# UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

## PETITION FOR RULEMAKING

<u>TO</u>: Thomas J. Vilsack, Secretary

United States Department of Agriculture

1400 Independence Avenue, SW Washington, DC 20250-3700

Kevin Shea, Administrator

Animal and Plant Health Inspection Service United States Department of Agriculture

4700 River Road Riverdale, MD 20737

<u>PETITION:</u> To Amend Regulations Pertaining to *Highly Pathogenic Avian Influenza*;

Conditions for Payment (9 C.F.R. § 53.11) to require an audited response action plan as an additional condition for payment of indemnity claims

**SUBMITTED BY:** Animal Welfare Institute

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<u>DATE</u>: June 15, 2023

#### I. Introduction and Requested Action

This petition is submitted on behalf of the Animal Welfare Institute (AWI) and requests that the United States Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS) initiate rulemaking to amend regulations pertaining to certain diseases of livestock and poultry and conditions for payment of highly pathogenic avian influenza (HPAI) indemnity claims. Specifically, we request that the agency require an audited HPAI response action plan that includes a plan for humanely depopulating animals as an additional condition for payment of indemnity claims.

The United States and countries around the world are currently in the midst of a widespread outbreak of HPAI. In the U.S., the impacts of the 2022-2023 outbreak exceeded those of the preceding 2014-2015 outbreak, which was previously the largest HPAI event ever recorded and arguably the nation's most significant animal health event. As of June 15, 2023, HPAI has been confirmed in 325 commercial and 511 backyard flocks in 47 states, resulting in the depopulation, or mass killing, of 58.79 million domestic birds.<sup>2</sup>

Pursuant to the Animal Health Protection Act (AHPA) and its implementing regulations, the USDA is authorized to provide indemnity payments to producers for birds and eggs that may be destroyed during a disease response, as well as compensation for depopulation, disposal, and virus elimination activities.<sup>3</sup> Under a final rule promulgated by APHIS in 2018 that established conditions for payments of HPAI claims, producers are required to have an approved poultry biosecurity plan in place that is audited at least once every two years in order to be eligible for payment of HPAI-related claims.<sup>4</sup> This condition was established in part because the agency recognized that "inadequate biosecurity measures may have led to HPAI introduction or spread within and among some commercial facilities," and "the development or revision of biosecurity requirements may help to avert future HPAI outbreaks or prevent the spread of disease during an outbreak." While biosecurity planning is critical to protecting birds and reducing the risk of disease introduction, it is not the only proactive preventative measure imperative to limiting disease spread and should not be the only precautionary measure required for payment eligibility. Another significant element of disease response and control—the rapid killing (or "depopulation") of infected animals that pose a disease risk—must also be addressed and adequately planned for.

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<sup>&</sup>lt;sup>1</sup> 9 C.F.R § 53.11 (2018).

<sup>&</sup>lt;sup>2</sup> 2022-2023 Confirmations of Highly Pathogenic Avian Influenza in Commercial and Backyard Flocks, U.S. DEP'T AGRIC., ANIMAL AND PLANT HEALTH INSPECTION SERV.,

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/avian/avian-influenza/hpai-2022/2022-hpai-commercial-backyard-flocks (last modified June 15, 2023) [hereinafter *Confirmations of HPAI*]. <sup>3</sup> 7 U.S. Code § 8306 (2008); 9 C.F.R § 53.11.

<sup>&</sup>lt;sup>4</sup> 9 C.F.R § 53.11(e).

<sup>&</sup>lt;sup>5</sup> Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims; Final Rule, 83 Fed. Reg. 40436, 40437 (Aug. 15, 2018) (to be codified at 9 C.F.R. 53) [hereinafter Avian Influenza Final Rule].

Following the 2014-2015 HPAI outbreak, the USDA set a goal of completing the depopulation of impacted poultry operations within 24-48 hours of a presumptive positive HPAI case in order to reduce the risk of virus amplification and further disease spread. This depopulation policy, which is discussed at greater length in Section IV below, serves as the foundation for determining when and how depopulation occurs on poultry operations, and what methods are permitted—including those with negative welfare implications that cause prolonged suffering, the use of which may be granted for the sake of meeting the 24-48 hour goal. Despite this policy, evidence and records related to the current disease outbreak show that even in situations where the USDA permitted the use of an extremely controversial method that some will argue is necessary for practicality, the depopulation timeline was still not met in a majority of cases involving large flocks (i.e., flocks with 100,000 or more birds). In the most extreme cases, depopulation took longer than two weeks after the reported date of HPAI confirmation to complete. Clearly, the size of an operation creates logistical challenges for performing depopulation in a timely manner, specifically within the USDA's goal of 24-48 hours. These challenges are undoubtedly exacerbated by a lack of preparedness.

Mass depopulation is the main element of the country's HPAI response strategy and is therefore one of the most critical elements of reducing disease spread, perhaps second only to prevention. The time- and resource-intensive nature of depopulation, coupled with the high number of large poultry operations in the U.S. and the USDA's unwillingness to limit the size of these facilities, demonstrates that incentivizing better preparation is absolutely necessary to ensure that depopulation can be carried out pursuant to the USDA's goal of 24-48 hours.

As such, AWI hereby petitions APHIS to exercise its authority under the AHPA to require owners or contract growers of poultry seeking payment of claims related to the destruction of poultry or eggs due to HPAI to have in place an audited HPAI response action plan that includes: 1) detailed procedures for depopulating animals within 24-48 hours of a presumptive positive classification using methods that rapidly render animals unconscious and kill all animals within one hour of introduction of any of the killing elements into the animals' environment; 2) a detailed explanation of how the use of methods categorized as "permitted under constrained circumstances" under the American Veterinary Medical Association's (AVMA) first edition of its *Guidelines for the Depopulation of Animals* will be avoided; and 3) procedures that minimize pain and distress from catching, handling, and confinement during depopulation procedures.

We submit this petition pursuant to the Administrative Procedure Act,<sup>6</sup> USDA regulations governing petitions,<sup>7</sup> and the First Amendment of the U.S. Constitution.<sup>8</sup> AWI requests a prompt

<sup>&</sup>lt;sup>6</sup> 5 U.S.C. § 553(e) (1966).

<sup>&</sup>lt;sup>7</sup> 7 C.F.R. § 1.28 (1995).

<sup>&</sup>lt;sup>8</sup> U.S. CONST. amend. I

response to this petition and that APHIS explain in writing the basis for the action the agency decides to take in response to the petition.<sup>9</sup>

#### II. Interests of the Petitioner

The Animal Welfare Institute (AWI) is a Washington, DC-based nonprofit founded in 1951. Since its founding, AWI has been dedicated to reducing animal suffering caused by people. AWI seeks better treatment of animals everywhere—in the laboratory, on the farm, in commerce, at home, and in the wild. This work includes efforts to improve the welfare of animals used in agriculture. In furtherance of its mission to alleviate animal suffering, AWI promotes higher-welfare farming systems and works to raise awareness about the issues associated with how large numbers of animals are farmed in the U.S.

As part of AWI's goal to promote improved farming systems, the organization advocates on behalf of farmed animals for stronger protections that will help mitigate the suffering they endure as a result of emergency situations. AWI educates its members and the public about the negative impacts that emergencies, including animal disease outbreaks, have on farmed animal welfare by monitoring animal health-related depopulation events and the methods used for such depopulations. AWI also advocates for the development and use of more humane methods of depopulation through engagement with agency officials and lawmakers, as well as the AVMA, which provides guidance to the veterinary community and animal health officials on depopulating animals.

## III. Legal Background

#### a. Animal Health Protection Act

In recognizing that the prevention, detection, control, and eradication of diseases and pests of animals is essential to protect the health and welfare of animals and the public, Congress enacted the AHPA through passage of the Farm Security and Rural Investment Act of 2002 (known as the "2002 Farm Bill"). Pursuant to the Act, the Secretary of Agriculture is authorized to "hold, seize, quarantine, treat, destroy, dispose of, or take other remedial action with respect to...any animal or progeny of any animal...that...the Secretary has reason to believe may carry, may have carried, or may have been affected with or exposed to any pest or disease of livestock at the time." The Secretary is also authorized to provide compensation to owners of animals or articles destroyed for the purpose of controlling disease spread.

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<sup>&</sup>lt;sup>9</sup> See 5 U.S.C. § 555(e) (1966).

<sup>&</sup>lt;sup>10</sup> 7 U.S.C. § 8301 (2002); *see* Farm Security and Rural Investment Act of 2002, Pub. L. No. 107–171, 116 Stat. 136 (2002)

<sup>&</sup>lt;sup>11</sup> 7 U.S.C. § 8306 (2008).

<sup>&</sup>lt;sup>12</sup> *Id*.

Pursuant to this authority, APHIS has provided indemnity payments to producers of poultry and eggs impacted by HPAI outbreaks that occurred in 2014-2015 and 2016, as well as the latest outbreak, the first confirmation of which occurred in February of 2022. Under APHIS policy, the agency provides indemnity payments for poultry and eggs that are destroyed based on their fair market value at the time that the HPAI virus is detected in the flock. Compensation is also provided for the cost of destruction and disposal activities of poultry and/or eggs infected with or exposed to the disease agent, and for cleaning and disinfection activities of premises, materials, and conveyances that came into contact with infected or exposed poultry. According to APHIS, "[t]he purpose of APHIS indemnity payments is to encourage prompt reporting of certain high consequence livestock and poultry diseases and to incentivize private biosecurity investment." 13

### b. Current HPAI Compensation Regulations

APHIS administers regulations at 9 CFR part 53 that provide for the payment of indemnity to owners of animals that are required to be destroyed due to particular diseases that, in the opinion of the Secretary of Agriculture, constitute an emergency and threaten the U.S. livestock or poultry population. This includes HPAI. Following the 2014-2015 HPAI outbreak, APHIS issued an interim rule in February 2016 specifying conditions for payment of indemnity claims for HPAI. Among the conditions established by APHIS was the requirement that parties seeking claims arising out of the destruction of animals or eggs provide to APHIS a statement that, at the time of detection of HPAI in the facility, the owner and contractor (if applicable) had in place and was following a biosecurity plan. 15

After accepting public comment, APHIS adopted the interim rule, with changes, as a final rule in 2018. APHIS maintained the requirement that eligibility for HPAI-related claims was contingent, in part, on the claimant's ability to show they had in place and were following a biosecurity plan at the time of detection of HPAI in their facilities. However, in response to concerns from commenters regarding the efficacy of self-certification, APHIS established additional provisions for verifying compliance with the biosecurity planning requirement. Pursuant to the final rule, claimants must have a poultry biosecurity plan that is approved by the APHIS administrator and incorporates approved biosecurity principles established under the National Poultry Improvement Plan (NPIP) Program Standards. The plan must be audited at least every 2 years by the "official state agency" and must involve a review of the plan, as well as

 $<sup>^{\</sup>rm 13}$  Animal and Plant Health Inspection Serv., U.S. Dep't of Agric., HPAI Response, Poultry Indemnity Valuation Policy (2023)

https://www.aphis.usda.gov/animal\_health/emergency\_management/downloads/hpai/hpai-poultry-indemnity-valu.pdf (last visited Jun. 8, 2023) [hereinafter APHIS POULTRY INDEMNITY VALUATION POLICY]. 

14 *Id.* 

<sup>&</sup>lt;sup>15</sup> Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims; Interim Rule, 81 Fed. Reg. 6750 (Feb. 9, 2016) (to be codified at 9 CFR 53).

<sup>&</sup>lt;sup>16</sup> Avian Influenza Final Rule *supra* note 5, at §§ 40433–38.

<sup>&</sup>lt;sup>17</sup> "Official State Agency" is defined as "The State authority recognized by the Department [of Agriculture] to cooperate in the administration of the [National Poultry Improvement] Plan." See 9 C.F.R. § 146.1 (2006).

documentation that it is being implemented.<sup>18</sup> Notably, the NPIP Program standards outline minimum management practices and principles that are designed to prevent the introduction and spread of infectious diseases. However, they do not address disease response or actions to be taken, including how to rapidly and humanely depopulate impacted animals, should disease be detected.<sup>19</sup> The final rule also provides an exemption from the biosecurity planning requirement for operations that fall under a certain size, the reason being that the operations that exceed the size threshold, and would thus be subject to the requirement, produce/house approximately 99 percent of the poultry in the U.S., and suffered the most devastating impacts of the 2014-2015 outbreak.<sup>20</sup>

## IV. Factual Background

a. Confirmations of HPAI in Commercial and Backyard Flocks (2022-Present)

Currently, the U.S., as well as other countries around the world, are in the midst of a widespread avian influenza outbreak, classified as highly pathogenic due to its severity. HPAI causes high mortality in domestic gallinaceous species (e.g., turkeys and chickens) and symptoms include decreased food and water consumption, coughing, sneezing, and decreased egg production. More severe signs of avian influenza infection include lack of energy, the production of soft or deformed eggs, swelling (of head, eyelids, comb, wattles, and/or hocks), purple discoloration (of wattles and/or comb), nasal discharge, loss of coordination, diarrhea, and sudden death. Transmission of HPAI typically occurs through direct contact with infectious respiratory secretions and feces, as well as through indirect contact with contaminated equipment and supplies.<sup>21</sup>

The first confirmation of HPAI in a commercial poultry flock in the U.S. occurred on February 8, 2022 in Dubois County, Indiana, on a turkey farm containing 29,000 turkeys. Since then, HPAI has been confirmed in a total of 325 commercial flocks and 511 backyard flocks, resulting in the depopulation of 58.79 million breeding and production birds, including over 44 million hens, 3 million broilers, 10 million turkeys, 377,000 ducks, and 352,000 additional birds

 $^{19}$  Animal and Plant Health Inspection Serv., U.S. Dep't of Agric., Veterinary Servs., National Poultry Improvement Plan Program Standards 60–63 (2019)

<sup>&</sup>lt;sup>18</sup> 9 C.F.R § 53.11(e) (2018).

https://www.poultryimprovement.org/documents/ProgramStandardsA-E.pdf (last visited June 15, 2023).

<sup>&</sup>lt;sup>20</sup> The following premises are exempted from the requirements of 9 CFR § 53.11(e): premises on which fewer than 100,000 broilers are raised annually; premises on which fewer than 30,000 meat turkeys are raised annually; commercial table-egg laying premises with fewer than 75,000 birds; and egg-type game bird and egg-type waterfowl premises with fewer than 25,000 birds. *See* 9 CFR § 53.10(g)(2) (2018).

<sup>&</sup>lt;sup>21</sup> ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., FINAL REPORT FOR THE 2014–2015 OUTBREAK OF HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI) IN THE UNITED STATES 1 (2016) https://www.aphis.usda.gov/animal\_health/emergency\_management/downloads/hpai/2015-hpai-final-report.pdf (last visited June 15, 2023) [hereinafter HPAI OUTBREAK FINAL REPORT].

classified by the agency as "WOAH poultry".<sup>22</sup> While the total number of states with confirmed HPAI infections reached 47, HPAI confirmations on commercial operations were limited to 29 states. In comparison, the 2014-2015 outbreak affected approximately 50.4 million birds, including approximately 43 million chickens (primarily layers or pullets), and 7.4 million turkeys; there were no recorded HPAI confirmations on commercial duck operations during this outbreak. Just 9 states experienced HPAI confirmations on commercial operations during the 2014-2015 outbreak, demonstrating just how widespread the current outbreak is in comparison.<sup>23</sup> Currently, the five states with the greatest number of birds affected by the ongoing outbreak are Iowa with a total of over 15.9 million birds, followed by Nebraska with over 6.7 million, Colorado with over 6.2 million, Pennsylvania with over 4.6 million, and Minnesota with over 4.2 million birds.<sup>24</sup>

#### b. The United States' Control and Eradication Strategy for HPAI in Domestic Poultry

Prior to the current HPAI outbreak, the outbreak that occurred between December 2014 and June 2015 was viewed as the largest and most serious animal health disease incident in U.S. history. As a result, a national Incident Coordination Group (ICG) was established within the USDA in December 2014, a primary purpose of which was to provide support in acquiring resources and formulating policy options, and to assist in developing and implementing response and recovery strategies. From April 2014 to January 2016, the ICG developed and issued at least 25 national-level policies and guidance documents that included guidance on indemnity procedures, depopulation, virus elimination, and restocking procedures. 26

Additionally, the National Preparedness and Incident Coordination Center—a branch within APHIS' Veterinary Services—has developed the *Highly Pathogenic Avian Influenza (HPAI) Response Plan: The Red Book* (hereinafter *The Red Book*), as a component of the USDA's overarching foreign animal disease strategy, the Foreign Animal Disease Preparedness and Response Plan (FAD PReP). *The Red Book* was updated in August 2015 and most recently in May 2017 to incorporate policy changes, guidance, and lessons learned from previous outbreaks. According to the plan's Executive Summary, its objectives are to "identify (1) the capabilities needed to respond to an HPAI outbreak and (2) the critical activities that are involved in responding to that outbreak, and time-frames for these activities." The plan "gives direction to

<sup>&</sup>lt;sup>22</sup> H5N1 Bird Flu Detections across the United States (Backyard and Commercial), CENTERS FOR DISEASE CONTROL AND PREVENTION (last updated June 15, 2023), https://www.cdc.gov/flu/avianflu/data-map-commercial.html (last visited June 8, 2023).

<sup>&</sup>lt;sup>23</sup> HPAI OUTBREAK FINAL REPORT *supra* note 21, at 3.

<sup>&</sup>lt;sup>24</sup> Confirmations of HPAI supra note 2.

<sup>&</sup>lt;sup>25</sup> HPAI OUTBREAK FINAL REPORT *supra* note 21, at v.

<sup>&</sup>lt;sup>26</sup> *Id.* at 22–24

 $<sup>^{27}</sup>$  Animal and Plant Health Inspection Serv., U.S. Dep't of Agric., Highly Pathogenic Avian Influenza (HPAI) Response Plan: The Red Book v (2017),

https://www.aphis.usda.gov/animal\_health/emergency\_management/downloads/hpai\_response\_plan.pdf (last visited June 15, 2023) [hereinafter THE RED BOOK].

emergency responders at the Federal, State, Tribal, local, and industry levels to facilitate HPAI control and eradication efforts in poultry in the United States."<sup>28</sup>

According to *The Red Book*, "[t]he United States' primary control and eradication strategy for HPAI in domestic poultry, as recommended by the World Organization for Animal Health (OIE), is 'stamping-out'." Stamping-out refers to the mass depopulation of clinically affected and in-contact susceptible poultry, which is viewed as necessary to prevent the amplification and continued shedding of HPAI virus and environmental contamination. In September 2015, APHIS issued policy guidance titled *Stamping-Out and Depopulation Policy* which has been updated as recently as January 2022 and is now titled *Response Goals & Depopulation Policy*. This policy serves as the foundation for decisions made regarding the mass depopulation of affected poultry. Under the policy, poultry that meet the HPAI presumptive positive case definition are depopulated as soon as possible, with a goal of achieving depopulation within 24-48 hours or less. Decisions regarding which flocks to depopulate are made by state animal health officials, or Tribal officials, and APHIS.

At the time of the most recent update to *The Red Book* in May 2017, guidelines for mass depopulation of animals had not yet been developed in the U.S. As such, it fails to include specific standards for carrying out depopulation or a list of approved or prohibited methods. Instead, *The Red Book* merely states that "euthanasia or mass depopulation should be provided to affected poultry as safely, quickly, efficiently, and humanely as possible. In addition, the emotional and psychological impact on animal owners, caretakers, their families, and other personnel should be minimized."<sup>31</sup> It then cites the international standards for "stamping-out," as defined by the *OIE Terrestrial Animal Health Code (2016)* and recognizes that "[i]n almost all cases, water-based foam or carbon dioxide are the depopulation methods available to rapidly stamp-out the HPAI virus in poultry."<sup>32</sup>

## c. Historic Use of Various Depopulation Methods (2014-2015 and 2016)

During the 2014-2015 outbreak, the primary depopulation methods used were water-based foam and carbon dioxide (CO<sub>2</sub>) gassing, with the former being most common for turkeys and the latter being most common for chickens. Nearly 73 percent of commercial operations utilized water-based foaming for depopulation, while 24 percent utilized CO<sub>2</sub> gassing.<sup>33</sup>

<sup>&</sup>lt;sup>28</sup> *Id*.

<sup>&</sup>lt;sup>29</sup> *Id.* at vi.

<sup>&</sup>lt;sup>30</sup> Animal and Plant Health Inspection Serv., U.S. Dep't of Agric., HPAI Response, Response Goals & Depopulation Policy 1 (2022).

https://www.aphis.usda.gov/animal\_health/emergency\_management/downloads/hpai/depopulationpolicy.pdf (last visited June 15, 2023).

<sup>&</sup>lt;sup>31</sup> THE RED BOOK *supra* note 27, at 543.

 $<sup>^{32}</sup>$  Id

<sup>&</sup>lt;sup>33</sup> HPAI OUTBREAK FINAL REPORT *supra* note 21, at 32–33.

According to the USDA, it took an average of 6.4 days to depopulate commercial operations during the 2014-2015 outbreak. The average time for depopulation of commercial chicken layer flocks in particular was even longer, with an average time of 15.4 days, compared to just 3.5 days for commercial turkey flocks.<sup>34</sup> Use of foam for depopulation proved to be problematic for chickens due to the fact that a majority of impacted operations involving chickens were layer operations, meaning birds were primarily caged and the type of foam that was widely available could not be built up to a height sufficient to smothers bird in elevated cages. Additionally, techniques and procedures for carrying out "whole house" CO<sub>2</sub> gassing (WHG) had not yet been developed for use in the U.S. Therefore, in most cases chicken layer depopulation was carried out using smaller CO<sub>2</sub> gas carts, which is a significantly longer process and requires handling of each individual bird.

Based on depopulation delays, the USDA determined there was a need to develop additional methods for depopulation, particularly on layer operations with hundreds of thousands or millions of birds. In September 2015, months after the last HPAI confirmation of the 2014-2015 outbreak, the USDA released guidance titled *Ventilation Shutdown Evidence & Policy* that sanctioned the use of ventilation shutdown (VSD), essentially as a method of last resort, and established criteria (Figure 1), as well as a multi-step decision tree to be used by state, Tribal and APHIS officials to determine whether to implement VSD. This method was used to depopulate birds impacted by HPAI for the first time in January 2016 on four commercial turkey operations in Dubois County, Indiana, during a brief resurgence of the virus in that state.

#### DOCUMENTATION OF SELECTING VSD As A DEPOPULATION METHOD

The decision to implement VSD as the depopulation in an HPAI outbreak indicates that

- Other depopulation methods are not available, or will not be available in a timely manner;
- The amplification of the virus on the premises poses a significant threat for further transmission and ongoing spread of HPAI; AND
- The questions in this Ventilation Shutdown Evidence and Policy document have been reviewed and discussed by APHIS officials, State/Tribal officials, and the Incident Management Team (IMT); AND
- ◆ The IMT recommends VSD as the most appropriate method; AND
- The State Animal Health Official, or designee, concurs with the selection of this method;
- The National Incident Coordinator, or designee, concurs with the selection of this method.

When these criteria have been completed, VSD may be implemented. Depending on the premises or State, written or electronic documentation of these criteria may be required.

Figure 1. Criteria established by USDA to permit use of ventilation shutdown for depopulation.<sup>35</sup>

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<sup>34</sup> Id at 34

<sup>&</sup>lt;sup>35</sup> Animal and Plant Health Inspection Serv., U.S. Dep't of Agric., Ventilation Shutdown Evidence & Policy, (2015).

d. Progression of Depopulation Methods and the USDA's Ventilation Shutdown Policy Following the 2014-2015 Outbreak

There have been a number of significant developments regarding depopulation since the 2014-2015 outbreak, all of which were intended to improve HPAI response and better prepare animal health officials and the industry in the event of a future outbreak. In 2019, the AVMA, using funding provided by the USDA, developed and published its first edition of the Guidelines for the Depopulation of Animals which describes common reasons for depopulating both sick and healthy animals and outlines different methods and special considerations for each species.<sup>36</sup> Methods are classified as "preferred," "permitted in constrained circumstances," and "not recommended." The guidelines also make clear that rapid response to the emergency is often the overarching consideration. Though they state that during depopulations animal welfare should be afforded as much consideration as is "practicable," "rapid destruction ... in response to urgent circumstances" is a primary consideration. Consequently, death may not be "painless and distress free."37 While this may be the case, the guidelines also notably state that preferred methods "are given highest priority and should be utilized preferentially when emergency response plans are developed," and "use of less preferred methods should not become synonymous with standard practice."38 Preferred methods for floor-reared poultry include water-based foaming methods, various gassing methods, cervical dislocation, and use of captive bolt guns. Preferred methods for caged poultry include gassing methods alone. Methods described in the AVMA's guidelines on euthanasia and slaughter are also approved for all categories of poultry.<sup>39</sup>

The depopulation guidelines also address the use of VSD, which is described as a process that "involves closing up the house, shutting inlets, and turning off the fans...until birds die from hyperthermia" or heatstroke.<sup>39</sup> Further, they distinguish between VSD alone and VSD plus heat (VSD+), which involves the addition of supplemental heat to more rapidly increase the temperature in the environment to help ensure mortality.<sup>40</sup> VSD+ is classified as "permitted in constrained circumstances" for both floor-reared and caged poultry.

Despite being classified as "permitted in constrained circumstances" rather than "not recommended," VSD+ is extremely controversial due to its negative welfare implications. At the

<sup>&</sup>lt;sup>36</sup> See generally Am. VETERINARY MED. ASS'N, GUIDELINES FOR THE DEPOPULATION OF ANIMALS, 2019 Ed., (2019) https://www.avma.org/sites/default/files/resources/AVMA-Guidelines-for-the-Depopulation-of-Animals.pdf (last visited June 15, 2023) [hereinafter AMVA DEPOPULATION GUIDELINES].

 $<sup>^{37}</sup>$  *Id.* at 4.

<sup>&</sup>lt;sup>38</sup> *Id.* at 4, 7, 8.

<sup>&</sup>lt;sup>39</sup> *Id.* at 87.

<sup>&</sup>lt;sup>39</sup> *Id.* at 45.

<sup>&</sup>lt;sup>40</sup> Under the AVMA guidelines, the addition of carbon dioxide is also discussed within the context of VSD+. However, VSD+CO<sub>2</sub> is considered by the USDA to be "a theoretical but not yet practical option" for depopulation and therefore will not be considered equivalent to VSD+ for purposes of this petition. *See* Letter from Rosemary B. Sifford, Deputy Adm'r, Animal and Plant Health Inspection Serv. to Dr. Gwendy Reyes-Illg, Veterinary Advisor, Animal Welfare Ins. (Apr. 27, 2022), https://awionline.org/sites/default/files/uploads/documents/Letter-from-APHIS-to-AWI-Apr-2022.pdf (last visited June 8, 2023).

time of the guidelines' development, there was only one research project funded by the U.S. Poultry and Egg Association that attempted to evaluate the use of VSD/VSD+ on live poultry. However, it was not carried out under commercial conditions and its findings have been heavily criticized by avian welfare experts. Despite this fact, the report, as well as a case study on the survival of pigs for 16 hours after accidental failure of a ventilation system, were used as the basis for including VSD/VSD+ in the AVMA guidelines. It is worth noting that VSD+, or any other depopulation methods that rely on heatstroke as the cause of death, are not recognized under the World Organisation for Animal Health's (WOAH) Terrestrial Animal Health Code.

Possible negative affective states associated with heatstroke include overheating, nausea, malaise, anxiety, fear, dizziness/disorientation, helplessness, frustration, thirst, debility, and exhaustion. An Negative emotional and behavioral reactions (e.g., heat distress, aggression, and frustration) may come into play early in cases of acute heat stress and pose further risks to animal welfare, while delirium and disorientation can develop as heatstroke progresses, prior to the onset of stupor and eventually loss of consciousness. Respiratory distress (dyspnea), which occurs during the terminal phase of heatstroke, is typically associated with severe anxiety in conscious animals.

Following the release of AVMA's depopulation guidelines, the USDA updated its VSD policy (now titled *Ventilation Shutdown Plus (+) Policy*) to reflect the distinction between VSD alone and VSD+, provide clearer recommendations on the addition of heat, and provide additional guidance on the operational factors the agency considers before permitting the use of VSD+, while maintaining the requirement that specific conditions (outlined above in Figure 1) be met for the use of VSD+ to be granted.<sup>46</sup>

Following the 2014-2015 outbreak, the National Veterinary Stockpile (NVS), which played an integral role in the disease response by deploying personnel and responding to over 2,700 requests for supplies, planned to acquire additional equipment for depopulation and offer further training for employees and contractors. This included procuring additional CO<sub>2</sub> carts and

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<sup>&</sup>lt;sup>41</sup> K.E. Anderson et al. *Evaluating Hen Behavior and Physiological Stressors during VSD for the Development of Humane Methodologies for Mass Depopulation during a Disease Outbreak*, N.C. STATE UNIV. (Mar. 30, 2017), https://www.documentcloud.org/documents/21590311-ncsu-pre-publication-version-from-awi-03302017 (last visited June 15, 2023).

<sup>&</sup>lt;sup>42</sup> Letter from Cathy Liss, President, Animal Welfare Ins. and Dena Jones, Farm Animal Program Dir., Animal Welfare Inst. to Dr. Janet Donlin, Am. Veterinary Med. Ass'n, Executive Vice President (Oct. 30, 2017), https://awionline.org/sites/default/files/uploads/documents/Letter-from%20AWI-to-AVMA-re-VSD-Research-2017.pdf (last visited June 8, 2023).

<sup>&</sup>lt;sup>43</sup> Gwendolen Reyes-Illg et al., *The Rise of Heatstroke as a Method of Depopulating Pigs and Poultry: Implications for the US Veterinary Profession*, 13 ANIMALS 140 (2022) https://www.mdpi.com/2038778.

<sup>44</sup> *Id.* 

<sup>&</sup>lt;sup>45</sup> Id

<sup>&</sup>lt;sup>46</sup> ANIMAL AND PLANT HEALTH INSPECTION SERV., U.S. DEP'T OF AGRIC., HPAI RESPONSE, VENTILATION SHUTDOWN PLUS (+) POLICY (January 2022) https://www.aphis.usda.gov/animal\_health/emergency\_management/downloads/hpai/ventilationshutdownpolicy.pdf (last visited Jun. 15, 2023)

initiating acquisitions for CO<sub>2</sub> WHG systems. WHG is recognized by both APHIS and the AVMA as a more humane method of depopulation, but it was not available for use during the 2014-2015 outbreak.<sup>47</sup> From 2015 to 2017, the NVS conducted four proof-of-concept tests for WHG units on different types of commercial operations. As a result of these tests, a protocol and best practices for WHG with CO<sub>2</sub> were developed and APHIS depopulation leads received training on implementation. As of 2017, the goal was to expand the availability of the units within the NVS and poultry-dense regions of the country, train additional APHIS personnel and contractors, and increase cooperation with the industry and CO<sub>2</sub> providers.<sup>48</sup> WHG and partial house gassing are classified as "preferred" for both floor-reared and caged poultry under the AVMA's depopulations guidelines.<sup>49</sup>

# e. Use of VSD+ During the Current HPAI Outbreak

Despite years of working toward development of WHG in commercial settings, the availability of other, more humane methods,<sup>50</sup> and having a strict VSD+ policy in place meant to limit the use of the method—an action that itself suggests the agency clearly recognizes an inherent problem with its use—VSD+ seems to have served as the default depopulation method, especially on large-scale operations and in the first several months of the outbreak. The use of VSD+ on large-scale operations has continued at high rates throughout the outbreak.

Through Freedom of Information Act requests, AWI was able to obtain from APHIS information regarding HPAI-related depopulation events between February 2022 and March 2023 that involved the depopulation of 53,305,571 birds on 430 commercial<sup>51</sup> operations.<sup>52</sup> Based on the

<sup>&</sup>lt;sup>47</sup> HPAI OUTBREAK FINAL REPORT *supra* note 21, at 42.

<sup>&</sup>lt;sup>48</sup> Dr. Scott Beutelschies, *NVS Development of CO2 Whole House Gassing for Emergency Depopulation of Poultry*, YOUTUBE (Oct. 12, 2017), https://www.youtube.com/watch?v=TKM\_yKFovj4 (last visited June 8, 2023); Dr. Scott Beutelschies, *NVS Development of CO2 Whole House Gassing for Emergency Depopulation of Poultry*, Animal Welfare Ins. (2016), https://awionline.org/sites/default/files/uploads/documents/NVS-CO2-Whole-House-Gassing-for-Bird-Depop-2016.pdf. (last visited June 15, 2023).

<sup>&</sup>lt;sup>49</sup> AMVA DEPOPULATION GUIDELINES *supra* note 36 at 87.

<sup>&</sup>lt;sup>50</sup> ANIMAL WELFARE INS., *More Humane Farmed Depopulation Methods: Info. and Sources* (last updated June 7, 2023) https://awionline.org/sites/default/files/uploads/documents/More-Humane-Farmed-Animal-Depopulation-Methods.pdf (last visited June 15, 2023).

<sup>&</sup>lt;sup>51</sup> For purposes of this analysis, "commercial" is defined as operations categorized by USDA as commercial (i.e., commercial broilers, commercial table-egg layers; commercial turkeys, and commercial upland game birds raised); "WOAH poultry"; and Live Markets. In other words, all flocks on USDA's 2022-2023 Confirmations of Highly Pathogenic Avian Influenza in Commercial and Backyard Flocks dashboard, except those designated as "WOAH non-poultry", *see Confirmations of HPAI* supra note 2.

This excludes information related to depopulations that occurred on 17 operations, involving 5,323,110 birds. For reasons unknown to AWI, this information was not provided in response to our Freedom of Information Act request. For purposes of this analysis, these depopulation events were not factored into the statistics included in this section. Additionally, AWI was provided partial information, including depopulation methods used, for an additional five depopulation events that are not recorded on the USDA's webpage, *Confirmations of HPAI* (supra note 2); these events were also not factored into the statistics included in this section. For a full list of depopulation events covered, *see* ANIMAL WELFARE INS., *Bird Depopulations Feb. 2022–Mar. 2023* (2023), https://awionline.org/sites/default/files/uploads/documents/Bird-Depopulations-Feb-2022-Mar-2023.pdf (last visited June 15, 2023).

provided records, it appears that at least 44,949,100 birds, or approximately 84 percent of all "commercial" birds, were killed in depopulation events in which VSD+ alone, or in combination with other methods, was utilized. The larger the operation, the higher the likelihood that VSD+ was used for depopulation. Of the 430 commercial depopulations, 53 involved 100,000 or more birds (accounting for approximately 82 percent of the birds depopulated on operations for which AWI was provided information). Of these 53 depopulation events, VSD+ alone or in combination with other methods was used in 37, or 70 percent. Commercial egg layer operations were also much more likely to utilize VSD+. Just 4 of the 28 depopulation events on commercial egg layer/pullet operations with 100,000 or more birds used methods other than VSD+.

## V. Arguments in Support of the Requested Action

a. Requiring Response Action Plans is Necessary to Meet the USDA's Depopulation Timeframe.

The reason the USDA set a depopulation goal of 24-48 hours was to ensure responses occur quickly enough to prevent continued HPAI virus shedding and amplification, which increases environmental contamination and disease spread. It is also the basis used to justify sanctioning the use of VSD+—an extremely controversial method that is not recognized by the world's leading authority on animal health, is linked to poor welfare outcomes and prolonged suffering, and often fails to achieve 100% mortality. However, evidence from the current disease outbreak and depopulation records show that even with the widespread use of VSD+, the USDA's depopulation timeline was still not met in a majority of cases involving large flocks (i.e., flocks with 100,000 or more birds). Of the 37 depopulations that involved 100,000 or more birds and utilized VSD+ alone or in combination with other methods, 24 (nearly 65 percent) exceeded 48 hours, taking 3 days or more to complete from the reported date of HPAI confirmation. Notably, of the 16 remaining events (in which VSD+ was not utilized), just 5 required longer than 48 hours after confirmation of HPAI to complete. In the most extreme cases in which one million or more birds were involved, depopulation took longer than two weeks after the reported date of HPAI confirmation to complete. Clearly, the size of the operation significantly hindered the ability to perform depopulation without resorting to the use of VSD+; even with its use, the timeline was still exceeded—in some cases by many days. Because the USDA has declined to limit the size of operations,<sup>53</sup> the only way to better ensure that depopulation can be carried out pursuant to USDA's goal of 24-48 hours is to incentivize better preparation.

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<sup>&</sup>lt;sup>53</sup> Letter from Thomas J. Vilsack, Secretary, USDA, to Cathy Liss, President, Animal Welfare Ins. (Sept. 8, 2022), https://awionline.org/sites/default/files/uploads/documents/Letter-from-USDA-Sec-to-AWI-Sep-2022.pdf (last visited June 9, 2023); U.S. DEP'T AGRIC., ANIMAL AND PLANT HEALTH INSPECTION SERV., HIGH PATHOGENICITY AVIAN INFLUENZA CONTROL IN COMMERCIAL POULTRY OPERATIONS – A NATIONAL APPROACH 77, (2015). see also The Humane Society of the United States, Comment Letter on Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims, Interim Rule (Docket Number APHIS-2015-0061) (Feb. 9, 2016).

b. Requiring Response Action Plans is Consistent with USDA's Overall Approach to HPAI Control and Eradication.

Proactive preparedness is at the heart of the United States' HPAI response. It is also central to USDA's National Response Framework which serves as "a guide to how the Nation conducts all-hazards response, through a whole community approach," as well as to the National Incident Management System (NIMS) which "provides a systematic, nationwide, proactive approach guiding departments and agencies at all levels of government, the private sector, and non-governmental organizations" to "prepare for, prevent, respond to, recover from, and mitigate the effects of incidents." In fact, the first element listed under the five key components of NIMS is preparedness. The development of *The Red Book*, and the fact that it is specific to HPAI, demonstrates just how vital preparedness planning is and that the agency and animal health officials recognize its value.

Effective preparedness efforts require cooperation and engagement from all relevant parties involved in the response. In the case of HPAI, this of course includes the operations whose animals are at risk of infection. Additionally, in order for preparedness efforts to be effective, it must encompass all elements of the response. Mass depopulation is the main element of the country's "stamping-out" policy and is therefore one of the most critical elements of reducing disease spread, perhaps second only to prevention. Based on the high number of large poultry operations in the U.S., and the key takeaways from prior outbreaks that demonstrate depopulation is both time and resource intensive, the need to prepare for the possibility of large-scale depopulation is clear. This includes establishing procedures for procuring necessary equipment, particularly in the event of specific material shortages as was supposedly the case with carbon dioxide toward the start of the current outbreak. Failure to adequately do so, even after what was learned from the 2014–2015 outbreak, led to excessive depopulation delays, as well as serious consequences for animal welfare due to the increased reliance on VSD+ during the ongoing HPAI outbreak.

c. Requiring Response Action Plans is Consistent with Current HPAI Indemnity Regulations.

As mentioned above, the USDA provides compensation and indemnity payments to producers of poultry and eggs impacted by HPAI. These indemnity payments serve to "encourage prompt reporting of certain high consequence livestock and poultry diseases and to incentivize private biosecurity investments." In other words, the assurance of indemnity payments and compensation creates an incentive for cooperation among producers in taking the necessary steps to prevent the introduction and spread of disease. This is thought to be in the best interest of the industry, animals, and the general public. According to the USDA's estimates, nearly \$850

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<sup>&</sup>lt;sup>54</sup> THE RED BOOK *supra* note 27, at 1–2.

<sup>&</sup>lt;sup>55</sup> APHIS POULTRY INDEMNITY VALUATION POLICY *supra* note 13.

million was obligated for HPAI response activities and indemnity payments, and another \$100 million was made available for further preparedness activities following the 2014-2015 outbreak, making it the most expensive animal health incident recorded in U.S. history at the time. <sup>56</sup> According to various media reports, as of February 2023, the federal government had already spent an additional \$661 million on response for the current HPAI outbreak, which is still ongoing. <sup>57</sup>

While Congress and the USDA recognized the need for incentives to ensure the cooperation of producers in the event of a disease outbreak, the department also recognized the importance of rewarding those who take meaningful action to protect their flocks and prevent the introduction of disease to avoid an outbreak in the first place. This was the reasoning behind the USDA establishing biosecurity planning requirements as a condition for payment of HPAI-related claims under federal regulations. When the requirement was first proposed pursuant to a 2016 interim rule issued by APHIS, it notably did not receive any opposition and was in fact supported by many poultry and agriculture industry groups, including United Egg Producers, the National Chicken Council, the National Turkey Federation, and the American Farm Bureau Federation.<sup>58</sup> The same principle regarding incentives must also apply to planning for depopulation given its importance to disease control and the financial investments it entails. The general idea of incentivizing greater preparedness planning is supported by the National Association of State Departments of Agriculture (NASDA), which represents the state departments of agriculture for all 50 states and four territories. In February 2023, NASDA adopted an action item stating, "NASDA encourages USDA to develop incentives to help producers develop depopulation and disposal plans to prepare for animal disease emergencies."59 Requiring HPAI response action plans as a condition for indemnity payments would be a very powerful incentive.

#### VI. Request for Rulemaking

Based on the arguments provided, AWI respectfully requests that APHIS amend its regulations pertaining to the conditions for payment of highly pathogenic avian influenza indemnity claims (9 C.F.R. § 53.11). Specifically, we request that APHIS require owners or contract growers of poultry seeking payment of claims related to the destruction of poultry or eggs due to HPAI to

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<sup>&</sup>lt;sup>56</sup> HPAI OUTBREAK FINAL REPORT *supra* note 21, at vi.

<sup>&</sup>lt;sup>57</sup> Muri Assunção Current Bird Flu Outbreak, *Entering Second Year, Has Cost U.S. More Than \$660 Million*, N.Y. DAILY NEWS (Feb. 19, 2023, 8:46 PM), https://www.nydailynews.com/news/national/ny-us-bird-flu-outbreak-second-year-661-million-20230220-xq2z5saqdbbprpraaswvhklqpa-story.html (last visited June 15, 2023).

<sup>&</sup>lt;sup>58</sup> United Egg Producers, Comment Letter on Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims, Interim Rule; National Chicken Council, Comment Letter on Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims, Interim Rule; National Turkey Federation, Comment Letter on Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims, Interim Rule; American Farm Bureau Federation, Comment Letter on Conditions for Payment of Highly Pathogenic Avian Influenza Indemnity Claims, Interim Rule (Docket Number APHIS-2015-0061) (Feb. 9, 2016).

<sup>&</sup>lt;sup>59</sup> Randy Romanski, *Action Item C: Animal Disease Emergency Preparedness* NAT'L ASS'N OF STATE DEP'TS OF AG, (Feb. 15, 2023) https://www.nasda.org/wp-content/uploads/2023/02/AI\_Animal-Disease-Emergency-Preparedness\_23.0215.pdf (last visited June 15, 2023).

have in place an audited HPAI response action plan that includes: 1) a detailed plan for depopulating animals within 24-48 hours of a presumptive positive classification using methods known to rapidly render animals unconscious and that ensure all animals are deceased within 1 hour of introduction of any of the killing elements into the animals' environment; 2) a detailed explanation of how the use of methods categorized as "permitted under constrained circumstances" under the AVMA's first edition of its *Guidelines for the Depopulation of Animals* will be avoided; and 3) plans to minimize pain and distress from catching, handling, and confinement during depopulation procedures. The first element is critical to this request as it is necessary to help ensure depopulation is carried out in a way that is consistent with APHIS' *Response Goals & Depopulation Policy* and *Ventilation Shutdown Plus (+) Policy*, and the AVMA's first edition of its *Guidelines for the Depopulation of Animals*, which prioritize the use of preferred methods of depopulation—especially within the development of emergency response plans—to give as much consideration to the welfare of the animals as practicable. To eliminate the use of VSD+, incentives must be put in place to avoid creating the precise "constrained circumstances" in which it is permitted.

#### VII. Conclusion

For the reasons detailed above, APHIS should amend its regulations related to conditions for HPAI-related claims in order to ensure producers invest in developing comprehensive HPAI response action plans that address how large numbers of animals on their operations will be humanely depopulated if needed. With the cost of the two most significant HPAI outbreaks in U.S. history now totaling well over \$1 billion in government funding alone, producers whose operations are at highest risk for infection, and the costly mass depopulations that could result, must be incentivized to better prepare for what the ongoing and future outbreaks will entail.

Thank you for considering this petition.

Sincerely,

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