

**RULEMAKING PETITION TO THE  
UNITED STATES DEPARTMENT OF AGRICULTURE**

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**CENTER FOR FOOD SAFETY** )

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*Petitioner,* )

Docket Number \_\_\_\_\_ )

***Filed With:*** )

**USDA AND ADDRESS** )

FSIS Docket Clerk )  
United States Department of Agriculture )  
Food Safety and Inspection Service )  
Room 2534 South Building )  
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**EXECUTIVE SUMMARY AND INTRODUCTION**

This Rulemaking Petition seeks to strengthen the Food Safety and Inspection Service’s (FSIS) administration of the National Residue Program (NRP). FSIS administers the NRP pursuant to its authorities under the Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act. Pursuant to these statutes, FSIS is responsible for “assuring” that meat, poultry, and egg products are unadulterated and safe for human consumption.

FSIS administers the NRP in cooperation with the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), among other agencies.<sup>1</sup> Under the Federal

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<sup>1</sup> See FSIS, National Residue Program for Meat, Poultry, and Egg Products: 2018 Residue Sampling Plans – Oct. 1, 2017 to Sept. 30, 2018, at 1, <https://www.fsis.usda.gov/wps/wcm/connect/0d633930-b5fa-4db1-965c-4f4769827301/2018-Blue-book.pdf?MOD=AJPERES>.

Food, Drug, and Cosmetic Act (FDCA), FDA “establishes tolerances for veterinary drugs and action levels for food additives and environmental contaminants.”<sup>2</sup> Under the FDCA, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA), EPA “establishes tolerances for registered pesticides.”<sup>3</sup>

FSIS’s current implementation of the NRP fails to sufficiently protect the public health and welfare and fails to comply with its statutory mandates. Specifically the NRP fails to test for the residues of all approved veterinary drugs, improperly relies on FDA-established tolerances to determine which positive results meet reporting thresholds, and fails to inform the public of the full picture of residue results, including when multiple residues are present. Accordingly through this petition, Petitioners seek to strengthen the NRP by requiring FSIS to comply with this statutory mandate, in particular to (1) test for residues of all drugs approved/used in food animals; (2) establish clear definitions and parameters for minimum levels of applicability (MLA); (3) improve annual reporting mechanisms; (4) ensure that staff utilize the best available technology and methods that allow for the lowest limits of detection (LOD) for each compound; (5) set the LOD for compounds in specific tissues (and if necessary, from specific species) as the threshold for recording a positive residue result in corresponding samples; (6) disclose the LOD used for every result; (7) allow “non-detectable” to be recorded for only for results that fall below the LOD; and (8) do not allow “non-detectable” to be ascribed to results/findings found above respective LOD levels.

### **PETITIONER’S INTERESTS**

Center for Food Safety (CFS) is a nonprofit public interest organization that empowers people, supports farmers, and protects the earth from the harmful impacts of industrial agriculture through groundbreaking legal, scientific, and grassroots action. Our membership includes more than 950,000 consumer and farmer supporters across the country who support organic food and farming, grow organic food, and regularly purchase organic products. A particular programmatic focus of CFS is the use of animal drugs and the role of pharmaceutical products in industrial food production. Animal drugs, both antibiotic and otherwise, enable large-scale industrial operations to remain economically viable despite inhumane and unsanitary conditions, by accelerating growth rates and preventing diseases that would otherwise threaten their productivity.

As part of our effort to assess the impacts of the routine and/or continuous use of approved animal drugs in the millions of animals raised for food in the U.S. each year, CFS relies on a range of independent research and government-generated data to understand the scope

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<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

of the issue, report on current scientific knowledge, and provide the public with accurate information. The FSIS National Residue Program (NRP) is one important governmental resource available regarding the fate, presence, and potential exposure for approved veterinary drugs. Unfortunately, CFS's thorough analysis of the FSIS data provided through the NRP has demonstrated substantial limitations in the accuracy and integrity of the program.

In particular, the program has the following problems:

- The NRP does not test for the residues of all veterinary drugs that are approved by the FDA and may be regularly used in food animals;
- The NRP relies on tolerances established by FDA to determine positive results that meet reporting thresholds rather than the levels to which methods are capable of accurately detecting and quantifying specific residues in tissues;
- The NRP does not define all scientific parameters necessary for careful and complete interpretation nor does it disclose the data behind all positive results; and
- Public reporting mechanisms, including the annual Red Book and the dataset spreadsheets available online, do not provide the full picture of residue results.

#### **PETITION RULEMAKING ACTIONS REQUESTED:**

In light of the above flaws, Petitioners request specific changes to the NRP program. Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,<sup>4</sup> the Administrative Procedure Act (APA),<sup>5</sup> and FSIS regulations,<sup>6</sup> Petitioners request FSIS take the following actions, in a timely fashion, in order to provide valuable information to the public and other federal agencies on the frequency and levels of drug residues in or on meat, poultry, and egg products in the U.S.:

- Incorporate all approved animal drugs into the NRP;
- The NRP must utilize the best available methods that provide for the lowest limits of detection and quantitation and disclose LOD used for each result;
- Use science-based thresholds, such as the LOD, for categorizing samples as positive for detectable residues and report all results for results found at or above the LOD;
- Establish clear definitions and parameters for MLAs; and

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<sup>4</sup> U.S. CONST. amend. I.

<sup>5</sup> 5 U.S.C. § 553(e).

<sup>6</sup> 9 C.F.R. Part 392.

- Improve the NRP reporting mechanisms to provide publicly-available information on all samples with positive residues regardless of whether the levels detected exceed minimum levels of applicability or FDA tolerances.

Failure by the Administrator to take the requested actions would severely harm Petitioners’ interests. It also would violate the mandates of the Federal Meat Inspection Act<sup>7</sup>, the Poultry Products Inspection Act<sup>8</sup>, and the Egg Products Inspection Act<sup>9</sup> to “protect the health and welfare of consumers” and would be arbitrary and capricious.

### **APPLICABLE LEGAL AND REGULATORY BACKGROUND**

Under the First Amendment to the U.S. Constitution, the people have a right “to petition the Government for a redress of grievances.”<sup>10</sup> This right “is cut from the same cloth as the other guarantees of that Amendment, and is an assurance of a particular freedom of expression.”<sup>11</sup> The Petition Clause ensures “that people ‘may communicate their will’ through direct petitions to the legislature and government officials.”<sup>12</sup> The right to petition “extends to all departments of the Government.”<sup>13</sup>

Under the APA, “[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”<sup>14</sup> If an agency denies a petition, “[p]rompt notice shall be given of the denial . . . accompanied by a brief statement of the grounds for denial.”<sup>15</sup> The denial of a petition is subject to judicial review.<sup>16</sup>

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<sup>7</sup> 21 U.S.C. § 601 *et seq.*

<sup>8</sup> 21 U.S.C. § 451 *et seq.*

<sup>9</sup> 21 U.S.C. § 1031 *et seq.*

<sup>10</sup> U.S. CONST. amend. I.

<sup>11</sup> *McDonald v. Smith*, 472 U.S. 479, 482 (1985).

<sup>12</sup> *Id.* (quoting James Madison, 1 Annals of Cong. 738 (1789)).

<sup>13</sup> *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

<sup>14</sup> 5 U.S.C. § 553(e).

<sup>15</sup> 5 U.S.C. § 555(e). *See Auer v. Robbins*, 519 U.S. 452, 459 (1997).

<sup>16</sup> 5 U.S.C. §§ 702, 706. *See Auer v. Robbins*, 519 U.S. at 459.

FSIS administers the NRP under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.<sup>17</sup> Pursuant to these statutes, FSIS is charged with “assuring” that meat, poultry, and egg products distributed to consumers are wholesome, not adulterated, and properly marked, labeled, and packaged.<sup>18</sup> These statutes are intended to primarily benefit and inform consumers so that they have confidence that meat, poultry, and egg products are in fact safe for consumption when purchased.<sup>19</sup> Any rulemaking procedure conducted under these statutes must “emphasize the understanding of the consumer[.]”<sup>20</sup>

FSIS administers the NRP in cooperation with the FDA and the EPA, among other agencies.<sup>21</sup> FDA “establishes tolerances for veterinary drugs and action levels for food additives and environmental contaminants” under the FFDCA.<sup>22</sup> EPA “establishes tolerances for registered pesticides under the FFDCA, FIFRA, and TSCA.”<sup>23</sup>

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<sup>17</sup> See FSIS, National Residue Program for Meat, Poultry, and Egg Products: 2018 Residue Sampling Plans – Oct. 1, 2017 to Sept. 30, 2018, <https://www.fsis.usda.gov/wps/wcm/connect/0d633930-b5fa-4db1-965c-4f4769827301/2018-Blue-book.pdf?MOD=AJPERES>.

<sup>18</sup> See 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs).

<sup>19</sup> See e.g., *Fed’n of Homemakers v. Hardin*, 328 F.Supp. 181, 184 (D.D.C. 1971) (“primary purpose” of Federal Meat Inspection Act “is to benefit the consumer and to enable him to have a correct understanding of and confidence in meat products purchased.”).

<sup>20</sup> *Id.*

<sup>21</sup> See FSIS, National Residue Program for Meat, Poultry, and Egg Products: 2018 Residue Sampling Plans – Oct. 1, 2017 to Sept. 30, 2018, at 1, <https://www.fsis.usda.gov/wps/wcm/connect/0d633930-b5fa-4db1-965c-4f4769827301/2018-Blue-book.pdf?MOD=AJPERES>.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

## **FACTUAL BACKGROUND AND ARGUMENT**

### **Regulation of approved animal drugs and their residues**

In the United States, there are over 400 drug compounds approved for administration to food animals for growth promotion, feed efficiency, disease prevention, disease control, disease treatment, or reproductive purposes.<sup>24</sup> Many of these drugs can be administered to animals continuously for long durations of time or up until the last days or hours before slaughter, some without any drug withdrawal times. Due to such regular patterns of use, the presence and frequency of single and multiple drug residues in both the edible tissues and waste products of food animals must be thoroughly understood to best protect human health, food safety, and the environment, including soil and water systems near food animal operations--which can be vectors of virulent bacteria contamination downstream.

Regulatory oversight of animal drugs in the U.S. is complex, and involves, in addition to FSIS, the Centers for Disease Control and Prevention (CDC), the Center for Veterinary Medicine (CVM) within FDA, and EPA.<sup>25</sup> Among these agencies, FDA must pre-approve animal drugs before they can be commercialized and regulates their use and distribution afterward. However, CDC, FSIS, and EPA also serve important functions in federal monitoring and surveillance of animal drugs used in livestock.

Under the FFDCA, in evaluating an application for approval of a drug in animals FDA must consider: (1) the probable consumption of the drug and of any substance formed in or on food because of the use of the drug, and (2) the cumulative effect the drug has on humans or animals, taking into account any chemically or pharmacologically related substance.<sup>26</sup> Once approved, FDA does not routinely monitor emerging data on approved drugs but relies on others to bring the data to its attention.

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<sup>24</sup> 21 C.F.R. § 520.23-520.2645 (Oral Dosage Form New Animal Drugs); 21 C.F.R. § 522.23-522.2690 (Implantation or Injectable Dosage Form New Animal Drugs); 21 C.F.R. § 558.3-558.680 (New Animal Drugs for Use in Animal Feeds).

<sup>25</sup> National Research Council, *The Use of Drugs in Food Animals: Benefits and Risks*. Washington, D.C.: National Academies Press, p. 88 (1999), available at <https://www.ncbi.nlm.nih.gov/books/NBK232571/>.

<sup>26</sup> 21 U.S.C. § 360b(d)(2).

Regardless of who requests review of a drug’s safety or provides new data, FDA has a mandatory duty to withdraw approval of an animal drug when it finds the drug to be unsafe.<sup>27</sup> FDA must withdraw an approval for an animal drug if new evidence, tests, or methods developed since approval of the application show that the drug is not safe for use “under the conditions of use upon the basis of which the application was approved.”<sup>28</sup> FSIS, along with CDC and EPA, maintain oversight of different agricultural pathways that can provide FDA with a more holistic understanding of the fate, effects, and safety of approved animal drugs to better inform the New Animal Drug Application (NADA) and potential withdrawal processes.

FSIS must “protect the health and welfare of consumers” by “assuring” that meat and meat food products distributed to consumers “are wholesome, not adulterated, and properly marked, labeled, and packaged.”<sup>29</sup> Congress enacted nearly identical statutes with respect to poultry and eggs.<sup>30</sup> “As a public health agency, FSIS uses science to achieve the statutory mission laid out for [it] by Congress.”<sup>31</sup> “FSIS must use science-based practices” to achieve its “continued mission . . . to ensure that consumers have the safest possible food supply.”<sup>32</sup> Accordingly, and in order to provide FDA with an accurate understanding of the frequency and levels at which residues of approved drugs are present on meat, poultry and eggs, FSIS must utilize the best available science and analytical methods to achieve the lowest limits of detection possible in order to ensure that consumers have the safest possible food supply.<sup>33</sup> Using the lowest limits of detection based on current methods, FSIS must also provide FDA and the public with complete information about all detectable residues in its random and targeted sampling each year and cannot limit reporting to violative residues.

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<sup>27</sup> 21 U.S.C. § 360b(e); *Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750, 752-53 (D.C. Cir. 1980) (upholding FDA’s order withdrawing the new animal drug approval for the use of diethylstilbestrol (DES)).

<sup>28</sup> 21 U.S.C. § 360b(e)(1)(B).

<sup>29</sup> 21 U.S.C. § 602.

<sup>30</sup> *See* 21 U.S.C. §§ 451 (poultry) and 1031 (eggs).

<sup>31</sup> FSIS, *One Team, One Purpose: Protecting Public Health and Preventing Foodborne Illness*, at 3 (Dec. 1, 2013), <https://www.fsis.usda.gov/wps/wcm/connect/7a35776b-4717-43b5-b0ce-aeec64489fd/mission-book.pdf?MOD=AJPERES>.

<sup>32</sup> FSIS, *FSIS as a Public Health Agency: Essentials of a Public Health Regulatory Agency*, at 15 (Sept. 4, 2012), [https://www.fsis.usda.gov/wps/wcm/connect/32fda672-a9b5-427f-aedb-f2466a0fc1b7/PHVt-Essentials\\_PH\\_Regulatory\\_Agency.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/32fda672-a9b5-427f-aedb-f2466a0fc1b7/PHVt-Essentials_PH_Regulatory_Agency.pdf?MOD=AJPERES).

<sup>33</sup> *Id.*; *see* 21 U.S.C. §§ 451, 602, and 1031.

Adequate understanding of the frequency and levels of animal drug residues on meat, poultry and eggs is essential to protecting public health and ensuring adequate regulatory oversight. Unfortunately, FSIS's current sampling program does not accurately capture the presence of single or multiple veterinary residues in meat, poultry, and eggs, and independent research indicates that residues may be more prevalent in our food supply than FSIS reporting suggests.

For example, a Consumer Reports study tested approximately 240 pork products, and found residual amounts of ractopamine in about one-fifth of the samples tested.<sup>34</sup> The majority of detected residues were present at levels below 5 ppb, which is well below FSIS's minimum levels of applicability (MLA) for swine muscle of 25 ppb. This illustrates the extent to which FSIS is failing to provide the public or other regulatory agencies with adequate information about the actual presence of single or multiple veterinary drug residues in animal tissues. By using technology and methodology that allowed for a low detection threshold, below 5 ppb, Consumer Reports scientists were able to accurately detect the presence of ractopamine residues in nearly 50 pork samples among a comparatively small sample set (n=240). In contrast, FSIS testing of just over 90,000 non-dairy cattle and pork in FY 2017 and 2016 identified only 24 samples with positive ractopamine residues, ranging from the lowest positive, non-violative residue level reported of 5 ppb to levels as high as 167 ppb.<sup>35</sup>

Ractopamine is just one example illustrating the likelihood that FSIS is underreporting the actual presence of single and multiple veterinary drug residues in meat, poultry, and eggs each year. It is likely that FSIS is similarly underreporting the presence of several, if not all, veterinary drug residues included in its sampling program. Additionally, the fact that FSIS residue protocols do not require testing for residues of dozens of approved animal drugs that may be routinely used in food animals, the public and the federal government are in the dark regarding the extent and frequency of acute and chronic exposure to multiple drug residues. A study by a researcher at the University of Michigan investigating residues of approved antimicrobial drugs in meat and egg samples found lasalocid residues in 11 of 15 samples, ranging from 2.8 to 15.5 ppb; clopidol in 15 of 15 samples ranging from 203.2 to 1,414.5 ppb; salinomycin in 10 of 15 samples ranging from 4.1 to 14.5 ppb; monensin in 8 of 15 samples

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<sup>34</sup> Consumer Reports, *Consumer Reports Investigation of Pork Products Finds Potentially Harmful Bacteria Most of Which Show Resistance to Important Antibiotics*, Press Release (Nov. 27, 2012), <https://www.consumerreports.org/media-room/press-releases/2012/11/my-entry-4/>.

<sup>35</sup> Datasets available as spreadsheets via FSIS at <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/red-books/red-book>. FY 2017 samples positive for ractopamine: 8 steer, 3 market swine. FY 2016 samples positive for ractopamine: 4 heifer, 3 steer, 6 market swine.



ranging from 1.6 to 6.6 ppb; decoquinone in 9 of 15 samples ranging from 30.2 to 191.5 ppb; halofuginone in 15 of 15 samples ranging from 1.1 to 4.4 ppb; and diclazuril in 14 of 15 samples ranging from 2.7 to 20.1 ppb.<sup>36</sup>

Continued detection of positive and variable veterinary drug residues at high frequency rates in meat, poultry, and eggs by independent scientific studies indicates that regulatory agencies lack sufficient information required to properly oversee the approval and use of animal drugs. During the NADA process, FDA is required to consider the likelihood that the drug or its residues may be consumed due to its presence in or on foods as well as the cumulative effect of exposure to the drug and any other pharmacologically related substances.<sup>37</sup> To accomplish these objectives, FDA must have access to complete, precise, reliable and accurate information regarding the frequency and levels at which residues of all approved veterinary drug may be present on meat, poultry, and eggs. Providing such data is critical to the regulation of animal drugs, especially given the complete lack of oversight, monitoring, or tracking of drug residues and public exposures through non-food pathways at this time

### **FSIS must test for all drugs approved for use in food animals in the U.S.**

Currently, the residues of most routinely used animal drugs are not tracked by any federal or state agency. FSIS is the only agency monitoring the residues of any veterinary drugs. However, FSIS's annual monitoring program—the NRP—includes only a limited number of approved veterinary drugs. In 2017, for example, the NRP tested for only 49 approved animal drugs (see Table 1). The remaining 171 compounds in the agency's testing protocol are either veterinary drugs not approved for use in food animals (and therefore illegal), pesticides, or metals. There are *hundreds* of other animal drugs that are legally used routinely in food animals that are not captured by FSIS's current testing protocols. Further, FSIS only consistently tests edible tissues gathered through randomly scheduled sampling or inspector-generated samples. No agency at this time monitors residues of any veterinary drugs in food animal waste products, which may enter the environment and impact public health depending on waste management strategies, including their use as fertilizer in crop production.

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<sup>36</sup> W. Banka, "Veterinary Drugs Not Approved for Human Use in the US Food Supply: Evidence and Policy Implications," *Mich. J. of Pub. Affairs*, 15 (May 28, 2018): pp. 5-17. <https://issuu.com/michiganjournalofpublicaffairs/docs/mjpa-vol15-final>.

<sup>37</sup> 21 U.S.C. § 360b(d)(2).

**Table 1: Veterinary Drugs Approved for Use in Food Animals and Included in FSIS NRP Testing - 2017**

<b>Multi-Residue Method</b>	Albendazole	Amoxicillin	Ampicillin	Azaperone	Carbadox
	Chlortetracycline	Cloxacillin	Danofloxacin	Doramectin	Enrofloxacin
	Eprinomectin	Erythromycin A	Fenbendazole	Florfenicol	Flunixin
	Gamithromycin	Levamisole	Lincomycin	Melengestrol acetate	Morantel tartrate
	Moxidectin	Oxytetracycline	Penicillin G	Pirlimycin	Ractopamine
	Sulfachlor-pyridazine	Sulfa-methoxine	Sulfaethoxy-pyridazine	Sulfamerazine	Sulfamethazine
	Sulfaquinoxaline	Tetracycline	Thiabendazole	Tildipirosin	Tilmicosin
	Tulathromycin A	Tylosin	Virginiamycin	Zeranol	
<b>Aminoglycosides Method</b>	Apramycin	Gentamycin	Hygromycin B	Neomycin	Spectinomycin
	Streptomycin				
<b>Beta-agonist Method</b>	Zilpaterol				
<b>Avermectin Method</b>	Ivermectin				
<b>Pesticides Method</b>	Dichlorvos	Imidacloprid (topical)			

Stringent regulation, oversight, and monitoring of animal drugs *and* their residues are imperative to protect public health and the environment. In particular, drugs that may be used routinely and/or continuously should be of high priority for federal monitoring and oversight to determine the extent of public exposure to pharmaceutical residues. The goal should be to ensure that people and the environment are not regularly exposed to pharmaceutical residues. In particular, monitoring all drugs that have indications for increased weight gain, improved feed efficiency, and continuous prevention or control of undiagnosed diseases or pathogens should be incorporated into all current and future federal residue monitoring programs. Drugs with these or similar indications can be administered to food animals for weeks, months, or possibly years at a time. Long duration of use, even at low levels, increases the risk of accumulating residues in the tissues or waste of animals at detectable or violative levels.

In addition, cumulative exposure and impacts from multiple drug residues must be better understood and addressed by current and future federal residue programs, including FSIS's NRP. An animal raised for food in the U.S. will likely receive multiple drugs through feed, water, injection, or oral dosage throughout its lifespan. For example, an animal may receive continuous doses of a drug approved for increased rate of weight gain and improved feed efficiency, an anti-parasitic for routine disease prevention, and an antibiotic prescribed by a veterinarian to treat or control bacterial infection. Research demonstrates that meat and poultry at the retail stage tests positive for multiple drug residues in a single cut or package. The University of Michigan research provides recent evidence supporting this, finding that every sample tested was positive

for three or more of the 12 veterinary drugs tested for, with six samples testing positive for nine or more residues.<sup>38</sup>

As such, individuals may be routinely exposed to several drugs or drug residues simultaneously, the interactions of which and their cumulative implications for human health are not being sufficiently researched or understood. Not only must cumulative exposure and impacts be considered during the new animal drug application process, it must also be factored into how FSIS reports on the presence of detectable residues in meat and poultry samples, whether violative or non-violative. Further, the University of Michigan study concludes that, “[t]he presence of multiple veterinary drug residues in every sample tested in this study suggests that the U.S. system for assigning MRL values requires significant updates...if the results of this small study are corroborated by larger studies, the conclusion must be that those who participate in eating this part of the U.S. food supply are exposed to multiple drug residues in every meat and egg sample consumed.”<sup>39</sup>

The University of Michigan study also demonstrates the frequency at which many drug residues are detected in meat and poultry that are not included in FSIS’s NRP. This means that meat and poultry samples that FSIS has determined are free of any detectable residues may nevertheless contain residues of multiple approved animal drugs for which the agency simply is not testing. For example, the study found that clopidol was present in all 15 products sampled, diclazuril in 14, and lasalocid in 11, none of which are routinely tested for by FSIS. Additional studies have consistently found food contaminated with lasalocid, clopidol in commercial egg samples, as well as nicarbazin, which is also not included in FSIS’s testing protocol.<sup>40</sup> Additional approved drugs that are not tested include: amprolium, bacitracin, decoquinatone, efrotomycin, ethopabate, halofuginone, laidlomycin, monensin, narasin, trenbolone, or zoalene.<sup>41</sup>

Several approved animal drugs can be administered to food animals continuously, for long durations of time, and with minimal or absent withdrawal times required before slaughter. In particular, drugs with indications for increased rate of weight gain, improved feed efficiency, or prevention of disease in healthy, asymptomatic animals are allowed to be used routinely. Such

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<sup>38</sup> W. Banka, *Veterinary Drugs Not Approved for Human Use in the US Food Supply: Evidence and Policy Implications*, Mich. J. of Pub. Affairs, 15 (May 28): pp. 5-17 (2018). <https://issuu.com/michiganjournalofpublicaffairs/docs/mjpa-vol15-final>.

<sup>39</sup> *Id.* at 15.

<sup>40</sup> Lesa Clarke, et al., *A review of coccidiostats and the analysis of their residues in meat and other food*, 97 Meat Science 358, 360, 363 (2014).

<sup>41</sup> FSIS, *United States National Residue Program for Meat, Poultry, and Egg Products 2017 Residue Sampling Plans*. October 1, 2016 to September 30, 2017 (2016).

patterns of use would be expected to increase the likelihood that residues of these drugs are accumulating at detectable levels in edible tissues and/or waste products. Despite this, many drugs with such indications are not included in FSIS testing protocols (See Table 2). There are at least 13 approved animal drugs allowed for extended or continuous use in at least one major species that FSIS does not look for in its testing of domestic meat and poultry products. Some, like amprolium, monensin, and decoquinatate, may be used for the entire life of the animal. Still others, like clopidol, lasalocid, and nicarbazin, are regularly detected on products tested by independent studies.

**Table 2: Approved Animal Drugs with Continuous Use and/or Short Withdrawals and not Included in FSIS NRP Testing - 2017**

<b>Drug Name</b>	<b>Species</b>	<b>Allowed Duration</b>	<b>Withdrawal Period</b>
<b>Amprolium</b>	Cattle	21 days	24 hours
	Broiler Chickens	Lifespan	None
	Laying Hens	Lifespan	None
	Turkeys	Lifespan	None
<b>Bacitracin zinc</b>	Chickens	Throughout growing stage (approx. X weeks)	None
	Laying Hens	No limit	None
	Swine	Throughout growing and finishing stages (approx. X weeks)	None
	Turkey	Throughout growing stage	None
<b>Clopidol</b>	Broiler Chickens	Lifespan	5 days
<b>Decoquinatate</b>	Cattle	28 days	None
	Broiler Chickens	Lifespan	None
<b>Diclazuril</b>	Broiler Chickens	Lifespan	None
	Turkeys	Lifespan	None
<b>Efrotomycin</b>	Swine	Continuously until 250lbs	None
<b>Laidlomycin</b>	Cattle	Throughout confinement	None
<b>Lasalocid</b>	Broiler Chickens	Lifespan	None
	Cattle	Throughout pasture-feeding and during confinement	None
<b>Monensin</b>	Cattle	Continuously while in confinement	Not stated
	Broiler Chickens	Lifespan	None
	Turkeys	Lifespan	None
<b>Narasin</b>	Broiler Chickens	Lifespan	5 days
	Swine	Continuously after 4 weeks of age	None
<b>Nicarbazin</b>	Broiler Chickens	Continuously after chicks are placed on litter	4 days
<b>Salinomycin</b>	Laying Chickens	Lifespan	None

	Broiler Chickens	5 days	24 hours
<b>Trenbolone acetate and estradiol (combination)</b>	Cattle	None established	None established

A national residue sampling program that does not test for hundreds of approved animal drugs that may be used regularly or continuously in food animals, and where results of independent studies demonstrate the likelihood of frequent and multiple residues present, is not sufficiently protecting the public from exposure to these drugs when meat, poultry and eggs are consumed.<sup>42</sup> In fact, this practice appears to hinder if not defeat the FFDCa mandate that requires FDA to determine (1) the probable consumption of the drug and of any substance formed in or on food because of the use of the drug, and (2) the cumulative effect the drug has on humans or animals, taking into account any chemically or pharmacologically related substance.<sup>43</sup> Without adequate testing, transparent and complete reporting, it is not possible to meet this mandate.

Testing methods for many untested drugs are available<sup>44</sup>, including multi-residue methods using liquid chromatography – tandem mass spectrometry (LC – MS/MS), which must be immediately incorporated into FSIS’s annual sampling plans. In 2012, researchers published two studies demonstrating the ability to reliably detect the residues of over 100 veterinary drugs using a single ultrahigh performance LC – MS/MS method, and demonstrated that FSIS needed to adopt newer analytical methods.<sup>45</sup>

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<sup>42</sup> 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs).

<sup>43</sup> 21 U.S.C. § 360b(d)(2).

<sup>44</sup> JW Kang, et al., *Veterinary drug residues in domestic and imported foods of animal origin in the Republic of Korea*, Food Additives & Contaminants: Part B, 8(2): pp. 106-112 (2015).

<sup>45</sup> S.J. Lehotay, et al. (2012). *Development and validation of a streamlined method designed to detect residues of 62 veterinary drugs in bovine kidney using ultra-high performance liquid chromatography – tandem mass spectrometry*, Drug Testing and Analysis, 4 (Suppl. 1): pp. 75-90; L. Geis-Asteggiante, et al. (2012). *Ruggedness testing and validation of a practical analytical method for >100 veterinary drug residues in bovine muscle by ultrahigh performance liquid chromatography - tandem mass spectrometry*, Journal of Chromatography A, 1258: pp. 43-54.

## **FSIS must establish clear definitions and parameters for MLAs.**

In addition to incorporating additional drugs into FSIS's annual sampling and testing protocol, and in order to "ensure the safest possible food supply" that "protect[s] the health and welfare of consumers," the agency must reevaluate its use of regulatory thresholds to determine that residue levels warrant reporting as detected versus not detected.<sup>46</sup> Currently, FSIS's MLAs for animal drugs are established based on regulatory tolerance levels set by FDA for specific species and tissues.<sup>47</sup> The FDA tolerance for ractopamine in pig tissue, for example, is 150 ppb for liver and 50 ppb for muscle.<sup>48</sup> Subsequently, FSIS's MLAs are 75 and 25 ppb, respectively.<sup>49</sup> According to FSIS officials, among other factors, drug residues in a sample must be above the established MLA for the respective species and tissue before it is considered to have screened positive for that residue.<sup>50</sup> That is not in line with scientific principles of testing which would typically characterize a detected result above the LOD to be a positive, and characterize any "negative finding" as below the LOD used. The LOD itself is a scientific threshold that is based on the sensitivity of the instrumentation to reliably detect a minimum quantity of biologic or chemical material from a given matrix. FSIS has convoluted the characterization of a positive finding and made it dependent on regulatory threshold rather than scientific principle. Atignac, et al. (2002) found that using liquid chromatography – positive electrospray tandem mass spectrometry to test for ractopamine residues in muscle, kidney, and liver samples from pigs has

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<sup>46</sup> See 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs); FSIS, FSIS as a Public Health Agency: Essentials of a Public Health Regulatory Agency, at 15 (Sept. 4, 2012).

<sup>47</sup> MLAs are only applicable to a small subset of veterinary drugs, those that have tolerances in specific species and tissues established by FDA. MLAs are set by FSIS at half the FDA tolerance level, and are used by the agency as part of the criteria for determining whether a detected residue is considered "positive." Not only are MLAs created by a regulatory rather than scientific threshold, their use by FSIS diminishes the overall value and applicability of the residue data.

<sup>48</sup> 21 C.F.R. § 556.570.

<sup>49</sup> FSIS, *Screening, Determination and Confirmation of Beta-Agonists by LC/MS/MS, Revision 10 - CLG – AGON1.10*, at 3 (Effective 11/05/2018), <https://www.fsis.usda.gov/wps/wcm/connect/c4a34027-7084-49c5-a16c-663b35ebab1e/CLG-AGON1.pdf?MOD=AJPERES>.

<sup>50</sup> Deposition of Emilio Esteban at 226-27, *Organic Consumers Ass'n v. Sanderson Farms, Inc.*, No. 3:17-cv-03592-RS (N.D. Cal. May 22, 2018). However, even if drug residues in a sample test above the established MLA, if other criteria are not met, then FSIS concludes that the compound was not detected in that particular sample. *Id.* at 227.

a detection capability of 30 parts per trillion (0.00003 ppb).<sup>51</sup> This represents a substantial disparity between the levels at which it is possible to detect ractopamine residues in tissues and the levels that trigger a positive detection result for FSIS.

The case of ractopamine illustrates the need for FSIS to reevaluate the way it defines and reports positive residues, including identifying limitations of the technology currently used, available methods and technologies that should be adopted by the Agency, and the limits of detection that can be achieved for each residue for each species and tissue type. In order to “ensure the safest possible food supply” that “protect[s] the health and welfare of consumers,” FSIS must track and keep records of all detectable residues, regardless of whether they exceed MLAs or exceed FDA tolerances.<sup>52</sup> Failure to do so is arbitrary and capricious agency action, in violation of the APA, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

This approach is critical for understanding potential cumulative exposure to and impacts of multiple veterinary drugs. The EPA has previously worked with FSIS to improve the Agency’s detection capabilities for pesticide residues and encouraged the Agency to provide records of all detected residues regardless of whether they exceed EPA’s action levels.<sup>53</sup> According to one senior FSIS official, this is precisely because they “would want to have information that is not toxic but that is lower than what is acceptable to do cumulative-type, what they call fuller – full-cup analysis.”<sup>54</sup> FSIS must adopt the strategy employed by EPA. Whether residue levels of a single drug exceed regulatory thresholds is not the only indicator of their potential impact on public health. In order to meaningfully understand the impacts from exposure to multiple drug residues on a single meat, poultry or egg product and their interactions, or cumulative exposure to multiple residues from regular consumption of several meat, poultry, or egg products, FSIS must provide the public with full information on the frequency at which detectable residues of all animal drugs are present on products. Failure to do so is a failure to take a hard look at this problem, to consider all the statutorily required factors, and to protect the public health from these drug residues.

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<sup>51</sup> J-P Antignac, et al., *Identification of ractopamine residues in tissue and urine samples at ultra-trace level using liquid chromatography – positive electrospray tandem mass spectrometry*, *Journal of Chromatography B*, 774: pp. 59-66 (2002).

<sup>52</sup> *See* 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs); FSIS, *FSIS as a Public Health Agency: Essentials of a Public Health Regulatory Agency*, at 15 (Sept. 4, 2012).

<sup>53</sup> Deposition of Emilio Esteban at 402, *Organic Consumers Ass’n v. Sanderson Farms, Inc.*, No. 3:17-cv-03592-RS (N.D. Cal. May 22, 2018).

<sup>54</sup> *Id.*

**Table 3: Approved Animal Drugs Included in FSIS NRP 2017 - MLAs versus Detection Capability**

<b>Drug Name</b>	<b>Detection Capability</b>	<b>Method Used</b>	<b>FDA Tolerance<sup>55</sup></b>	<b>FSIS MLA</b>
Zilpaterol <sup>a</sup>	LOD: 0.4 ppb LOQ: 1.3 ppb	Waters Micromass	Liver: 12 ppb	Liver: 6 ppb
Melengestrol acetate <sup>a</sup>	LOD: 3 ppb LOQ: 10 ppb	Agilent 6410	Fat: 25 ppb	1 ppb
Melengestrol acetate <sup>b</sup>	LOD: 0.20 ppb	Agilent 1100	Fat: 25 ppb	1 ppb
Zeranol <sup>a</sup>	LOD 0.3 ppb LOQ: 1 ppb	Agilent 6410	“not needed”	1 ppb
Ractopamine <sup>d</sup>	LOD: 0.00003 ppb	Alliance 2690/QuatroLC triple quadrupole	Liver: 150 ppb Muscle: 50 ppb	Liver: 75 ppb Muscle: 25 ppb
Ractopamine <sup>e</sup>	LOD: 0.39 ppb LOQ: 0.66 ppb	Agilent 6890/Agilent 5973	Liver: 150 ppb Muscle: 50 ppb	Liver: 75 ppb Muscle: 25 ppb
Carbadox				

LOD: Limit of Detection – the level at which the method/technology will be able to detect the presence of the residue

LOQ: Limit of Quantitation – the level at which the method/technology is able to reliably quantify the amount of residue.

<sup>a</sup>: J.W. Kang, et al. (2015).

<sup>b</sup>: M. Pedersen & J.H. Andersen (2011).

<sup>d</sup>: Atignac, et al. (2002).

<sup>e</sup>: M-Z Zhang, et al. (2009).

**Table 4: Detection Capability, Method, and FDA Tolerance for Approved Animal Drugs not Included in FSIS NRP 2017**

<b>Drug Name</b>	<b>Detection Capability</b>	<b>Method Used</b>	<b>FDA Tolerance<sup>56</sup></b>
Amprolium <sup>a</sup>	LOD: 20 ppb LOQ: 70 ppb	Shimadzo 8030	Liver: 500 ppb
Clopidol <sup>a</sup>	LOD: 2 ppb LOQ: 8 ppb	Shimadzo 8030	Liver: 1500 ppb
Ethopabate <sup>a</sup>	LOD: 1 ppb LOQ: 4 ppb	Shimadzo 8030	Liver: 1500 ppb
Nicarbazin <sup>a</sup>	LOD: 10 ppb LOQ: 30 ppb	Shimadzo 8030	Liver: 4000 ppb

<sup>55</sup> FDA tolerances can be found at 21 C.F.R. Part 556.

<sup>56</sup> FDA tolerances can be found at 21 C.F.R. Part 556.



Zoalene <sup>a</sup>	LOD: 0.4 ppb LOQ: 1.3 ppb	Shimadzo 8030	Liver: 3000 ppb
Trenbolone acetate <sup>a</sup>	LOD: 1.5 ppb LOQ: 6.3 ppb	Agilent 6410	“not needed”
Trenbolone acetate ( $\alpha$ -trenbolone) <sup>c</sup>	LOD: 0.33 ppb	Varian 320	“not needed”
Trenbolone acetate ( $\alpha$ -trenbolone) <sup>b</sup>	LOD: 0.33 ppb	Agilent 1100	“not needed”
Trenbolone acetate ( $\beta$ -trenbolone) <sup>b</sup>	LOD: 0.5 ppb	Agilent 1100	“not needed”
Trenbolone acetate ( $\beta$ -trenbolone) <sup>c</sup>	LOD: 0.27 ppb	Varian 320	“not needed”
Altrenogest <sup>a</sup>	LOD: none LOQ: 3.5 ppb	Agilent 6410	Muscle: 1 ppb
Altrenogest <sup>b</sup>	LOD: 0.5 ppb	Agilent 1100	Muscle: 1 ppb

LOD: Limit of Detection – the level at which the method/technology will be able to detect the presence of the residue

LOQ: Limit of Quantitation – the level at which the method/technology is able to reliably quantify the amount of residue.

<sup>a</sup>: J.W. Kang, et al. (2015).

<sup>b</sup>: M. Pedersen & J.H. Andersen (2011).

<sup>c</sup>: R.T. Cristina, et al. (2017).

As demonstrated in Tables 3 and 4 above, research over the past decade has consistently demonstrated that various methods and technologies are available that reliably detect common animal drug residues at levels well below the thresholds utilized by FSIS to make a positive determination. This, combined with the fact that FSIS does not test for numerous approved animal drugs, means that data from samples tested by FSIS could be routinely entered into Agency records as negative or non-detects despite actual presence of multiple drug residues in or on the tissue tested. FSIS’s current failure to consider this information ignores the scientific evidence to the contrary and fails in “assuring” that meat, poultry, and egg products are safe for human consumption.

It is clear that FSIS’s current NRP protocols are severely limited, out of date, and inaccurately representing the frequency and amount of veterinary drug residues present on meat, poultry, and eggs in the U.S. every year. As such, FSIS is failing in its duty “to protect the health and welfare of consumers” in violation of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.<sup>57</sup> Given the very limited available independent scientific research investigating the safety of many of these drugs, FSIS is required to provide full, accurate information about the degree to which foods may be one pathway of

<sup>57</sup> 21 U.S.C. §§ 451, 602, and 1031.

routine public exposure. FDA relies heavily on research by the drug sponsors during the application process. Independent studies are required to develop an accurate understanding of the safety, efficacy, and fate of pharmaceuticals from their intended uses. As new research becomes available, accurate residue data will be vital to understanding the implications of the research and for FDA reevaluations of relevant drug approvals. Improving FSIS's data processes is additionally critical and legally required because no other federal agency at this time monitors, tests, or reports on veterinary drug residues in other matrices, such as waste products, manure based composts and agro-ecosystems.

### **Summary: Limitations of the NRP sampling, testing, and reporting protocols**

#### NRP does not include all approved animal drugs

FSIS's NRP currently tests for 104 approved and unapproved veterinary drugs through a total of seven testing methods.<sup>58</sup> However, NRP fails to test for residues of the hundreds of other approved veterinary drugs that may be used for a wide range of therapeutic or non-therapeutic purposes in food animals. In particular, at least 13 veterinary drugs are approved for indications that allow for the regular and continuous patterns of use, such that they may be administered for weeks or months at a time, with minimal withdrawal times. The failure to test for these drugs is arbitrary and capricious agency action, making it difficult for the public or federal agencies to assess the rates and levels at which consumers may be exposed to one or multiple veterinary drugs through foods. This must be corrected and include all approved animal drugs.

#### NRP relies on regulatory, not scientific, thresholds for positive residue determinations

FSIS does not base its determinations of positive residue detections on the capacity of the best available methods and tools, but rather on tolerance levels established by FDA. This substantially limits the understanding of the rates and levels of drug residues that are actually present on foods in the U.S. FSIS's role is to determine *the presence* of residues on meat, poultry, and eggs in order to ensure that products entering the market are free of unsafe residues. A component of this responsibility is determining at which level residues of specific compounds must be considered violative and therefore trigger interventions by the manufacturer and/or agency that prevent violations from reoccurring. However, new methods and technologies have been developed which would allow FSIS to accurately detect residues at levels well below FDA tolerances. FSIS's current failure to utilize the best available scientific methods and tools renders its analysis and conclusions arbitrary and capricious, in violation of the APA, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

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<sup>58</sup> FSIS, *United States National Residue Program for Meat, Poultry, and Egg Products 2017 Residue Sampling Plans*. October 1, 2016 to September 30, 2017 (2016).

## Annual NRP reporting does not provide full data

FSIS is not currently providing complete information about positive detections within its annual sampling. Failure to provide this information is arbitrary and capricious agency action. First, the annual summaries of the residue sample results, called the Red Book, only provides information on specific drug residues detected if they were detected at violative levels. This provides a very narrow, arbitrary picture to the public of the actual details of positive detections for each year, including the specific compounds that had positive, non-violative test results and the levels at which they were present.

Information on non-violative positive results can be found in datasets available on the USDA FSIS website. However, the information in the data sets is incomplete. According to the 2016 Red Book, in FY2016 there were 50 total samples (all species) with positive residues in the Domestic Scheduled Sampling and 3,649 positive samples from the inspector-generated sampling, regardless of whether or not the levels were violative. In total between these two sampling programs, 3,699 samples were positive for residues.<sup>59</sup> However, the datasets that FSIS makes publicly available on its website and which provide the positive non-violative and positive violative samples for each fiscal year, include only 1,679 sample results.<sup>60</sup> This amounts to *less than half* of the actual positive results from that year according to the Red Book. Similarly, for FY2017 the Red Book reports 37 positive samples gathered under the Domestic Scheduled Sampling and 4,162 positive samples gathered through inspector-generated sampling, for a total of 4,199.<sup>61</sup> The dataset available online includes only 1,636 positive samples in FY2017, roughly 39% of the actual positive samples gathered in that year.<sup>62</sup>

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<sup>59</sup> FSIS, *United States National Residue Program for Meat, Poultry, and Egg Products: FY 2016 Residue Sample Results* (May 2017).

<sup>60</sup> Datasets available as spreadsheets via USDA at <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/red-books/red-book>.

<sup>61</sup> FSIS, *United States National Residue Program for Meat, Poultry, and Egg Products: FY 2017 Residue Sample Results* (March 2018).

<sup>62</sup> Datasets available as spreadsheets via USDA at <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/red-books/red-book>.

NRP’s annual sample volume is a tiny fraction of production volumes and relies almost entirely on inspector-generated samples rather than randomly scheduled sampling

In order to be lawful, a residue sampling program must capture a meaningful subset of the meat, poultry, and eggs produced and support a robust regulatory framework. However, in FY 2016 and 2017 FSIS collected 55,784 non-dairy cattle<sup>63</sup> samples and 36,463 market swine samples. This amounts to less than 100,000 samples collected from the roughly 100 billion pounds of beef and pork produced in the U.S. during that the same period.<sup>64</sup> In this same period there were no inspector-generated samples for chicken or turkey, and only 3,227 chicken and turkey samples collected under the Domestic Scheduled Sampling program.<sup>65</sup>

Additionally, 95 percent of non-dairy cattle and market swine samples were gathered through inspector-generated sampling rather than the FSIS-led Domestic Scheduled Sampling program. This means that only 5 percent of samples were gathered through a random, systematized approach that provides for the best potential snapshot of the industry as a whole. On-site inspectors play a vital role in food safety by submitting samples for testing from animals and carcasses that fail visual inspection. However, due to the high variability in sampling that may occur between sites and inspectors, relying almost exclusively on such samples for the federal residue program may distort the accuracy of the data results. FSIS’s statutory mandate<sup>66</sup> to “protect the health and welfare of consumers” requires more to determine the actual extent of public exposure to acute and chronic exposures to single and multiple antibiotic residues.

NRP is only part of the veterinary drug residue picture

It is critical to note that NRP is currently the only federal structure in place to track any veterinary drug residues from their use in food animals. At this time, no agency within or outside USDA monitors veterinary drug residues on farms or in the soil, water, or air in agroecosystems and communities in close proximity to food animal operations. Several independent studies have

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<sup>63</sup> Including beef cow, heifer, and steer samples.

<sup>64</sup> The U.S. produces roughly 24 billion pounds of beef and 24 billion pounds of pork each year. Based on USDA spreadsheets, “Beef: Supply and disappearance (carcass weight, million pounds) and per capita disappearance (pounds),” 1970-2016, and “Pork: Supply and disappearance (carcass weight), million pounds) and per capita disappearance (pounds),” 1970-2016, downloaded March 29, 2017.

<sup>65</sup> FSIS, *United States National Residue Program for Meat, Poultry, and Egg Products: FY 2016 Residue Sample Results* (May 2017); FSIS, *United States National Residue Program for Meat, Poultry, and Egg Products: FY 2017 Residue Sample Results* (March 2018).

<sup>66</sup> See 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs).

detected veterinary drugs and their residues in aquatic ecosystems near large operations<sup>67</sup>, and at least one recent study has demonstrated that drug residues may be present in air samples downwind from feedlots.<sup>68</sup> While environmental monitoring may fall under the authority of other federal agencies, the lack of comprehensive sampling and residue detection systems makes strengthening FSIS's meat, poultry, and egg testing program and addressing its limitations all the more vital for public health and food safety.

## CONCLUSION

FSIS has a duty to “ensure the safest possible food supply” in order to “protect the health and welfare of consumers.”<sup>69</sup> FSIS's current National Residue Program does not comply with the agency's overarching mandates to protect the public health and must be remedied. FSIS must create a more robust program that accurately and lawfully captures the presence, extent and frequency of veterinary drugs on or in foods. Specifically, in order to protect public health and better ensure the safety of meat, poultry, and eggs produced in the U.S., FSIS must:

- 1) Test for residues of all drugs approved for use in food animals in the U.S. Hundreds of drugs approved for use in food animals are not included in the NRP, and more than a dozen of these drugs are likely administered to animals routinely over extended periods of time with minimal withdrawal times. Independent studies demonstrate the likelihood that many of these drugs are accumulating in the edible tissues of animals. Until FSIS includes all drugs approved for use in food animals in its residue testing program, the agency is failing to capture the full scope of pharmaceuticals in meat, poultry, and eggs in violation of its duty to “ensure the safest possible food supply” that “protect[s] the health and welfare of consumers.”<sup>70</sup>
- 2) Evaluate current detection and analysis methods employed by the agency and identify any measures necessary to ensure that staff utilizes the best available methods that allow

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<sup>67</sup> S. Bartelt-Hunt, D. Snow, & T. Damon-Powell, *Occurrence of Steroid Hormones and Antibiotics in Groundwater Impacted by Livestock Waste Control Facilities*, World Environmental and Water Resources Congress: 1052 (2010).

<sup>68</sup> K.J. Wooten, et al., *Ractopamine in Particulate Matter Emitted from Beef Cattle Feedyards and Playa Wetlands in the Central Plains*, *Environmental Toxicology and Chemistry*, 37(4): pp. 970-974 (2017).

<sup>69</sup> See 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs); FSIS, *FSIS as a Public Health Agency: Essentials of a Public Health Regulatory Agency*, at 15 (Sept. 4, 2012).

<sup>70</sup> *Id.*

for the lowest limits of detection (LOD) for each compound. Research demonstrates that a range of methods, including a variety of liquid chromatography – tandem mass spectrometry, are available that can accurately detect veterinary drug residues at very low levels—less than 1 ppb for certain compounds. In order to “ensure the safest possible food supply” and “protect the health and welfare of consumers,” FSIS must take steps to identify the capabilities of its current methodologies and opportunities to shift to alternative methodologies that accurately achieve lower limits of detection.<sup>71</sup>

- 3) Set the LOD for compounds in specific tissues from specific species as the threshold for recording a positive residue result in corresponding samples. In order to “ensure the safest possible food supply” and “protect the health and welfare of consumers,” for all veterinary drugs included in FSIS’s annual testing program, the level at which available methods are capable of accurately detecting the presence of a particular residue in a species and/or tissue must be used to establish the trigger for the agency to record a positive result.<sup>72</sup> This is necessary for complete understanding of the frequency of which residues are present on meat, poultry, and eggs rather than the frequency of which they exceed certain regulatory limits. Positive results at low levels may not trigger action against a producer depending on other criteria. However, these data are vital to the ability to qualify and quantify the fate, interactions, and potential impacts of veterinary drugs from their use in food animals now and in the future.
- 4) Establish clear definitions and parameters for MLAs. It is unclear from publicly available information whether MLAs are consistently defined. It is also unclear the precise function that an MLA serves for FSIS reporting data and taking regulatory action on veterinary drug residues. According to a 2014 US. Government Accountability Office (GAO) report:

FSIS uses the term “minimum level of applicability” to refer to the lowest residue concentration that has been validated to be accurately and consistently reported by its testing method in a type of animal product. According to the executive associate, if a pesticide has an established tolerance, FSIS typically sets the minimum level of applicability at one-half of the tolerance.<sup>73</sup>

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<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> GAO, *Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations*, Report the Ranking Member, Subcommittee on Environment and the Economy, Committee on Energy and Commerce, House of Representatives, GAO-15-38 (October 2014).

The GAO report discusses FSIS’s pesticide residue testing, but current FSIS leadership indicates that MLAs are similarly established for veterinary drugs as one-half the tolerance set by FDA.<sup>74</sup> However, this is not consistently the case. For example, the MLA for the hormones melengestrol acetate is 1 ppb while FDA tolerance is set at 25 ppb. Additionally, residues exceeding the MLA are not considered “violative” and therefore do not require the agency to notify or take action against the producer. This is revealed in the FSIS datasets for FY 2016 and 2017, which include positive residue results that are below the established MLAs in certain cases. In order to “ensure the safest possible food supply” that “protect[s] the health and welfare of consumers,” FSIS must establish clear definitions and parameters for MLAs.<sup>75</sup>

- 5) Improve annual reporting mechanisms to provide the public and relevant regulatory agencies with information on all detected residues and their levels, if quantifiable, that were present on meat, poultry, and egg samples. In order to “ensure the safest possible food supply” and “protect the health and welfare of consumers,” FSIS must provide the public with clear information on the frequency of which meat, poultry, and egg samples of positive for detectable residues and the levels at which those residues were detected, regardless of whether they are considered violative under current regulatory structures.<sup>76</sup> The annual Red Book and datasets must provide results from all samples that had detectable residues, including the source of the sample, species, tissue type, compound, and quantity of residue. These results must be made available to the public in a manner and format that is accessible.

### **REQUEST FOR EXPEDITED REVIEW**

Pursuant to 9 C.F.R. § 392.8, CFS respectfully requests expedited review of this petition. The scientific information submitted with this petition “demonstrates that the requested action will reduce or remove foodborne pathogens or other potential food safety hazards that are likely to be present in or on meat, poultry, or egg products”<sup>77</sup> by 1) testing for residues of *all* drugs approved for use in food animals in the U.S.; 2) ensuring that staff utilizes the best available methods that allow for the lowest LOD for each compound; 3) setting the LOD for compounds in

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<sup>74</sup> Deposition of Emilio Esteban at 377, *Organic Consumers Ass’n v. Sanderson Farms, Inc.*, No. 3:17-cv-03592-RS (N.D. Cal. May 22, 2018).

<sup>75</sup> See 21 U.S.C. §§ 451 (poultry), 602 (meat), and 1031 (eggs); FSIS, *FSIS as a Public Health Agency: Essentials of a Public Health Regulatory Agency*, at 15 (Sept. 4, 2012).

<sup>76</sup> *Id.*

<sup>77</sup> 9 C.F.R. § 392.8(b).

specific tissues from specific species as the threshold for recording a positive residue result in corresponding samples; 4) establishing clear definitions and parameters for MLAs; and 5) improving annual reporting mechanisms to provide the public and relevant regulatory agencies with information on all detected residues and their levels, if quantifiable, that were present on meat, poultry, and egg samples.

Respectfully submitted,

A handwritten signature in cursive script that reads "Ryan Talbott".

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