CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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29

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FSIS Docket Clerk
Room 102
Cotton Annex Building
300 12th Street, S.W.
Washington, D.C. 20250-3700

00-026N
00-026N-29
Karen Egbert

Re: Notice: Reopening Of Comment Period on Target Tissue/Marker Residue Policy, Docket No. 00-026R, 66 Fed. Reg. 56,533 (Nov. 8, 2001)

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the proposal by the Food Safety and Inspection Service (FSIS) to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to the target tissue/marker residue policy in testing animal tissues for residues of new animal drugs. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

CSPI supports FSIS's proposal to modify its residue policy by condemning the entire carcass of an animal where levels of chemical residue that exceed established tolerances are found in target tissues, unless residue limits and a testing method specific to muscle tissue have

been established.[1] The fact that the current system – which allows a carcass to pass if violative residues are found only in the target tissue but not muscle meat -- has been in use for 25 years does not provide a rationale for keeping the current system in place. The existing policy and approach was established before the implementation of the Hazard Analysis and Critical Control Point system (HACCP) and well before the impact of antimicrobial drug use in animals emerged as a human public health concern.

1. Coordinating FSIS's policy with FDA's will result in safer food and provide important public health benefits.

Antimicrobial drugs have been used for years in livestock production for the purposes of prevention and treatment of diseases as well as improving animal productivity. There is increasing concern among health professionals and others about the contribution of these antibiotics to the development of resistant bacteria that may be harmful to human health. The Centers for Disease Control and Prevention (CDC) has identified numerous clinically important pathogens that are rapidly developing resistance to available antimicrobials, including bacteria that cause pneumonia, ear infections, and meningitis (*e.g., Streptococcus pneumoniae*), skin, bone, lung, and bloodstream infections (*e.g., Staphylococcus aureus*), urinary tract infections (*e.g., Escherichia coli*), and foodborne infections (*e.g. Salmonella*).[2] One study has isolated ciprofloxacin-resistant *Campylobacter* from approximately 20% of domestic retail chicken

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[1] CSPI opposes the sub-therapeutic use of medically-significant antibiotics as growth promoters in food animals and, with other groups, petitioned FDA in 1999 to rescind approvals of the sub-therapeutic uses in livestock of antibiotics used in (or related to those used in) human medicine.

[2] Centers for Disease Control and Prevention, *Antimicrobial Resistance, A Public Health Action Plan to Combat Antimicrobial Resistance: Introduction and Overview*, at p.1, <*http://www.cdc.gov/drugresistance/actionplan/html/intro.htn*>.

products sampled.[3]

According to FSIS, the "prevention of illegal chemical residues in the food supply is an integral aspect of maintaining a high level of food safety."[4] The FDA's Center for Veterinary Medicine (CVM) also has recognized that the problem of antimicrobial resistance due to the use of drugs in animals is "one of the highest priority issues" facing it.[5] At the same time, CVM has acknowledged that "the human health impact due to the use of antimicrobial drugs in food-producing animals can be difficult to assess" and that "minimizing the emergence of antimicrobial-resistant bacteria in animals and their subsequent spread to humans through the food supply is a complex problem requiring a coordinated multifaceted approach.[6]

Minimizing the emergence of antibiotic-resistant bacteria in animals and their subsequent spread to humans through the food supply requires a coordinated approach among the federal agencies, including FSIS and FDA, that are charged with public health protection. Condemning the entire carcass where levels of marker residue exceed established tolerances for target tissues is necessary because, for some new animal drugs, it is difficult to predict which microorganisms are going to develop resistance, how fast the resistance will develop, and what the overall impact will be on public health. Indeed, the CVM has admitted that it is "aware of no [] predictive models to estimate with precision the rate and extent of bacterial resistance that may emerge

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[3] *See* Kirk E. Smith, et al., *Quinolone-Resistant Campylobacter jejuni Infections in Minnesota, 1992-1998*, 340 New England Journal of Medicine 1525-32 (May 20, 1999), at p. 1529.

[4] Food Safety and Inspection Service, *1999 National Residue Program* (the "Blue Book") at 1-2.

[5] FDA, Center for Veterinary Medicine, Information for Consumers, *Antibiotic (Antimicrobial) Resistance and Animals* (Oct. 2001), *<http://www.fda.gov/cvm/index/consumer/ar200.htm>*.

[6] FDA, Center for Veterinary Medicine, *An Approach for Establishing Thresholds in Association with the Use of Antimicrobial Drugs in Food-Producing Animals: A Discussion Document* (Dec. 19, 2000), at p. 5 [hereinafter FDA, *An Approach for Establishing Thresholds*].

from the use of antimicrobial drugs in food animals."[7]

Therefore, unless FDA has determined that there is a "tolerable" concentration of a particular chemical residue in muscle tissue and testing of muscle demonstrates that the level is not exceeded, condemnation of the whole carcass where the target tissue violates the established tolerance is the only way to maintain the integrity of the use of drugs in animals and minimize the risk that resistant zoonotic organisms will be transferred from animals to humans. Whole carcass condemnation also is consistent with USDA's statutory mandate under the Federal Meat Inspection Act to prevent the introduction of adulterated meat into commerce.[8]

2. Condemning The Whole Carcass Where Violative Levels of Chemical Residues Are Found Assists in HACCP Implementation.

Under the HACCP system, all establishments are required to conduct an analysis to consider each of the potential hazards in their operations. Under FSIS regulations, chemical residues, including antibiotic residues, are a specific hazard that must be considered in the hazard analysis.[9]

In the absence of established chemical tolerances and testing of muscle meat, condemnation of the whole carcass is one way to assure that producers are following appropriate drug-use practices, including proper withdrawal periods before sale. Condemning the whole carcass where residue levels in target tissues exceed the established tolerances provides an

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[7] FDA, *An Approach for Establishing Thresholds*, at p. 10.

[8] 21 U.S.C. § 602 (finding that, among other things, "[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome [and], not adulterated . . . ."). FSIS-regulated products may be called adulterated where they bear or contain residues of drugs, pesticides, and other chemicals used in animal production or present in the animals' environment. 21 U.S.C. §§ 453(g)(1), (g)(2) & (g)(3); 601(m)(1), (m)(2), & (m)(3).

[9] 9 C.F.R. § 417.1 (defining food safety hazard to include "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption"); §§ 417.2(a)(3)(iii), (a)(3)(iv), and (a)(3)(v) (providing that food safety hazards might be expected to arise from chemical contamination, pesticides, and drug residues).

important incentive for producers to take responsibility to prevent residue-violative animals from entering the human food chain. It also provides them with an added incentive to implement farm-based controls and strategies to minimize agricultural use of antimicrobial drugs.[10] At bottom, on-farm HACCP systems are a crucial element in reducing the levels of drug residues in animals destined for food. One of these critical controls should be the requirement that producers *monitor and keep records* concerning the period of time in which drugs are administered and subsequently withdrawn in animals before they are shipped for slaughter. In short, FSIS's proposal should lead to more effective and efficient residue control.

3. USDA and the FDA Must Act As Partners In Reducing The Risk Associated With Chemical Residues In Meat Destined For Human Consumption.

The regulatory approach adopted by FDA and its Center for Veterinary Medicine in setting tolerance levels for animal drugs and the EPA in setting pesticide tolerances is one that is aimed at protecting human health. FSIS, as a partner in this effort, should be working to ensure the same level of human health protection in enforcing those tolerances in food-producing animals. In the absence of certainty as to the tolerable level of drug residues in the muscle meat and other animal parts consumed by humans, FSIS should act to harmonize its residue policies with those of the FDA. The public is entitled to the same level of health protection, no matter which federal agency has regulatory responsibility for the activity involved.

CONCLUSION

CSPI supports FSIS's effort to harmonize its policy toward chemical residues in animals intended for human consumption with that of the Food and Drug Administration. The emerging

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[10] FSIS has advanced this effort by announcing that it will identify and publish on its Web site a Residue Violation Alert List containing the names of companies and producers who sell livestock or poultry containing violative drug and chemical residues. 66 Fed. Reg. 40,965 (Aug. 6, 2001).

resistance of some food-borne pathogens to antibiotics heightens the need to assure that chemical residues, including antimicrobials, are not disseminated through the food chain. Only by preventing establishments from selling meat from carcasses in which violative residues are discovered can the public health truly be protected. We therefore urge the adoption of the proposed revisions to FSIS's target tissue/marker residue policy.

Sincerely,

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