**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**9 CFR Part 53**

**[Docket No. APHIS–2023–0088]**

**RIN 0579–AE79**

# Payment of Indemnity and Compensation for Highly Pathogenic Avian Influenza

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are amending the regulations pertaining to conditions for payment of indemnity for highly pathogenic avian influenza (HPAI). Specifically, we are requiring commercial poultry premises to successfully pass a biosecurity audit prior to restocking if they were previously HPAI-infected and wish to be eligible for indemnity for the restocked poultry. We are also requiring a biosecurity audit for commercial poultry premises in the buffer zone prior to movement of poultry onto the premises, if the premises wishes to be eligible for indemnity for the poultry moved onto the premises. We are also revising the regulations to preclude indemnity payments for poultry moved onto premises in infected zones if the poultry become infected with HPAI within 14 days following the dissolution of the control area in which the infected zone is located. This action is necessary on an immediate basis in order to ensure that commercial poultry producers who receive indemnity payments for HPAI are taking measures to preclude the introduction and spread of HPAI, and avoiding actions that contribute to its spread. This action amends the regulations to condition indemnity for HPAI accordingly.

**DATES:** This interim rule is effective December 31, 2024. We will consider all comments that we receive on or before March 3, 2025.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2023–0088 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2023–0088, Regulatory Analysis and Development, PPD, APHIS, Station 2C–10.16, 4700 River Road, Unit 25, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *Regulations.gov* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Dr. Leonardo L. Sevilla, DVM, Veterinary Medical Officer, Poultry Health Team, VS Strategy and Policy Aquaculture, Swine, Equine, and Poultry (ASEP), ASEP Health Center, 920 Main Campus Drive, Raleigh, NC 27606; (984) 766–1528; *Leonardo.sevilla@usda.gov.*

**SUPPLEMENTARY INFORMATION:**

## Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) administers regulations at 9 CFR part 53 (referred to below as the regulations) that provide for the payment of indemnity to owners of animals that are required to be destroyed because of foot-and-mouth disease, pleuropneumonia, Newcastle disease, highly pathogenic avian influenza (HPAI), infectious salmon anemia, spring viremia of carp, or any other communicable disease of livestock or poultry that, in the opinion of the Secretary of Agriculture, constitutes an emergency and threatens the U.S. livestock or poultry population. Payment for animals destroyed is based on the fair market value of the animals at the time of their destruction.

Section 53.2 of the regulations authorizes the APHIS Administrator to cooperate with a State in the control and eradication of disease, as that term is defined in § 53.1. Section 53.2(b) allows for payments to cover the costs for purchase, destruction, and disposition of animals required to be destroyed because of being infected with or exposed to such disease. Section 53.10 of the regulations provides conditions under which indemnity claims are not allowed, whereas § 53.11 provides conditions under which payment will be made on indemnity claims resulting from HPAI outbreaks.

## HPAI Outbreaks and Responses

HPAI is an extremely infectious and fatal form of avian influenza in poultry. An HPAI outbreak can have significant consequences for the poultry industry, wildlife, and producers' livelihoods, as well as significant impacts on international trade in poultry and poultry products. Certain strains of avian influenza have the potential to affect humans. An HPAI outbreak in poultry in the United States is declared when the first case in domestic poultry meets the case definition of HPAI as defined in USDA APHIS' National List of Reportable Animal Diseases (NLRAD) (*https://www.aphis.usda.gov/sites/default/files/avian-influenza-case-definition.pdf*). Stakeholders are notified of HPAI outbreaks through several routes of information; for example, online announcements are posted on the APHIS website at: *https://www.aphis.usda.gov/news.* Additionally, pursuant to the World Organization for Animal Health (WOAH) standards,[1] at the onset of an HPAI outbreak in the United States, national level outbreak information is posted on the World Animal Health Information System.[2] The HPAI outbreak applies to the entire country, and to the State in which the initial premises that tested positive is located. The outbreak ends in a specific State when the State regains freedom from HPAI pursuant to the WOAH standards. WOAH does not grant official recognition of freedom from HPAI in poultry. Per WOAH standards, the national HPAI outbreak ends when the United States declares freedom from HPAI in poultry by providing evidence demonstrating that the requirements for the disease status have been met in accordance with WOAH standards. Specifically, an outbreak ends when the country provides scientific data that explains the epidemiology of avian influenza in the region concerned and also demonstrates how all the risk factors are managed. This includes proof of effective surveillance strategies that mitigate the introduction of HPAI. The United States cannot declare freedom from HPAI in poultry for the entire country if HPAI exists in poultry in any State or territory within the country.

Beginning in December 2014, the U.S. poultry industry experienced a severe outbreak of HPAI, discovered in

[1] Countries declare freedom from HPAI by providing evidence demonstrating that the requirements for the disease status have been met in accordance with WOAH standards found here: *https://www.woah.org/fileadmin/Home/eng/Health_standards/tahc/2023/chapitre_avian_influenza_viruses.pdf.* For more information on eradication *see https://www.aphis.usda.gov/sites/default/files/hpai_response_plan.pdf.*

For more information on control area release *see https://www.aphis.usda.gov/sites/default/files/control_area_release.pdf.*

[2] For more information on reporting outbreaks *see* WAHIS—*https://wahis.woah.org/#/home.*

backyard flocks in the Pacific Northwest, and in two commercial turkey and chicken flocks in California. APHIS issued a final July 2015 report of the 2014–2015 outbreak, (*https://www.aphis.usda.gov/animal_health/emergency_management/downloads/hpai/2015-hpai-final-report.pdf*), regarding surveillance and other response services by APHIS, which has been provided to the public. APHIS determined that from January 2015 to March 2015, the disease spread slowly to multiple States, including Minnesota, Missouri, Arkansas, and Kansas. In June 2015, the last case of HPAI was confirmed in a commercial flock. However, the cost associated with response activities was the most expensive animal health incident recorded in U.S. history. The final cost associated with the 2014–2015 outbreak was nearly $1 billion. The cost obligated for response activities totaled $650 million and indemnity payments totaled $200 million, and an additional $100 million was made available for further preparedness activities.

The impact of the 2014–2015 HPAI outbreak spread beyond financial resources and economic concerns. The outbreak resulted in regulatory revisions to address biosecurity [3] concerns identified during the outbreak. In the July 2015 report, APHIS determined that, amongst other factors, poor biosecurity was responsible for the introduction of HPAI into some commercial poultry facilities. More specifically, APHIS stated in the report that ''biosecurity measures must be improved on premises to not only stop HPAI transmission during an outbreak but prevent HPAI introductions into commercial poultry flocks in the future.'' Biosecurity basics are aimed at evaluating a premises for possible introduction of disease onto the premises, and taking appropriate mitigations to address these possible sources of introduction and to limit the spread of disease, if introduced. Within the context of HPAI, these include, but are not limited to, the following: (1) Keeping visitors on the premises to a minimum (HPAI can be transmitted by fomites, such as clothing); (2) washing hands before coming in contact with live poultry (HPAI virus can be transmitted by persons coming into physical contact with affected poultry); (3) cleaning/disinfecting tools or equipment before moving them to a new poultry facility (HPAI virus can survive on the surfaces of farm equipment, including tools and means of conveyance); and (4) removing wild bird nesting and harborage, preventing access of wild birds to poultry enclosures, and precluding wild birds from coming in contact with feed used at the premises (as discussed below, wild birds can be a significant pathway for the spread of HPAI). APHIS poultry biosecurity recommendations can be found at: *https://www.aphis.usda.gov/livestock-poultry-disease/avian/defend-the-flock.*

During the 2014–2015 outbreak, APHIS initially paid full indemnity to bird owners of poultry infected with HPAI, regardless of whether or not the owners had a biosecurity plan in place at their facilities at the time of introduction. In response, APHIS amended the regulations, in an interim rule published in the **Federal Register,** and effective, on February 9, 2016, (81 FR 6745–6751, Docket No. APHIS–2015–0061),[4] pertaining to conditions for payment of HPAI indemnity claims. We added a requirement for owners and contractors to provide a statement that at the time of detection of HPAI in their facilities, they had in place and were following a poultry biosecurity plan. Section 53.1 defines a ''poultry biosecurity plan'' as ''[a] document utilized by an owner and/or contractor describing the management practices and principles that are used to prevent the introduction and spread of infectious diseases of poultry at a specific facility.'' The interim rule also exempted owners and contractors from this requirement if any of the following apply:

- Premises meet the size criteria of the National Poultry Improvement Plan (NPIP) [5] regulations in that they are either:
  - ○ Commercial table-egg laying premises with fewer than 75,000 birds;
  - ○ Egg-type game bird and egg-type waterfowl premises with fewer than 25,000 birds;
- Premises on which fewer than 100,000 broilers are raised annually; or
- Premises on which fewer than 30,000 meat turkeys are raised annually.

We took comment on the interim rule for 60 days, ending April 11, 2016. In response to comments received during the comment period, in a final rule published in the **Federal Register** on August 15, 2018 (83 FR 40433–40438, Docket No. APHIS–2015–0061),[6] we amended § 53.11 of the regulations to require biosecurity plan audits. Specifically, the final rule required facilities that are subject to the provisions of the 2016 interim rule to have their biosecurity plans audited at least once every 2 years. The final rule also subjected facilities to additional audits, as needed, during this biennial period to satisfy their Official State Agency (OSA). The OSA is the State authority that we recognize as a cooperator in the administration of the requirements of the NPIP. While this auditing mechanism was recommended by the comments on the 2016 interim rule, it is worth noting that the auditing mechanism was also recommended by NPIP at their 2016 biennial conference.[7] As part of the audit, the OSA will, at minimum, evaluate the poultry biosecurity plan itself, which will include an evaluation of the poultry biosecurity plan against 14 biosecurity principles articulated in the NPIP Program Standards policy document,[8] and review the documentation showing that the poultry biosecurity plan is being implemented.

APHIS believed that the provisions of the 2016 HPAI indemnity rule, as amended to include this auditing provision, would be sufficient to reduce spread of the virus in the event of another HPAI outbreak.

## The 2022–2024 HPAI Outbreak and the Need for Revised Auditing Procedures

Our experience with a subsequent outbreak of HPAI in poultry in 2022–2024 has indicated that the 2016 interim rule and the subsequent 2018 final rule were insufficient to address initial introduction of HPAI into flocks on premises in proximity to an infected premises, or subsequent reintroduction of HPAI into flocks on premises previously infected with HPAI. As of

[3] ''Biosecurity'' refers to everything people do to keep diseases—and the viruses, bacteria, funguses, parasites, and other microorganisms that cause disease—away from birds, property, and people. Biosecurity includes both structural biosecurity and operational biosecurity. Structural Biosecurity refers to measures used in the physical construction and maintenance of coops, pens, poultry houses, family farms, commercial farms, and other facilities. Operational Biosecurity refers to practices, procedures, and policies that people follow consistently. For more information *see https://www.aphis.usda.gov/livestock-poultry-disease/avian/defend-the-flock.*

[4] To view the interim rule, its supporting documentation, or the comments that we received, go to *https://www.regulations.gov/docket/APHIS-2015-0061.*

[5] NPIP is a cooperative Federal-State-industry certification program administered by APHIS. For more information on NPIP, *see https://www.poultryimprovement.org.*

[6] To access the 2018 final rule, go to *https://www.regulations.gov/document/APHIS-2015-0061-0021.*

[7] For more information on the NPIP biennial conference, *see https://www.poultryimprovement.org/.*

[8] Approved biosecurity principles are listed in the NPIP Program Standards found here: *https://www.poultryimprovement.org/documents/ProgramStandardsA-E.pdf.*

November 2024, the costs associated with the ongoing outbreak have exceeded $1.4 billion, including $1.25 billion in indemnity and compensation payments. Of this, APHIS has spent approximately $227 million on indemnity payments to premises that have been infected multiple times with HPAI. A total of 67 unique commercial poultry premises have been infected at least twice with HPAI during the current outbreak, including 19 premises that have been infected 3 or more times.

While reinfections may occur with even a perfectly implemented biosecurity plan, the data suggest that the current paper-based audit process does not always illustrate how well the premises are practicing biosecurity to prevent HPAI infection or reintroduction. To determine how well a biosecurity plan is being implemented, a visual inspection of the poultry premises is necessary. We discuss this at greater length later in this document.

In April 2022, APHIS issued a HPAI response guidance for the current outbreak.[9] This guidance has assisted with addressing the current outbreak, however gaps in the implementation of biosecurity measures to mitigate the risk of HPAI spread and introduction exist. The current guidance only covers biosecurity audits for premises moving poultry into the buffer zone. This interim rule includes biosecurity requirements for previously infected premises and codifies restocking guidelines for those premises. The current guidance fails to address restocking audits for previously infected premises, that are currently implemented on a State-by-State basis. APHIS has found that some States do not have a restocking policy. Furthermore, epidemiological data shows continued reinfection after the 2022 guidance was implemented. The guidance discourages movement and encourages and requires a higher level of biosecurity within an infected zone, this interim rule provides specifics for the biosecurity audit process and helps ensure that proper biosecurity measures are being implemented within infected zones and by previously infected premises to mitigate future infections.

First, we have learned more about how proximity of poultry premises impacts HPAI spread.[10] During the 2014–2015 HPAI outbreak, States designated ''control areas'' as the perimeter of at least 10 kilometers (km) beyond the perimeter of the premises infected with HPAI. Control areas consist of an infected zone and a buffer zone. The infected zone is the area that immediately surrounds an infected premises, up to the beginning of the buffer zone. The buffer zone has typically been identified as an uninfected zone situated 3–10 km around an infected premises. The size of control areas is based on several factors including, but not limited to, the infected premises transmission pathways and estimates of transmission risk, poultry movement patterns and concentrations, distribution of susceptible wildlife in proximity, natural terrain, and jurisdictional boundaries.[11] The boundaries of control areas can be modified or redefined when tracing and other epidemiological information becomes available. Premises that are located in the infected zone and buffer zone of a control area are usually notified of this status by the State Animal Health Official (SAHO), although within this interim rule we are making allowance for notification by APHIS instead.

During the current outbreak, it has become increasingly clear that premises within the infected zone and the buffer zone are at a higher risk of becoming infected with HPAI than premises outside of the control area.[12] In June 2023, an epidemiological analysis found that wild bird introductions were the primary means of spread during this current poultry outbreak. To improve the understanding of risk factors associated with HPAI on table egg farms and turkey farms in the United States, case-control studies were conducted identifying risk factors for HPAI and biosecurity challenges. The most significant farm-level risk factor for HPAI on table egg farms was being located within an existing control area. For turkey farms, the farm-level risk factors also included seeing wild waterfowl on the farm, farm location near a wetlands, seeing wild waterfowl or shorebirds on the closest waterbody, and not having a restroom facility available to crews visiting the farm. In addition, having feed or feed ingredients accessible to wild birds was identified as a risk factor. This risk may be heightened by a lack of protocol to clean spilled feed and/or presence of water around the premises where wild birds may congregate; both of these factors can serve as wild bird attractants to a premises. The findings confirm the need for both biosecurity and surveillance on poultry farms near an infected premises, to prevent infection and ensure rapid detection, whether the virus is likely spreading by wild birds or laterally between farms. Because premises in control areas are at a higher risk of being infected with HPAI, adequate biosecurity measures need to be implemented on these premises to prevent the introduction and spread of HPAI from premises to premises within the control area, and from premises within the control area to premises outside the control area.

Second, we have learned that, for premises in control areas and premises that have had previous introductions of HPAI within the same outbreak (that is, from the start of the outbreak until the HPAI outbreak is declared eradicated nationally pursuant to the WOAH standards as described above) biennial paper-based audits are insufficient. Paper-based audits alone do not enable us to determine whether a premises has sufficient biosecurity measures in place to reduce the risk of introduction or reintroduction of HPAI. Our experiences have indicated that the effectiveness of a poultry biosecurity plan is determined not only by its provisions, but also by how well the plan is implemented. Visual inspection of the premises is needed to evaluate how well the plan is implemented.

Effective implementation of a poultry biosecurity plan can directly influence the amount of indemnity that APHIS pays. Effective implementation of a poultry biosecurity plan likely reduces the risk of introduction of HPAI onto a premises and mitigates its spread, if introduced. Less risk of HPAI introduction and spread would, in turn, reduce the need to destroy birds and thus reduce the need of APHIS to make indemnity payments. As noted previously, since 2022, APHIS has spent approximately $227 million on indemnity payments to premises that have been infected multiple times with HPAI. A total of 67 unique commercial poultry premises have been infected at least twice with HPAI during the current outbreak, including 19 premises that have been infected 3 or more times. In addition, there are two non-commercial premises that have had repeat HPAI infections. Based on epidemiologic findings in the ongoing 2022–2024 outbreak, biosecurity improvements reduced the likelihood of a premises contracting HPAI, as compared to farms that were infected with HPAI. However, the current

[9] For more information on APHIS' HPAI response, *see https://www.aphis.usda.gov/sites/default/files/permitting-live-poultry-infected-zone.pdf.*

[10] For HPAI Depopulation Analysis Report, *see https://www.aphis.usda.gov/sites/default/files/hpai-2022-2023-summary-depop-analysis.pdf.*

[11] For more information on control area size consideration, *see https://www.aphis.usda.gov/sites/default/files/hpai_response_plan.pdf.*

[12] For report of epidemiologic and other analysis of HPAI affected poultry, *see https://www.aphis.usda.gov/sites/default/files/epi-analyses-avian-flu-poultry-2nd-interim-rpt.pdf.*

outbreak has surpassed the 2014–2015 outbreak as the largest animal health emergency in U.S. history, and APHIS' experiences to date in 2024 indicate that the risk of introduction of HPAI onto premises persists.

This interim rule will serve to reduce the risk that a producer becomes inclined to disregard biosecurity because they believe that APHIS will continue to cover the costs associated with damages related to an HPAI outbreak through indemnity payments regardless of their biosecurity status. The current regulations do not provide a sufficient incentive for producers in control areas or buffer zones to maintain biosecurity throughout an outbreak. The current regulations provide for indemnity for poultry that are depopulated, without visually confirming that the premises are taking appropriate biosecurity measures to prevent future infection and spread. The compensation provided covers the value of the poultry that would otherwise be of, at most, minimal salvage value because they would have likely died naturally because of HPAI infection. Conversely, a flock may need to be depopulated before it has reached maturity, and a producer could maximize the profit associated with its poultry and products. The requirements of this interim rule will address both of these issues in the current regulations: Indemnity will now be conditioned in certain instances on visual evaluation of biosecurity, and adequate biosecurity, in turn, will increase the likelihood that poultry reach the age of maturity for the product (*e.g.,* table eggs, hatching eggs, meat, etc.) they are being marketed for. As of November 2024, APHIS has spent approximately $296 million on indemnity and response payments to premises infected multiple times during the 2022–2024 outbreak, and an estimated $128 million in indemnity and response payments for premises that were infected while in a buffer zone. This interim rule allows APHIS to restrict indemnity payments to those previously infected producers and those producers in buffer zones who have undergone biosecurity audits to verify biosecurity measures, thereby reducing the incentive to undertake that risky behavior.

**HPAI in Dairy Cattle**

In March 2024, a development occurred relative to the lateral spread of HPAI that further underscored the need for revision to the indemnity regulations in poultry: HPAI was detected in dairy cattle. Typically, HPAI is sporadically detected in mammals, particularly those with close contact to infected poultry and wild birds, those that share feed or water sources, or those that scavenge carcasses. However, the confirmation of HPAI in dairy cattle in late March 2024, and the subsequent transmission of the disease within and between dairy herds, marked a significant change in the epidemiology of HPAI. The presence of HPAI in cattle also posed another potential source of the virus for poultry flocks. USDA and State teams have conducted extensive epidemiological work to investigate the links between HPAI-affected dairy premises and spillover into poultry premises. Data collected since March 2024 indicates that virus can be transmitted on equipment, people, or other items that move from farm to farm. Epidemiological investigations identified the potential factors for the transmission between premises as the movement of livestock, numerous people, vehicles, and other farm equipment frequently moving on and off an affected premises and on to other premises, often a part of normal business operations. In particular, transmission factors include shared equipment which is not cleaned between farms; contaminated equipment; shared personnel and housing; frequent visitors with access to animals; and presence of other species on farms.[13]

Additionally, since April 2024, several cases in workers on affected dairy and poultry premises have been reported. The fact that shared personnel, frequent visitors, vehicles and other equipment are transmission factors may indicate the inadequacy of current biosecurity measures (*e.g.,* inadequate cleaning and disinfection of personnel and vehicles prior to leaving an infected premises and/or inadequate restriction of movement on and off premises, all foundational components of biosecurity, could allow transmission of HPAI to a new, previously uninfected premises).

**Regulatory Revisions**

APHIS is amending § 53.10 to require biosecurity audits for two statuses of poultry premises in order for owners and/or contractors (hereafter collectively referred to in this section of the preamble as ''producers'') to qualify for indemnity arising out of the destruction of poultry destroyed due to an outbreak of HPAI. One status of poultry premises for which this interim rule will require biosecurity audits are premises located in the buffer zone of a control area for HPAI. If a producer intends to move poultry onto a premises located in a buffer zone and wishes the poultry moved onto the receiving premises to be eligible for future indemnity payments in the event that the receiving premises is later infected with HPAI and the poultry must be destroyed, the receiving premises must pass a biosecurity audit. If the receiving premises passed a biosecurity audit within the six (6) months preceding the intended date of movement of the poultry onto the receiving premises, a new biosecurity audit is unnecessary. The audit will be done virtually unless the SAHO requests an in-person audit.

The other status of poultry premises for which this interim rule will require biosecurity audits are previously infected premises. If producers intend to restock the previously infected premises, that premises must pass a biosecurity audit prior to the movement of poultry onto the premises. In order for the premises to maintain eligibility for indemnity for a future infection within the same outbreak, the premises must pass a virtual biosecurity audit every six (6) months, until the State in which the premises is located, declares freedom from HPAI. As discussed previously, to declare freedom from HPAI, the State must provide the relevant epidemiological evidence that shows proof of an effective surveillance program and demonstrate, through testing, an absence from infection in susceptible poultry populations in that State.

Through requiring a biosecurity audit as a condition to receiving indemnity for the destruction of poultry on premises located in the buffer zone and previously infected premises, these regulatory revisions will incentivize producers to ensure that their commercial poultry premises are implementing and maintaining appropriate poultry biosecurity plans. As previously discussed, enhanced compliance with poultry biosecurity plans is expected to mitigate the introduction and spread of HPAI.

APHIS is also amending § 53.11 to set forth the process for conducting the biosecurity audits required by § 53.10, including use of the biosecurity audit tool, the process for reconsideration of a final audit determination, and the process for revising the biosecurity audit tool.

In addition, APHIS is also amending § 53.1 to add definitions for the terms ''buffer zone,'', ''control area,'' and ''infected zone,'' which are used in amended § 53.10 and/or § 53.11.

The specific nature of the revisions is discussed immediately below.

[13] For more information on transmission, *see https://www.aphis.usda.gov/sites/default/files/highly-pathogenic-avian-influenza-national-epidemiological-brief-09-24-2024.pdf.*

**Revisions to § 53.10 and § 53.1**

As we noted above, § 53.10 of the regulations provides conditions under which indemnity claims are not allowed. We are only proposing changes to § 53.10(g).

We are proposing some minor changes to § 53.10(g)(1). All references to the word ''animals'' in this section is being changed to ''poultry'' for clarity. Additionally, we are breaking up § 53.10(g)(1). Revised § 53.10(g)(1) will solely contain the introductory language indicating that APHIS will not allow indemnity claims unless certain conditions are met and the first condition of having in place and following a poultry biosecurity plan is moved to new § 53.10(g)(1)(i).

We are also revising § 53.10(g) to provide several additional conditions under which indemnity claims are not allowed. Under new § 53.10(g)(1)(ii), APHIS will not pay indemnity for the destruction of poultry destroyed due to an outbreak of HPAI for poultry moved onto a premises located in a buffer zone of a control area unless the premises passes a biosecurity audit conducted in accordance with new § 53.11(f)(1)(i) prior to the movement of poultry on the premises; or the premises passed a biosecurity audit within the preceding six (6) months. Under certain circumstances, the Administrator may, upon request by the producer, permit audits to be conducted after the poultry is placed onto the premises if the Administrator determines that such action will not result in the dissemination of HPAI within the United States. For example, poultry may be in transit prior to the receiving premises being notified of its buffer zone status, preventing an audit to be conducted before the poultry arrives on the premises. To ensure the welfare of the poultry, the receiving premises may be required to accommodate the poultry prior to passing a biosecurity audit. If the request for an audit after the poultry is placed onto a premises is denied, the premises will not be eligible to receive future indemnity payment for the poultry placed on the premise until the premises passes a biosecurity audit conducted in accordance with new § 53.11(f)(1)(i) if the poultry are placed irrespective of the Administrator's determination.

Additionally, under new § 53.10(g)(1)(iii), APHIS will not pay indemnity for the destruction of poultry destroyed due to an outbreak of HPAI for poultry moved onto a premises that has previously been infected with HPAI during the same outbreak, unless the premises passed a biosecurity audit conducted in accordance with new § 53.11(f)(1)(ii) prior to the movement of poultry onto the premises. APHIS views an occurrence of HPAI as being during the same outbreak if it occurs before the HPAI outbreak is declared eradicated nationally, pursuant to the WOAH standards as described above; unless the movement occurs after the U.S. declares freedom from HPAI. We appreciate that an outbreak may span several years; however, effective biosecurity is possible throughout the duration of an outbreak. This is evidenced by the many premises that have not had a single introduction of HPAI during the current outbreak, despite the presence of risk factors for HPAI introduction, such as being in the flyway of migratory wild birds.

Notwithstanding the impact this outbreak has had on financial resources and the continuing economic concerns, this interim rule is not retroactive. Once issued, infections which were detected prior to the publication will not be considered in the statuses of premises. Further, upon publication, a small number of premises may find themselves located within a buffer zone. If these premises have scheduled movements which occur within a few days of the rule publication, they would have two options to satisfy the rule's requirements: (1) If possible, delay the shipment until an audit can be performed or (2) utilize § 53.10(g)(1)(ii) to request a post-placement audit from the Administrator (if the shipment cannot be delayed). All previously infected premises in a State must pass virtual biosecurity audits every six (6) months until the State in which the premises is located declares freedom from HPAI. The additional audits are based on APHIS' review of chronological outbreak data regarding date of all case detections relative to virus elimination and audit dates for known infected poultry premises. The data analysis indicated that previously infected premises that had biosecurity audits conducted on a voluntary basis did not have any HPAI introduction within 180 days post-audit and movement of poultry. Based on this data, APHIS found that the risk of HPAI reintroduction on a previously infected premises is low within 6 months. Additionally, the 180 days roughly aligns with wild bird migratory patterns, when increased risk of introduction from wild birds is elevated, and it would be appropriate to ensure poultry premises are implementing heightened biosecurity practices.

As stated previously, the regulations currently exempt producers from having to develop and follow a poultry biosecurity plan as a condition of indemnity for HPAI if any of the following apply:

- Commercial table-egg laying premises with fewer than 75,000 birds;
- Egg-type game bird and egg-type waterfowl premises with fewer than 25,000 birds;
- Premises on which fewer than 100,000 broilers are raised annually; or
- Premises on which fewer than 30,000 meat turkeys are raised annually.

Because these premises are not currently required to develop and follow a poultry biosecurity plan, we are also exempting them from being required to pass a biosecurity audit. As we noted in the 2016 interim rule, more than 97 percent of turkeys and 99 percent of broilers are raised on farms that are above these size thresholds. Additionally, whereas the regulations had previously cited the relevant provisions of the NPIP regulations for the first two size standards, to aid in readability of the section, we are removing the reference to the NPIP regulations and, in their place, adding the actual size standards that are being referenced. We are not changing the size standards themselves, simply restating them within § 53.10(g)(2).

Finally, we are adding a new paragraph (g)(3) to the section. This paragraph states that, notwithstanding the conditions in paragraphs (g)(1) and (2), the Department will not pay claims arising out of the destruction of poultry destroyed due to an outbreak of HPAI if the poultry was moved onto a premises in an infected zone and if the poultry becomes infected with HPAI within 14 days following the dissolution of the control area in which the infected zone is located. The incubation period for HPAI viruses in naturally infected chickens ranges from 3–14 days. Once a control area is released, there is significantly less risk of disease spread caused by common-source lateral transmission.

To clarify the scope of the new requirements to receive indemnity for poultry, we are adding definitions for *buffer zone, infected zone,* and *control area* to § 53.1 of the regulations, which contains definitions of terms used in 9 CFR part 53. We are defining *buffer zone* as ''[t]he zone within a control area that immediately surrounds an infected zone.'' We are defining *infected zone* as ''[t]he zone within a control area that immediately surrounds a premises infected with highly pathogenic avian influenza, up to the beginning of the buffer zone.'' As we noted above, currently buffer zones are usually the area situated between 3 and 10 km from an infected premises, and the SAHO

determines and communicates to producers whether they are in the infected zone or the buffer zone, or outside of the control area entirely. However, to allow for the possibility of larger or smaller control areas, infected zones, and/or buffer zones in the future, we are not specifying a particular distance from the infected premises in our definitions. As previously stated, multiple factors are considered in determining control area size for HPAI, including infected premises transmission pathways and estimates of transmission risk, poultry movement patterns and concentrations, distribution of susceptible wildlife in proximity, natural terrain, and jurisdictional boundaries. We are defining *control area* as ''[t]he area around a premises infected with highly pathogenic avian influenza and consisting of an infected zone and a buffer zone, the bounds of which are determined and communicated to producers by Federal or State officials.'' Again, we envision that in most instances the SAHO will make the final determination for setting the perimeter of the control area and communicating the bounds of the control area to producers. This is, as noted above, the current practice. However, our definition does provide latitude for APHIS to determine and set the bounds of the control area. We envision that we will defer to the SAHO except in extraordinary circumstances, such as when a declaration of extraordinary emergency within the State has been made pursuant to 7 U.S.C. 8306(b) of the Animal Health Protection Act.

The prohibition on indemnity claims that we are adding to the regulations in paragraph (g)(3) of § 53.10 is warranted because, based on our definitions, poultry premises in the infected zone either are infected with HPAI or are in close proximity to an infected premises, and the incubation period for HPAI is up to 14 days. This additional requirement for future federal indemnity eligibility is necessary to limit movement of poultry into an area where poultry are at an increased risk for exposure and infection with HPAI.

**Revisions to § 53.11**

Section 53.11 provides conditions under which payment will be made on indemnity claims resulting from HPAI outbreaks. We are amending § 53.11 to describe how the biosecurity audits, required by the revisions to § 53.10(g), will be conducted. We are redesignating current paragraph (f) of the section as paragraph (g), and we are adding a new paragraph (f), which discusses the parameters surrounding and content of these biosecurity audits and how the biosecurity audit tool will be updated. The relevant biosecurity audit is determined by the status of a premises prior to movement of poultry onto that premises.

New paragraph (f)(1) of § 53.11 provides that APHIS requires a biosecurity audit to be conducted on the following poultry premises:

- For premises in a buffer zone, a biosecurity audit shall be conducted virtually by the auditor, unless the SAHO in the State where the premises is located requests an in-person audit. For example, if the facility lacks necessary equipment or IT infrastructure on the premises to conduct a virtual audit, a SAHO could request an in-person audit.
- For previously infected premises, a biosecurity audit shall be conducted in-person by the auditor, unless the auditor determines that extenuating circumstances warrant a virtual audit. Extenuating circumstances include, but are not limited to, severe adverse weather conditions and employee safety considerations. All previously infected premises must pass virtually conducted biosecurity audits every six (6) months after the initial in-person audit until the State in which the premises is located declares freedom from HPAI.

We are allowing biosecurity audits of poultry premises in a buffer zone to be conducted remotely because, while the premises are at risk of becoming affected with HPAI, they are, by definition, currently uninfected but in proximity to infected premises, and because premises in the buffer zone, as a whole, undergo periodic surveillance. Surveillance activities include but are not limited to, gathering epidemiological information through observation and communication with other agencies. Active sampling of poultry is conducted on premises at control area establishment, then at set time intervals of 5–7 days (or more frequently if warranted) until the control area is closed. In addition, because premises in a buffer zone may have poultry onsite during a biosecurity audit, a virtual biosecurity audit helps to mitigate the risk of introduction of HPAI into the premises due to the increased vehicular and foot traffic on the premises from personnel that are conducting the audit. Moreover, in-person audits require more time and personnel resources and are logistically more complex compared to virtual audits. If the number of buffer zone audits conducted to date is an indication of what to expect as the current outbreak continues, mandating these audits to be in-person would stretch available resources that are already currently being utilized for other HPAI response activities and routine non-HPAI activities. For these reasons, a virtual visual inspection (which is conducted using a phone camera, computer, or other transmitting device) should usually suffice for the biosecurity audit of the premises itself. If a producer is unable to participate in a virtual inspection, due to lack of internet or a transmitting device at the premises, the audit may be conducted in-person.

Conversely, because previously infected poultry premises have experienced an outbreak of HPAI and have the highest risk of reintroduction resulting from significant biosecurity lapses, we must verify how well the plan is implemented and maintained on site. In order to ensure that reintroduction risks are being effectively mitigated at previously infected premises, we are requiring that these biosecurity audits be conducted in person, absent extenuating circumstances. Examples of extenuating circumstances include, but are not limited to, severe adverse weather conditions and employee safety considerations. APHIS would require an in-person audit because once HPAI response activities are completed, including depopulation, the premises would not contain any poultry on the premises that would be at risk for HPAI from conducting the audit. With an in-person audit, APHIS will be able to be more meticulous in our approach of looking at the premises and ensuring that producers are taking appropriate biosecurity measures. Additionally, the absence of poultry on the premises eliminates any further risks of HPAI spread and introduction.

APHIS considered, but did not pursue, two alternate options for the auditing process. One was to require more documentation, such as photos of the property, Google Earth™ stills, and examples of signage, as part of an OSA paper-based review of the premises. However, this option was discarded because this approach does not allow for a holistic review of the maintenance and physical security of the structures at the facility, and it may not capture seasonal changes at the facility that could present a biosecurity risk. A second option considered was to conduct all audits virtually. This option was discarded for premises that have previously experienced an outbreak and wish to restock because the virtual audit is limited by what the phone camera, computer, or other transmitting device relays to the auditor. Given that previously infected premises have experienced an outbreak of HPAI, such

a limited view may not disclose all possible risks of reintroduction of HPAI to the premises, and require an in-person audit for better visual and auditory context, absent extenuating circumstances. To provide two examples that underscore the importance of in-person audits for visual and auditory context, a component of the audit involves evaluating whether feed and bedding at the facility may have been contaminated by exposure to rodents. Evidence (visual or auditory) of previous or current rodent infestation at the premises may be much easier to identify in person than virtually. Another component requires the inspector to inspect and/or monitor the enclosed structures housing live poultry to ensure sound construction and that they are kept in good repair. An in-person auditor may hear air circulation suggesting a hole or breach in the facility that would not necessarily be easy to detect through a virtual audit.

To implement these two biosecurity audit processes within the Agency, APHIS developed the Biosecurity Compliance Audit Program (BCAP), which includes a BCAP Program Manager within APHIS' Veterinary Services program, and an auditing team comprised of an auditor and a reviewer. The auditor makes the initial determination of whether a premises passes a biosecurity audit. Generally, APHIS expects the auditor role will be filled by a State employee. However, if a State lacks the human resources to fill the position, an APHIS employee can fill the role. Conversely, the reviewer makes the final determination of whether a premises passes a biosecurity audit. This position will always be an APHIS employee because a final audit determination is an Agency decision that affects the eligibility of the producer to receive future indemnity payments for poultry destroyed due to HPAI. All biosecurity auditors and audit reviewers will undergo a USDA-led training program prior to being added to a team. The training includes ensuring consistent application of the biosecurity audit tool, awareness of different poultry production types and farm layouts, and different methods and technologies for implementation of biosecurity.

During biosecurity audits, the audit team will conduct the audits using a biosecurity audit tool (*https://www.aphis.usda.gov/sites/default/files/biosecurityaudit.pdf*), developed by APHIS with State and industry input. From January 2024 through May 2024, industry provided APHIS with oral and written feedback regarding the operational feasibility of implementing on an ongoing basis a biosecurity audit checklist in use provisionally for poultry biosecurity audits conducted since the start of the current outbreak. The tool includes aspects of the current paper-based biosecurity audit that is conducted by OSA's on at least a biennial basis. In addition, the biosecurity tool was built upon the NPIP biosecurity criteria and the HPAI Control Area Placement Biosecurity Audit Checklist that was developed in 2022. As stated previously, as part of the biennial biosecurity audit, the OSA will, at a minimum, evaluate the poultry biosecurity plan itself, which includes an evaluation of the poultry biosecurity plan, against 14 biosecurity principles articulated in the NPIP Program Standards policy document, and review the documentation showing that the poultry biosecurity plan is being implemented. A member of the audit team will conduct this review as well. The audit tool also includes visual verification of perimeter buffer areas; line-of-separation (LOS) procedures for personnel, visitors, equipment, and vehicles; and on-premises rodent and wildlife mitigations, some of the 14 NPIP biosecurity principles. Use of the audit tool will ensure that audit teams consistently review premises and identify deficiencies in biosecurity. APHIS is making a copy of the tool available as a supporting document for this interim rule on *Regulations.gov*.

Revisions to the audit tool are addressed in new § 53.11(f)(6). The BCAP Program Manager will review the tool at least on an annual basis. As biosecurity audits are conducted and additional data is gathered, as updated epidemiological information becomes available, or as other advancements in technology and production practices occur, APHIS may determine that the audit tool needs to be revised. APHIS has two processes to revise the audit tool. Under the standard process, if the Administrator determines that revisions to the audit tool are necessary, APHIS will publish a notice in the **Federal Register** informing the public of our intention to amend the biosecurity audit tool. In the notice, APHIS will describe the proposed revisions to the audit tool, the reasons for the revisions, and provide a public comment period. Under the immediate process, the biosecurity audit tool will be immediately revised if the Administrator determines that the biosecurity tool is no longer sufficient for auditors to use to conduct biosecurity audits pursuant to new § 53.11(f)(1)(i) or (ii). APHIS will update the audit tool and subsequently publish a notice in the **Federal Register** advising the public of the revisions and the reasons for the revisions, providing an effective date for the revisions, and providing for a public comment period.

Under new § 53.11(f)(2), the producer must allow auditors access to their premises (whether virtually or in-person) and access to documentation in order for the auditors to complete the biosecurity audit using the biosecurity audit tool. APHIS expects that any producer interested in moving poultry onto a premises in a buffer zone or onto a previously infected premises will contact APHIS to schedule the biosecurity audit. A premises will initially pass a biosecurity audit if the auditor determines that the minimum requirements are met for all biosecurity audit criteria in the biosecurity audit tool. If deficiencies are identified, the auditors will communicate the identified deficiencies to producers. Producers may ask clarifying questions about the nature of the deficiencies and/or provide additional documentation to remediate the identified deficiency. The auditor, where appropriate, may work with the producer to identify solutions to resolve the deficiencies and may revise the audit results based on the additional information provided. If the producer needs further guidance on addressing a deficiency that goes beyond the auditor's training, the auditor will send the request to the audit reviewer and, if needed, the BCAP Program Manager. Once the audit process concludes, the auditor will submit the audit package to a reviewer based in the State where the premises is located.

New § 53.11(f)(3) provides that the reviewer reviews the audit package for completeness, accuracy, and consistency with other audits. After review, the reviewer will render a final audit determination of pass or fail. To aid in that determination, the reviewer may request to view the premises in question to make virtual visual verifications; the reviewer must be afforded the same access previously afforded to the auditor. As provided in our previous discussion regarding § 53.10(g), premises are required to pass a biosecurity audit in order for the poultry on the premises to be eligible for indemnity.

New § 53.11(f)(4) provides a reconsideration process for failed outcomes of biosecurity audits. If the producer disagrees with the final audit determination of the reviewer, the producer may send a request for reconsideration to the BCAP Program Manager through email or by postal mail

to the addresses listed in the regulations. The request for reconsideration must be in writing, state the material facts and reasons upon which the producer relies to show that the producer wrongfully failed the biosecurity audit, and be received by the BCAP Program Manager within 14 calendar days of communication of the reviewer's final audit determination. After receipt of the reconsideration request, the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. If the BCAP Program Manager disagrees with the reviewer's final determination the results of the biosecurity audit become a pass; if the BCAP Program Manager agrees that a biosecurity deficiency exists, the reconsideration request proceeds to panel review. A panel consisting of the SAHO of the State where the premises is located, the APHIS Area Veterinarian in Charge, and the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. The panel's decision is final, and the outcome of the reconsideration process will be communicated to the producer, by the auditor, as promptly as circumstances allow and will state, in writing, the reasons for the decision.

Finally, the duration of the validity of a biosecurity audit is addressed in new § 53.11(f)(5). A final audit determination of pass will remain valid for six (6) months except for any premises that changes its biosecurity plan, biosecurity coordinator, ownership, or infrastructure during that six-month period. If such premises makes any of the aforementioned changes, the premises must pass a new biosecurity audit in accordance with § 53.11(f)(1)(i) or (ii), as applicable, prior to the movement of poultry onto the premises. APHIS determined the length of time for which a biosecurity audit should be valid based on a review of data from the HPAI outbreak in poultry. The data indicated that since the onset of this current outbreak in 2022, the number of poultry premises located in buffer zones that had an HPAI introduction within 180 days of undergoing a biosecurity audit and moving birds onto the premises is less than 3 percent. Although data are limited based on the voluntary nature of the biosecurity audits, analysis of the chronological data for previously infected premises shows there was no indication that the previously infected premises had an HPAI introduction within 180 days post-audit and movement of poultry. Once this interim rule becomes effective, APHIS will continue to monitor this data to use in the Agency's decision-making process.

**Immediate Action**

Immediate action is necessary to incentivize commercial poultry owners and contractors (hereafter referred to in this section of the preamble as ''producers'') to implement critical biosecurity measures to reduce the risk of introduction of HPAI and avoid actions that contribute to its spread. During the most recent HPAI outbreak, which began in 2022 and is ongoing, APHIS has learned more about the disease risk for poultry premises in proximity to other infected poultry premises and has discovered the limits of the current regulatory approach. APHIS modified guidance documents for the current outbreak; however, continued inconsistent application of biosecurity measures by producers despite the ongoing risk of introduction of HPAI from wild birds and nearby infected premises has resulted in continued repeat infections on some poultry premises. Since March 2024, APHIS has further encountered developments associated with spread of HPAI to, from, and within dairy cattle herds, as well as farm workers in contact with those herds. Cumulatively, all of these lessons learned from the 2022–2024 outbreak underscore the need for immediate action to incentivize producers with at-risk premises, through conditioning indemnity payments on passing biosecurity audits, to take the necessary steps to implement biosecurity measures to mitigate the introduction and spread of HPAI, regardless of potential source of infection. Therefore, immediate action is needed to mitigate the introduction and spread of HPAI.

Since 2016, APHIS has required that, as a condition for indemnity for poultry destroyed due to an HPAI outbreak, poultry producers above certain size thresholds must provide a statement that at the time of detection of HPAI in their premises, they had in place and were following a poultry biosecurity plan. Since 2018, APHIS has also required that the poultry biosecurity plans be audited at least once every 2 years by the producer's OSA. Recent lessons learned from the ongoing HPAI outbreak have highlighted that this regulatory approach is insufficient in certain instances and reinforced the importance of biosecurity in decreasing the chance of a virus introduction or reintroduction occurring in a premises or having the virus spread from premises to premises.

First, we have learned more about how proximity to infected premises impacts HPAI spread. During an HPAI outbreak, States designate ''control areas'' as the perimeter of at least 10 km beyond the perimeter of the poultry premises affected with HPAI. During this current outbreak, it has become increasingly clear that poultry premises within these control areas, consisting of an infected zone and a buffer zone, are at a higher risk of becoming infected with HPAI than premises outside of control areas. To improve the understanding of risk factors associated with HPAI on table egg farms and turkey farms in the United States, APHIS conducted case-control studies to identify risk factors for HPAI and biosecurity challenges.[14] The findings confirm the need for both biosecurity and surveillance on poultry farms near an infected premises, to prevent infection and ensure rapid detection, whether the virus is likely spreading by wild birds or laterally between farms. Because premises in control areas are at a higher risk of being infected with HPAI, it is even more imperative that producers implement adequate biosecurity measures to prevent the introduction and spread of HPAI from premises to premises within the control area, and from premises within the control area to premises outside the control area.

Second, we have learned during this current outbreak that enhanced regulatory oversight of poultry premises in control areas is necessary to ensure that producers for which a poultry biosecurity plan is required are effectively implementing the poultry biosecurity plan. Currently, the regulations only require the poultry biosecurity plan to be audited every two (2) years or a sufficient number of times during that period to satisfy the producer's OSA. Additionally, the audits are currently paper-based. The current biennial audit failure rate is zero, however despite these biosecurity plans being present, APHIS has continued to see HPAI detections on poultry farms with a plan and epidemiologic findings on these premises show a failure of biosecurity in one or more areas. The effectiveness of a poultry biosecurity plan, however, is determined not only by its provisions (which is the focus of a paper-based

[14] For more information on the case-control studies, *see https://www.aphis.usda.gov/sites/default/files/hpai-challenges-implementing-biosecurity.pdf.*

audit), but also by how well the plan is implemented and maintained on-site.

Through the current outbreak, APHIS has found that the effectiveness of a poultry biosecurity plan would likely be better evaluated by visual inspection of the premises in question, specifically visual inspection of the more at-risk premises in the control area. When producers fail to effectively implement and maintain their poultry biosecurity plan, the deficiencies can be quite pronounced and the consequences quite significant—namely that the premises gets infected with HPAI multiple times. In one particular case, APHIS determined that a producer had avoided the required biennial audits and had not effectively implemented a poultry biosecurity plan before HPAI was introduced onto the producer's premises. Ultimately, six premises owned by the same producer and within the same control area were infected with HPAI. Significant biosecurity lapses were also identified at each of the affected premises. Biosecurity deficiencies may also be a contributing factor to premises becoming reinfected with HPAI. During the current HPAI outbreak, a total of 67 unique commercial poultry premises have been infected with HPAI at least twice, including 19 premises that have been infected 3 or more times.

Third, in March 2024, HPAI was detected in dairy cattle. Prior to this, HPAI was sporadically detected in mammals, particularly those with close contact to infected poultry and wild birds, those that share feed or water sources, or those that scavenge carcasses. However, the confirmation of HPAI in dairy cattle in late March 2024, and the subsequent transmission of the disease largely due to the interstate and regional movement of livestock, people, and equipment, marked a significant change in the epidemiology of HPAI and posed another potential source of the virus for poultry flocks.

As of November 2024, APHIS and State teams have conducted extensive epidemiological work to investigate the links between HPAI-affected dairy premises and evidence of spillover into poultry premises. This new, distinct HPAI virus genotype poses a new animal disease risk as it can infect both cattle and poultry. The phylogenetic and epidemiological data indicate spread between dairy premises, and from dairy premises to poultry premises.[15] While many factors contribute to transmission between premises, small amounts of unpasteurized milk from affected dairy animals can harbor high levels of virus and can be easily spread among dairy farms and between dairy and poultry farms through the movements of people, vehicles, trucks, and other animals including non-migratory, peridomestic birds. Poultry are much more susceptible to small amounts of virus that results in infection, which increases the potential for ongoing disease spread. Finally, since April 2024, several cases in workers on affected dairy and poultry premises have been reported.

This recent lateral spread of HPAI within and between dairy herds and spillover into poultry flocks, poses increased risks of HPAI introduction and spread for poultry that effectively implemented poultry biosecurity plans may mitigate. Without the biosecurity audits for at-risk poultry premises to confirm effective implementation of poultry biosecurity plans as established by this interim rule, the spread of HPAI in the United States could escalate, not only in poultry, but also in other livestock, increasing the impact of the current outbreak. As demonstrated by the current outbreak, that impact extends beyond the economic implications for the livelihood of poultry producers to the physical health of individual workers who come into contact with infected animals. In response to the current outbreak in dairy cattle, APHIS has issued a second Federal Order to require national surveillance to continue to address the risk the disease in dairy cattle, and as a result, potential spread to other species. Escalation in the introduction and spread of HPAI needs to be addressed immediately.

Under these circumstances, the Administrator has determined for good cause under 5 U.S.C. 553(b)(B) that prior notice and opportunity for public comment is impracticable and that there is good cause under 5 U.S.C. 553(d)(3) for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the interim rule.

**Executive Orders 12866, 13563, and Regulatory Flexibility Act**

This interim rule has been determined to be significant for the purposes of Executive Order 12866 as amended by Executive Order 14094, ''Modernizing Regulatory Review,'' and, therefore, has been reviewed by the Office of Management and Budget (OMB).

We have prepared an economic analysis for this interim rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic effects of this interim rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. The full analysis may be viewed on the *Regulations.gov* website (see **ADDRESSES** above for instructions for accessing *Regulations.gov*) or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

APHIS is establishing requirements for certain poultry premises to complete a biosecurity audit as a condition for receiving indemnity payments for poultry depopulated because of an outbreak of HPAI. APHIS' response to HPAI via regulation is not new. In 2016, APHIS published an interim rule (81 FR 6745–6751, Docket No. APHIS–2015–0061)[16] that amended § 53.10 of the indemnity regulations to require producers provide, as a condition for receiving indemnity payments, a statement that at the time of HPAI detection on their premises, that they had in place and were following a poultry biosecurity plan consistent with NPIP biosecurity standards. In response to comments received during the comment period on the interim rule, in the final rule published in 2018, APHIS amended § 53.11 of the indemnity regulations to require poultry biosecurity plan audits at least once every 2 years or enough times during that period to satisfy the Official State

[15] For more information on the phylogenetic and epidemiological data, *see https://www.aphis.usda.gov/sites/default/files/hpai-dairy-faqs.pdf* and *https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza/hpai-livestock.*

[16] To view the interim rule, its supporting documentation, or the comments that we received, go to *https://www.regulations.gov/docket/APHIS-2015-0061.*

Agency.[17] APHIS believed that the provisions of the 2016 HPAI indemnity rule, as amended to include this auditing provision, would be sufficient to reduce spread of the virus in the event of another HPAI outbreak. However, APHIS' experience with a subsequent outbreak of HPAI in 2022–2024 indicated that the 2016 interim rule and the subsequent 2018 final rule were insufficient to address initial introduction of HPAI into flocks on premises in proximity to an infected premises, or subsequent reintroduction of HPAI into flocks on premises previously infected with HPAI.

This interim rule amends § 53.10(g) to require biosecurity audits for two statuses of premises in order for owners and/or contractors (hereafter collectively referred to in this section of the preamble as ''producers'') to qualify for indemnity arising out of the destruction of poultry destroyed due to an outbreak of HPAI and that exceed defined size thresholds delineated by poultry type. One status of premises for which this interim rule will require biosecurity audits are premises located in a buffer zone of a control area for HPAI. If a producer intends to move poultry onto a premises located in a buffer zone and wishes the poultry moved onto the receiving premises to be eligible for future indemnity payments in the event that the receiving premises is later infected with HPAI and the poultry must be destroyed, the receiving premises must pass a biosecurity audit. If the receiving premises passed a biosecurity audit within the six (6) months preceding the intended date of movement of the poultry onto the receiving premises, a new biosecurity audit is unnecessary. The audit will be done virtually unless the SAHO requests an in-person audit. The other status of premises for which this interim rule will require biosecurity audits are previously infected premises. If producers intend to restock the previously infected premises, that premises must pass a biosecurity audit prior to the movement of poultry onto the premises. In order for the premises to maintain eligibility for indemnity for a future infection within the same outbreak, the premises must pass a virtual biosecurity audit every six (6) months, until the State in which the premises is located, declares freedom from HPAI.

Current § 53.10(g) exempts producers from having to develop and follow a poultry biosecurity plan as a condition of indemnity for HPAI if any of the following apply:

The producer is a(n):

- commercial table-egg-laying premises with fewer than 75,000 birds;
- egg-type game bird and egg-type waterfowl premises with fewer than 25,000 birds;
- premises on which fewer than 100,000 broilers are raised annually; or
- premises on which fewer than 30,000 meat turkeys are raised annually.

Because these premises are not currently required to develop and follow a poultry biosecurity plan, in this interim rule, we are also exempting them from being required to pass a biosecurity audit. More than 97 percent of turkeys and 99 percent of broilers are raised on farms that exceed these size thresholds. However, flock size is non-significantly associated with increased risk, provided that larger operations are more at risk than smaller operations in terms of number of poultry on the operation, not the implementation of a biosecurity plan.

Regarding the defined size thresholds delineated by poultry type, current § 53.10(g) cited the relevant provisions of the NPIP for the first two size standards. The NPIP is a cooperative Federal-State-industry certification program administered by APHIS to promote biosecurity in poultry. To aid in readability and comprehension of the regulation, APHIS is removing the reference to the NPIP regulations and, in their place, adding the actual size standards that are being referenced. APHIS is not changing the size standards themselves, simply restating them within revised § 53.10(g)(2).

To clarify the scope of the new requirements to receive indemnity payments for poultry, APHIS is adding definitions for *buffer zone, infected zone,* and *control area* to § 53.1 of the regulations, which contains definitions of terms used in part 53. APHIS is defining *buffer zone* as ''[t]he zone within a control area that immediately surrounds an infected zone.'' APHIS is defining *infected zone* as ''[t]he zone within a control area that immediately surrounds a premises infected with highly pathogenic avian influenza, up to the beginning of the buffer zone.'' APHIS is defining *control area* as ''[t]he area around a premises infected with highly pathogenic avian influenza and consisting of an infected zone and a buffer zone, the bounds of which are determined and communicated to producers by Federal or State officials.''

Currently buffer zones are usually the area situated between 3 and 10 km from an infected premises. However, to allow for the possibility of larger or smaller control areas, infected zones, and/or buffer zones in the future, APHIS does not specify a particular distance from the infected premises in the definitions. Multiple factors are considered in determining control area size for HPAI, including infected premises transmission pathways and estimates of transmission risk, poultry movement patterns and concentrations, distribution of susceptible wildlife in proximity, natural terrain, and jurisdictional boundaries.

With respect to limitations on receipt of indemnity payments, APHIS is revising § 53.10(g) to provide several additional conditions under which indemnity claims are not allowed. Specifically, APHIS will not pay indemnity for the destruction of poultry destroyed due to an outbreak of HPAI for poultry moved onto a premises located in a buffer zone of a control area unless the premises passes a biosecurity audit conducted in accordance with new § 53.11(f)(1)(i) prior to the movement of poultry onto the premises. Premises that passed a biosecurity audit within the preceding 6 months are not required to pass a new audit. Additionally, under new § 53.10(g)(1)(iii), APHIS will not pay indemnity for the destruction of poultry destroyed due to an outbreak of HPAI for poultry moved onto a premises that has previously been infected with HPAI during the same outbreak, unless the premises passed a biosecurity audit conducted in accordance with new § 53.11(f)(1)(ii) prior to the movement of poultry onto the premises. APHIS views an occurrence of HPAI as being during the same outbreak if it occurs before the HPAI outbreak is declared eradicated nationally. Finally, APHIS will not pay indemnity claims arising out of the destruction of poultry destroyed due to an outbreak of HPAI if the poultry was moved onto a premises in an infected zone and if the poultry becomes infected with HPAI within 14 days following the dissolution of the control area in which the infected zone is located.

In this interim rule, APHIS is also amending § 53.11 to set forth the process for conducting the biosecurity audits required by § 53.10, including use of the biosecurity audit tool, the process for reconsideration of a final audit determination of fail, and the process for revising the biosecurity audit tool.

For premises in a buffer zone, a biosecurity audit shall be conducted virtually by the auditor, unless the SAHO in the State where the premises is located requests an in-person audit. For previously infected premises, a

[17] To access the 2018 final rule, go to *https://www.regulations.gov/docket/APHIS-2015-0061.*

biosecurity audit shall be conducted in-person by the auditor, unless the auditor determines that extenuating circumstances warrant a virtual audit. Extenuating circumstances, include, but not limited to, severe adverse weather conditions and employee safety considerations. All previously infected premises must pass virtually conducted biosecurity audits every six (6) months until the State in which the premises is located declares freedom from HPAI.

Under new § 53.11(f)(1), APHIS requires biosecurity audits to be conducted as follows:

- For premises in a buffer zone, a biosecurity audit shall be conducted virtually by the auditor, unless the SAHO in the State where the premises is located requests an in-person audit; and
- For previously infected premises, a biosecurity audit shall be conducted in-person by the auditor, unless the auditor determines that extenuating circumstances warrant a virtual audit. Extenuating circumstances, include, but not limited to, severe adverse weather conditions and employee safety considerations.

Under new § 53.11(f)(2), the producer must allow auditors access to their premises (whether virtually or in-person) and access to documentation in order for the auditors to complete the biosecurity audit using the biosecurity audit tool. If deficiencies are identified, the auditors will communicate the identified deficiencies to producers and, where appropriate, may work with the producer to identify solutions to resolve the deficiencies and may revise the audit results based on the additional information provided.

New § 53.11(f)(3) provides that the reviewer reviews the audit package for completeness, accuracy, and consistency with other audits. After review, the reviewer will render a final audit determination of pass or fail. If requested, the reviewer must be afforded the same access to premises previously afforded to the auditor.

New § 53.11(f)(4) provides a reconsideration process for failed outcomes of biosecurity audits. If the producer disagrees with the final audit determination of the reviewer, the producer may send a written request for reconsideration to the BCAP Program Manager through email or by postal mail within 14 calendar days of communication of the reviewer's final audit determination. The BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer final audit determination. If the BCAP Program Manager determines that the producer wrongfully failed the biosecurity audit, he or she will change the final audit determination from fail to pass, notify the producer of the change in writing, and close the reconsideration request. If the BCAP Program Manager agrees that the producer failed the biosecurity audit, the reconsideration process will continue to a panel review. A panel consisting of the State Animal Health Official, the APHIS Area Veterinarian in Charge, and the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. The panel's decision is final and will be communicated to the producer as promptly as circumstances allow and will state, in writing, the reasons for the decision.

Under new § 53.11(f)(5), a final audit determination of pass for a premises that had a biosecurity audit conducted in accordance with § 53.11(f)(1)(i) or (ii) will remain valid for six (6) months except for any premises that changes its biosecurity plan, biosecurity coordinator, ownership, or infrastructure during that 6-month period. If such premises makes any of the aforementioned changes, the premises must pass a new biosecurity audit in accordance with § 53.11(f)(1)(i) or (ii) as applicable, prior to the movement of poultry onto the premises.

APHIS is allowing biosecurity audits of premises in a buffer zone to be conducted remotely because, while the premises are at risk of becoming affected with HPAI, they are, by definition, currently uninfected but in proximity to infected premises, and because premises in the buffer zone, as a whole, undergo periodic surveillance. In addition, because premises in a buffer zone may have poultry onsite during a biosecurity audit, a virtual biosecurity audit prevents the introduction of HPAI into the premises. For these reasons, a virtual visual inspection (which is conducted using a phone camera, computer, or other transmitting device) should usually suffice for the biosecurity audit of the premises itself. If a producer is unable to participate in a virtual inspection, due to lack of internet or a transmitting device, the audit may be conducted in-person. Conversely, because previously infected premises have experienced an outbreak of HPAI and have the highest risk of reintroduction resulting from significant biosecurity lapses, we must verify how well the plan is implemented and maintained on-site. In order to ensure that reintroduction risks are being effectively mitigated at previously infected premises, we are requiring that these biosecurity audits be conducted in person, absent extenuating circumstances.

Revisions to the audit tool are addressed in new § 53.11(f)(6). Under the standard process for revisions to the audit tool, if the Administrator determines that revisions to the biosecurity audit tool are necessary, APHIS will publish a notice in the **Federal Register** advising the public of the Administrator' determination. The notice will describe the proposed revisions and the reasons for the proposed revisions and will invite public comment on the proposed revisions. Under the immediate process for revisions to the audit tool, if the Administrator determines that the biosecurity audit tool is no longer sufficient for auditors to use to conduct biosecurity audits pursuant to § 53.11(f)(1)(i) or (ii), APHIS will immediately update the biosecurity audit tool. APHIS will publish a notice in the **Federal Register** advising the public of the Administrator's determination. The notice will specify the revisions and the reasons for the revisions, provide an effective date for the revisions, and will invite public comment on the revisions. The primary intent of the preceding revisions to part 53 is to enhance effective implementation of and adherence to poultry biosecurity plans to mitigate and reduce the introduction, reintroduction, and spread of HPAI. Effective implementation of a poultry biosecurity plan likely reduces the risk of introduction of HPAI onto a premises and mitigates its spread, if introduced. Less risk of HPAI introduction and spread would, in turn, reduce the need to destroy birds and thus reduce the need of APHIS to make indemnity payments. Requirements for biosecurity audits also emphasize and validate biosecurity principles that many individual producers are already implementing on their premises because of participation in the NPIP. Finally, the preceding revisions to part 53 also incentivize timely cleanup of HPAI infected premises to mitigate further disease spread. Producers are more likely to implement biosecurity measures if it will ensure indemnity payments should their premises become infected with HPAI, and their birds must be destroyed. Because many of the biosecurity principles needed to pass the biosecurity audit are already in place, we expect that most producers will not incur large costs from this interim rule. We further find that plausible reductions in indemnity and virus elimination costs are far higher than costs to producers.

As of November 2024, APHIS has spent approximately $227 million on indemnity payments to premises infected multiple times during the 2022–2024 outbreak. Epidemiological data attribute most of the source introductions in the current outbreak to wild birds, likely due to biosecurity gaps. Revising the current regulations to further tie indemnity payments to verified implementation of proven biosecurity improvements will reduce the occurrence of multiple infections of the same premises. Reinfections (like first time infections) result in direct economic losses not only from the loss of stock but also from downtime to sanitize the premises and to complete other HPAI response activities (*e.g.,* the biosecurity audit). This interim rule should reduce these losses.

Since 2012, there have been two (2) major HPAI outbreaks in the United States; the first between December 10, 2014, and August 16, 2015, and the second from February 2, 2022, to present. Aggregating price data for broiler meat, turkey meat, and table eggs into two (2) groups (prices on those dates during an HPAI outbreak and prices on dates that were not in a HPAI outbreak) show that broiler meat, turkey meat, and table egg prices are higher during a HPAI outbreak when compared to prices during periods of limited HPAI infection.

APHIS expects this interim rule to result in costs to affected producers. Examples of costs include time and labor to implement improvements to current biosecurity practices, time to complete and pass biosecurity audits, delays to restocking, and costs associated with the purchase of or upgrade to equipment needed to conduct a virtual audit, if the producer wishes to have a virtual audit. APHIS expects the benefits of reduced infections from HPAI will outweigh the aforementioned costs associated with this interim rule.

APHIS estimates that this interim rule will reduce costs to APHIS and State partners between $39.56 million and $88.66 million. These estimates include reductions in indemnity and response costs less costs incurred by APHIS and State partners for buffer zone movement audits and previously infected premises audits. APHIS anticipates a slight increase in staff time costs that it will incur as a result of conducting buffer zone movement audits and previously infected premises audits. APHIS expects this interim rule to have costs for producers to facilitate the audit (including up-front costs for the purchase of any equipment necessary to conduct an audit virtually) and to address any resultant biosecurity deficiencies. Producers may also incur additional costs if their premises fails an audit and must go through the reconsideration process meaning more time will pass before poultry may be moved onto the premises or the premises is restocked. Producers in infected zones will face costs from delays to restocking based on forgone profits. APHIS estimates that these costs will result in $0.49 to $0.79 million in time, materials, and recordkeeping costs to producers. Overall, APHIS estimates that this interim rule will have a net benefit of between $38.55 and $87.65 million. In addition to these quantified benefits, APHIS also anticipates that this interim rule will have small unquantified effects on international trade, consumer prices, animal welfare, public health, and producer welfare.

TABLE 1—SUMMARY OF ESTIMATED COSTS AND BENEFITS OF THE INTERIM RULE

| | Reduction in costs to APHIS and State partners | | Cost to producers | | Net benefits | |
|---|---|---|---|---|---|---|
| | Low | High | Low | High | Low | High |
| | *$, millions* | | | | | |
| Buffer zone movement audits | 15.53 | 31.23 | 0.03 | 0.08 | 15.45 | 31.20 |
| Previously infected premises audits | 14.63 | 29.53 | 0.13 | 0.18 | 14.45 | 29.40 |
| Infected zone waiting period | 9.40 | 27.90 | 0.06 | 0.26 | 9.14 | 27.84 |
| Recordkeeping and paperwork | 0.0 | 0.0 | 0.27 | 0.27 | (0.27) | (0.27) |
| Total | 39.56 | 88.66 | 0.49 | 0.79 | 38.55 | 87.65 |

**Note:** Reduction in costs to APHIS and State partners includes estimated reduction in indemnity and response costs less audit costs incurred by APHIS and State partners.

APHIS estimates the total annualized cost of the paperwork and recordkeeping associated with this interim rule to be $286,723.13. Reporting and recordkeeping requirements associated with this interim rule are discussed under the heading ''Paperwork Reduction Act.'' This interim rule will mostly affect larger commercial poultry operations dealing with HPAI. APHIS estimates that 5.9 percent of all poultry operations will be affected by this interim rule although they are classified as small by the Small Business Administration.

The full economic analysis provides a benefit-cost analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also examines the potential economic effects of this interim rule on small entities, as required by the Regulatory Flexibility Act.

**Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No.10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

**Executive Order 12988**

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule (1) preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

**Executive Order 13175**

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination With Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

APHIS has assessed the impact of this interim rule on Indian Tribes and determined that this interim rule does not, to our knowledge, have Tribal implications that require tribal consultation under Executive Order 13175. Additionally, a virtual listening session, ''Tribal Listening Session on Highly Pathogenic Avian Influenza Biosecurity Compliance Audit Program,'' was held on July 24, 2023, with no Tribes in attendance expressing concerns regarding the provisions of the interim rule.

If a Tribe requests consultation, APHIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

**Paperwork Reduction Act**

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB).

Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Please send a copy of your comments to: (1) Docket No. APHIS–2023–0088, Regulatory Analysis and Development, PPD, APHIS, Station 2C–10.16, 4700 River Road, Unit 25, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, Room 404–W, 14th Street and Independence Avenue SW, Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this interim rule.

The U.S. poultry industry is undergoing a severe outbreak of highly pathogenic avian influenza (HPAI); it experienced a similar one in 2015. Pursuant to its existing policy, APHIS is working with State and local animal health officials to combat the outbreak, using, in part, biosecurity plans and audits consistent with principles outlined in the National Poultry Improvement Plan (NPIP). APHIS has denied indemnity for poultry operations without biosecurity plans that destroy eggs and poultry due to HPAI since 2018 unless the premises is exempted. Further, the current paper-based audit process does not always illustrate how well the premises is practicing biosecurity to prevent HPAI infection or reintroduction. APHIS has found that it often needs visual inspection to see how well a premises is carrying out its biosecurity plan.

To help address the spread of HPAI by verifying that commercial premises have poultry biosecurity plans with appropriate mitigations that are being implemented and maintained, APHIS is amending its regulations to require biosecurity audits for two statuses of premises as conditions for indemnity for HPAI, and to include procedures for reconsideration of audit results. One audit is for HPAI-infected premises that intend to restock and wish to be eligible to receive subsequent payments of indemnity for poultry destroyed during an outbreak. The other is for premises in the buffer zone of a control area that intend to move poultry onto a premises within the buffer zone and wish to be eligible to receive payments of indemnity for poultry that have been moved onto the premises. (The buffer zone is the zone within a control area that immediately surrounds an infected zone). Premises in the buffer zone are usually notified of this status by the State Animal Health Official (SAHO), although within this interim rule we are making allowance for notification by APHIS instead.

APHIS plans to allow virtual biosecurity audits of buffer zone premises because, while the premises are at risk of becoming affected with HPAI, they are, by definition, currently unaffected. They are in proximity to affected premises, however, the premises in the buffer zone, as a whole, undergo periodic surveillance. For these reasons, virtual visual inspection should usually suffice. Conversely, previously affected premises will be audited in person (absent extenuating circumstances or a SAHOs request) to ensure that reintroduction risks are being effectively mitigated.

These amendments require the creation of three new information collection activities.

*APHIS Biosecurity Audit.* Buffer zone poultry premises can be audited virtually unless the SAHO in the State where the premises is located requests an in-person audit. Previously affected premises will be audited in-person, absent extenuating circumstances, unless the SAHO requests a virtual audit. All previously infected premises must pass additional biosecurity audits every 6 months, until the State in which the premises is located declares freedom from HPAI. Producers may use successful biosecurity audits completed within the preceding 6 months, otherwise a new biosecurity audit must be conducted. If premises in a control area change their biosecurity plan, biosecurity coordinator, ownership, or infrastructure during the 6-month period, they are required to pass a new biosecurity audit in accordance with § 53.11(f)(1)(i) or (ii) of this interim rule, as applicable, before moving poultry onto the premises.

A premises will initially pass a biosecurity audit if the auditor determines that the minimum requirements are met for all biosecurity audit criteria in the biosecurity audit tool. If deficiencies are identified, the auditors will communicate the identified deficiencies to producers. Producers may ask clarifying questions about the nature of the deficiencies and/or provide additional documentation to remediate the identified deficiency. The auditor, where appropriate, may work with the producer to identify solutions to resolve the deficiencies and may revise the audit results based on the additional information provided. If the producer needs further guidance on addressing a deficiency that goes beyond the auditor's training, the auditor will send the request to the audit reviewer and, if needed, the BCAP Program Manager. Once the audit process concludes, the auditor will submit the audit package to a reviewer based in the State where the premises is located.

*Biosecurity Audit Tool.* Claims for avian influenza indemnity, unless exempted, require producers to have a poultry biosecurity plan meeting the biosecurity principles in the NPIP Program Standards. Poultry biosecurity plans support continuity of business and are specific to the premises and its operational procedures. The NPIP Program Standards describe the 14

biosecurity principles that must be included in the biosecurity plan.

APHIS developed the Biosecurity Compliance Audit Program (BCAP) to administer the audits. The BCAP administration includes a BCAP Program Manager within APHIS' Veterinary Services program, and local auditing teams comprised of an auditor and reviewer. The BCAP members will use a biosecurity audit tool APHIS developed with State and industry input. This new biosecurity audit tool includes an evaluation of the premises' poultry biosecurity plan against the 14 biosecurity principles articulated in the NPIP Program Standards and includes an evaluation of the poultry biosecurity plan itself and documentation showing that the plan is being implemented. However, the tool also includes visual verification of perimeter buffer areas; line of separation procedures for personnel, visitors, equipment, and vehicles; and on-premises rodent and wildlife mitigations. Use of the tool will ensure consistency of reviewing premises and identifying deficiencies in biosecurity. The tool may be revised as audits are conducted and additional data is gathered, as updated epidemiological information becomes available, or as other advancements in technology and production practices occur. To that end, the BCAP Program Manager will review the tool at least annually. Changes to the tool will appear in a notice published in the **Federal Register** inviting public comment.

*Reconsideration Process for Audit Results.* If the producer disagrees with the final audit determination of the reviewer, the producer may send a request for reconsideration to the BCAP Program Manager through email or by postal mail to the addresses listed in the regulations. The request for reconsideration must be in writing, state the material facts and reasons upon which the producer relies to show that the producer wrongfully failed the biosecurity audit, and be received by the BCAP Program Manager within 14 calendar days of communication of the reviewer's final audit determination. After receipt of the reconsideration request, the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. If the BCAP Program Manager disagrees with the reviewer's final determination the results of the biosecurity audit become a pass; if the BCAP Program Manager agrees that a biosecurity deficiency exists, the reconsideration request proceeds to panel. A panel consisting of the SAHO of the State where the premises is located, the APHIS Area Veterinarian in Charge, and the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. The panel's decision is final and the outcome of the reconsideration process will be communicated to the producer, by the auditor, as promptly as circumstances allow and will state, in writing, the reasons for the decision.

We are soliciting comments from the public (as well as affected agencies) concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses).

The Agency estimates there will be 52 State and 473 business respondents affected by the three new information collections in this interim rule. For the APHIS Biosecurity Audit information collection, the Agency estimates there will be 104 State and 473 business responses, with 624 total annual burden hours for State respondents and total annual 2,728 burden hours for business. For the Biosecurity Audit Tool information collection, the Agency estimates there will be 52 State and 473 business responses, with total burden hours of 208 for State respondents and 1,892 for business respondents. For the Reconsideration Process for Audit Results information collection, the Agency estimates there will be 200 business responses and 200 hours of burden annually. Total burden estimates in summary include:

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 4 hours per response.

*Respondents:* Commercial poultry farm owners and managers; private veterinarians; poultry agencies and organizations; and State animal health officials and laboratory personnel.

*Estimated annual number of respondents:* 525.

*Estimated annual number of responses per respondent:* 2.

*Estimated annual number of responses:* 1,302.

*Estimated total annual burden on respondents:* 5,652 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* website or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Information about the information collection process may be obtained from Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2533. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

## E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. The audit activities and appeals prescribed in this information collection must be in writing and may be transmitted by email.

For assistance with E-Government Act compliance related to this interim rule, please contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2533, or the Veterinary Service contact listed above under **FOR FURTHER INFORMATION CONTACT**.

## Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2).

## List of Subjects in 9 CFR Part 53

Animal diseases, Indemnity payments, Livestock, Poultry and poultry products.

Accordingly, we are amending 9 CFR part 53 as follows:

## PART 53—FOOT-AND-MOUTH DISEASE, PLEUROPNEUMONIA, AND CERTAIN OTHER COMMUNICABLE DISEASES OF LIVESTOCK OR POULTRY

■ 1. The authority citation for part 53 continues to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Amend § 53.1 by adding definitions for ''buffer zone,'' ''control area,'' and ''infected zone,'' in alphabetical order, to read as follows:

### § 53.1 Definitions.

* * * * *

*Buffer zone.* The zone within a control area that immediately surrounds an infected zone.

*Control area.* The area around a premises infected with highly pathogenic avian influenza and consisting of an infected zone and a buffer zone, the bounds of which are determined and communicated to producers by Federal or State officials.

* * * * *

*Infected zone.* The zone within a control area that immediately surrounds a premises infected with highly pathogenic avian influenza, up to the beginning of the buffer zone.

* * * * *

■ 3. Amend § 53.10 by revising paragraph (g) to read as follows:

### § 53.10 Claims not allowed.

* * * * *

(g)(1) Except as provided in paragraph (g)(2) of this section, the Department will not allow claims arising out of the destruction of poultry or eggs destroyed due to an outbreak of highly pathogenic avian influenza unless the following conditions apply:

(i) *Approved biosecurity plan:* The owner of the poultry or eggs and, if applicable, any party that enters into a contract with the owner to grow or care for the poultry or eggs, had in place, at the time of detection of highly pathogenic avian influenza, and was following a poultry biosecurity plan that meets the requirements of § 53.11(e).

(ii) *Buffer zone movement audit:* For indemnity claims for poultry moved onto a premises located in a buffer zone of a control area for highly pathogenic avian influenza, the premises receiving the poultry must pass a biosecurity audit conducted in accordance with § 53.11(f)(1)(i) prior to the movement of poultry onto the premises; unless the premises receiving the poultry passed a biosecurity audit within the preceding six (6) months. *Provided,* that the Administrator may, upon request by a producer and upon his or her determination that such action will not result in the dissemination of highly pathogenic avian influenza within the United States, allow a premises to pass a biosecurity audit in accordance with § 53.11(f)(1)(i) after the placement of poultry onto the premises. The producer must make such a request in writing and state in the request all the facts and reasons justifying the request. If the request is denied, the premises must pass a biosecurity audit in accordance with § 53.11(f)(1)(i) prior to the placement of poultry onto the premises to be eligible to receive future indemnity payment if the poultry is later infected with highly pathogenic avian influenza.

(iii) *Previously infected premises audit:* For indemnity claims for poultry moved onto any premises that was previously infected with highly pathogenic avian influenza during the same outbreak, the premises must pass a biosecurity audit conducted in accordance with § 53.11(f)(1)(ii) prior to the movement of poultry onto the premises; unless the movement occurs after the United States declares freedom from highly pathogenic avian influenza. In addition, all previously infected premises must pass virtually conducted biosecurity audits every six (6) months until the State in which the premises is located declares freedom from highly pathogenic avian influenza.

(2) Owners and contractors are exempted from the requirements of paragraph (g)(1) of this section if the facilities where the poultry or eggs are raised or cared for falls under one of the following categories:

(i) Commercial table-egg laying premises with fewer than 75,000 birds;

(ii) Egg-type game bird and egg-type waterfowl premises with fewer than 25,000 birds.

(iii) Premises on which fewer than 100,000 broilers are raised annually; and

(iv) Premises on which fewer than 30,000 meat turkeys are raised annually.

(3) Notwithstanding the conditions in paragraphs (g)(1) and (2) of this section, the Department will not pay claims arising out of the destruction of poultry destroyed due to an outbreak of highly pathogenic avian influenza if the poultry was moved onto a premises in an infected zone and if the poultry becomes infected with HPAI within 14 days following the dissolution of the control area in which the infected zone is located.

* * * * *

■ 4. Amend § 53.11 by redesignating paragraph (f) as paragraph (g), and adding a new paragraph (f) to read as follows:

### § 53.11 Highly pathogenic avian influenza; conditions for payment.

* * * * *

(f)(1) The Department requires that a biosecurity audit be conducted by an auditing team comprised of an auditor and a reviewer using the biosecurity audit tool available at *https://www.aphis.usda.gov/sites/default/files/biosecurityaudit.pdf.* The auditor makes the initial determination of whether a premises passes a biosecurity audit and will be a State employee. If the State lacks the human resources to fill the position, an APHIS employee can fill the position. The reviewer makes the final determination of whether a premises passes a biosecurity audit and will be an APHIS employee. The audit will be conducted as follows:

(i) Biosecurity audits for premises in a buffer zone as described in § 53.10(g)(1)(ii), shall be conducted virtually by an auditor unless the State Animal Health Official, in the State where the premises is located, requests an in-person audit.

(ii) Biosecurity audits for previously infected premises as described in § 53.10(g)(1)(iii), shall be conducted in-person by an auditor unless the State Animal Health Official determines that extenuating circumstances warrant a virtual audit instead. Extenuating circumstances include, but are not limited to, severe adverse weather conditions, employee safety considerations, and lack of necessary equipment on the premises to conduct a virtual audit.

(2) To assist auditors in conducting the biosecurity audit, producers must allow auditors access to their premises and access to documentation to review and verify whether the premises meets the minimum requirements of the biosecurity audit criteria described in the biosecurity audit tool. A premises will initially pass a biosecurity audit if the auditor determines that the minimum requirements are met for all biosecurity audit criteria in the biosecurity audit tool. Auditors will communicate all identified deficiencies to producers and collaborate, where appropriate, to identify solutions to resolve the identified deficiencies. Producers must provide timelines to auditors for remediation of all identified deficiencies. Auditors will submit the audit package to a reviewer based in the State where the premises is located.

(3) The reviewer will review the audit package for completeness, accuracy, and consistency with other audits and render a final audit determination of

pass or fail. The reviewer must be afforded the same access to the premises previously afforded to the auditor, if requested.

(4) If the producer disagrees with the final audit determination, the producer may send a request for reconsideration to *APHIS.HPAI.BCAP.audits@usda.gov* or by postal mail to: Biosecurity Audit Reconsideration, 920 Main Campus Drive, Raleigh, NC 27606. The request for reconsideration must be in writing, state all the facts and reasons upon which the producer relies to show that the producer wrongfully failed the biosecurity audit, and be received by the Biosecurity Compliance Audit Program Manager within 14 calendar days of communication of the reviewer's final audit determination. After receipt of the reconsideration request, the process proceeds as follows:

(i) The Biosecurity Compliance Audit Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. If the Biosecurity Compliance Audit Program Manager determines that the producer wrongfully failed the biosecurity audit, he or she will change the final audit determination from fail to pass. The auditor will notify the producer of the change in writing, and the Biosecurity Compliance Audit Program Manager will close the reconsideration request. If the Biosecurity Compliance Audit Program Manager agrees that the producer failed the biosecurity audit, the reconsideration process will continue to a panel review.

(ii) A panel consisting of the State Animal Health Official of the State where the premises is located, the APHIS Area Veterinarian in Charge, and the Biosecurity Compliance Audit Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. The panel's decision is final and will be communicated to the producer as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(5) A final audit determination of pass for a premises that had a biosecurity audit conducted in accordance with paragraph (f)(1)(i) or (ii) of this section will be valid for six (6) months, unless the premises changes its poultry biosecurity plan, biosecurity coordinator, ownership, or infrastructure. If such premises makes any of the aforementioned changes, the premises must pass a new biosecurity audit conducted in accordance with paragraph (f)(1)(i) or (ii) of this section, as applicable, prior to the movement of poultry onto the premises.

(6) The biosecurity audit tool referenced in paragraph (f)(1) of this section will be reviewed by APHIS on an annual basis and revised as follows:

(i) *Standard process for revising the biosecurity audit tool:* If the Administrator determines that revisions to the biosecurity audit tool are necessary, APHIS will publish a notice in the **Federal Register** advising the public of the Administrator' determination. The notice will describe the proposed revisions and the reasons for the proposed revisions and will invite public comment on the proposed revisions.

(ii) *Immediate process for revising the biosecurity audit tool:* If the Administrator determines that the biosecurity audit tool is no longer sufficient for auditors to use to conduct biosecurity audits pursuant to paragraph (f)(1)(i) or (ii) of this section, APHIS will immediately update the biosecurity audit tool. APHIS will publish a notice in the **Federal Register** advising the public of the Administrator's determination. The notice will specify the revisions and the reasons for the revisions, provide an effective date for the revisions, and will invite public comment on the revisions.

* * * * *

Done in Washington, DC, this 23rd day of December 2024.

**Jennifer Moffitt,**

*Undersecretary, Marketing and Regulatory Programs, USDA.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 101

**[Docket No. FDA–2000–N–0011]**

### Uniform Compliance Date for Food Labeling Regulations

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Final action; announcement of a uniform compliance date.

**SUMMARY:** The Food and Drug Administration (FDA or we) is establishing January 1, 2028, as the uniform compliance date for food labeling regulations that are published on or after January 1, 2025, and on or before December 31, 2026. We periodically announce uniform compliance dates for new food labeling requirements to minimize the economic impact of labeling changes.

**DATES:** This final action is effective December 31, 2024. Either electronic or written comments on the final action must be submitted by March 3, 2025.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 3, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''