DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 53, 56, 145, 146, and 147
[Docket No. APHIS-2005-0109]
RIN 0579-AB99

Low Pathogenic Avian Influenza;
Voluntary Control Program and
Payment of Indemnity

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are adopting as a final rule, with changes, an interim rule that amended the regulations by establishing, under the auspices of the National Poultry Improvement Plan, a voluntary program for the control of the H5/H7 subtypes of low pathogenic avian influenza in commercial poultry. As amended by this document, the rule provides that the amount of indemnity for which contract growers are eligible will be reduced by any payment they have already received on their contracts when poultry in their care are destroyed, clarifies the roles of cooperating State agencies with respect to H5/H7 low pathogenic avian influenza outbreaks, provides that consistency with humane euthanasia guidelines will be considered when selecting a method for the destruction of poultry, and provides additional guidance for cleaning and disinfecting an affected premises. The control program and indemnity provisions established by the interim rule are necessary to help ensure that the H5/H7 subtypes of low pathogenic avian influenza are detected and eradicated when they occur within the United States.

EFFECTIVE DATE: March 9, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew R. Rhorer, Senior Coordinator, Poultry Improvement Staff, National Poultry Improvement Plan, Veterinary Services, APHIS, USDA, 1498 Klondike Road, Suite 101, Conyers, GA 30094-5104; (770) 922-3496.

SUPPLEMENTARY INFORMATION:

Background

The National Poultry Improvement Plan (NPIP, also referred to below as “the Plan”) is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control poultry diseases. Participation in all Plan programs is voluntary, but breeding flocks, hatcheries, and dealers must first qualify as “U.S. Pullorum-Typhoid Clean” as a condition for participating in the other Plan programs.

The Plan identifies States, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan’s various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions. The regulations in 9 CFR parts 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan.

In an interim rule, effective and published in the Federal Register on September 26, 2006 (71 FR 53601-53633, Docket No. APHIS-2005-0109), we amended the regulations to establish a voluntary control program for the H5/H7 subtypes of low pathogenic avian influenza (H5/H7 LPAI) in commercial poultry—specifically, in table-egg layers, meat-type chickens, and meat-type turkeys. The provisions of this program were established in a new part 146. The interim rule also established a new part 36, titled “Control of H5/H7 Low Pathogenic Avian Influenza,” in 9 CFR chapter I, subchapter B, to provide for the payment of indemnity for costs associated with the eradication of H5/H7 LPAI.

We solicited comments on the interim rule for 60 days ending November 27, 2006. We received 11 comments by the due date. They were from State governments, industry associations, advocacy groups, and private citizens. We have carefully considered all of the comments we received. They are discussed below by topic.

General Comments

One commenter stated that the conditions under which commercial poultry are produced cause disease, and that the U.S. Department of Agriculture (USDA) should prohibit current poultry production practices.

We do not agree with the commenter’s recommendation and do not believe it is necessary or appropriate to consider such regulation of poultry production practices in this rulemaking. H5/H7 LPAI is caused by a virus. The interim rule provided for surveillance programs and emergency response provisions to detect and eradicate the virus.

The “Background” section of the interim rule stated that there are 15 recognized hemagglutinin (H) subtypes of avian influenza (AI). One commenter stated that there are 16 such subtypes. The commenter is correct. Since the regulations do not refer to the number of hemagglutinin subtypes, no change in the regulations established by the interim rule is necessary.

The “Background” section also stated the following: “Diagnostic surveillance [for AI in the United States] is conducted through industry, State, and university diagnostic laboratories. These laboratories routinely test for AI, both serologically and by virus isolation, whenever birds are submitted from a flock with clinical signs compatible with HPAI or LPAI.” One commenter suggested that this statement should refer to testing for AI by serology, antigen detection, and/or virus isolation, because serology cannot be performed on dead birds.

We agree with the commenter. Diagnostic surveillance laboratories in the United States use whatever means are appropriate to test poultry for AI. This comment does not necessitate a change in the regulations established by the interim rule.

On the subject of surveillance for AI, the interim rule stated that “Texas established a surveillance program for commercial poultry flocks near the Mexican border following the Mexican HPAI outbreak in 1994-95. One commenter suggested deleting the words “near the Mexican border” from this statement. We agree; the program in Texas was statewide. This comment does not necessitate a change in the regulations established by the interim rule.

The interim rule established the new part 146 for table-egg layers, meat-type chickens, and meat-type turkeys as the NPIP regulations for commercial poultry. One commenter suggested that we amend the NPIP regulations for breeding poultry in 9 CFR part 145 to refer to “commercial breeding flocks” and “commercial breeding poultry.” We have determined that such a change would be inappropriate. The regulations established by the interim rule use the term “commercial” to refer to large-scale operations producing poultry for meat or eggs for consumption. The commenter apparently intends that the term “commercial” be used to refer to any large-scale operation. This could create confusion, since the poultry regulated in 9 CFR part 145 would not be clearly distinct from the poultry regulated in part 145. In addition, using the term “commercial” to refer to the poultry covered by 9 CFR part 145 would be inaccurate, as the breeders who participate in the Plan under subpart E
of part 145, which covers waterfowl, exhibition poultry, and game bird breeding flocks and products, typically are hobbyist breeders rather than large-scale breeders. We are making no changes in response to this comment.

Auditing

In the regulations established by the interim rule, § 146.11 provides for inspection of participating flocks and slaughter plants. Paragraph (a) of § 146.11 requires each participating slaughter plant to be audited at least once annually or a sufficient number of times each year to satisfy the Official State Agency that the participating slaughter plant is in compliance with the provisions of 9 CFR part 146.

One commenter stated that this language implies but does not specifically state that the Official State Agency will both audit and determine compliance. If we do not envision any potential conflict of interest and the inference is correct, the commenter recommended amending the text to clarify. The commenter suggested using the following text: “Each participating slaughter plant shall be audited at least once annually by the head of the Official State Agency or a sufficient number of times each year to satisfy him/her self that the participating slaughter plant is in compliance with the provisions of this part.”

Our intention in § 146.11(a) was to refer to audits of records of testing, and the results of that testing, that are kept by the slaughter plant, rather than to any audit of the slaughter plant facility itself. Audits by the Official State Agency of testing records should not create any conflict of interest; this process is also used in the NPIP regulations in 9 CFR part 145.

In a final rule published in the Federal Register on April 1, 2009 (74 FR 14710-14719, Docket No. APHIS-2007-0042), and effective on May 1, 2009, we amended § 146.11 so that it refers specifically to auditing testing records and provides additional detail about the auditing process. We believe these changes addressed the commenter’s concerns, and we are making no further changes to the auditing provisions in § 146.11 in this final rule.

Testing

In the regulations established by the interim rule, § 146.13 sets out requirements for testing Plan flocks for AI. Paragraph (b)(1) of § 146.13 provides that any samples that are found to be positive by the agar gel immunodiffusion test must be further tested and subtyped by Federal Reference Laboratories using the hemagglutination inhibition test.

One commenter asked that we include a list in the regulations of laboratories that are Federal Reference Laboratories. The regulations for testing for AI in breeding poultry, in § 145.14(d), also refer to further testing and subtyping by Federal Reference Laboratories. Currently, the only Federal Reference Laboratory for AI is the National Veterinary Services Laboratories (NVSL) in Ames, IA. In response to this comment, we will post a list of Federal Reference Laboratories on the NPIP Web site, at (http://www.aphis.usda.gov/animal_health/animal_dis_spec/poultry/index.shtml).

Diagnostic Surveillance Program

In the regulations established by the interim rule, § 146.14 requires all States participating in the Plan for commercial poultry to develop a diagnostic surveillance program for all poultry, not just commercial poultry, in that State. The diagnostic surveillance program is one of the three components that were identified as key to the H5/H7 LPAI program at a meeting APHIS organized with State and industry representatives that took place in May 2002 in San Antonio, TX.

The exact provisions of the program are at the discretion of the States, but under the program, AI must be a disease reportable to the responsible State authority (State veterinarian, etc.) by all licensed veterinarians. To accomplish this, all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry must examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for AI by both an approved serological test and an approved antigen detection test.

Memoranda of understanding or other means must be used to establish testing and reporting criteria (including criteria that provide for reporting H5 and H7 LPAI directly to the Service) and approved testing methods. In addition, States should conduct outreach to poultry producers, especially owners of smaller flocks, regarding the importance of prompt reporting of clinical symptoms consistent with AI.

One commenter had a specific concern with requiring all laboratories (private, State, and university laboratories) that perform diagnostic procedures on poultry to examine all submitted cases of unexplained respiratory disease, egg production drops, and mortality for AI by both an approved serological test and an approved antigen detection test. The commenter stated that this requirement should apply only to commercial poultry. Such a change is necessary, the commenter stated, because owner consent is critical for diagnostic laboratories and, in the commenter’s State, laboratories that perform tests must also charge fees.

It is true that some poultry owners may have to bear the burden of additional testing costs associated with the diagnostic surveillance program’s testing requirements. Although some States do not impose charges for such testing, many States do. However, producers smaller than the size standards established in 9 CFR part 146 are only required to participate in the diagnostic surveillance program, which means testing for AI is only required for submitted cases of unexplained respiratory disease, egg production drops, and mortality.

The diagnostic surveillance program is a key component of the H5/H7 LPAI program because it allows surveillance to reach all sectors of the poultry industry. In addition, the index case in an outbreak will likely be detected through the diagnostic surveillance program, since it focuses on sick poultry. Detecting H5/H7 LPAI quickly will expedite the response and control or eradication of H5/H7 LPAI before they have the chance to mutate to highly pathogenic strains of AI. Therefore, it is crucial to the success of the H5/H7 LPAI program to have the diagnostic surveillance program apply to all poultry. We are making no changes to the regulations established by the interim rule in response to this comment.

Surveillance of Live Bird Markets and Pet Birds

As noted earlier, the voluntary control program established by the interim rule requires diagnostic surveillance for all poultry in participating States. It also requires active surveillance for participating commercial flocks and slaughter plants over certain size thresholds, but does not include requirements for active surveillance for other flocks and slaughter plants. In the “Background” section of the interim rule, we briefly discussed the active surveillance that we carry out in live bird markets, noting that APHIS has entered into cooperative agreements with States that have live bird market activities, as well as Official State Agencies and NPIP authorized laboratories participating in the NPIP LPAI program.

One commenter stated that, while increased surveillance activities at live bird markets lower the risk of AI transmission, continued outbreaks of
the disease indicate that this approach is inadequate. The commenter encouraged APHIS to take a further step and permanently prohibit the sale and slaughter of birds at public markets. In the commenter’s view, this action would not only provide for disease control but would benefit animal welfare, as the commenter stated that animals in these markets are frequently held and killed in an inhumane manner.

If the sale of live birds at public markets is not to be prohibited, the commenter recommended that: 1) Surveillance be increased, 2) housing and welfare conditions be included in the auditing of markets, and 3) no producers be compensated in any way for birds killed for disease control purposes at these high-risk venues.

We are confident that the surveillance mechanisms we have developed in cooperation with States are sufficient to detect any H5/H7 LPAI present in the markets and to allow us to address the disease expeditiously. We do not believe it necessary to prohibit the sale of poultry at live bird markets, where there are appropriate surveillance mechanisms and related disease safeguards available.

With regard to the commenter’s recommendations, we have determined that current levels of surveillance are adequate to detect outbreaks of H5/H7 LPAI in live bird markets. While our audits of markets relate only to the prevention of the introduction or spread of disease, live bird markets must comply with all laws and regulations applicable to their operation, including any applicable State animal welfare laws and regulations; we would report circumstances that we know to be violations of such laws and regulations to State authorities. Finally, if a person has complied with all applicable regulations and agreements pertaining to surveillance and biosecurity for H5/H7 LPAI at a live bird market, it would be inappropriate to declare that person ineligible for indemnity, as that person would have incurred costs eligible for indemnity while complying with the regulations. In addition, denying indemnity as the commenter suggests would establish a negative incentive for reporting potential H5/H7 LPAI infection, thus potentially leading to late reporting of H5/H7 LPAI outbreaks and hampering our surveillance efforts. We are making no changes in response to this comment.

This commenter also asked us to regulate the sale of birds in the retail pet industry. At pet stores, the commenter stated, from many different geographical locations are mixed together and are often housed in close proximity to domestic fowl in retail pet shops. The commenter believes there are inadequate licensing, regulatory oversight, and recordkeeping requirements to track birds sold in pet shops, and, as a result, APHIS is missing the chance to detect disease early, and control, if not prevent, its spread.

We expect that, under the regulations in 9 CFR parts 56 and 146, any outbreaks of H5/H7 LPAI in commercial poultry would be confined to the premises on which they occur. Our regulations governing the importation of pet birds in 9 CFR part 93 are sufficient to prevent the introduction of LPAI via the importation of pet birds. If H5/H7 LPAI were to spread to pet birds, these birds would be considered infected with or exposed to H5/H7 LPAI under the regulations in 9 CFR part 56 and thus would be subject to the requirements of the relevant State’s initial response and containment plan for H5/H7 LPAI. These restrictions on the interstate movement of pet birds are sufficient to prevent the spread of H5/H7 LPAI.

State H5/H7 Avian Influenza Monitored Classifications

In the regulations established by the interim rule, subparts B through D of 9 CFR part 146 provide special conditions for participation in the Plan by commercial table-egg layer flocks, commercial meat-type chicken slaughter plants, and commercial meat-type turkey slaughter plants, respectively. Within subparts B and D, §§ 146.24 and 146.44 provide for U.S. H5/H7 Avian Influenza Monitored State classifications for table-egg layers and meat-type turkey slaughter plants; there is no U.S. H5/H7 Avian Influenza Monitored State classification for meat-type chicken slaughter plants in subpart C.

One commenter stated that it seems incongruous not to have a U.S. H5/H7 Avian Influenza Monitored State status for meat-type chickens if it is rational to have such a status for meat-type turkeys. As we stated in the interim rule, in consultation with our State and industry cooperators, we have determined that it is not necessary to provide for a U.S. H5/H7 Avian Influenza Monitored State classification for meat-type chickens at this time. The regulations for meat-type chicken slaughter plants provide the same level of surveillance as occurs at table-egg layer premises and meat-type turkey slaughter plants, the diagnostic surveillance program required by the regulations covers all poultry in the State, and the regulations in 9 CFR part 56, including the requirement for an initial State response and containment plan for H5/H7 LPAI infections, are sufficient to ensure that H5/H7 LPAI infections in meat-type chickens are handled appropriately. We will continue to examine the issue, and if we determine at some point in the future that it is useful to be able to designate States as U.S. H5/H7 Avian Influenza Monitored, we will implement such a classification.

In the regulations established by the interim rule, § 56.10(b) provides that if a State is designated a U.S. Avian Influenza Monitored State, Layers under § 146.24(a) or a U.S. Avian Influenza Monitored State, Turkeys under § 146.44(a), it will lose that status during any outbreak of H5/H7 LPAI and for 90 days after the destruction and disposal of all infected or exposed birds and cleaning and disinfection of all affected premises are completed.

One commenter asked us to clarify what is meant by an outbreak, and specifically whether the discovery of H5/H7 LPAI in a live bird market would constitute an outbreak that would result in a State losing its U.S. Avian Influenza Monitored State status. Consistent with the World Organization on Animal Health (OIE) guidelines for AI, we consider any outbreak of H5/H7 LPAI in domesticated poultry to be an outbreak for the purposes of § 56.10(b). This includes live bird markets. However, as indicated in §§ 146.24(a)(2) and 146.44(a)(2), a State will maintain its U.S. H5/H7 Avian Influenza Monitored State status after a single outbreak of H5/H7 LPAI as long as long as the State responds to the outbreak in accordance with 9 CFR part 56, there are not repeated outbreaks, and the outbreak does not spread beyond the originating premises. If any of those circumstances did not occur, APHIS would have grounds to revoke the State status, although APHIS would have to make a thorough investigation and give the State an opportunity for a hearing before doing so.

Definition of H5/H7 LPAI Virus Infection (Infected)

The regulations established by the interim rule in §§ 56.1 and 146.1 define H5/H7 LPAI virus infection (infected) by stating that poultry will be considered to be infected with H5/H7 LPAI for the purposes of parts 56 and 146 if:

- H5/H7 LPAI virus has been isolated and identified as such from poultry; or
- Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry; or

2 As found in the Terrestrial Animal Health Code. The guidelines are available on the Internet at (http://www.oie.int/eng/normes/mcode/en_chaptre_1_10_4.htm).
We are making one other change to the definition of "H5/H7 LPAI virus infection (infected)" in this final rule. We are adding a sentence indicating that NVSL makes the final determination that H5/H7 LPAI virus has been isolated and identified, viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected, or antibodies to the H5 or H7 subtype of AI virus have been detected. This change is intended to clarify for readers who makes an official diagnosis related to the H5/H7 LPAI virus infection (infected) definition.

Special State Agency and Cooperating State Agency Roles in Emergency Response

The regulations in 9 CFR part 56, which were established by the interim rule, provide for cooperation amongAPHIS, Official State Agencies, and Cooperating State Agencies in response to disease outbreaks. The term "Cooperating State Agency" is defined in §146.1 and 56.1 (as well as §145.1) as the State authority recognized by the Department to cooperate in the administration of the Plan. The term "Cooperating State Agency" is defined in §56.1 as any State authority recognized by the Department to cooperate in the administration of the provisions of 9 CFR part 56. Such cooperation requires the Cooperating State Agency to have the authority to restrict intrastate movement, conduct cleaning and disinfection, and quarantine premises, among other things. The Cooperating State Agency is typically the State animal health authority.

In some States, the Official State Agency is also the State animal health authority; in some States, the Official State Agency includes representation from, but is not identical to, the State animal health authority. For example, the Official State Agency may include representatives from the poultry industry and from agricultural extension universities in addition to representatives from the State animal health authority. While the expertise of the nongovernmental participants is invaluable in determining how best to respond to an LPAI outbreak, only the State animal health authority has the authority to perform the functions described above in response to an outbreak in accordance with the provisions of part 56. In addition, the regulations in 9 CFR part 56 contain provisions that apply to all poultry, not just the breeding and commercial poultry included in the NPIP programs administered by the Official State Agencies. For poultry not included in those programs, we cooperate with the State animal health authority to eradicate an H5/H7 LPAI outbreak and pay indemnity under part 56. These circumstances necessitated the additional definition of "Cooperating State Agency."

One commenter stated that in several sections of the interim rule relating to activities described in 9 CFR part 56, the regulations should reflect and clearly recognize that in some jurisdictions the Official State Agency is not the responder to or manager of disease events; rather, the Cooperating State Agency is the entity authorized by State law to manage animal diseases of regulatory significance such as AI. Therefore, the commenter stated, disease management actions such as hold orders, quarantined flock management plans, movement restrictions on animals, equipment or supplies, and cleaning and disinfection procedures will be under the direction and control of the Cooperating State Agency. In the regulations, functions that are analogous to functions carried out by the Official State Agency under the Plan regulations in 9 CFR part 145 have been assigned to the Official State Agency in parts 56 and 146. However, in States where the Cooperating State Agency is different from the Official State Agency, the Cooperating State Agency is the appropriate entity to take on some specific functions for disease control, as the commenter suggests.

The commenter suggested several specific places in which a responsibility or function given to the Official State Agency in the regulations established by the interim rule should be instead assigned to the Cooperating State Agency.

Paragraphs §§146.2(f) and 56.2(c) have stated that States will be responsible for making the determination to request Federal assistance in the event of an outbreak of H5/H7 LPAI. (The “Background” section of the rule erroneously referred to the Official State Agency, but the rule text refers only to “States.”) The commenter stated that we should clarify that the Cooperating State Agency, rather than Official State Agency, should make this request for assistance. We agree, and we are making that change to clarify the regulations in this final rule. (This change necessitates adding the definition of Cooperating State Agency to §146.1.)

Section 56.10 describes the initial State response and containment plans that must be developed for a State and poultry in that State to be eligible for 100 percent indemnity for costs related
to an H5/H7 LPAI outbreak. Paragraph (a) of § 56.10 has stated that the initial State response and containment plan must be developed by the Official State Agency and administered by the Cooperating State Agency of the relevant State. The commenter suggested that the regulations should require that the plan be developed jointly by the Official State Agency and the Cooperating State Agency and implemented by the Cooperating State Agency. The commenter stated that giving the responsibility of developing the plan solely to the Official State Agency is undesirable and might become the root of significant difficulty when the Official State Agency is independent from the Cooperating State Agency, which would create a situation where one entity creates the plan without the authority, resources, or responsibility for executing the plan, after which another agency executes the plan. The commenter stated that involving the responding agency in the development of the response plan should be expected to develop a superior plan to one developed without input from the responders. We agree, and we have amended § 56.10(a) in this final rule. That paragraph now states that the initial State response and containment plan must be developed by the Official State Agency and further provides that, in states where the Official State Agency is different than the Cooperating State Agency, the Cooperating State Agency must also participate in the development of the plan. In addition, we have corrected references to the initial State response and containment plan in paragraphs (a)(2) and (a)(3) of § 56.2 that indicated that the Official State Agency was the sole developer of the initial State response and containment plan.

● The definition of commercial meat-type flock in §§ 56.1 and 146.1 allows any group of poultry which is segregated from another group in a manner sufficient to prevent the transmission of H5/H7 LPAI and has been so segregated for a period of at least 21 days to be considered as a separate flock, at the discretion of the Official State Agency. The commenter stated that this discretion should be given to the Cooperating State Agency, due to the emergency response responsibilities of the Cooperating State Agency. We assigned this responsibility to the Official State Agency because it is a type of task that the Official State Agency has typically been responsible for in other NPIP activities, and the definition applies to activities conducted under the NPIP regulations in 9 CFR part 146 as well as in 9 CFR part 56. We are making no changes in response to this comment.

● The regulations established by the interim rule in § 56.1 defined flock plan as: “A written flock management agreement developed by APHIS and the Official State Agency with input from the flock owner and other affected parties. A flock plan sets out the steps to be taken to eradicate H5/H7 LPAI from a positive flock, or to prevent introduction of H5/H7 LPAI into another flock. A flock plan shall include, but is not necessarily limited to, poultry and poultry product movement and geographically appropriate infected and control/monitoring zones. Control measures in the flock plan should include detailed plans for safe handling of conveyances, containers, and other associated materials that could serve as fomites; disposal of flocks; cleaning and disinfection; downtime; and repopulation.” The commenter stated that the responsibilities discussed in this definition are more properly assigned to the Cooperating State Agency. Again, we assigned this responsibility to the Official State Agency because it is a task that the Official State Agency has typically been responsible for in NPIP activities. We are making no changes in response to this comment.

● The “Background” section of the interim rule stated that, while the provisions of 9 CFR part 146 are APHIS requirements for participation in the Plan, and protocols for sampling, testing, and other surveillance activities must be approved by APHIS, the active and diagnostic surveillance undertaken under part 146 is run by the Official State Agencies in cooperation with poultry producers; the costs of the surveillance are borne by the Official State Agencies as well. The commenter stated that the costs of surveillance are borne by Cooperating State Agencies rather than Official State Agencies. However, the commenter is incorrect. The cost of the routine, active surveillance described in 9 CFR part 146 is, in fact, borne by Official State Agencies and industry when they cooperate to participate in the Plan.

Vaccination

In the regulations established by the interim rule, paragraphs (a)(2) and (b)(2) of § 56.2 set out conditions for the transfer of vaccine for H5/H7 LPAI to Cooperating State Agencies, provided that the use of vaccine is included in the initial State response and containment plan, as described in § 56.10(a)(12).

We received one comment that addressed vaccination in general. The commenter strongly supported the use of vaccination as an emergency response for table-egg layer flocks. The commenter recommended that APHIS undertake outreach efforts to remind States that their initial State response and containment plans should request authority to use vaccination in advance, rather than waiting for an outbreak. The commenter also recommended that APHIS notify States that, if they have already submitted initial State response and containment plans that did not include provisions for vaccination, they may amend those plans to include such provisions.

We agree that vaccination has the potential to be a cost-effective method of eradicating H5/H7 LPAI, especially for table-egg layer flocks. Under the regulations, the Official State Agency and Cooperating State Agency for a State will determine whether vaccination is part of the State’s initial response and containment plan. APHIS will approve the use of vaccination if the initial State response and containment plan contains appropriate provisions for its use. We encourage States to include provisions allowing for the use of vaccination in their initial State response and containment plans, especially States in which table-egg layer premises are located. We also encourage States to submit updated initial State response and containment plans for APHIS approval if they have new ideas about effective response to and containment of H5/H7 LPAI in their States.

Payment of Indemnity

In the regulations established by the interim rule, § 56.3 sets out provisions for payment of indemnity. One commenter asked generally whether indemnity would be provided if the H5/H7 LPAI virus entered a flock due to illegal activity on the part of the flock owners or manager.

In § 56.9, “Claims not allowed,” paragraph (c) prohibits the payment of indemnity for any poultry that become or have become infected with or exposed to H5/H7 LPAI because of a violation of 9 CFR part 56. This provision addresses the commenter’s concern.

Paragraph (a) of § 56.3 describes the activities for which the Administrator may pay indemnity. These are:

● Destruction and disposal of poultry that were infected with or exposed to H5/H7 LPAI;

● Destruction of any eggs destroyed during testing of poultry for H5/H7
LPAI during an outbreak of H5/H7 LPAI and

- Cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that were infected with or exposed to H5/H7 LPAI or, in the case of materials, if the cost of cleaning and disinfection would exceed the value of the materials or cleaning and disinfection would be impracticable for any reason, the destruction and disposal of the materials.

One commenter recommended that APHIS consider indemnifying any vaccination-related costs that are borne by producers in cases in which vaccination is used as a response to an outbreak of H5/H7 LPAI. The commenter cited possible costs including, but not limited to, labor required both for vaccination and for ongoing surveillance, ultimate disposal costs, and expenses incurred in controlled marketing, such as the need to purchase more packaging materials than normal.

The regulations as established by the interim rule cover the cost of disposal of poultry that were infected with or exposed to H5/H7 LPAI and have been destroyed. The regulations in §56.2 provide for APHIS to transfer payment to the Cooperating State Agency for administering vaccine and conducting surveillance related to an outbreak of H5/H7 LPAI. APHIS does not believe it is appropriate to provide indemnity for business costs such as the packaging costs cited by the commenter. We are making no changes to the regulations in response to this comment.

One commenter expressed concern that egg producers in the commenter’s State might not be able to fulfill the testing requirements necessary to be eligible for 100 percent indemnity.

Under §56.3(b) of the interim rule, if a table-egg layer premises has 75,000 or more birds, it must participate in the U.S. H5/H7 Avian Influenza Monitored program in §146.23(a) in order for the poultry on that premises to be eligible for 100 percent indemnity. Table-egg layers on smaller premises are eligible for 100 percent indemnity. Table-egg layers on smaller premises are eligible for 100 percent indemnity if the State in which the table-egg layers are located participates in the diagnostic surveillance program as described in §146.14, and has an initial State response and containment plan that is approved by APHIS under §56.10. The commenter stated elsewhere that the average commercial layer flock in the commenter’s State ranges from 10,000 to 50,000 table-egg layers per farm. Thus, it appears possible that table-egg layer premises in that State would not have to participate in the U.S. H5/H7 Avian Influenza Monitored program in §146.23(a) in order to be eligible for 100 percent indemnity, as long as the State has in place a diagnostic surveillance program and an initial State response and containment plan.

Paragraph (b) of §56.3 generally provides that establishments above certain size standards must participate in an NPIP AI surveillance program in order to be eligible to receive 100 percent indemnity; otherwise, they are only eligible to receive 25 percent indemnity. However, in the “Background” section of the interim rule, we asked whether it would be appropriate to provide an indemnity incentive for owners of smaller poultry flocks to participate in a State program that has testing requirements equivalent to those in part 146, similar to the incentive we provide for larger flocks to participate in the programs in part 146. Such an incentive, we stated, could encourage owners of smaller flocks to participate in the State AI testing programs designed for those flocks. For examples, the regulations could include provisions for APHIS to recognize the testing requirements of State active surveillance programs as equivalent to the testing requirements for the H5/H7 LPAI surveillance programs in part 146.

We could then provide that if infected or exposed poultry are eligible to participate in an equivalent active surveillance program, but do not participate in that program, we would pay indemnity for less than 100 percent of costs related to an H5/H7 LPAI outbreak in those poultry.

We invited public comment on:

- Whether we should recognize State AI surveillance programs for smaller poultry flocks or other types of poultry as equivalent to the NPIP surveillance programs in part 146;
- If so, which programs we should recognize; and
- What changes in the regulations may be appropriate to provide poultry owners with an incentive to participate in State AI surveillance programs.

One commenter, from a State department of agriculture, stated that its surveillance program would likely be considered equivalent to the requirements in part 146 and that recognizing equivalent programs for indemnity purposes would encourage many backyard flocks to participate in such State surveillance programs. The commenter stated that any program that encourages bird owners to monitor for AI is valuable not only for the surveillance information it provides, but also as another opportunity to educate individuals engaged in backyard and other alternative production methods about biosecurity and good management practices.

We appreciate the commenter addressing the issues we raised in the interim rule. After considering the possible implications of recognizing State surveillance plans as equivalent for the purposes of establishing an indemnity incentive, however, we have decided not to do so in this final rule. While the NPIP active surveillance plans are appropriate for any flock or slaughter plant that is larger than the size standards promulgated in the interim rule, it is less clear that it would be possible to design an active surveillance program that was appropriate for flocks that are smaller than those same size standards. Indeed, in practice, State programs for flocks and slaughter plants smaller than the size standards in the interim rule typically focus on diagnostic surveillance, such as testing birds that have clinical symptoms consistent with AI, rather than actively testing a certain number of birds from each participating flock for AI. Diagnostic surveillance activities in State surveillance programs are typically in line with the diagnostic surveillance program required for participating States under §146.14.

Rather than establish an indemnity incentive for flocks and slaughter plants that are smaller than the size standards in part 146 to participate in State surveillance programs, we prefer to conduct outreach to owners of such flocks and slaughter plants to encourage them to practice appropriate biosecurity and to promptly report clinical symptoms consistent with AI. We would also encourage owners of flocks or slaughter plants that are smaller than the size standards to participate in any State AI surveillance programs that are available to them. (As noted earlier, commercial table-egg laying premises with fewer than 75,000 birds, meat-type chicken slaughter plants that slaughter fewer than 200,000 meat-type chickens in an operating week, and meat-type turkey slaughter plants that slaughter fewer than 2 million meat-type turkeys in a 12-month period are not required to participate in the active surveillance programs in subparts B, C, and D of 9 CFR part 146 in order to receive 100 percent indemnity.)

We are making changes to paragraph (b)(7) in §56.3 in this final rule. This paragraph has stated that poultry will be eligible for 25 percent indemnity if they are associated with a flock or slaughter plant that participates in the Plan, but they are located in a State that does not participate in the NPIP diagnostic surveillance program for H5/H7 LPAI, as described in §146.14 of this chapter,
or that does not have an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS. They may be eligible for 100 percent indemnity, however, if they participate in the Plan with another State that does participate in the NPIP diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14 of this chapter, and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS. It is important to note that, under § 56.3(b)(7), poultry that do not participate in the Plan and do not meet the size standards in paragraphs (b)(4) through (b)(6) of § 56.3 have been eligible for 100 percent indemnity even if the State in which they are located does not have a diagnostic surveillance program or an initial State response and containment plan. Since the publication of the interim rule, we have reviewed this provision and found that its inclusion is inconsistent with the rationale we gave in the interim rule for providing for the payment of 100 percent indemnity in certain circumstances.

In the “Background” section of the interim rule, we stated that providing for the payment of 100 percent of eligible costs is appropriate because participants in the H5/H7 LPAI control program established by the interim rule assume an economic burden in complying with the requirements of the control program. The requirements of the control program make it more likely that an outbreak of H5/H7 LPAI will be quickly detected and contained; this would tend to lower the amount of indemnity APHIS may have to pay, but the cost of participating in the program is mostly borne by producers and Official State Agencies.

However, States that do not have a diagnostic surveillance program and an initial State response and containment plan have not assumed the economic burden of participation in the control program. Because they have not set up an infrastructure by which producers can participate in the control program, the producers in those States do not assume costs related to the control program either, unless they participate in the Plan with another State that has the required diagnostic surveillance program and initial State response and containment plan. We did not intend to provide that producers in States without diagnostic surveillance programs or without initial State response and containment plans would be eligible for 100 percent indemnity. Accordingly, we are amending paragraph (b)(7) in § 56.3 to indicate that the Administrator is authorized to pay indemnity for only 25 percent of the costs associated with any infected or exposed poultry located in a State without a diagnostic surveillance program or an initial State response and containment plan, unless they participate with another State as described earlier.

We are also amending § 56.3(b)(7) to refer simply to a diagnostic surveillance program, rather than a “National Poultry Improvement Plan diagnostic surveillance program,” as the regulations in § 146.14 require that the diagnostic surveillance program encompass all poultry, not just NPIP flocks.

Paragraph (c) of § 56.3 states that if the recipient of indemnity for any of the activities listed in paragraphs (a)(1) through (a)(3) of § 56.3 also receives payment for any of those activities from a State or from other sources, the indemnity provided under this part will be reduced by the total amount of payment received from the State or other sources.

One commenter stated that some States have producer or government-funded programs that provide funds to be made available in the case of an AI infection. Most of these types of programs, the commenter stated, include a provision requiring the local monies to be returned to the local source if Federal or other funds are later available to indemnify the affected parties. The purpose of these local funds is to provide a much quicker response than possible under the Federal program. The commenter recommended that the Federal program acknowledge that such funds exist and provide that the recipients of these funds will not have their Federal indemnity reduced as long as the local indemnity funds are ultimately returned to the local source.

We may provide the full indemnity for which the poultry are eligible to poultry owners who have received indemnity from State or industry sources, as long as the owner provides us with proof that the indemnity received from those sources has been returned to its source. A receipt from the owner of the indemnity that was previously received would be one such proof. It is not necessary to amend the regulations to accommodate this process, as the indemnity funds received have been returned, the provision in § 56.3(c) no longer applies.

**Determination of Indemnity Amounts and Appraisals**

In the regulations established by the interim rule, § 56.4 described the process by which indemnity amounts would be determined, including the appraisal process. We received several comments on the appraisal process.

One commenter stated that a complicated appraisal process should never be allowed to interfere with the prompt eradication of disease. As the regulations are written, the commenter stated, no depopulation could occur until the official appraiser has completed the paperwork and signed off on the appropriate form with the owners’ and mortgagees’ (if necessary) signatures. However, the commenter stated, in reality there are very few USDA appraisers; if the State’s appraisal system is not permitted to be used, then actions to control the H5/H7 LPAI outbreak could be delayed. The commenter noted that this could have a negative effect on poultry production in the entire State in which the outbreak occurred, as the 90 days that must elapse before U.S. Avian Influenza Monitored State status can be restored does not begin until the birds are depopulated and the premises are cleaned and disinfected.

The commenter’s suggestion for how to address the problem was to have pre-approved State and Federal appraisers in every State. Another suggestion was to have a prescribed list of information that must be collected concerning each flock prior to depopulation which the USDA appraiser could use after the fact to calculate an exact dollar amount.

We appreciate the commenter’s concerns and share a desire to ensure that the appraisal process does not hinder response efforts for a disease outbreak. The regulations established by the interim rule in § 56.4(a) and (b) include statements that appraisals of poultry or eggs must be signed by the owners of the poultry prior to the destruction of the poultry or eggs, unless the owners, APHIS, and the Cooperating State Agency agree that the poultry may be destroyed immediately. (The interim rule neglected to include a similar statement in § 56.4(c)(2) regarding the appraisal process for materials for which the cost of cleaning and disinfection would exceed the value of the materials or cleaning and disinfection would be impracticable for any reason. We are correcting that omission in this final rule.) We believe this provision addresses the commenter’s concern.

We agree that having a list of pre-approved appraisers would be useful, and we are working to develop one to improve our response efforts for all diseases, not just H5/H7 LPAI. With regard to the commenter’s second suggestion, we typically conduct appraisals for poultry by reviewing...
exposed

Under the definition of 

eligible for indemnity under 9 CFR part 56. Under the definition of H5/H7 LPAI exposed, poultry can be determined to be exposed to H5/H7 LPAI if there is a reason to believe that association has occurred with H5/H7 LPAI or vectors of the virus by the Cooperating State Agency and confirmed by APHIS.3 Absent our determination that poultry were infected with or exposed to H5/H7 LPAI, we will not authorize the payment of indemnity for the destruction and disposal of that poultry. As noted earlier, for poultry that are infected with or exposed to H5/H7 LPAI, we will use records of production to determine how much indemnity should be paid.

In § 56.4, paragraph (a)(1) states that, for laying hens, the appraised value should include the hen’s projected future egg production. One commenter agreed with this provision but recommended that the appraisal should also take into account whether the hen would have undergone a molt had she not been euthanized. The commenter stated that not all flocks are molted, but those that have a longer productive life — typically 110-115 weeks rather than approximately 80 weeks. The commenter is correct that molted hens have a longer productive life than hens that are not molted. However, there would be considerable difficulties in determining whether a hen would have been molted and properly valuing the hen based on that information. Based on industry figures for hen values, the appraised value of a hen starts out low for a day-old chick, increases as the bird grows, and reaches a maximum soon after egg laying begins. As eggs are laid, the hen’s value declines. When molting takes place, the hen’s value increases during the molting phase, followed by a decline in value as eggs are laid. The process repeats itself for a second molt.

If we were to adopt the commenter’s recommendation, our appraisal model would not increase the value of a hen in its molting phase, but would have to assign that increase in value to the initial lay. This would result in no increase in value for hens in the molting phase, which would mean that our appraisal values of a hen in the molting phase would not reflect the fair market value of the hen. In addition, if we made the change suggested by the commenter, we would have to take the owner’s word for whether the hen was to be molted, meaning the owner would have a strong incentive to state that the hen would be molted, thus increasing the hen’s value, regardless of the actual plans for molting. We have determined that our present valuation model for hens more accurately determines their fair market value, as required by the Animal Health Protection Act. We are making no changes in response to this comment.

In § 56.4, paragraph (a)(2) sets out the conditions for determining the amount of indemnity paid for disposal of poultry. The conditions include a requirement that any disposal of poultry infected with or exposed to H5/H7 LPAI for which indemnity is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS.3 Paragraph (c)(1) sets out the conditions under which the amount of indemnity paid for cleaning and disinfection will be determined; similarly, the conditions include a requirement that any cleaning and disinfection of premises, conveyances, and materials for which indemnity is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS.4 One commenter stated that requiring that completed, signed appraisal documents and a written compliance agreement be in place prior to disposal of infected poultry would severely hamper efforts to quickly and effectively deal with the infection. The commenter recommended that we recognize as adequate any disposal activities undertaken under the approved initial State response and containment plan. The commenter also stated that cleaning and disinfection should be allowed to commence without a compliance agreement as long as a Cooperating State Agency oversees and directs the work and documentation of expenses is provided. In the event of a disputed claim, the commenter stated, a process for resolving differences should be provided.

The regulations require that the destruction and disposal of the indemnified poultry be conducted in accordance with the initial State response and containment plan for H5/H7 LPAI. Similarly, the regulations indicate that APHIS will review claims for indemnity for cleaning and disinfection to ensure that all expenditures relate directly to activities described in § 56.5 and in the initial State response and containment plan described in § 56.10.

Allowing disposal of infected poultry or cleaning and disinfection to begin without a compliance agreement in place, but promising to pay indemnity for expenses related to these activities, would amount to approving expenditures on APHIS’ behalf without having a mechanism in place by which APHIS can provide oversight. This could create disputes regarding the payment of indemnity. Our oversight of activities for which we pay indemnity is essential to the responsible use of funds made available to APHIS for indemnity.

Based on previous disease response efforts, including the effort to eradicate exotic Newcastle disease outbreaks in 2002-2003, we are confident that we can conclude compliance agreements with States and flock owners with sufficient timeliness to ensure an effective disease response.

One commenter had two comments about how the provisions in § 56.9, “Claims not allowed,” relate to the provisions in § 56.4.

Paragraph (a) of § 56.9 states that the USDA will not allow claims arising out of the destruction of poultry unless the poultry have been appraised as prescribed in part 56 and the owners have signed the appraisal form indicating agreement with the appraisal amount as required by § 56.4(a)(1). The commenter asked whether the poultry could be appraised after they are destroyed based on the information collected by the Cooperating State Agency prior to their destruction.

We expect to use a process in which birds are destroyed and appraisal is performed after destruction in some cases, regardless of whether the Cooperating State Agency or APHIS collects the necessary information for the appraisal. This is why the regulations in § 56.4(a)(1) provide that poultry may be destroyed before the owners of the poultry sign their agreement.

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1Two sentences in § 56.4(a)(2) as it was established by the interim rule incorrectly referred to “compensation” rather than “indemnity.” We are correcting the error in this final rule.
appraisals if the owners, APHIS, and the Cooperating State Agency agree that the poultry may be destroyed immediately. Paragraph (b) of § 56.9 states that the USDA will not allow claims arising out of the destruction of poultry unless the owners have signed a written agreement with APHIS in which they agree that if they maintain poultry in the future on the premises used for poultry for which indemnity is paid, they will maintain the poultry in accordance with a plan set forth by the Cooperating State Agency and will not introduce poultry onto the premises until after the date specified by the Cooperating State Agency.

The commenter stated that this requirement was inconsistent with the provisions in § 56.4 that require a compliance agreement to be in place for the disposal of poultry and for cleaning and disinfection, and that both paragraphs should simply require an agreement rather than a compliance agreement.

The two requirements refer to two different agreements. The requirement in § 56.9(b) refers to an agreement for maintenance and repopulation of the flock, while the requirements in § 56.4 refer to a compliance agreement under which APHIS will pay for cleaning and disinfection work that APHIS does not perform. As stated earlier, we are confident that we can conclude the necessary compliance agreements promptly under disease emergency conditions, based on past experience.

**Destruction and Disposal of Poultry and Cleaning and Disinfection of Premises, Conveyances, and Materials**

In the regulations established by the interim rule, § 56.5 sets out provisions relating to the destruction and disposal of poultry and cleaning and disinfection of premises, conveyances, and materials. Paragraph (a) of § 56.5 sets out the factors on which the Cooperating State Agency and APHIS will base their selection of a method of destruction for poultry. These factors include:

- The speed with which destruction must be conducted.
- The species, size, and number of the poultry to be destroyed;
- The environment in which the poultry are maintained;
- The risk to human health or safety of the method used;
- Whether the method requires specialized equipment or training;
- The risk that the method poses of spreading the H5/H7 LPAI virus;
- Any hazard the method could pose to the environment;
- The degree of bird control and restraint required to administer the destruction method; and
- The risk to human health or safety of the method used;
- Consistency of the method with humane euthanasia guidelines as an additional factor to be considered when selecting the destruction method in § 56.5(a).

We appreciate the information the commenters supplied on specific destruction methods, and we will take it into consideration when determining what destruction method to use during an LPAI outbreak.

Paragraph (c) of § 56.5 sets out conditions under which controlled marketing may occur. The interstate movement of poultry that has been infected with or exposed to H5/H7 LPAI for controlled marketing may occur only at the discretion of the Cooperating State Agency and APHIS and only if the initial State response and containment plan described in § 56.10 provides for it. In addition, controlled marketing may only occur in accordance with the following requirements:

- Poultry infected with or exposed to H5/H7 LPAI must not be transported to a market for controlled marketing until 21 days after the acute phase of the infection has concluded, as determined by the Cooperating State Agency in accordance with the initial State response and containment plan described in § 56.10;
- Within 7 days prior to slaughter, each flock to be moved for controlled marketing must be tested for H5/H7 LPAI using a test approved by the Cooperating State Agency and found to be free of the virus.

These restrictions ensure that poultry that are moved for controlled marketing do not pose a risk of spreading H5/H7 LPAI.

One commenter asked whether the requirements in this paragraph refer only to poultry flocks that participate in the Plan or to any poultry. Specifically, the commenter asked whether a State could allow poultry from an H5/H7 LPAI positive live bird market to be sold for several days prior to depopulation and cleaning and disinfection, a process known as “selldown.”

Poultry that have been moved to a live bird market for sale have already reached the end of the marketing cycle, and thus would not need to be moved for controlled marketing; they are already at a market and being sold directly to consumers. Therefore, the controlled marketing requirements do not apply to the sale of poultry at live bird markets. However, the movement of these infected or exposed birds would be restricted under the initial State response and containment plan.

Paragraph (c)(2) of § 56.5 indicates that poultry moved for controlled marketing will not be eligible for
indemnity under § 56.3. Since the publication of the interim rule, outbreaks of H5/H7 LPAI have occurred in which producers sold infected or exposed birds through controlled marketing. Indemnity was not paid for the poultry themselves, but the regulations were unclear on whether we would pay indemnity for costs related to cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that are moved for controlled marketing.

Although producers who move infected or exposed poultry interstate for controlled marketing are able to recoup the cost of production of the poultry through their sale, they still incur costs related to cleaning and disinfection, which after an H5/H7 LPAI outbreak must be more thorough than typical cleaning and disinfection. Therefore, in this final rule, we are adding a provision to this paragraph indicating that costs related to cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that are moved for controlled marketing will be eligible for indemnity. This provision is intended to provide additional clarity.

Paragraph (d) in § 56.5 sets out guidelines for the development of a cleaning and disinfection plan for a premises and for the materials and conveyances on that premises. Cleaning and disinfection must be performed in accordance with the initial State response and containment plan described in § 56.10, which must be approved by APHIS. One commenter had several comments on paragraph (d).

Paragraph (d)(1)(i) of § 56.5 provides guidance to secure and remove all feathers that might blow around outside the house in which the infected or exposed poultry were held by raking them together and burning the pile. The commenter stated that this action may be in violation of applicable environmental regulations.

In response to this comment, we are including a general statement at the beginning of paragraph (d) that indicates that all cleaning and disinfection activities must comply with Federal, State, and local environmental regulations.

It is important to note that paragraph (d) is intended to provide guidelines for the development of a cleaning and disinfection plan; if some aspect of the guidelines in paragraph (d) is not applicable to a specific State or locality, or to the poultry operations affected by an LPAI outbreak, a State has the option to address the disinfection differently in its initial State response and containment plan.

The commenter also noted that there is no alternate feather disposal option presented, e.g., composting, burial in approved locations, onsite treatment, or secure transport to offsite landfill or treatment.

As stated in the regulations, paragraph (d) of § 56.5 provides guidelines for the development of a cleaning and disinfection plan for a premises and for the materials and conveyances on that premises. The feather disposal method provided in the regulations is not the only possible effective method, and other methods may be appropriate in certain situations. In the event of an H5/H7 LPAI outbreak, APHIS reserves the option to approve another disposal method if a State requests it and we determine the disposal method to be effective. It is not necessary to set out all potentially appropriate feather disposal methods in the guidelines in paragraph (d).

Paragraph (d)(1)(iii) of § 56.5 provides guidance to close the house (except for allowing enough ventilation to remove moisture) for a minimum of 21 days following application of insecticides and rodenticides to allow as much H5/H7 LPAI virus as possible to die a natural death. The commenter stated that there is no mention made of concurrent in-house composting or whether there is initial raising of the in-house temperature and that allowing the house sit for 21 days in a cold, moist environment may do little to reduce the LPAI virus titer in the house.

We had intended for composting to be performed during the 21-day period after the closing of the poultry house. We have amended paragraph (d)(1)(iii) to reflect that. We are also amending paragraph (d)(1)(iii) to indicate that the house should be heated to 100 °F before beginning in-house composting.

Paragraph (d)(1)(iv) of § 56.5 provides guidance to heat the house to 100 °F for 72 hours prior to cleaning and disinfection. The commenter stated that it appears that this temperature raising occurs after the 21-day downtime and prior to litter removal or in-house composting. It is unclear, the commenter stated, whether this temperature recommendation is based on acceptable field test data specific for the LPAI virus. If raising the temperature occurs prior to removal or composting of litter, the litter might act as a blanket to protect the virus from the heat. The commenter stated that raising the temperature to the indicated level at the start of composting rather than at the end will accelerate the in-house composting process and will aid in the natural die-off of the LPAI virus in the poultry house during the 21-day downtime.

These comments are addressed by the change discussed previously.

The commenter also stated that there is no guidance provided as to how to deal with a house with open sides in a cold environment.

The guidelines in paragraph (d) are intended to address the most common situations associated with commercial poultry production. Houses with open sides are typically not used in commercial poultry production, as open sides put the poultry within at risk of infection by wild birds. In the event of an H5/H7 LPAI outbreak, APHIS reserves the option to approve another composting method if a State requests it and we determine the disposal method to be effective; a composting method approved in this manner would also be an approved activity for indemnity payment purposes, as would any other cleaning and disinfection provision used to deal with an unusual situation. It is not necessary to set out all potentially appropriate composting methods in the guidelines in paragraph (d).

Paragraph (d)(2)(i) of § 56.5 provides guidance to clean up or compost all manure, debris, and feed in the house if possible before cleaning and disinfection. The commenter stated that it is not clear whether this composting should occur at the start of the 21-day pre-cleaning and disinfection period.

Under these guidelines, all material in the house would be composted during the 21-day pre-cleaning and disinfection period, after which any manure, debris, and feed would undergo an additional composting.

Paragraph (d)(2)(i) also indicates that equipment should be washed and disinfected. The commenter stated that the regulations should more appropriately provide guidance to clean and disinfect equipment.

We agree, and we have made this change in the final rule.

Paragraph (d)(2)(ii) of § 56.5 provides guidance to spray contaminated surfaces with soap and water. The commenter stated that it may have been more appropriate to indicate instead spraying with detergent (rather than soap) and water. Also, the commenter stated, the guidance should indicate that detergent should be rinsed with fresh water to prevent a potentially negative interaction between the detergent and the successively applied disinfectant.

We agree with the commenter, and we have made the suggested changes. Paragraph (d)(2)(ii) of § 56.5 provides guidance to use disinfectants authorized by 9CFR 71.10(a).
stated that this reference to 9 CFR 71.10(a) may be inappropriate as cresylic disinfectants, liquefied phenol, chlorinated lime, and sodium hydroxide are not present as active ingredients on the labels of any current registered AI virus disinfectant, nor is there any exemption present to use Environmental Protection Agency (EPA)-registered tuberculocidal disinfectants against AI virus. The commenter stated further that there is no recommendation to use any of the approximately 100 EPA-registered AI virus disinfectants as per label instructions or a disinfectant approved by the EPA for use under a Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA) section 18 exemption.

We agree with the commenter, and we have amended the regulations to refer to a disinfectant registered with the EPA for AI virus per label instructions or a disinfectant approved by the EPA for use under a FIFRA section 18 exemption, instead of referring to a disinfectant authorized by § 71.10(a).

The commenter also stated that there is no guidance on how to disinfect surfaces that are prevalent in poultry houses but are not considered as nonporous, e.g., cement, concrete, wood, clay, etc., as there are no EPA-registered disinfectants and there is no authorization from EPA to treat surfaces that are not considered nonporous with disinfectant.

We would not use a disinfectant on any surface on which its use is not authorized by its EPA label. We have added text to paragraph (d)(2)(iii) of § 56.5 to clarify this issue. Given the diversity of construction in commercial poultry houses, disinfection of surfaces considered to be nonporous will need to be addressed in each individual State’s initial State response and containment plan, rather than in the guidelines in paragraph (d).

Conditions For Payment to Contractors

In the regulations established by the interim rule, § 56.8 provides that when poultry or eggs have been destroyed pursuant to part 56, the Administrator may pay claims to any party with which the owner of the poultry or eggs has entered into a contract for the growing or care of the poultry or eggs. Section 56.8 also sets out a formula for calculating the proportion of indemnity paid to the owner of poultry or eggs destroyed under part 56 that may be paid to the contract grower:

- The value of the contract the owner of the poultry or eggs entered into with another party for the growing or care of the poultry or eggs in dollars is divided by the duration of the contract as it was signed prior to the H5/H7 LPAI outbreak in days.
- This figure is multiplied by the time in days between the date the other party began to provide services relating to the destroyed poultry or eggs under the contract and the date the birds were destroyed due to H5/H7 LPAI.
- If compensation is paid to a grower under § 56.8, the owner of the poultry or eggs will be eligible to receive the difference between the indemnity paid to the growers and the total amount of indemnity that may be paid for the poultry or eggs.

These regulations work well for the contract grower model prevalent in the meat-type poultry industry, where contract growers are typically paid on delivery of the poultry and in which the poultry increase in value over time until they are ready for sale in the market. However, since the publication of the interim rule, we reviewed these provisions and found that they are less suitable for contract growers maintaining egg-laying birds (table-egg layers and breeding poultry). Such growers are typically compensated at set intervals during the contract (either weekly or monthly). Under the regulations as established by the interim rule, growers could receive payment for their labor both from the owner and from APHIS if poultry in their care were destroyed due to infection with or exposure to H5/H7 LPAI after growers had already received a payment from the poultry owner.

Therefore, in this final rule, we are adding a provision to the regulations in § 56.8 indicating that if a contract grower receiving indemnity under § 56.8 has received any payment under his or her contract from the owner of the poultry at the time the poultry are destroyed, the amount of indemnity for which the contract grower is eligible will be reduced by the amount of the payment the contract grower has already received.

Miscellaneous Changes

The interim rule stated that the information collection and recordkeeping requirements included in the interim rule had been submitted for emergency approval to the Office of Management and Budget (OMB). Since the publication of the interim rule, we received approval for those information collection and recordkeeping requirements, as well as a paperwork control number for those requirements. The OMB control number for the information collection associated with this rule is 0579-0007. In this final rule, we are adding the paperwork control number to the sections of the regulations established by the interim rule that contain information collection and recordkeeping requirements. These sections are §§ 56.4, 56.6, 56.7, 56.9, 146.4, 146.11, 146.13, 146.14, 146.24, and 146.44.

We are also making minor, nonsubstantive corrections and changes.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule, with the changes discussed in this document.

This final rule also affirms the information contained in the interim rule concerning Executive Order 12372.

Effective Date

Pursuant to the administrative procedure provisions in 5 U.S.C. 553, we find good cause for making this rule effective less than 30 days after publication in the Federal Register. The interim rule adopted as final by this rule became effective on September 26, 2006. This rule amends the interim rule to provide that the amount of indemnity for which contract growers are eligible will be reduced by any payment they have already received on their contracts when poultry in their care are destroyed, to clarify the roles of cooperating State agencies with respect to H5/H7 low pathogenic avian influenza outbreaks, to provide that the welfare of poultry to be destroyed will be considered when selecting a method for the destruction of poultry, and to provide additional guidance for cleaning and disinfecting an affected premises in the interim rule. Immediate action is necessary to make these changes in order to help ensure that the H5/H7 subtypes of low pathogenic avian influenza are detected and eradicated when they occur within the United States. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the Federal Register.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by
contacting the person listed under FOR FURTHER INFORMATION CONTACT.

Under the interim rule, the USDA established a voluntary control program for H5/H7 LPAI. As part of the program, participating owners and growers are indemnified for losses arising from depopulation of birds affected with H5/H7 LPAI.

In general, benefits of containing the spread of a livestock or poultry disease fall into three categories: 1) Avoided producer losses from disease morbidity and mortality; 2) avoided consumer losses due to price increases resulting from decreased supplies (net of avoided gains to producers attributable to the price increases); and 3) avoided reduced demand if markets are closed to affected commodities. LPAI is rarely fatal to infected birds. However, the longer an outbreak is not controlled, with more birds becoming infected with H5/H7 LPAI, the more likely it is that the virus may mutate to a highly pathogenic form. The more timely and well-planned the response to an LPAI occurrence, the less likely it will result in harmful price and trade effects. This final rule has the objectives of reducing the risk of H5/H7 LPAI outbreaks and improving responsiveness and eradication measures at the grower, industry, and State levels when the disease does occur.

The groups who enjoy the primary benefit of a disease eradication campaign are consumers and those owners/growers whose flocks have remained healthy. Owners and growers of the depopulated flocks bear the primary burden of an eradication effort, if not indemnified. In addition to the value of lost production, the owners/growers of affected birds may also bear costs of cleanup, disinfection, transportation, forgone income, and other financial hardships. The benefits of a voluntary avian influenza control program derive from disease prevention and from cost minimization when an outbreak does occur. Evidence of the types of benefits gained from control of avian influenza is found in a USDA-Economic Research Service study of a 1983-84 outbreak.4 A 2002 outbreak in Virginia also exemplifies the types of costs incurred due to an avian influenza incident. While these occurrences show that the costs of an avian influenza outbreak can be substantial, recent outbreaks have typically been smaller in scale. An ongoing surveillance program contributes to our ability to detect outbreaks early and limit their effects.

To the extent that the final rule contributes to the elimination of AI, all affected entities should benefit over the long term. The program that APHIS is establishing is a voluntary program; producers are not required to participate. The benefits of this rule, from preventing LPAI outbreaks and minimizing losses should an outbreak occur, are expected to exceed costs to producers and States of participating in the program’s disease prevention efforts.

Under the rule, producers will be required to keep flocks and facilities clean, slaughter plants will be required to conduct sampling, and States will be required to conduct annual inspections and develop response and containment plans. APHIS will provide full indemnities for specific costs to participating producers and States should an outbreak occur.

The final rule explicitly provides indemnity for cleaning and disinfection in the case of birds moved for controlled marketing. Since the interim rule was implemented, APHIS has paid these costs on a few occasions. These costs vary widely. The variations may be attributed to factors such as the type of production, where the operation is located, the size of the operation, the company involved in the cleaning and disinfection, as well as other factors.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in the interim rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0007.

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. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS’ Information Collection Coordinator, at (301) 851-2908.

List of Subjects

9 CFR Part 56

Animal diseases, Indemnity payments, Low pathogenic avian influenza, Poultry.

9 CFR Part 146

Animal diseases, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, the interim rule amending 9 CFR parts 53, 56, 145, 146, and 147 that was published at 71 FR 53601-56333 on September 26, 2006, is adopted as a final rule with the following changes:

PART 56—CONTROL OF H5/H7 LOW PATHOGENIC AVIAN INFLUENZA

1. The authority citation for part 56 continues to read as follows:


2. Section 56.1 is amended by revising the definition of H5/H7 LPAI virus infection (infected) to read as follows:

§ 56.1 Definitions.

H5/H7 LPAI virus infection (infected).

(i) Poultry will be considered to be infected with H5/H7 LPAI for the purposes of this part if:

(1) H5/H7 LPAI virus has been isolated and identified as such from poultry; or

(ii) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry; or

(iii) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry. If vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected. In the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of H5/H7 LPAI infection, as determined by APHIS.

(ii) The official determination that H5/H7 LPAI virus has been isolated and identified, viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected, or antibodies to the H5 or H7 subtype of AI virus have been detected may only be made by the National Veterinary Services Laboratories.

§ 56.2 [Amended]

3. Section 56.2 is amended as follows:

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6. Section 56.3 is amended as follows:

a. In paragraphs (a)(2) and (a)(3), by removing the words “developed by the Official State Agency and” each time they occur.

b. In paragraph (a)(3), by adding a period at the end of the paragraph.

c. In paragraph (c), by removing the word “States” and adding the words “Cooperating State Agencies” in its place.

d. By revising paragraph (b)(7) to read as follows:

§ 56.3 Payment of indemnity.

(a) * * * * * * *

(b) * * *

(7) The poultry are located in a State that does not participate in the diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14 of this chapter, or that does not have an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS under § 56.10, unless such poultry participate in the Plan with another State that does participate in the diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14 of this chapter, and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS under § 56.10.

* * * * * * *

5. Section 56.4 is amended as follows:

a. In paragraph (a)(2), in the second and third sentences, by removing the word “compensation” and adding the word “indemnity” in its place.

b. In paragraph (c)(2), by adding two new sentences after the third sentence to read as set forth below.

c. By adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 56.4 Determination of indemnity amounts.

* * * * * * *

(c) * * *

(2) * * * Appraisals of materials must be reported on forms furnished by APHIS and signed by the appraisers and must be signed by the owners of the materials to indicate agreement with the appraisal amount. Appraisals of materials must be signed prior to the destruction of the materials, unless the owners, APHIS, and the Cooperating State Agency agree that the materials may be destroyed immediately.

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6. Section 56.5 is amended as follows:

a. In paragraph (a)(1), by removing the word “and” at the end of the paragraph.

b. In paragraph (a)(6), by removing the period and adding the word “; and” in its place.

c. By adding a new paragraph (a)(9) to read as set forth below.

d. By revising paragraph (c)(2) to read as set forth below.

e. In the introductory text of paragraph (d), by adding a new sentence before the last sentence to read as set forth below.

f. By revising paragraphs (d)(1)(iii), (d)(2)(i), and (d)(2)(ii) to read as set forth below.

g. In paragraph (d)(2)(i), by removing the word “washed” each time it occurs and adding the word “cleaned” in its place.

§ 56.5 Destruction and disposal of poultry and cleaning and disinfection of premises, conveyances, and materials.

(a) * * *

(9) Consistency of the method with humane euthanasia guidelines.

* * * * * * *

(c) * * *

(2) Poultry moved for controlled marketing will not be eligible for indemnity under § 56.3. However, any costs related to cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that are moved for controlled marketing will be eligible for indemnity under § 56.3.

(d) * * *

“Cleaning and disinfection must also be performed in accordance with any applicable State and local environmental regulations.

(1) * * *

(iii) Close the house in which the poultry were held, maintaining just enough ventilation to remove moisture. Heat the house to 100 °F and begin in-house composting. Leave the house undisturbed for a minimum of 21 days and for as long as possible thereafter, in order to allow as much H5/H7 LPAI virus as possible to die a natural death.

* * * * * * *

(2) * * *

(ii) Cleaning of premises and materials. Cleaning and washing should be thorough to ensure that all materials or substances contaminated with H5/H7 LPAI virus, especially manure, dried blood, and other organic materials, are removed from all surfaces. Spray all contaminated surfaces above the floor with detergent and water to knock dust down to the floor, using no more water than necessary. Wash equipment and houses with detergent and water. Disassemble equipment as required to clean all contaminated surfaces. Special attention should be given to automatic feeders and other closed areas to ensure adequate disinfection.

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§ 56.6 [Amended]

7. Section 56.6 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 56.7 [Amended]

8. Section 56.7 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

9. Section 56.8 is amended as follows:

a. In paragraph (a)(2), by removing the word “birds” and adding the words “poultry or eggs” in its place.

b. By redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and adding a new paragraph (c) to read as set forth below.

§ 56.8 Conditions for payment.

* * * * * * *

(c) If a contractor receiving indemnity under this section has received any payment under his or her contract from the owner of the poultry or eggs at the time the poultry or eggs were destroyed, the amount of indemnity for which the contract grower is eligible will be reduced by the amount of the payment the contract grower has already received.

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§ 56.9 [Amended]

10. Section 56.9 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.
In § 56.10, the introductory text of paragraph (a) is revised to read as follows:

§ 56.10 Initial State response and containment plan.

(a) In order for poultry owners within a State to be eligible for indemnity for 100 percent of eligible costs under § 56.3(b), the State in which the poultry participate in the Plan must have in place an initial State response and containment plan that has been approved by APHIS. The initial State response and containment plan must be developed by the Official State Agency. In States where the Official State Agency is different than the Cooperating State Agency, the Cooperating State Agency must also participate in the development of the plan. The plan must be administered by the Cooperating State Agency of the relevant State. This plan must include:

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PART 146—NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL POULTRY

12. The authority citation for part 146 continues to read as follows:


13. In § 146.1, a new definition of Cooperating State Agency is added and the definition of H5/H7 LPAI virus infection (infected) is revised to read as follows:

§ 146.1 Definitions.

Cooperating State Agency. Any State authority recognized by the Department to cooperate in the administration of the provisions of part 56 of this chapter. This may include the State animal health authority or the Official State Agency.

H5/H7 LPAI virus infection (infected).

- (1) Poultry will be considered to be infected with H5/H7 LPAI for the purposes of this part if:
  - (i) H5/H7 LPAI virus has been isolated and identified as such from poultry; or
  - (ii) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry; or
  - (iii) Antibodies to the H5 or H7 subtype of the AI virus that are not a consequence of vaccination have been detected in poultry. If vaccine is used, methods should be used to distinguish vaccinated birds from birds that are both vaccinated and infected. In the case of isolated serological positive results, H5/H7 LPAI infection may be ruled out on the basis of a thorough epidemiological investigation that does not demonstrate further evidence of H5/H7 LPAI infection, as determined by APHIS.

- (2) The official determination that H5/H7 LPAI virus has been isolated and identified, viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected, or antibodies to the H5 or H7 subtype of AI virus has been detected may only be made by the National Veterinary Services Laboratories.

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§ 146.2 [Amended]

14. In § 146.2, paragraph (f) is amended by removing the word “States” and adding the words “Cooperating State Agencies” in its place.

§ 146.4 [Amended]

15. Section 146.4 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 146.11 [Amended]

16. Section 146.11 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 146.13 [Amended]

17. Section 146.13 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 146.14 [Amended]

18. Section 146.14 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 146.24 [Amended]

19. Section 146.24 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.

§ 146.44 [Amended]

20. Section 146.44 is amended by adding the OMB citation “(Approved by the Office of Management and Budget under control number 0579-0007)” at the end of the section.