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**Via Email ([Mary.Porretta@fsis.usda.gov](mailto:Mary.Porretta@fsis.usda.gov)) and Overnight Mail**

FSIS Docket Clerk  
Department of Agriculture  
Food Safety and Inspection Service  
Room 2534 South Building  
1400 Independence Avenue SW  
Washington, DC 20250-3700

Dear Ms. Porretta:

On behalf of the Animal Legal Defense Fund, Animal Welfare Institute, Compassion in World Farming, Compassion Over Killing, Farm Forward, Farm Sanctuary, and Mercy For Animals, I am submitting the attached supplemental comments in support of Farm Sanctuary et al.'s rulemaking petition 14-02 to amend regulations related to the Humane Methods of Slaughter Act and Federal Meat Inspection Act, with a focus on banning the slaughter of nonambulatory disabled (NAD) pigs.

FSIS has already banned the slaughter of NAD cattle and veal calves, explaining that, in part, such a ban would decrease the chance of producers sending weakened animals to slaughter. Banning the slaughter of NAD cattle and calves therefore incentivizes producers to reduce the number of cows that become nonambulatory by adopting humane practices on the farm, and in transit.

This logical analysis is equally relevant to the slaughter of NAD pigs and therefore must be applied by FSIS to the current petition.

As outlined in detail below, the majority of pigs sent to slaughter in the US are treated with a drug called ractopamine, which increases the chance that pigs are injured or fatigued at slaughter. By allowing the slaughter of NAD pigs, producers have no deterrent to sending to market these drugged and weakened pigs, increasing the chance that they will be subjected to inhumane treatment. A ban on the slaughter of NAD pigs would incentivize producers to improve their handling of all pigs prior to shipment and slaughter.

FSIS has recognized that there is a causal link between slaughter bans and the humane treatment of animals, both on farm and at the slaughterhouse. To claim that this link

exists for NAD cattle and veal calves but not for NAD pigs would be arbitrary and capricious.

### Background

Several years ago, FSIS denied a 2010 petition seeking a ban on the slaughter of nonambulatory pigs and other animals. At that time, FSIS attempted to distinguish its decision to allow the slaughter of NAD pigs from its ban on the slaughter of mature down cattle (as well as its anticipated ban on the slaughter of nonambulatory calves).<sup>1</sup> The agency explained that it had:

[B]anned the slaughter of cattle that became non-ambulatory after ante-mortem inspection, in part because dairy producers had an incentive to hold dairy cattle until they were exceptionally old or weak before sending them to slaughter (see 74 FR 11463; March 18, 2009). This practice allowed producers to extract as much milk as possible in the hope that the cattle would pass ante-mortem inspection before going down. Sending such weakened cattle to slaughter increased the chances that they would go down and then be subjected to inhumane conditions. FSIS has also determined that there is an incentive for establishments to inhumanely force NAD veal calves to rise and for veal calf producers to send weakened calves to slaughter.

The Agency stated that Farm Sanctuary's 2010 petition:

[D]oes not provide any information to show that pigs, sheep, goats, and other livestock are routinely handled aggressively or that they are too weak to walk when they are sent to slaughter. In fact, the petition does not provide any information on the processing and transport of NAD livestock other than pigs. Because healthy pigs may go down at slaughter because of a temporary metabolic condition, which is unrelated to on-farm practices, prohibiting the slaughter of non-ambulatory pigs is unlikely to improve practices prior to slaughter or affect humane handling at slaughter.<sup>2</sup>

In an internal agency memo, submitted to the Humane Society of the United States (HSUS) as part of a FOIA request, FSIS stated

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<sup>1</sup> Letter from Alfred V. Almanza, Administrator, FSIS, to Kathy Hessler, Professor, Lewis & Clark Law School (March 13, 2013), *available at*

[http://www.fsis.usda.gov/wps/wcm/connect/11e2996a-a496-49f4-b096-e9b99232cab6/Petition\\_FSIS\\_Resp\\_Farm\\_Sanctuary\\_031313.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/11e2996a-a496-49f4-b096-e9b99232cab6/Petition_FSIS_Resp_Farm_Sanctuary_031313.pdf?MOD=AJPERES)

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

[P]igs are typically not transported to slaughter when they are very young or in a weakened condition, a fact that makes these animals less susceptible to inhumane treatment at slaughter than veal calves. In addition, because pigs typically become non-ambulatory because of a temporary and reversible metabolic condition, prohibiting the slaughter of downer pigs would have likely have [sic] little effect on the way that pigs are treated on the farm or the condition in which they are sent to slaughter.<sup>3</sup>

FSIS, when denying the petition, overlooked HSUS' 86-page comments in support of that petition, which were timely submitted and contained more than 1,000 pages of attached sources. Those comments and sources exhaustively showed that pigs are routinely handled aggressively, and are frequently too weak to walk when they are sent to slaughter.<sup>4</sup>

Current petition:

HSUS' comments and all of their attachments are attached to this letter. The Agency now has a second chance to look at the entire record, as required by law, when deciding whether to prohibit the slaughter of non-ambulatory pigs.<sup>5</sup>

As many as 60-80%<sup>6</sup> of U.S. pigs sent to slaughter are fed a growth-promoting drug called ractopamine.<sup>7</sup> The FDA mandates that ractopamine carry a warning label stating "CAUTION: Ractopamine may increase the number of injured and/or fatigued pigs during marketing."<sup>8</sup> The drug is only given to pigs in the last few days before they are slaughtered. Because FDA allows a withdrawal period of "zero days," this drug may be

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<sup>3</sup> Exh. 1 (FDA FOIA responses), at 5.

<sup>4</sup> Exh. 2 (HSUS comments).

<sup>5</sup> See *Achernar Broad. Co. v. Fed. Comm'ns Comm'n*, 62 F.3d 1441, 1446-47 (D.C. Cir. 1995) (failure to weigh entire record is reversible error).

<sup>6</sup> SwineCast, SwineCast 0719, Ractopamine Clears the Codex Hurdle, July 6, 2012, at <http://www.swinecast.com/swinecast-0719-ractopamine-clears-the-codex-hurdle> (quoting Laurie Hueneke, Director of International Trade and Policy for the National Pork Producer's Council).

<sup>7</sup> Helena Bottemiller, *Dispute Over Drug in Feed Limiting U.S. Meat Exports*, Food & Environment Reporting Network (Jan. 25, 2012), at <https://thefern.org/2012/01/dispute-over-drug-in-feed-limiting-u-s-meat-exports/>.

<sup>8</sup> Exh. 3 (Greger Decl.), at ¶ 14; Elanco Animal Health, Freedom of Information Summary, Supplemental New Animal Drug Application NADA 140-863 Ractopamine Hydrochloride (PAYLEAN®) (2002), available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADDrugSummaries/ucm062442.pdf>.

given to pigs the day they are forced onto transport trucks and driven great distances to slaughter.<sup>9</sup>

Allowing the slaughter of NAD pigs means that producers have no incentive to reduce their use of ractopamine and thereby increases the risk of weak or injured pigs at slaughter. Producers could simultaneously increase humane treatment at the farm, in transport, and at slaughter, and reduce NAD pigs, by ceasing the use of drugs containing ractopamine. The drug's physiological, behavioral and cardiovascular effects, the stress it compounds, the hoof deformities it causes, and the combined effect of all of these elements is materially indistinguishable from the on-farm practices FSIS relied on in concluding that nonambulatory calves and mature cattle must be promptly euthanized.

Though it has only been approved for use in pigs since 1999, ractopamine has reportedly caused more adverse events in pigs than any other animal drug on the market.<sup>10</sup> The most common adverse events for ractopamine are trembling, lameness, broken limbs, reluctance or inability to move, stiffness, hyperactivity, collapse, and death.<sup>11</sup> One of the reasons ractopamine may result in more lameness in pigs is that ractopamine-fed pigs suffer a significantly greater number of front and rear hoof lesions, such as cracks, splits, erosions, and bruises, than do control pigs.<sup>12</sup> These adverse events contribute to pigs going down at the slaughterhouse and during transport.

Ractopamine also increases levels of both classes of stress hormones, which may impair immune function.<sup>13</sup> Researchers have found that pigs fed ractopamine had increased cortisol concentrations when handled aggressively compared with pigs not fed the drug.<sup>14</sup> An increase in cortisol concentration has been shown to suppress a variety of immune function parameters, such as the proliferation and function of stimulated white blood cells.<sup>15</sup>

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<sup>9</sup> See FDA, Freedom of Information Summary (2013), *available at* <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIA/ADrugSummaries/UCM374306.pdf>.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Exh. 3, at ¶ 14; R. Poletto, et al., *Effects of "Step-Up" Ractopamine Feeding Program, Sex, and Social Rank on Growth Performance, Hoof Lesions, and Enterobacteriaceae Shedding in Finishing Pigs*, 87 J. ANIMAL SCI. 304 (2009).

<sup>13</sup> Exh. 3, at ¶ 10.

<sup>14</sup> *Id.*; B.W. James, et al., *Effect of Dietary L-Carnitine and Ractopamine-HCl (Paylean) on the Metabolic Response to Handling in Growing-Finishing Pigs*, 91(9) J. ANIMAL SCI. 4, 426 (2014).

<sup>15</sup> Exh. 3, at ¶ 10; J. de Groot, et al., *Long-Term Effects of Social Stress on Antiviral Immunity in Pigs*, 73 PHYSIOLOGY & BEHAV. 145 (2001).

Ractopamine makes the heart beat faster, relaxes blood vessels, and contracts cardiac tissue.<sup>16</sup> Ractopamine is linked to cardiovascular stress, muscular skeletal tremors, increased aggression, acute toxicity, and genotoxicity.<sup>17</sup> Ractopamine-fed pigs have heightened concentrations of the stress-hormone norepinephrine, which increases the growth and production of virulence factors in foodborne pathogens.<sup>18</sup> “[E]ven brief exposure of enteric pathogens to physiological concentrations of stress hormones can result in massive increases in growth and marked changes in expression of virulence factors such as adhesins and toxins.”<sup>19</sup> Adhesins facilitate infection by allowing pathogens to attach to the intestinal lining. *Campylobacter* and *E. coli* O157:H7 both increase the expression of virulence factors when exposed in vitro to norepinephrine.<sup>20</sup> Increased norepinephrine exposure also appears to increase the adherence of toxin-producing *E. coli* to porcine colonic mucosa,<sup>21</sup> and may cause a 10,000-fold increase in growth of toxin-containing bacteria such as *Salmonella*.<sup>22</sup> Norepinephrine also dramatically increases the growth of *Yersinia enterocolitica*.<sup>23</sup> In short, ractopamine makes pigs more susceptible to stress and disease, both of which can increase the rates of NAD pigs at slaughterhouses.<sup>24</sup>

Additionally, by making pigs more excitable, ractopamine makes pigs more difficult to handle. This, in turn, induces slaughterhouse workers to use harsher handling methods on ractopamine-fed pigs. A 2003 study published in the *Journal of Animal Science* found

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<sup>16</sup> Center for Food Safety, *America’s Secret Animal Drug Problem* 11 (2015), at [http://www.centerforfoodsafety.org/files/animal\\_drug\\_final\\_63173.pdf](http://www.centerforfoodsafety.org/files/animal_drug_final_63173.pdf); Bottemiller, *supra* note 7.

<sup>17</sup> Center for Food Safety, *supra* note 16, at 11.

<sup>18</sup> Exh. 3, at ¶ 11; J.N. Marchant-Forde, et al., *The Effects of Ractopamine on the Behavior and Physiology of Finishing Pigs*, 81 J. ANIMAL SCI. 416 (2003); M. Lyte, *Microbial Endocrinology and Infection Disease in the 21<sup>st</sup> Century*, 12(1) TRENDS MICROBIOLOGY 14 (2004); M.J. Toscano, et al., *Cultivation of Salmonella Enterica Serovar Typhimurium in Norepinephrine-Containing Medium Alters in Vivo Tissue Prevalence in Swine*, 43 J. EXP. ANIMAL SCI. 329 (2007).

<sup>19</sup> *Id.*

<sup>20</sup> Exh. 3, at ¶ 11; P. Freestone & M. Lyte, *Stress and Microbial Endocrinology: Prospects for Ruminant nutrition* 4(7) ANIMAL 1248 (2010).

<sup>21</sup> Exh. 3, at ¶ 11; B.T. Green, et al., *Adrenergic Modulation of Escherichia Coli O157:H7 Adherence to the Colonic Mucosa*, 287 AM. J. PHYSIOL. GASTROINTEST. LIVER PHYSIOL. G1, 238-56 (2004).

<sup>22</sup> Exh. 3, at ¶ 11; M. Lyte, *supra* note 18.

<sup>23</sup> Exh. 3, at ¶ 12; M. Lyte & S. Ernst, *Catecholamine Induced Growth of Gram Negative Bacteria*, 50 LIFE SCI’S 203 (1992). Nearly 100,000 Americans are sickened by the foodborne *Yersinia* every year, and 100% of the attributable *Yersinia* outbreaks reported in the U.S. from 1999-2008 were caused by pork. Exh. 3, at ¶ 12; E. Scallan, et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17(1) EMERGING INFECTIOUS DISEASES 7 (2011); M.B. Batz, et al., *Ranking the Disease Burden of 14 Pathogens in Food Sources in the United States Using Attribution Data from Outbreak Investigations and Expert Elicitation*, 75(7) J. FOOD PROTECTION 1, 27 (2012).

<sup>24</sup> See Exh. 2, at 34.

that pigs fed Ractopamine needed 52% more pats, slaps, and pushes from the handler to enter the weighing scales.<sup>25</sup> There are reports of animals on ractopamine becoming so aggressive and hyperactive that they must be medicated to calm down enough for shipping to slaughter.<sup>26</sup>

The FDA's adverse drug experience reports confirm that on-the-farm use of ractopamine affects the number of downer pigs arriving at slaughterhouses.<sup>27</sup> The reports are rife with accounts of increased numbers of dead or downed pigs after producers began using ractopamine.<sup>28</sup>

The reports also show that multiple on-farm and transit practices can result in increased numbers of dead and downed animals. Producers reported that the combination of ractopamine and rougher handling resulted in more downed pigs. Producers were only able to reduce the number of downed pigs by changing handling practices, truck density, and/or eliminating the use of ractopamine.<sup>29</sup>

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<sup>25</sup> Jeremy Marchant-Forde, et al., *The Effects of Ractopamine on the Behavior and Physiology of Finishing Pigs* 81 J. ANIMAL SCI. 416-22 (2003) (difficulty walking due to use of ractopamine may contribute to a greater incidence of non-ambulatory pigs).

<sup>26</sup> Center for Food Safety, *supra* note 16, at 13.

<sup>27</sup> Exh. 4 (ADE reports).

<sup>28</sup> *See, e.g., id.* at 169; 179-81; 18 (gilts fed ractopamine showed trembling, difficulty walking, hind leg weakness, hoof splitting, and vaginal discharge); 186 (University of Illinois study showed that ractopamine and magnesium sulfate resulted in many dead animals as well as animals demonstrating signs of stress such as immobility, rapid breathing, severe redness of skin, and muscle tremors); 189 (producer compared death rates at slaughterhouse of hogs fed ractopamine versus hogs not fed ractopamine, and found that hogs fed higher amounts of ractopamine had much higher death and downer rates at slaughterhouse and at the barns); 298 (feeding experiments demonstrated that ractopamine use caused 10% death loss); 208; 210 (pigs fed ractopamine demonstrated stiffness, shoulder lameness, and foot pad lesions); 215 (pigs fed ractopamine were more difficult to handle, more excitable and scared, and more difficult to load and unload); 220 (of 192 pigs shipped, 25 pigs were down on arrival, and one was dead; no pigs dead previously when fed lower dose of ractopamine); 224 (several finishers fed ractopamine died or became weak and slow to move); 226 (twice owner shipped 180 hogs and had 5-6 animals go down; owner had had no downers prior to using ractopamine); 228; 256 (downer rate doubled when sending ractopamine-fed pigs to market); 267; 273; 274; 275.

<sup>29</sup> *See, e.g., id.* at 170 (facility saw large increase in downers after began using ractopamine, and although the facility saw reduced numbers of downers after changing handling and transit practices, continued to see downers); 174 (experiment showed that aggressive handling coupled with ractopamine use resulted in the highest rates of downers); 179, 184; 213 (pigs fed ractopamine had double the rates of downers when shipped longer distances; rates of downers decreased with decreased numbers of pigs per truck and improved handling techniques); 214-15 (research trial demonstrated that pigs fed ractopamine had altered behavior and physiology, were more difficult to handle, and more susceptible to handling and transport stress); 218 (death and downer rates for pigs fed ractopamine decreased only after changing handling and loading procedures); 263 (ractopamine-fed pigs had increased death rates, which were only

One report showed that, after the producer began using ractopamine, in one load alone seven pigs had to be euthanized on the trailer due to inability to move, sixty-one pigs had to be “assisted to the facility by mechanical means,” and twenty-three pigs became recumbent a few hours after arrival.<sup>30</sup> Only eighty-four of the pigs from that load were slaughtered normally.<sup>31</sup> The facility was only able to lower its rate of downers after changing handling practices.<sup>32</sup>

The reports also demonstrate that pigs showing the effects of ractopamine use can be treated cruelly at the slaughterhouse. One report notes that pigs fed a high dose of ractopamine were “reluctant” to leave their trailer, and had “no energy.” The pigs only moved after receiving an “excessive amount of prodding” and a “hot shot.”<sup>33</sup>

According to USDA, roughly 115,000,000 pigs were slaughtered in 2015.<sup>34</sup> If 60% percent of those animals were drugged with ractopamine, that means about 69,000,000 pigs were suffering many of the conditions discussed above. The National Pork Producer’s Council estimates that 80% of all pigs sent to slaughter have been drugged with ractopamine.<sup>35</sup> Under that estimate, roughly 92,000,000 pigs per year are sent to slaughter likely suffering from one or more of the side effects of ractopamine.

Even if every calf sent to slaughter in 2015 became non-ambulatory and suffered the cruel raising and handling practices that led the agency to ban the slaughter of down calves, only 434,051 calves would have suffered.<sup>36</sup> In other words, at least 68.5-91.5 million fewer calves were subjected to cruel treatment per year than pigs were fed ractopamine.<sup>37</sup> The inhumane incentives and practices that cause pigs to go down and suffer at slaughter are indistinguishable from practices that led FSIS to ban the slaughter of down calves. The Agency cannot reasonably defend prohibiting the slaughter of downed calves, while allowing the slaughter of pigs too weak, stressed, sick or injured to stand.

When FSIS issued its final rule prohibiting the slaughter of downed calves, it stated:

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minimized after adjusting “loading process, facilities and staff”); 270 (pigs fed ractopamine had 18 deads on arrival after trucks were overloaded).

<sup>30</sup> *Id.* at 171.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 194.

<sup>34</sup> See USDA, Livestock Slaughter: 2015 Summary 8 (2016), available at <http://usda.mannlib.cornell.edu/usda/current/LiveSlauSu/LiveSlauSu-04-20-2016.pdf>.

<sup>35</sup> SwineCast, *supra* note 6.

<sup>36</sup> Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves, 81 Fed. Reg. 46,570, 46,575 (July 18, 2016) (to be codified at 9 C.F.R. pt. 309.1(b)). FSIS estimates there were 720 to 1,187 NAD calves in 2015. *Id.*

<sup>37</sup> *Id.*

FSIS is amending the regulations to improve compliance with the [Humane Methods of Slaughter Act] and improve the Agency's inspection efficiency by eliminating the time that FSIS inspectors spend re-inspecting non-ambulatory disabled veal calves.

If the calf rule improves FSIS efficiency by eliminating time spent re-inspecting a comparatively tiny number of down calves, then FSIS' reasoning applies with even greater force here: inspectors must re-inspect a far greater number of downed pigs at slaughter.

Agency action is arbitrary when similar situations are treated differently without a reasoned justification.<sup>38</sup> Pigs, like calves, go down as a result of inhumane practices on the farm and during transit. Pigs, like calves, are subjected to cruel treatment when they go down. And pigs, like calves, historically must be re-inspected – at cost to the Agency. Indeed, as discussed above, these things are true of pigs even more than calves. As such, denying this petition by attempting to distinguish between the humane incentives of a NAD cattle or calf slaughter ban and a NAD pig slaughter ban would be arbitrary and capricious.

Thank you for your consideration.

Sincerely,



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<sup>38</sup> See, e.g., *Ashkar v. Burzynski*, 384 F.3d 1193, 1998 (9th Cir. 2004); *SKF USA Inc. v. United States*, 263 F.3d 1369, 1382 (Fed. Cir. 2001).