the United States for violative residues. In addition, every country that exports meat or poultry to the United States is required to have a residue control program that is equivalent to that of the United States. This program needs to include laws and regulations that control the use of animal drugs, pesticides, and environmental contaminants and an organizational structure to implement those requirements; a residue sampling and testing program equivalent to the United States' residue program (the National Residue Program); and the ability to take enforcement actions when residue violations are detected.

A few commenters suggested that muscle tissue should be tested to see if it contains residues that exceed the science-based standards set by FDA. They argued that if the muscle tissue is not tested, or if FDA has not established an official analytical method for testing, a ''blanket'' condemnation of carcasses could occur.

Muscle tissue will be tested if there is an FDA established tolerance for muscle tissue and an analytical method for detection established by FDA. If not, action on the carcass will be based on the marker residue findings in the target tissue. Carcasses will be condemned only if the residue in the target tissue exceeds the applicable tolerance. This is an appropriate outcome because if a violative animal drug residue level is found in a target tissue for a drug for which there is no muscle tolerance established, FSIS cannot determine that the carcass is not adulterated.

FSIS does not believe that its approach will result in a blanket condemnation of carcasses. FSIS has reviewed the potential impact of its modified testing approach and has concluded that the percentage of carcass condemnation as a result of this change will be only 2% (see economic review). Additionally, there are only seven commonly used veterinary drugs that do not have established muscle tolerances or an analytical method for detection.

One commenter stated that FSIS' current procedure of testing muscle tissue meets FSIS statutory obligations.

FSIS has tried to maintain an equitable residue program. While the Agency considered its approach appropriate, the Agency has now determined that the better, more scientific approach is to harmonize its residue policy procedures with those of FDA with respect to target tissue/marker residues.

One commenter expressed concerns about the downstream discovery of residues after slaughter and the lack of responsibility and traceback.

In a November 28, 2000, **Federal Register** notice (65 FR 70809), FSIS discussed meetings that it had held with a coalition of industry members, trade associations, and other interested parties to discuss concerns related to residue violations and laboratory reporting procedures. As a result of those meetings and FSIS' response, several slaughter establishments indicated that they would begin to explore how to effectively institute the best preventive practices available to slaughterers. These included ensuring, through the use of a receiving critical control point in their HACCP Plans, that all animals brought into an establishment for slaughter were identified so they would be traced back to the producer; notifying animal producers in writing of violative levels of residue findings, making clear the issues involved, the purchaser's expectations, and the fact that repeat violators would not be future suppliers; exploring the possibility of establishing state-certified, and possibly USDA Cooperative State Research, Education and Extension Service-verified, voluntary residue avoidance programs comparable to those developed by major producer trade organizations, and requiring suppliers to participate in such programs and to supply certifications to that effect; and exploring the possibility of live animal testing. FSIS believes that adoption of these types of practices by packers will facilitate accountability and traceback.

Two commenters suggested that if a tolerance and analytical methodology for muscle have been developed for one species, it should be used for other species when there are no tolerances or detection methods developed for them.

Tolerance levels are derived from an evaluation of residue and metabolism studies for each species for which data

[1] Dr. S.D. Vaughn, Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, June 2003.

are provided to FDA. Because there are significant differences among species, applying a tolerance level established for one species to another species without metabolic studies would be inappropriate.

One commenter suggested that it is premature to change existing rules until other tasks have been completed.

FSIS is not changing any rules in this proceeding. Rather, it is announcing a change in how it will determine whether a product is not adulterated and thus eligible to bear the mark of inspection.

One commenter asked whether FSIS will issue a directive or provide additional training to all inspectors.

FSIS will issue a new directive to its inspectors that clearly explains this procedural change and their responsibilities.

Two commenters requested that the procedural change be implemented at a later time. One argued that it needed sufficient time to discuss the feasibility of muscle tolerances for certain compounds with a pharmaceutical company and FDA. Another stated that there is a lack of a strategy within FDA for establishing tolerances for drugs for which muscle tolerances are currently not established.

In the August 6, 2001, **Federal Register** notice (66 FR 40964; confirmed 68 FR 540 (1/6/03)), FSIS asked for comments on its intent to change its current procedures to be consistent with FDA's marker residue/target tissue policy for new animal drugs. In a November 8, 2001, **Federal Register** notice (66 FR 56533), FSIS reopened the comment period on this issue for an additional thirty days. More than two years have passed since FSIS published its initial notice. FSIS believes that it has allowed adequate time for comments on, and consideration of, this change. Therefore, FSIS will begin operating in accordance with the marker residue/target tissue policy on June 7, 2004.

One commenter stated that FSIS' changed approach does not give producers an incentive to stop inappropriately administering veterinary drugs, while it continues to punish the packer. Another commenter stated that packers do not have the option of buying food animals that have been pre-screened for veterinary drugs.

On August 6, 2001, FSIS published ''Residue Testing Procedures; Response to Comments'' (66 FR 40965), which announced its policy effective as of September 5, 2001, on repeat chemical residue violators and announced the public availability of the list of repeat violators on the Agency's Web site (*http://www.fsis.usda.gov*). This list will enable slaughter establishments to incorporate into their purchasing practices control measures that are designed to decrease the likelihood of purchasing animals from producers and sellers that violate the Federal law by inappropriately administering veterinary drugs.

FSIS received a comment from the Small Business Administration (SBA) that raised four specific concerns. First, SBA asserted that FSIS' August 6, 2001, residue policy notice (66 FR 40964) did not simply announce a change in FSIS' procedures but in fact was a rulemaking action that FSIS needed to publish in the **Federal Register** and give interested persons an opportunity to comment upon, in accordance with the Administrative Procedure Act (APA). Second, SBA stated that FSIS had to comply with the Regulatory Flexibility Act (RFA) and certify, as well as provide a factual basis for the certification, that the procedural changes would not have a significant economic impact on a substantial number of small entities. Third, based on their calculations, SBA contended that FSIS'' intended action had a potential to be economically significant under Executive Order 12866, and that FSIS needed to prepare a Regulatory Impact Analysis. Lastly, SBA stated that it believed FSIS should suspend the August 6, 2001, notice and republish it as a proposed rule.

FSIS does not agree with any of SBA's statements. The action announced in the August 6, 2001, **Federal Register** notice is not a rulemaking. It does not impose any regulatory requirements on industry. FSIS' residue policy notice simply provides information on the procedures the Agency will use to ensure that meat establishments do not distribute meat containing unsafe levels of animal drug residues. Thus, there is no reason for FSIS to republish its August 6, 2001, notice as a proposed rule. Further, although not required, FSIS has, in fact, employed a notice and comment procedure in adopting its residue policy. The policy was not implemented when it was announced in August of 2001. Rather, at that time, the Agency simply announced how it intended to proceed. It is only now after FSIS solicited, received, and has responded to comments that the announced policy is being implemented. In regard to SBA's RFA and E.O. 12866 concerns about the economic impact of the procedural changes FSIS is implementing, FSIS does not expect its action will have a significant economic impact on a substantial number of small entities or will be economically significant.

Economic Review

Of the veterinary drugs commonly used in swine and cattle there are only seven for which the FDA has established a marker residue tolerance in a specific target tissue without also establishing a tolerance for the residue of the drug in the muscle tissue or an analytical method for detecting muscle animal drug residues. These seven drugs are: apramycin, carbadox, fenbendazole, melengestrol acetate, morantel tartrate, oxfendazole, and tiamulin. Four of these are ones that the FDA has established and codified tolerances for the liver; two are ones for which the FDA has established and codified tolerances for the kidney; and one is one for which the FDA has established and codified tolerances for fat (See Tables 1 and 2).

TABLE 1.—VETERINARY DRUGS AND UNAVOIDABLE CONTAMINANTS WITH A TOLERANCE IN BOTH ORGAN AND/OR MUSCLE FOR CATTLE [1] [2]

Substance	Liver	Kidney	Muscle	Fat
Apramycin	None	None	None	None.
Carbadox	None	None	None	None.
Fenbendazole	Yes (0.8)	None	None	None.
Melengestrol acetate	None	None	None	Yes (0.025).
Morantel tartrate	Yes (0.7)	None	None	None.
Oxfendazole	Yes (0.8)	None	None	None.
Tiamulin	None	None	None	None.

[1] Tolerances are expressed in parts per billion (ppm).
[2] Source: 2000 FSIS Red Book.

Thus, the modified testing procedure FSIS is implementing would be utilized for only a very small number of meat carcasses. In turn, only very small amount of meat carcasses would be expected to be condemned as a result of any findings of violative drug residues.

TABLE 2.—VETERINARY DRUGS AND UNAVOIDABLE CONTAMINANTS WITH A TOLERANCE IN BOTH ORGAN AND/OR MUSCLE FOR SWINE [1] [2]

Substance	Liver	Kidney	Muscle	Fat
Apramycin	None	Yes (0.1)	None	None.
Carbadox	None	Yes (0.03)	None	None.
Fenbendazole	None	None	None	None.
Melengestrol acetate	None	None	None	None.
Morantel tartrate	None	None	None	None.
Oxfendazole	None	None	None	None.
Tiamulin	Yes (0.6)	None	None	None.

[1] Tolerances are expressed in parts per billion (ppm).
[2] Source: 2000 FSIS Red Book.

This fact is supported by two results of FSIS'' drug residue testing in prior years. In these prior years, 2000–2002, as is the case each year, FSIS only tests for residues of certain animal drugs based on risk analysis and past experiences. In the years 2000–2001, FSIS conducted residue testing for only two of the seven drugs, melengesterol acetate and carbadox, for which FSIS is implementing a modified testing approach. In 2002, FSIS only tested for melengesterol acetate. All of FSIS' test results (29) for this drug in 2002 indicated that there were no violative residue levels for the drug. In the previous two years (2000 and 2001), only 19 of 925 tests for melengestrol acetate resulted in a finding of violative drug residues. During that same time period, 2000–2001, FSIS also conducted tests for carbadox. Only one of the 322 carbadox tests conducted resulted in a finding of a violative drug residue. Thus, between 2000 and 2002, only 20 of the 1,276 tests conducted for drug residues resulted in a finding of violative animal drug residues. Therefore, only 2 percent of the meat carcasses prepared at establishments during the years 2000 through 2002 would have been condemned under FSIS'' modified procedures, as a result of a finding of a violative level of animal drug residue. Therefore, FSIS believes no significant economic impact upon small entities or any other entities can be expected to be generated by the issuance of this notice.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that the public, and in particular minorities, women, and persons with disabilities, are aware of this notice, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov*.

The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov*.

FSIS also will 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, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS web page. Through Listserv and the web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information contact the Congressional and Public Affairs Office, at (202) 720–9113. To be added to the free e-mail subscription service (Listserv) go to the ''Constituent Update'' page on the FSIS Web site at *http://www.fsis.usda.gov/oa/update/update.htm*. Click on the ''Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

Done at Washington, on May 3, 2004.

Barbara Masters,

Acting Administrator.

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DEPARTMENT OF AGRICULTURE

Forest Service

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–930–6334–DT]

Notice of Availability (NOA) Record of Decision (ROD) To Remove or Modify the Survey and Manage Mitigation Measure Standards and Guidelines

AGENCIES: Forest Service, USDA; Bureau of Land Management, USDI.

ACTION: Notice of availability of record of decision.

SUMMARY: In accordance with the National Environmental Policy Act, the Federal Land Policy and Management Act, and the National Forest Management Act, the USDI Bureau of Land Management and the USDA Forest Service announce the decision to amend selected portions of the 1994 Record of Decision for the Northwest Forest Plan by removing the Survey and Manage Mitigation Measure Standards and Guidelines. Survey and Manage provided conservation measures for rare and little known species associated with late successional, old growth forests. These Standards and Guidelines were frustrating the Agencies' ability to meet the other resource management goals of the Northwest Forest Plan (timber harvest, hazardous fuels treatment, forest restoration). Although the Survey