



United States Department of Agriculture

Food Safety and
Inspection Service

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20250

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SEP 16 2019

Dear Ms. Watkins:

The Food Safety and Inspection Service (FSIS) has completed its review of the petition submitted on behalf of the Farm Sanctuary and various other animal welfare advocacy organizations requesting that the Agency amend its ante-mortem inspection regulations to require that all non-ambulatory disabled (NAD) pigs be condemned and promptly euthanized. The petition states that the action is needed to enhance food safety, to better ensure humane handling of NAD pigs, and to improve inspector efficiency at swine slaughter establishments. After carefully considering the issues raised in the petition, and the referenced information and other letters received in support of the petition, FSIS has concluded that its existing regulations and inspection procedures are sufficient and effective in ensuring that NAD pigs are handled humanely at slaughter and in preventing diseased animals from entering the human food supply. Thus, for the reasons discussed below, the Agency is denying the petition.

Food Safety

The petition asserts that FSIS should prohibit the slaughter of NAD pigs to fulfill its food safety mandate. The petition argues that NAD pigs are more likely to be contaminated with *Salmonella* and other pathogens of concern because they typically spend more time in lairage than ambulatory pigs. The petition references studies that link long holding times and fecal contamination at pig slaughter establishments to increased contamination of live animals with *Salmonella*, *Campylobacter*, and *Yersinia enterocolitica*. The petition asserts that NAD pigs are held longer than other pigs in lairage and exposed to more fecal matter because they cannot rise from the holding pen floor. The petition notes that studies have identified ante-mortem fecal contamination of live animals as the primary source of *Salmonella* contamination of carcasses at slaughter. Thus, according to the petition, ante-mortem condemnation of NAD pigs is necessary to reduce the risk of product contamination.

Available research indicates that the stress of transportation and the holding of animals in lairage may increase the prevalence of certain pathogens and may be potential sources of pathogen cross-contamination for live animals. Thus, as noted in the petition, FSIS has issued guidance that states "lairage is the most cost

effective stage to prevent cross-contamination that leads to rapid infection.”¹ However, while longer holding times may be associated with pathogen cross-contamination of live animals, FSIS is not aware of, nor did the petition include, data that suggests that products made from NAD pigs that have passed ante-mortem and post-mortem inspection present a higher public health risk than products made from ambulatory pigs. In fact, from 1999-2017, FSIS is aware of only one swine slaughter establishment implicated in an illness outbreak linked to raw pork products contaminated with *Salmonella*,² and FSIS’s investigation of that *Salmonella* outbreak did not identify consumption of products derived from NAD pigs as a contributing factor. Furthermore, available Centers for Disease Control and Prevention (CDC) data supports that outbreaks linked to *Y. enterocolitica* are rare.³ In addition, the results from FSIS’s Raw Pork Products Exploratory Program, launched in April 2015, showed the prevalence of *Campylobacter* and *Y. enterocolitica* in raw pork products is very low.⁴ These findings also reinforce that slaughter establishments, including those that handle NAD pigs, are consistently and effectively implementing measures to control pathogens that can cause foodborne illness as required under 9 CFR part 417 for all swine. Therefore, FSIS does not believe condemnation of NAD pigs for food safety is warranted because existing FSIS safeguards, including rigorous ante-mortem/post-mortem inspection and verification of process control procedures appear to be effectively preventing potential public health risks associated with all swine, including NAD pigs.

The petition also asserts that NAD pigs are more likely to carry swine influenza H1N1 and H3N2⁵ and are commonly affected with lameness, which may be a clinical symptom of other bacterial, prion, and viral diseases. According to the petition, because the inspection of NAD pigs before slaughter is unlikely to detect these diseases, FSIS should require that all NAD pigs offered for slaughter be condemned and promptly euthanized.

FSIS disagrees with the assertion that FSIS inspectors are unlikely to detect these diseases in NAD pigs. Swine influenza is characterized by sudden onset, coughing, difficulty breathing, fever, and prostration – all of which are quite evident during ante-mortem inspection, regardless of whether the animal is ambulatory or NAD, and affected animals are condemnable under 9

¹ *Compliance Guideline for Controlling Salmonella in Market Hogs*, available at <https://www.fsis.usda.gov/wps/wcm/connect/f970603e-96ce-4476-9dfd-5f768298bef7/Controlling-Salmonella-in-Market-Hogs.pdf?MOD=AJPERES>.

² <https://www.cdc.gov/salmonella/pork-08-15/index.html>

³ <https://www.cdc.gov/fdoss/annual-reports/index.html>

⁴ <https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/special-sampling-projects/raw-pork-sampling>

⁵ To support the assertion that NAD pigs are more likely to carry swine influenza H1N1 and H3N2 the petition references a study conducted at 5 large pig slaughter establishments accounting for 15-20% of US pork production funded by the Pork Industry Institute (Petition Attachment 3, Mhairi A. Sutherland, et al., Health of non-ambulatory, non-injured pigs at processing, 116 LIVESTOCK SCI. 237–245 (2008)). According to the petition, the study found that 53.8% of NAD pigs were infected with H1N1 compared to 34.8% of ambulatory pigs, and 51.9% of NAD pigs were infected with H3N2 compared to 26.1% of ambulatory pigs. We have reviewed the study and note the petition fails to mention that the study measured H1N1 and H3N2 serum titers in a sample of pigs from only one of the participating plants, not all five. The petition also does not mention that the study did not determine whether these titers were formed in response to an active infection or from a past infection or clarify that, although a higher percentage of NAD pigs were positive for H1N1 and H3N2, the NAD pigs had significantly lower viral titers to H1N1 and H3N2 compared with control pigs.

CFR 309.4(a). Furthermore, the virus is highly contagious, and outbreaks spread rapidly through the entire herd post infection. Clinical signs of influenza infection in susceptible herds may appear within 1-3 days post infection. Therefore, swine flu is not likely to result from exposure during lairage. Isolated incidents of swine influenza are relatively rare. NAD pigs affected with *Brucella suis* (very rare) or *Erysipelothrix rhusiopathiae* (routinely vaccinated for), if they do occur, also typically present with identifiable signs/symptoms other than lameness, such as fever, acute skin lesions, and swollen joints. Unlike in mature cattle and veal calves, FSIS has found that lameness in swine is typically associated with chronic and localized musculoskeletal conditions, such as disuse atrophy and arthroses of a joint. Finally, the petition states that FSIS inspectors will not identify pigs with the prion disease Porcine Spongiform Encephalopathy. That statement is only theoretical as there have been no naturally occurring cases of Porcine Spongiform Encephalopathy reported to date.⁶

Humane Handling

The petition also states that FSIS should prohibit the slaughter of NAD pigs to improve animal handling from farm to slaughter. The petition states that prohibiting the slaughter of NAD pigs will deter producers from sending older, weaker, or other potentially NAD animals to slaughter where the potential exists for them to be inhumanely handled. In addition, the petition asserts that FSIS's current policy creates an incentive for establishments to use inhumane methods to get NAD pigs to rise for re-inspection. To support the claim that some establishments continue to inhumanely handle NAD pigs, the petition references the 2013 Office of the Inspector General report on swine inspection activities (2013 Report), in part, and observations made by FSIS inspection program personnel at a slaughter establishment in that same year.

FSIS has reviewed the incidents referenced in the petition, as well as FSIS humane handling Non-compliance Records (NRs) documented since the petition was submitted, and disagrees with the petition's conclusion that NAD pigs are routinely inhumanely handled at slaughter. In FSIS's experience, the incidents are isolated and do not depict behavior throughout Federally-inspected operations. Furthermore, FSIS has found that pigs become non-ambulatory for different reasons than mature cattle and veal calves do, and therefore, potential incentives that establishments may have to handle NAD cattle and NAD veal calves inhumanely do not apply to NAD pigs.

For example, as we noted in our response to a prior petition, FSIS banned the slaughter of cattle that became NAD 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.⁷ This practice allowed producers to extract as much milk as possible in the hope that 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 subject to inhumane conditions. In addition, FSIS decided to prohibit the slaughter of NAD veal calves because the Agency determined that there was an incentive for establishment to force NAD veal calves to rise and for

⁶ <https://www.thepigsite.com/diseaseinfo/98/porcine-spongiform-encephalopathy-pse/>.

⁷ Petition response available at: https://www.fsis.usda.gov/wps/wcm/connect/11e2996a-a496-49f4-b096-e9b99232cab6/Petition_FSYS_Resp_Farm_Sanctuary_031313.pdf?MOD=AJPERES

veal producers to send weakened calves to slaughter.⁸ FSIS determined that veal production practices, namely deprivation of colostrum and nutrients to bob veal before slaughter, increase the chance that veal calves will become non-ambulatory at the time of slaughter. Market swine are not subject to these same practices prior to slaughter and thus do not arrive at slaughter under conditions that increase the risk that they will become non-ambulatory or be inhumanely handled.

Pigs often become non-ambulatory because of a temporary metabolic condition characterized by profound fatigue. The condition is usually completely reversible after the animals are cooled and rested. There is a great deal of research and literature from Dr. Temple Grandin and others on the science of handling pigs to reduce stress. Research in this area recognizes that permitting NAD or potentially NAD pigs to recover for a period of time after arriving at the slaughter plant, allows these animals to rest quietly and recover from the stress of being transported and return to a physiological state similar to that experienced prior to transport.^{9,10,11} Rest is part of the humane handling management strategy for NAD pigs as confirmed by the often temporary nature of the non-ambulatory state that remedies itself with time. This research supports FSIS's current policy of allowing for NAD pigs to recover from the stress of transport prior to making a determination on the suitability of these animals for slaughter.

Additionally, in response to the 2013 OIG Report, FSIS strengthened its approach to humane handling and made it more data-driven. For example, FSIS established a new Humane Handling Enforcement Coordinator position. Through frequent correlation with Office of Field Operations personnel, the Coordinator functions to improve the inspectors' objective analysis when enforcing the humane handling regulations, and to reduce subjective interpretation of inhumane events and their regulatory outcome. In addition, the Coordinator maintains a database to track the review of humane handling NRs, as well as review and track related suspensions and Notices of Intended Enforcement.

NAD Pigs—Inhumane Handling as a Cause/Financial Incentives.

The petition also states that industry studies show that inhumane handling causes pigs to become non-ambulatory. To support this assertion, the petition references industry studies that show that certain handling practices at production, transport, and slaughter contribute to pigs becoming

⁸ Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves (81 FR 46570, July 18, 2016). Available at: <https://www.fsis.usda.gov/wps/wcm/connect/3e42d239-982d-4634-9b51-d7189a08ce71/2014-0020.pdf?MOD=AJPERES>

⁹ Brown, S.N., Knowles, T.G., Edwards, J.E. and Warriss, P.D. (1999). *Behavioral and physiological responses of pigs to being transported for up to 24 hours followed by six hours recovery in lairage*. Veterinary Record 145:421-426. Summary: Allowing recovery times returns physiological values to normal.

¹⁰ Warriss, P.D., Brown, S.N., Edwards, J.E., Anil, M.H., and Fordham, D.P. (1992). *Time in lairage needed by pigs to recover from transport stress*. Veterinary Record, 131:194-196. Summary: A period of rest in lairage allowed the pigs to recover from transport and the associated handling and the recovery appeared to be complete within two to three hours.

¹¹ Perez, M.P., Palacir, J., Santolaria, M.P., delAcena, M.C., Chacon, G., Verde, M.T., Calvo, J.H., Zaragoza, M.P., Gascon, M. and Garcia-Belenguer, S. (2002). Influence of lairage time on some welfare and meat quality parameters in pigs, Veterinary Record, 33:239-250. Summary: Changes in blood profile and meat quality parameters indicated that three hours of lairage in Spanish commercial conditions may reduce the amount of stress exhibited by pigs at slaughter and better meat quality can be obtained.

non-ambulatory. The petition asserts that these inhumane handling practices continue because there are weak financial incentives to keep pigs ambulatory.

FSIS agrees that the swine industry recognizes that inhumane handling can contribute to increased numbers of non-ambulatory pigs. Consequently, industry has pro-actively developed the Pork Quality Assurance®¹² and Transport Quality Assurance®¹³ certification programs designed to help pig farmers and their employees use best animal handling practices to promote food safety and minimize the non-ambulatory pigs. The programs were modeled after the Hazard Analysis Critical Control Point (HACCP) programs used by food manufacturers to ensure the safety of food products but was customized for on-farm use. The programs rely on experts in agriculture and veterinary medicine to fulfill its mission. Farmer training and on-farm assessments are performed by certified PQA Plus Advisors. The industry reports that to date, more than 71,000 farmers and farm personnel have voluntarily participated in the program by earning PQA Plus certification, and that site assessments have been conducted on more than 18,000 farms. Under these programs, incidents of poor animal handling or abuse are considered to be ethically wrong and unacceptable. Producers and transporters are incentivized to participate in these programs because slaughter establishments require current certifications as a purchase specification. Thus, while industry studies recognize that inhumane handling can contribute to pigs becoming NAD, the industry has responded by implementing programs to prevent these practices and minimize NAD pigs.

In addition, FSIS disagrees with the assertion that there are weak financial incentives throughout the industry to prevent NAD pigs. Each segment of the industry incurs costs associated with NAD pigs. Producers incur costs because slaughter establishments exact financial penalties for each non-ambulatory pig. Transporters incur costs because non-ambulatory pigs increase turnaround time, decrease efficiency, and damage morale. Establishments incur costs because NAD pigs slow production, damage employee morale, and increase costs due to extra labor and employee turnover.

Establishments also experience financial costs when FSIS observes egregious animal handling non-compliance. The petition asserts that NAD pigs are more likely to be mistreated; however, it is also reasonable to conclude that an establishment that mistreats pigs is more likely to be subject to FSIS regulatory control action and further enforcement. Excess prodding, kicking animals, and dragging non-ambulatory animals are egregious animal handling non-compliance and result in, at a minimum, FSIS effecting an immediate suspension of slaughter operations without notice as authorized by 9 CFR 500.3(b). Costs to the establishment associated with such a suspension can exceed thousands of dollars per hour, depending upon the size of the establishment, lost production, the number of employees affected, and the corrective actions conducted by the establishment required to address the noncompliance. Consequently, we disagree that establishments have a financial incentive to handle the livestock entrusted to their care in an inhumane manner.

¹² <https://www.pork.org/certifications/pork-quality-assurance-plus/>

¹³ <https://www.pork.org/certifications/transport-quality-assurance/>

Agricultural Marketing Service and NAD pigs. The petition also asserts that FSIS's policy on the slaughter of NAD pigs is arbitrary because it is inconsistent with USDA's Agricultural Marketing Service (AMS) policy on NAD pigs. We have reviewed the references cited in support of this assertion, as well as AMS's Federal Purchase Program Specifications (FPPS) for Animal Handling and Welfare, and have concluded that AMS and FSIS have consistent policies with respect to the humane handling of NAD pigs.

In the supporting documentation, the petition references a May 15, 2008, AMS informational memo that states that beginning in July 2008, AMS's purchase specifications will prohibit the processing of all NAD livestock.¹⁴ However, the petition also references a May 29, 2008, e-mail exchange in which an AMS representative stated that for animal welfare purposes, AMS is "revising the establishment-wide prohibition on the slaughter of non-ambulatory swine and sheep [but that] [AMS has] support for sticking with cattle..."¹⁵ The most recent AMS FPPS for Animal Handling and Welfare reflects this position and provides that "[f]or all species, animals/carcasses that are inspected and passed by the [FSIS] are eligible for AMS purchase programs."¹⁶ Thus, the disposition of NAD pigs under AMS's FPPS is consistent with the disposition of NAD pigs under FSIS's regulations, i.e., the animals are identified as "US Suspects" and may proceed to slaughter.

Although FSIS believes that its current initiatives are achieving success, the Agency is continually considering new ways to ensure the humane handling of animals and has taken many actions to raise the level of awareness among its employees and industry regarding the humane handling of animals in general and more specifically the importance of properly restraining and stunning animals. In 2016, FSIS released its Fiscal Year (FY) 2017-2021 Strategic Plan. As explained in the Plan, FSIS intends to develop and implement an education and outreach campaign, targeting small and very small establishments, to ensure more consistent application of humane handling best practices and compliance with the humane handling requirements. In the Plan, FSIS also explains that FSIS District Veterinary Medical Specialists will promote humane handling best practices by delivering educational material and guidance to establishments when conducting their routine humane handling verification visits, focusing on the most recent information and recommendations.

Inspection Effectiveness and Efficiency

The petition argues that, similar to the prohibition on the slaughter of NAD cattle and calves, prohibiting the slaughter of NAD pigs will improve effectiveness and efficiency of the inspection system by eliminating the time that FSIS inspectors spend assessing and supervising the handling and disposition of NAD pigs.

FSIS does not believe that prohibiting the slaughter of NAD pigs is likely to result in more efficient use of FSIS inspection time because ante-mortem inspection of market-age hogs in many slaughter establishments is done under a Voluntary Segregation Program (VSP) (see

¹⁴ Petition Attachment 26.

¹⁵ Petition Attachment 27.

¹⁶ USDA, AMS Federal Program Purchase Specifications for Animal Handling and Welfare (effective date August 17, 2017) available at: <https://www.ams.usda.gov/selling-food-to-usda/federal-purchase-program-specifications>.

Section VII of FSIS Directive 6100.1, Rev. 1, *Ante-mortem Livestock Inspection*).¹⁷ Under this program, establishment employees segregate animals showing signs of abnormalities or diseases from healthy animals to facilitate the scheduling of animals for slaughter. In establishments with a VSP, employees segregate market hogs that temporarily become non-ambulatory due to heat or fatigue to allow them to rest and recover. The establishment does not present these animals for ante-mortem inspection until they have recovered and are fully ambulatory. Thus, under the VSP, FSIS inspectors only conduct a single ante-mortem inspection of non-ambulatory pigs that have recovered.

Second, NAD livestock other than cattle that are presented for ante-mortem inspection, and that do not have a condition that would require that they be condemned, may be designated as a "US Suspect" by an FSIS Public Health Veterinarian (PHV). Non-ambulatory "US Suspect" livestock other than cattle are permitted to proceed to slaughter without any additional ante-mortem inspection. An FSIS PHV must perform post-mortem inspection of the carcasses of all "US Suspect" livestock. Thus, prohibiting the slaughter of non-ambulatory pigs is unlikely to improve inspection efficiency or effectiveness significantly.

Economic Impact

The petition discusses the potential economic impact of banning the slaughter of NAD pigs. The petition claims that while the economic impact should not be considered, if it were, the cost would be less than the cost of the NAD cattle ban, while such a ban would offer similar benefits. However, FSIS has determined that the economic costs of requiring NAD pigs be condemned are not necessary to consider at this time because FSIS has concluded that its existing regulations and inspection procedures are sufficient and effective in ensuring that NAD pigs are handled humanely at slaughter and in preventing diseased animals from entering the human food supply.

Ractopamine

Finally, a letter received in support of the petition was especially concerned about the use of Ractopamine, a beta-agonist, in pigs. Specifically, the letter asserts that FSIS's current policy is creating an incentive for producers to misuse the drug in pigs immediately destined for slaughter.

FSIS disagrees with the assertion. Animals exhibiting lameness, fatigue, or signs more commonly attributed to beta-agonist use, such as heavy musculature and hyperexcitability, are subject to FSIS residue sampling and testing. FSIS enforces the tolerance levels set by the Food and Drug Administration for Ractopamine as well as other beta-agonists in meat. Carcasses found to contain violative levels of these substances are adulterated and prohibited for use as human food.

Furthermore, the Hazard Analysis and Critical Control Point (HACCP) regulations (9 CFR 417.2(a)(3)) make clear that violative residues present a food safety hazard that may be reasonably likely to occur, and, therefore, slaughter establishments must consider the likelihood

¹⁷ FSIS Directive 6100.1, Rev. 1, *Ante-mortem Livestock Inspection*, available at <https://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b593-7dc5a0263504/6100.1.pdf?MOD=AJPERES>.

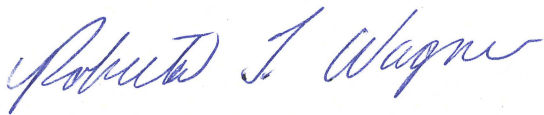
of residues occurring in their HACCP plan. The Agency will verify that an establishment that slaughters pigs has addressed violative residues in its hazard analysis and will verify that the establishment's system is effective at preventing meat that contains residues that would adulterate it from entering the human food supply. Furthermore, FSIS will take action against an establishment that does not have an adequate residue control program in place (see FSIS Directives 5000.1 and 10,800.1). That said, FSIS has found that residues in market hogs are historically very low.¹⁸

FSIS also maintains a list of repeat residue violators. The Repeat Residue Violator List includes producers associated with more than one residue violation on a rolling 12-month basis. The list provides helpful information to processors and producers and serves to deter violators.

For all of these reasons, FSIS is denying the petition requesting the Agency to require NAD pigs be condemned and humanely euthanized. FSIS has concluded that its existing regulations and inspection procedures comply with the Federal Meat Inspection Act and the Humane Methods of Slaughter Act and properly ensure the appropriate disposition and humane handling of pigs at slaughter, including those that are NAD.

In accordance with FSIS regulations, the petition was posted on the FSIS website, and the Agency intends to post this response as well.

Sincerely,



Roberta F. Wagner
Assistant Administrator
Office of Policy and Program Development

¹⁸ See Tables 3 and 7 at <https://www.fsis.usda.gov/wps/wcm/connect/93ae550c-6fac-42cf-8c11-006748a4d817/2017-Red-Book.pdf?MOD=AJPERES>.