Consumer Reports

August 29, 2018

Sonny Perdue, Secretary
U.S. Department of Agriculture
1400 Independence Avenue SW
Washington, D.C. 20250

Dear Secretary Perdue:

We are writing to you about our serious concerns regarding how the U.S. Department of Agriculture (USDA) is carrying out its responsibility to ensure that unapproved drugs do not get into the meat and poultry Americans eat every day. A recent Consumer Reports review of USDA testing data from 2015-16, obtained by a Freedom of Information Act (FOIA) request by another organization, found residues of unapproved drugs in numerous samples of meat and poultry, on which the USDA has taken no action.

We brought our concerns about these findings to the Food Safety and Inspection Service (FSIS). After several exchanges, we never received a scientifically convincing rationale for how so many of the entries in the final data set issued by the agency could be recorded as non-detectable residues after the initial data set we reviewed contained thousands of data points showing detectable amounts. After considering the explanations provided and a careful review of the data and FSIS methods by our scientists and others, we continue to believe this data merits further attention and action.

**Legal Responsibilities of the FDA and USDA**

Ensuring the safety of drug use in food animals is a joint responsibility of the USDA and the Food and Drug Administration. The Food, Drug and Cosmetic Act requires that for any drug intended for use in food animals, the FDA must determine that it is safe for humans and animals. If approved, the FDA should establish a tolerance for the drug in meat and poultry that cannot be exceeded.

If a drug is not approved by the FDA for use in food animals, it may still sometimes be used under a veterinarian's supervision. However, in no case may there be residues in meat and poultry. For a small number of drugs, such as chloramphenicol and nitroimidazoles, the FDA prohibits any use at all in food animals, as well as prohibiting residues in meat, because of the risk to human health.

101 Truman Avenue
Yonkers, NY 10703
(914) 378-2000

The USDA has the responsibility of monitoring the meat and poultry supply for possible residues of approved and unapproved drugs, and reporting violations to the FDA for enforcement action. The USDA monitors and identifies violations through the National Residue Program.

**National Residue Program Not Effective**

The USDA does not appear to be monitoring and identifying violators effectively with regard to unapproved drugs. The National Residue Program tests approximately 7,000 randomly chosen samples of chicken, turkey, swine, and cattle for drugs and chemicals annually. Officially, for the past two years, the USDA has reported only about two dozen violations in this program, only a handful of which are for unapproved drugs. Yet, USDA 2016 test data released in response to a series of FOIA requests—and analyzed by Consumer Reports—showed hundreds of samples with residues of unapproved drugs. Any residue of an unapproved drug, which has no approved tolerance, is considered violative. As the NRP states, "A violation occurs when an FSIS laboratory detects a chemical compound level in excess of an established tolerance or action level as well as if the residue detected has no approved tolerance." Some of the results for residues of unapproved drugs, which do not have tolerances and in some cases can never be used in food animals even under a veterinarian's supervision, are quite concerning, such as for chloramphenicol and phenylbutazone, both of which can cause fatal blood disorders.

The USDA has apparently taken no action based on this data. To our knowledge, the agency has not informed the producers of the presence of unapproved drugs in their products, nor has it informed the FDA, which has enforcement responsibility for illegal drug residues.

The FSIS maintains that the data Consumer Reports reviewed was preliminary and not confirmed; thus, no further action was required. However, based on the judgment of Consumer Reports scientists as well as other experts we consulted who are familiar with the type of testing the USDA conducts, the data warrants additional action and attention. Other agencies handle this type of test result quite differently. For example, in 2016 the FDA blocked the import of shrimp from Malaysia that tests showed contained chloramphenicol at levels as low as 0.3 parts per billion. However, the FSIS NRP takes no action even when it finds chloramphenicol in meat and poultry at levels more than ten times as high.

**Recommendations for the USDA National Residue Program**

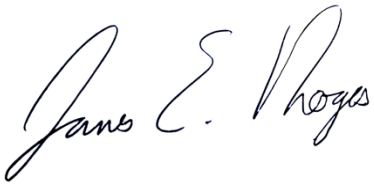
To ensure that there are no unsafe residues of unapproved drugs in meat and poultry, CR recommends:

1. The USDA should establish the limits of detection (LODs) and limits of quantitation (LOQs) for the testing equipment it is currently using, as is common practice for scientists using liquid chromatography/mass spectrometry testing equipment.

2. Given that the tolerance for a residue of an unapproved drug is zero, then for all test results for unapproved drugs that are above the LOD, the USDA should indicate that it sees a violation.
3. The USDA should publicly post the violations data each year, including the establishment that operates the facility where the USDA collected the sample.
4. The USDA should forward notices of violations where it detects a residue above the LOD for a drug that is not approved for use in food animals to the FDA, so the agency can notify the company and if necessary take enforcement action. It may be appropriate to focus enforcement on samples that exceed the LOQ as well as the LOD.
5. The USDA should abandon its use of minimum levels of applicability (MLAs). The USDA has established these levels for unapproved drugs and says that anything that falls below them is not of concern. However, the USDA has been unable to explain satisfactorily to us how these levels are derived, and has no specific requirement in current law to create them. To our knowledge, they are also not used by other federal regulatory agencies. They do not even seem that useful to the USDA itself, since in many cases the USDA has not taken action regardless of whether a residue falls above or below the MLA. For example, for chloramphenicol, in the 2015-16 NRP data, 12 beef and nine pork samples exceeded the MLA, but the USDA took no action on them.
6. The USDA should continue to monitor for residue levels of approved antibiotics and any other approved drugs in beef and pork for which there are FDA tolerances, through its Inspector Generated Sampling Program, which collects some 180,000 samples at slaughter plants and sends them to USDA labs for testing each year. In 2016, under this program, the USDA identified 724 carcasses with violative residues. Almost all of these were residues of antibiotics that are legal to use, but the residue exceeded the legal tolerance.
7. The USDA also tested swine and cattle carcasses from the 2016 Inspector Generated Sampling Program for unapproved drugs and should classify all positive results for unapproved drugs exceeding the LOD as violations, and provide information so that the FDA may focus enforcement on samples exceeding the LOQ. The database we received through a FOIA request shows dozens of positive test results for residues of such drugs. Residues of unapproved drugs are not legal. Yet, the USDA officially declared them to be violations in only a handful of cases.
8. The USDA should consider testing liver and kidney samples rather than muscle first in the NRP. Although most people do eat muscle cuts more frequently than organ meats, residues tend to be higher in the liver and kidneys. Testing those tissues first will give the USDA a better early warning system on where violations may be occurring.
9. Together with the FDA, the USDA should investigate and determine how and why drugs that produce illegal residues may be getting into the food supply. If certain unapproved drugs are absolutely needed in food-producing animals to control common diseases, the FDA should encourage manufacturers to submit applications for approval of the drug, and should establish tolerances that define a safe level in a residue. The USDA should prioritize devoting research dollars to finding safe methods of controlling these diseases or addressing other problems with the raising and slaughter of the animals.

We appreciate your considering our views and recommendations, and would be happy to meet with you or other officials of the Food Safety and Inspection Service and the National Residue Program to discuss these issues. Thank you for your concern.

Sincerely,



Jean Halloran
Director of Food Policy Initiatives
Consumers Union[1]

James E. Rogers, Ph.D.
Director, Food Safety Research and Testing
Consumer Reports

[1] Consumers Union is the advocacy division of Consumer Reports.