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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: Interim rule and request for comments.

SUMMARY: We are amending the regulations to establish a voluntary program for the control of the H5/H7 subtypes of low pathogenic avian influenza in commercial poultry under the auspices of the National Poultry Improvement Plan (the Plan). The control program was voted on and approved by the voting delegates at the Plan's 2004 National Plan Conference. We are also providing for the payment of indemnity for costs associated with eradication of the H5/H7 subtypes of low pathogenic avian influenza in poultry. The H5/H7 subtypes of low pathogenic avian influenza can mutate into highly pathogenic avian influenza, a disease that can have serious economic and public health consequences. This combination of a control program and indemnity provisions is 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. DATES: This interim rule is effective on [Insert date of publication in the Federal Register].

We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov and, in the "Search for Open Regulations" box, select "Animal and Plant Health Inspection Service" from the agency drop-down menu, then click on "Submit." In the Docket ID column, select APHIS-2005-0109 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "User Tips" link.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. APHIS-2005-0109, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2005-0109.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 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) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

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 that consists of a variety of programs intended to prevent and control certain poultry diseases. Participation in all Plan programs is voluntary, but flocks, hatcheries, and dealers of breeding poultry 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, and dealers that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that have tested clean of certain diseases or that have been produced under appropriate disease-prevention conditions. Prior to the publication of this interim rule, the regulations in 9 CFR parts 145 and 147 (referred to below as the regulations) contained the provisions of the Plan.

In this interim rule, we are amending 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. This program will be administered under the auspices of the NPIP. Until now, the Plan has only addressed disease issues, including avian influenza (AI), in flocks of breeding poultry. To accommodate the addition of commercial poultry to the NPIP, this interim rule establishes a new part 146, titled "National Poultry Improvement Plan for Commercial Poultry," in 9 CFR chapter

I, subchapter G. This voluntary control program is intended to complement the voluntary control programs for AI in breeding poultry—specifically, table-egg layer, meat-type chicken, meat-type turkey, and waterfowl, exhibition poultry, and game bird breeding flocks—that are currently contained in part 145 of the Plan's provisions.

This interim rule also establishes a new part 56, 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. The regulations in part 56 provide the authority to pay indemnity for 100 percent of costs associated with the eradication of H5/H7 LPAI to most poultry owners. To provide owners of large commercial poultry flocks and current participants in the Plan for breeding poultry with an incentive to participate in the voluntary control programs for AI in parts 145 and 146, this interim rule provides the authority to pay indemnity for only 25 percent of costs associated with eradication of H5/H7 LPAI to those poultry owners if they do not participate in those voluntary control programs.

The regulations in part 56 also provide the authority to pay indemnity to States that participate in the Plan for 100 percent of certain costs associated with their efforts to eradicate outbreaks of H5/H7 LPAI. For States that do not participate in the plan, the regulations authorize the payment of indemnity for 25 percent of those costs.

The reasons we are establishing the voluntary control program for commercial poultry and providing for the payment of indemnity in case of outbreaks of H5/H7 LPAI, and the provisions of the control program and indemnity regulations, are described below.

Increasing Threat of AI

AI is an infectious disease of birds caused by type A strains of the influenza virus. The disease, which was first identified in Italy more than 100 years ago, occurs worldwide. All birds are thought to be susceptible to infection with AI, though some species are more resistant to infection than others. Wild waterfowl, shorebirds, and gulls serve as a natural host and reservoir for AI viruses. Fifteen subtypes of influenza virus are known to infect birds, thus providing an extensive reservoir of influenza viruses potentially circulating in bird populations. In addition, the hemagglutinin (H) protein on each subtype of the AI virus can theoretically be partnered with any one of nine neuraminidase (N) surface proteins; thus, there are potentially nine different forms of each subtype. (For example, the nine forms of subtype H5 would be notated as H5N1, H5N2, H5N3, etc., through H5N9.)

AI viruses can be classified into low pathogenic and highly pathogenic forms based on the severity of the illness they cause. Most AI virus strains are low pathogenic and typically cause few or no clinical signs in infected birds. The World Organization for Animal Health (also known as the OIE), an international body that, among other things, classifies animal diseases, considers subtypes of LPAI other than H5 and H7 to be low-risk diseases and does not require outbreaks of them to be reported by OIE members, of which the United States is one. (Diseases whose outbreaks OIE members are required to report to the OIE are often referred to as notifiable diseases, referring to the process by which members notify the OIE. The OIE has approved changes in its classification scheme for LPAI that became effective on January 1, 2006; further discussion of these changes can be found under the heading "Trade Restrictions"

and OIE Guidelines Related to H5/H7 LPAI" later in this document.) While it can, in rare cases, be transmitted from birds to humans, the LPAI virus poses no threat to human health.

However, the LPAI virus can mutate into a highly contagious and rapidly fatal disease, resulting in severe epidemics. The more severe form of the disease is known as highly pathogenic avian influenza (HPAI). To date, all outbreaks of the highly pathogenic form have been caused by influenza A viruses of subtypes H5 and H7.

During the past 20 years, several examples of H5 and H7 LPAI viruses mutating into HPAI viruses have been documented worldwide (table 1).

Table 1.—<u>Instances in which LPAI viruses of subtypes H5 and H7 mutated into HPAI viruses</u>

| Location | Year |
|-----------------------------|-----------|
| Pennsylvania, United States | 1983-1984 |
| Mexico | 1994-1995 |
| Italy | 1999 |
| Chile | 2002 |
| British Columbia, Canada | 2004 |

Evidence continues to accumulate that LPAI viruses of the H5 and H7 subtypes, if permitted to circulate in poultry populations, can mutate into HPAI viruses; the larger the number of birds infected with H5/H7 LPAI, the more likely it is that the virus will mutate into HPAI in one of them.

HPAI is characterized by sudden onset, severe illness, and rapid death, with a mortality rate that can approach 100 percent. HPAI is listed by the OIE as a notifiable disease, meaning that outbreaks of HPAI must be reported by OIE members. Diseases listed as notifiable are those that exhibit some combination of potential for international spread, potential for significant

morbidity or mortality among populations not exposed to the disease, and potential for transmission to humans (and, if that potential is present, potential for severe consequences of infection in humans). The OIE also takes into account whether the disease is an emerging disease when determining whether to list it. Although it is not an emerging disease, HPAI fulfills all the other conditions for being listed as a notifiable disease, including having the potential for severe consequences of infection in humans.¹

The number of outbreaks of HPAI in the world's commercial poultry has grown in the years since 1955 (table 2), with particularly dramatic growth in the last 10 years. There is also evidence that AI virus has been directly transmitted from birds to humans several times in recent years (table 3). Incidents of human infection with HPAI are specifically noted in the table.

Table 2.—Outbreaks of HPAI by decade since 1955

| Years | Number of outbreaks |
|-----------|---------------------|
| 1955-1964 | 3 |
| 1965-1974 | 1 |
| 1975-1984 | 4 |
| 1985-1994 | 5 |
| 1995-2004 | 10 |

Table 3.—Transmission of AI virus from birds to humans

| Location | Year | Virus subtype |
|-------------------------|------|--|
| Hong Kong | 1997 | H5N1 (HPAI) |
| Hong Kong | 1999 | H9N2 |
| Virginia, United States | 2002 | H7N2 (mild upper respiratory infection |
| | | and conjunctivitis) |
| The Netherlands | 2003 | H7N7 (HPAI) |
| New York, United States | 2003 | H7N2 (immunosuppressed individual) |

¹ The OIE's criteria for listing a disease as one that must be reported by OIE members may be viewed on the Internet at

http://www.oie.int/eng/normes/mcode/en_chapitre_2.1.1.htm#chapitre_2.1.1.

| Southeast Asia, Iraq, Turkey | 2003-2006 | H5N1 (HPAI) |
|------------------------------|-----------|-------------|
| British Columbia, Canada | 2004 | H7N3 (HPAI) |

As mentioned previously, the transmission of HPAI from birds to humans poses serious risks for public health. The first documented infection of humans with an avian influenza virus occurred in Hong Kong in 1997, when the H5N1 strain caused severe respiratory disease in 18 humans, of whom 6 died. The infection of humans coincided with an epidemic of HPAI, caused by the same strain, in Hong Kong's poultry population.

Since December 2003, a growing number of Southeast Asian countries have reported outbreaks of HPAI responsible for the deaths of millions of birds and at least 105 humans. The World Health Organization (WHO) reports that these outbreaks of H5N1 HPAI among poultry are the largest and most severe on record, and that all the conditions for a human pandemic of H5N1 influenza have been met save the establishment of efficient and sustained human-to-human transmission of the virus. The WHO further warns that "the risk that the H5N1 virus will acquire this ability will persist as long as opportunities for human infections occur. These opportunities, in turn, will persist as long as the virus continues to circulate in birds, and this situation could endure for some years to come."

Trade Restrictions and OIE Guidelines Related to H5/H7 LPAI

Given the information discussed above about the ability of H5/H7 LPAI to mutate into HPAI, several U.S. trading partners have put in place restrictions on the importation of poultry and poultry products in an effort to prevent the introduction of H5/H7 LPAI. Additionally, the U.S. Department of Agriculture has observed that some trading partners now require a greater

level of assurance that neither HPAI nor LPAI exist in source flocks for poultry exported from the United States.

The European Union (EU) has reported that it is currently considering the option of including H5/H7 LPAI in its statutory definition of AI. This would mean that poultry or poultry products exported to the EU from countries where H5/H7 LPAI is present would be subject to the same stringent requirements that apply to poultry or poultry products exported to the EU from countries where HPAI is present. The EU is also considering what regulatory responses, possibly including the use of vaccines, may be appropriate for outbreaks of H5/H7 LPAI in the EU.

In addition, spurred by the increasing importance of controlling H5/H7 LPAI, the OIE adopted new guidelines for AI in its Terrestrial Animal Health Code chapter on AI in May 2005. These guidelines became effective on January 1, 2006.³ The OIE guidelines in the Terrestrial Animal Health Code are recognized by the World Trade Organization as international recommendations for animal disease control.

The new OIE guidelines define notifiable avian influenza (NAI) as an infection of poultry caused by any influenza A virus of the H5 or H7 subtypes or by any AI virus with an intravenous pathogenicity index greater than 1.2, or, as an alternative, an AI virus with at least 75 percent mortality. NAI viruses are divided into highly pathogenic notifiable avian influenza and low pathogenicity notifiable avian influenza. However, with regard to such issues as restrictions on

² See "WHO Avian influenza frequently asked questions" at http://www.who.int/csr/disease/avian_influenza/avian_faqs/en/index.html (as of August 11, 2006).

³ The recommendations may be viewed on the Internet at http://www.oie.int/eng/normes/mcode/en_chapitre_2.7.12.htm.

importation, eradication of outbreaks, and determination of whether a country or a region within a country is free of AI, the guidelines treat HPAI and H5/H7 LPAI as posing similar risks.

Under the new guidelines, therefore, OIE members are obligated to report outbreaks of H5/H7 LPAI in addition to outbreaks of HPAI. In addition, in order to export poultry and poultry products to countries whose regulations are modeled on the OIE guidelines, countries or regions within countries may conceivably be required to have in place surveillance mechanisms sufficient to demonstrate freedom from both H5/H7 LPAI and HPAI and disease response measures sufficient to eradicate H5/H7 LPAI and HPAI. Establishing such surveillance mechanisms and disease response measures is one of the purposes of this interim rule.

Current AI Control and Surveillance Within the United States

HPAI does not currently exist in the United States. However, H7N2 LPAI viruses have been present in the poultry markets of New York and New Jersey since 1994. The amino acid sequences of the hemagglutinin proteins from some of these viruses have been found to carry more than two basic amino acids adjacent to the hemagglutinin cleavage site, raising concern that additional mutations could result in a highly pathogenic virus.

In addition, occasional LPAI outbreaks in commercial poultry in the United States, such as the LPAI outbreaks in Virginia, Delaware, Connecticut, Maryland, and Texas, have led some countries to place restrictions on the importation of poultry and poultry products from the United States.

In the United States, a combination of active and diagnostic surveillance for AI is used.

Diagnostic surveillance 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.

Active surveillance for AI in U.S. poultry has been conducted in three settings. The first involves the National Poultry Improvement Plan disease control provisions for breeding poultry in 9 CFR part 145. The Plan provides for a "U.S. Avian Influenza Clean" classification for table-egg layer breeding flocks in § 145.23(h); for meat-type chicken breeding flocks in § 145.33(l); and for waterfowl, exhibition poultry, and game bird breeding flocks in § 145.53(e). The Plan also provides for a "U.S. H5/H7 Avian Influenza Clean" classification for turkey breeding flocks in § 145.43(g). These active surveillance programs are used to certify baby chicks, poults, and hatching eggs for interstate commerce or export from the United States. All flocks tested since these programs began in 2000 have returned negative results for AI.

Second, in recent years a number of broiler and turkey meat producers have begun conducting AI serology tests on samples collected from their flocks just prior to slaughter to meet the requirements Mexico has established for exporting poultry meat to that country. Since Mexico established this requirement, all flocks tested in order to fulfill it have returned negative results for AI.

Third, several States have established AI surveillance programs based on the risk of AI exposure unique to their States or regions. For example, Minnesota has a long-standing AI surveillance program for turkeys; Texas established a surveillance program for commercial poultry flocks near the Mexican border following the Mexican HPAI outbreak in 1994-95; and Pennsylvania, New York, and New Jersey have ongoing surveillance programs in live bird

markets and their supply flocks as a result of the LPAI infections that persist in that marketing system.

However, given the risk that a persistent H5/H7 LPAI infection could mutate into HPAI, the possible trade disruptions that may be associated with H5/H7 LPAI now and in the future, and the OIE's adoption of guidelines designating H5/H7 LPAI as a notifiable disease, we believe that it is necessary to establish a national control program that provides for active and diagnostic surveillance for H5/H7 LPAI in both commercial and breeding poultry flocks. In case H5/H7 LPAI is discovered, we believe it is also necessary to establish a plan for controlling and eradicating H5/H7 LPAI outbreaks and to provide the authority to pay indemnity for costs associated with control and eradication of the disease.

Overall Approach of the Voluntary Control and Indemnity Program

Accordingly, the Animal and Plant Health Inspection Service (APHIS), the U.S. Animal Health Association's Transmissible Diseases of Poultry Committee, and the National Poultry Improvement Plan have worked to develop regulatory options for H5 and H7 LPAI for commercial poultry—specifically, table-egg layers, meat-type chickens, and meat-type turkeys. These options were intended to augment the current active surveillance programs for breeding flocks of table-egg layers, meat-type chickens, meat-type turkeys, and waterfowl, exhibition poultry, and game birds that have been included in the NPIP. (We may develop programs for surveillance and control of H5/H7 LPAI in other types of commercial or breeding poultry in the future.)

During a meeting APHIS organized with State and industry representatives that took place in May 2002 in San Antonio, TX, participants identified three key components that the

H5/H7 LPAI program should contain. In cooperation with States and industry, APHIS developed provisions describing such a program; these provisions were approved at the July 2004 NPIP meeting in San Francisco, CA, and they form the basis of this interim rule. In each of these components, Federal, State, and industry stakeholders all have an important part to play, and efforts to detect and eradicate outbreaks of H5/H7 LPAI will rely on cooperation among all three groups. Each component of the program is discussed in detail below.

The first component discussed here is a diagnostic surveillance program for all poultry, undertaken by the Official State Agencies according to plans approved by APHIS. In the new part 146 establishing the voluntary control program, § 146.14 sets out criteria for a diagnostic surveillance program. Each State that wishes to participate in the Plan for commercial poultry must implement a diagnostic surveillance program that is approved by APHIS. However, the diagnostic surveillance programs that States are required to implement apply to all poultry in the State, not just those included in the NPIP.

Diagnostic surveillance programs developed under this interim rule will designate H5/H7 LPAI as a disease reportable to the State veterinarian and require that 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. This is consistent with the recommendation in paragraph 2a of Article 3.8.9.2 of the OIE Guidelines for Surveillance of Avian Influenza.⁴

⁴ These guidelines may be viewed on the Internet at http://www.oie.int/eng/normes/mcode/en_chapitre_3.8.9.htm#chapitre_3.8.9.

The second component discussed here is the initial State response and containment plans for each participating State that are required by the new part 56 established by this interim rule. These plans detail what actions will be taken in response to an outbreak of H5/H7 LPAI; they will also be developed by the States, and they must be approved by APHIS before a State can begin participation in the voluntary control and indemnity program. Where the regulations in part 56 set out uniform requirements for emergency response, they are consistent with the OIE guidelines.

The requirements for both the diagnostic surveillance plan and the initial State response and containment plan provide for some level of variation on the State level, as long as the plans meet certain performance standards. As noted previously, several States already have diagnostic surveillance and emergency response measures of some kind in place for H5/H7 LPAI. (We are aware of State LPAI surveillance programs in Arkansas, California, Delaware, Georgia, Iowa, Maryland, Minnesota, North Carolina, Pennsylvania, Texas, and Virginia. However, it is difficult to estimate the proportion of U.S. poultry that are covered by State programs, as other States may also have such initiatives in place.) We believe it is better to build a Federal program that recognizes State activities than to replace them with a strictly Federal program. In our judgment, the States that already have control measures in place to address H5/H7 LPAI may be able to adapt those measure to meet the performance standards that this interim rule sets out for surveillance and emergency response measures with few or no changes. For States that do not have control measures in place to address H5/H7 LPAI, the combination of State autonomy with Federal review will give States flexibility to develop plans based on local conditions, including industry organization, marketing patterns, and anticipated disease risks, while ensuring that the

State-developed control measures meet minimum standards for surveillance and emergency response.

The third component in the voluntary control program is active surveillance, based on testing of birds or eggs for breeding poultry and commercial table-egg layers and testing at the flock level or at slaughter for commercial meat-type chickens and meat-type turkeys, and conducted according to plans detailed in the regulations. The active surveillance program focuses on establishing that individual compartments are free of H5/H7 LPAI. The OIE defines a compartment as "one or more establishments under a common biosecurity management system containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade." For poultry types grown to produce eggs (breeding poultry and table-egg layers), the compartment level of organization is the flock. For poultry types grown to produce meat (meat-type chickens and meat-type turkeys), the compartment level of organization is the slaughter plant and all the flocks under the same ownership as or otherwise affiliated with the slaughter plant. (For information on affiliation with a slaughter plant, see the section headed "Administration" later in this document.)

In 9 CFR part 145, the Plan provides for a "U.S. Avian Influenza Clean" classification for table-egg layer breeding flocks, for meat-type chicken breeding flocks, and for waterfowl, exhibition poultry, and game bird breeding flocks. The Plan also provides for a "U.S. H5/H7 Avian Influenza Clean" classification for turkey breeding flocks. The "Clean" designation is used because these programs require testing of 30 birds per flock; these requirements are

sufficient to establish the flocks as free of AI (or, in the case of turkeys, H5/H7 AI) at a 95 percent confidence interval for a 10 percent infection rate.

Table-egg layer flocks, meat-type chicken and meat-type turkey slaughter plants, and States participating in the voluntary control program in 9 CFR part 146 may earn the "U.S. H5/H7 Avian Influenza Monitored" classification. In the case of table-egg layer and meat-type chicken flocks, the programs require testing of 11 birds per flock or per shift, which is sufficient to establish the flocks and slaughter plants as free of H5/H7 LPAI at a 95 percent confidence interval for a 25 percent infection rate, for any size group of birds. In the case of meat-type turkeys, fewer birds are tested, but the testing is concentrated on birds showing clinical symptoms consistent with H5/H7 LPAI. The higher infection rate targeted in the testing for commercial poultry is appropriate because, in practice, an H5/H7 LPAI infection in one bird in a commercial poultry flock would quickly spread to almost all the other birds in the flock.

The active surveillance programs for the NPIP apply only to the types of poultry cited above and only to flocks or slaughter plants that participate in the NPIP. In addition, for commercial poultry, a participating flock or slaughter plant is required to participate in the active surveillance program only if it is larger than a certain size standard. For table-egg layer flocks, the standard is 75,000 birds, which is consistent with the American Egg Board's definition of commercial egg producers. For meat-type chicken slaughter plants, the standard is slaughtering 200,000 meat-type chickens in an operating week, while for meat-type turkey slaughter plants, the standard is slaughtering 2 million meat-type turkeys in a 12-months period; both of these

⁵ See the Terrestrial Animal Health Code General Definitions at http://www.oie.int/eng/normes/mcode/en_chapitre_1.1.1.htm#terme_compartiment.

standards are consistent with Watt Publishing Companies' listing of commercial meat-type chicken and turkey slaughter operations, respectively.

Although we chose these size standards based on standard industry references, the purpose behind having size standards is to concentrate resources on testing flocks and slaughter plants that are associated with a relatively high percentage of the total U.S. population of commercial poultry of these types. Estimates indicate that the poultry associated with flocks and slaughter plants above these size standards comprise a very high percentage of the total number of commercial poultry:

- According to the American Egg Board, the top 260 table-egg layer producers own over
 3,000 flocks with 75,000 hens or more. Together, these flocks comprise approximately
 95 percent of all table-egg layers in the United States.
- According to Watt Publishing Companies, the top 20 U.S. meat-type chicken producers produce 91 percent of the entire U.S. production of chicken meat; these companies slaughter approximately 152.71 million birds a week. The next 20 companies slaughter approximately 17.5 million birds a week. Meat-type chicken slaughter plants owned by these companies slaughter well over 200,000 birds a week. The top 40 chicken companies in the United States produce close to 100 percent of the annual U.S. broiler meat production.
- According to Watt Publishing Companies, the top 27 meat-type turkey companies
 produce over 6992.9 million pounds of live weight turkey meat annually, approximately
 97 percent of US annual production of turkey meat. The slaughter plants owned by all of
 these 27 companies slaughter more than 2 million birds in a 12-month period.

By concentrating the active surveillance on such flocks and slaughter plants, we believe we will be employing the Federal, State, and industry resources that will be used to conduct this surveillance as effectively as possible. We invite comment from the public on whether these size standards and our use of them are appropriate.

Flocks and slaughter plants that participate in these programs thus can make statements about their freedom from H5/H7 LPAI. In addition, for table-egg layers and meat-type turkeys, a State can be declared a H5/H7 LPAI Monitored State with respect to those types of poultry if all large flocks or slaughter plants are participating in the relevant program in part 146 and certain other conditions are fulfilled. (No State-level program exists for meat-type chickens; we do not believe such a program is necessary.) Records of testing under the active surveillance programs will be made available for inspection by State and APHIS personnel.

The OIE guidelines also recommend that surveillance mechanisms be established for high-risk populations of poultry such as places where birds and poultry of different origins are mixed, such as live bird markets, and poultry in close proximity to waterfowl. These surveillance mechanisms are not part of this interim rule. However, it is important to note that these issues are addressed in other APHIS programs and activities. For example, in the live bird marketing system, 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. In addition, in spring 2006, under the interagency HPAI plan, the USDA and its cooperators planned to collect between 75,000 and 100,000 samples from live and dead wild birds in all States and 50,000 samples of water or feces from

high-risk waterfowl habitats across the United States for the purposes of AI surveillance. These programs are consistent with the OIE recommendation.

The program we are establishing is voluntary because some producers and some States may not wish to participate. Fulfilling the requirements of the program will entail some additional costs for producers and States. However, the incentives to participate are also considerable. Under this interim rule, APHIS is authorized to pay 100 percent indemnity for the destruction and disposal of poultry infected with or exposed to H5/H7 LPAI; 100 percent indemnity for the destruction of any eggs destroyed during testing of poultry for H5/H7 LPAI during an outbreak of H5/H7 LPAI; and 100 percent indemnity for cleaning and disinfecting premises, conveyances, and materials (or, in certain cases, for the destruction and disposal of materials) to most producers, including all participants in the voluntary control programs, provided that the State in which the outbreak occurs is a participant in the control program and has developed an initial State response and containment plan that has been approved by APHIS. For commercial poultry producers who do not choose to participate in the voluntary H5/H7 LPAI control programs in part 146, and for breeding poultry producers who participate in the Plan but do not participate in the AI control programs in part 145, this interim rule authorizes APHIS to pay indemnity for only 25 percent of the costs of those activities. (A detailed description of the conditions that would cause a producer to be eligible for 25 percent indemnity can be found later in this document under the heading "Payment of Indemnity.")

In addition, under this interim rule, APHIS is authorized to establish cooperative agreements with Cooperating State Agencies to pay for costs associated with the eradication of H5/H7 LPAI outbreaks and to transfer vaccine for H5/H7 LPAI for use by Cooperating State

Agencies in accordance with the initial State response and containment plan, as approved by APHIS. Costs that may be paid under a cooperative agreement include the cost of surveillance and monitoring associated with poultry that have been infected with or exposed to H5/H7 LPAI and the cost of vaccine administration by Cooperating State Agencies. APHIS is authorized to pay 100 percent of these costs to participating States and 25 percent of these costs to nonparticipating States.

All States with commercial poultry operations that meet the size standards of the control program we have developed currently participate in the NPIP for breeding poultry, and they are expected to participate in the program established by this interim rule. In addition, the State Poultry Executive Association has indicated that all State poultry associations strongly support the control program; the National Chicken Council, National Turkey Federation, United Egg Producers, and U.S. Poultry and Egg Association have indicated their strong support as well.

On the producer level, 100 percent of commercial table-egg layer chickens, meat-type chickens, and meat-type turkeys that meet the size standards of the control program we have developed are currently produced from breeding flocks that participate in the NPIP. Besides this natural link to the NPIP, and the indemnity incentives described earlier, another incentive for participation is the fact that participation in the H5/H7 LPAI control program has the potential to serve as a seal of approval for producers who wish to export their products to foreign markets; as discussed earlier in this document, countries modeling their regulations on the OIE guidelines may in the future establish requirements that poultry and poultry products originate from flocks in H5/H7 LPAI control programs. It is believed that the possible loss of export markets for nonparticipants in the event of an outbreak of H5/H7 LPAI, combined with the indemnity

incentives, will bring a very high percentage of the commercial poultry industry into the new voluntary program. We expect that at least 90 percent of commercial poultry operations that meet the size standards will participate. This is similar to the participation level in the current Plan programs for breeding flocks, in which we have a nearly 100 percent participation level from chicken and turkey companies. With the proposed surveillance levels, a 90 percent participation rate would accomplish the goals of the program. Outreach and education from NPIP office through the Official State Agencies will be necessary to maintain participation levels.

For these reasons, we do not believe that making the program voluntary will have an adverse effect on its ability to prevent outbreaks of H5/H7 LPAI within the United States; rather, we believe most commercial poultry producers and States with substantial commercial poultry industries will participate in the voluntary program, particularly given that on the State level the program allows for some flexibility. In addition, the diagnostic surveillance portion will allow for the detection of H5/H7 LPAI in any non-participating establishments.

As described, the voluntary control program established by this interim rule is consistent with the three key characteristics that a control program for H5/H7 LPAI in the commercial poultry industry should have, as identified at the May 2002 meeting:

- 1. Autonomy for the Official State Agency (the animal health authority in a particular State recognized by APHIS to cooperate in the administration of the Plan) wherever possible;
- 2. Federal review of surveillance and response measures at the State level; and
- 3. Voluntary participation for producers on a cooperative basis with State and Federal authorities.

<u>Differences Between This Approach and the Approach Used to Control LPAI Outbreaks in Virginia and Texas in 2002</u>

In 2002, nearly 4 million birds were depopulated under State and Federal authority in Virginia and Texas due to outbreaks of H7 LPAI (in Virginia) and H5 LPAI (in Texas). In order to provide an incentive for poultry owners and contract growers to participate in the depopulation effort, APHIS provided compensation to poultry owners and contract growers in Virginia in an interim rule published in the Federal Register on November 4, 2002, and made effective December 9, 2002 (67 FR 67089-67096, Docket No. 02-048-1). A subsequent final rule effective and published in the Federal Register on July 18, 2003 (68 FR 42565-42570, Docket No. 02-048-2) provided compensation to poultry owners and contract growers in Texas for the same costs for which Virginia poultry owners and contract growers were compensated in the November 2002 interim rule and adjusted the percentage of costs for which indemnity was provided to poultry owners in both States.

The specific provisions relating to these outbreaks established by the November 2002 interim rule and the July 2003 final rule in the general indemnity regulations in 9 CFR part 53 have been the only regulations in 9 CFR chapter I dealing specifically with compensation for outbreaks of H5 or H7 LPAI. Since the approach of the regulations we are establishing in 9 CFR part 56 differs in some respects from the approach of the regulations established by the November 2002 interim rule and the July 2003 final rule, we will discuss here how and why the approaches differ.

The November 2002 interim rule allowed for poultry owners to receive compensation for 50 percent of the costs they incurred related to destruction and disposal of birds affected by H5

or H7 LPAI, minus the amount paid in compensation to contract growers; the July 2003 final rule increased that amount to 75 percent. Under both rules, contract growers were eligible to receive indemnity for 100 percent of the costs they incurred; this compensation was subtracted from the compensation paid to the poultry owners. Costs eligible for indemnity under 9 CFR part 53 included the market value of the birds destroyed and the costs of destruction and disposal of animals and materials required to be destroyed to eradicate a disease and the cost of cleaning and disinfection of premises, conveyances, and materials. (While the regulations did not state this explicitly, compensation was paid for eggs destroyed during the Virginia and Texas LPAI outbreaks for testing for H5/H7 LPAI.)

Prior to the publication of this interim rule, any Federal indemnification relating to H5/H7 LPAI would have been paid under the authority of the general indemnity regulations in 9 CFR part 53; indemnity would have been provided in the context of a cooperative program with a State, and APHIS was authorized to provide indemnity for 50 percent of the above costs in accordance with § 53.2(b).

The new part 56 we are establishing will provide indemnity for the market value, destruction, and disposal of poultry that have been infected with or exposed to H5/H7 LPAI; the destruction of any eggs destroyed during an outbreak for testing for H5/H7 LPAI; and cleaning and disinfection of premises, conveyances, and materials that were 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, indemnity for the destruction and disposal of the materials. These costs are identical to the costs for which indemnity was provided for the LPAI outbreaks in Virginia and Texas.

However, the new part 56 also establishes mechanisms to address some additional costs not explicitly included in the indemnity provided for the outbreaks in Virginia and Texas. This interim rule also provides for the establishment of cooperative agreements with Cooperating State Agencies to pay for the costs of surveillance and monitoring, to transfer vaccine from APHIS to a State under certain controls, and to pay for vaccine administration associated with an outbreak. Although the November 2002 and July 2003 rules did not discuss the issue, the costs of surveillance and monitoring were also assumed by APHIS in the Virginia and Texas outbreaks; vaccination was not used in those control and eradication efforts.

Cooperative agreements established under this interim rule will provide for payment of the costs of surveillance and monitoring only as they relate to a specific disease outbreak. We are providing for the authority to pay the cost of surveillance and monitoring as they relate to a disease outbreak because we believe it is appropriate for APHIS to pay for actions undertaken at APHIS' direction to confirm successful eradication of an outbreak of H5/H7 LPAI.

Cooperative agreements established under this interim rule may also provide for the transfer of vaccine from APHIS to a State for disease control purposes, provided that the vaccine is transferred and used in accordance with a previously approved initial State response and containment plan, and provide for the payment to the States of the cost of administering the vaccine. Compared to the cost of depopulation of poultry, vaccination of poultry can be a more cost-effective method of controlling the spread of LPAI. (It should be noted that, under this interim rule, vaccination for H5/H7 LPAI may not be performed except as a disease control method after an outbreak has occurred.) For example, a table-egg layer can be vaccinated for AI with two inoculations at a total cost of 25 cents per bird. By comparison, the total cost to

APHIS, the Cooperating State Agency, and the poultry owner of depopulating and replacing a table-egg layer can reach \$10 per bird. Thus, for a typical 2-million-bird table-egg layer complex, the difference in cost between vaccination and depopulation could reach \$19.5 million. Therefore, we believe it is important to explicitly provide for both the transfer of vaccine and its administration, subject to appropriate controls, to ensure that this means of controlling the spread of LPAI is available to APHIS and to Cooperating State Agencies.

As noted previously, the new regulations in part 56 will provide for the authority to pay indemnity of 100 percent of eligible costs for most producers and will provide for the establishment of cooperative agreements with participating States through which States will be eligible to receive 100 percent of the costs covered under the cooperative agreements. We believe that providing for the payment of 100 percent of eligible costs, rather than 75 percent as in the July 2003 final rule, is appropriate because participants in the H5/H7 LPAI control program that this interim rule establishes 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.

While APHIS has recently provided funding to States for ongoing LPAI surveillance under cooperative agreements, these do not come close to covering the total State and industry cost of participation in the program; for example, the NPIP budgeted \$2 million in fiscal year 2006 for cooperative agreements with 24 States for LPAI surveillance in commercial poultry, but the State costs for surveillance for LPAI were reported to be \$15 million, while the industry costs

were reported to be \$25 million, based on the costs of the testing conducted in the NPIP. We expect that the States and industry would continue to bear most of the cost burden after the publication of this interim rule, as they have for the provisions of the NPIP relating to breeding poultry. Therefore, in the event of an outbreak, it is appropriate to indemnify participating owners of commercial poultry flocks that meet certain size standards for the full amount of the costs that are eligible for indemnity and that are associated with the outbreak and to pay for the full amount of costs that Cooperating State Agencies incur in eradicating the outbreak.

The interim rule also provides for the authority to pay 100 percent indemnity to owners of flocks that do not meet these size standards, regardless of whether these smaller flocks are participating in the NPIP. We believe that providing for the payment of 100 percent of eligible costs to all flock owners is appropriate because the OIE now lists all H5 and H7 AI viruses, both LPAI and HPAI, as serious diseases that are required to be reported by member countries. In essence, the premise of the OIE guidelines is that, because H5/H7 LPAI has the potential to mutate into HPAI, it should be treated very similarly to HPAI by member countries. Therefore, we believe that it is consistent to provide for payment of 100 percent indemnity for costs associated with H5/H7 LPAI to large commercial poultry producers and breeding poultry producers who participate in the voluntary control program, all small poultry producers, and participating States, as we do for costs associated with HPAI under the general indemnity regulations in § 53.2(b). Given expected participation rates, this will mean that 100 percent indemnity will be available for almost all producers and States. Providing indemnity for 25 percent of associated costs for the small number of commercial poultry producers and States who do not participate in the Plan and breeding poultry producers who participate in the Plan but not

in its AI programs serves to encourage participation in the voluntary control program, whose surveillance requirements are consistent with the OIE guidelines.

Finally, the indemnity regulations established in this interim rule also provide for the distribution of payments between producers and contract growers. The distribution of payments provided for in this interim rule is similar to the one APHIS used to distribute indemnity that was paid to producers and contract growers due to LPAI outbreaks in Virginia and Texas in 2002. This will help ensure full participation by contract growers in the diagnostic surveillance program described later in this document. This formula is described in detail under the heading "Conditions For Payment" later in this document.

Prior to the publication of this interim rule, 9 CFR part 53 still contained indemnity provisions relating to the LPAI outbreaks in Virginia and Texas in 2002. We have paid all the indemnity claims related to these incidents that we anticipate paying. To update the regulations, this interim rule removes the indemnity provisions relating to the LPAI outbreaks in Virginia and Texas in 2002 from 9 CFR part 53.

Section-by-Section Explanation of New Parts 146 and 56

In this interim rule, in a new part 146, we are providing for the establishment of active and diagnostic surveillance programs for commercial table-egg layers, meat-type chickens, and meat-type turkeys; these programs will be developed by each participating State and approved by APHIS. Participating commercial table egg-layer, meat-type chicken, and meat-type turkey flocks may earn the classification "U.S. H5/H7 Avian Influenza Monitored." States participating in the active surveillance programs may also earn the classification "U.S. H5/H7 Avian Influenza Monitored State" with respect to commercial table-egg layers and meat-type turkeys. (As

discussed earlier in this document, the AI programs in 9 CFR part 145 for table-egg layer, meat-type chicken, and waterfowl, exhibition poultry, and game bird breeding flocks provide the classification "U.S. Avian Influenza Clean," and the AI program for turkey breeding flocks provides the classification "U.S. H5/H7 Avian Influenza Clean." Currently, the NPIP contains no State classifications relating to AI for breeding poultry.) The new part 146 also contains specific requirements for collecting samples to test for AI and guidelines for States to use in establishing a diagnostic surveillance program.

Where possible, the language and structure of new 9 CFR part 146 is modeled on that of 9 CFR part 145, which, as noted above, contains the provisions of the NPIP that apply to breeding poultry. The NPIP provisions in part 145 are well established and familiar to many poultry producers, and we believe that modeling the new part 146 on part 145 will enhance the effectiveness of the new Plan provisions for commercial poultry. We have not included provisions from part 145 that are not relevant to commercial poultry in the new part 146.

The new part 56 provides for the payment of indemnity in the event of an H5/H7 LPAI outbreak and for the establishment of cooperative agreements between APHIS and Official State Agencies to control H5/H7 outbreaks. It also sets out requirements for determining the value of destroyed poultry and eggs, for cleaning and disinfecting affected premises, for presenting claims, for distribution of payments, and for developing an initial State response and containment plan.

The provisions of part 146 provide for testing and diagnostic surveillance in commercial table-egg layers, meat-type chickens, and meat-type turkeys. Part 56 includes those poultry in its provisions for eradication of H5/H7 LPAI and payment of indemnity, and many of the provisions

of part 56 refer to provisions of part 146, such as the State diagnostic surveillance plan for all poultry in the State or the active surveillance programs for commercial poultry.

However, because part 56 is intended first and foremost to allow APHIS to pay indemnity to help eradicate outbreaks of H5/H7 LPAI, the regulations in part 56 allow us to pay indemnity to owners of breeding poultry and both commercial and non-commercial poultry, such as poultry grown for live bird markets. This represents a change from the indemnity provisions developed at the July 2004 NPIP meeting, but we expect that it will be necessary to pay indemnity for all types of poultry in order to eradicate H5/H7 LPAI outbreaks.

As explained later in this document (see the section titled "Payment of Indemnity" below), commercial producers that are above certain size standards will still have an indemnity-based incentive to participate in the NPIP provisions in part 146, and they will still be eligible to receive 100 percent indemnity if they do.

The specific provisions of parts 146 and 56 are discussed in more detail below.

Control Program Provisions in 9 CFR Part 146

Definitions

Section 146.1 sets out definitions for the terms <u>Administrator</u>, <u>Animal and Plant Health</u>

<u>Inspection Service (APHIS)</u>, <u>Authorized Agent</u>, <u>authorized laboratory</u>, <u>Department</u>,

<u>domesticated</u>, <u>equivalent</u>, <u>Official State Agency</u>, <u>person</u>, <u>Plan</u>, <u>program</u>, <u>Service</u>, and <u>State</u>

<u>Inspector</u> that are substantively identical to the definitions of those terms in § 145.1. In addition, § 146.1 sets out definitions of <u>State</u> and <u>United States</u> that are drawn directly from the Animal Health Protection Act.

The other definitions below are new in part 146. For the convenience of the reader, we have set out the definitions of <u>Official State Agency</u> and <u>Plan</u> below.

Affiliated flock. A meat-type flock that is owned by or has an agreement to participate in the Plan with a slaughter plant and that participates in the Plan through that slaughter plant.

For meat-type poultry, the control program in part 146 is organized around the participation of slaughter plants, which typically own the flocks that are slaughtered at the plants. Affiliation with a slaughter plant through an agreement can be a way for a flock not owned by a slaughter plant to participate in the Plan. This issue is discussed in more detail under the heading "Participation" later in this document.

<u>Classification</u>. A designation earned by participation in a Plan program.

<u>Commercial meat-type flock</u>. All of the meat-type chickens or meat-type turkeys on one farm. However, at the discretion of the Official State Agency, 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 may be considered as a separate flock.

We are allowing for groups of meat-type poultry to be considered separate flocks if they have been segregated from other poultry on the farm for 21 days in case H5/H7 LPAI infects one group of poultry on a farm but not another one, and the Official State Agency determines that biological security measures sufficient to prevent the transmission of H5/H7 LPAI in place were adequate to prevent the transmission of H5/H7 LPAI between the two groups. (The H5 and H7 subtypes of LPAI can in some cases have low enough virulence to make such measures practical, although final judgment is up to the Official State Agency.) The 21-day period is consistent with the new OIE guidelines regarding NAI discussed earlier in this document. This provision will

allow the number of meat-type poultry that would be depopulated in the case of an H5/H7 LPAI outbreak to be kept to a minimum if possible.

<u>Commercial table-egg layer flock</u>. All table-egg layers of one classification in one barn or house.

<u>Commercial table-egg layer premises</u>. A farm containing contiguous flocks of commercial table-egg layers under common ownership.

The regulations address commercial table-egg layers on the premises level because a single commercial table-egg layer premises typically contains several poultry houses with flocks of different ages.

H5/H7 low pathogenic avian influenza (LPAI). An infection of poultry caused by an influenza A virus of H5 or H7 subtype that has an intravenous pathogenicity index test in 6-week-old chickens less than 1.2 or any infection with influenza A viruses of H5 or H7 subtype for which nucleotide sequencing has not demonstrated the presence of multiple basic amino acids at the cleavage site of the hemagglutinin.

H5/H7 LPAI virus infection (infected). Poultry will be considered to be infected with H5/H7 LPAI for the purposes of part 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
- 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.

The definitions of H5/H7 LPAI and H5/H7 LPAI infection thus provide specific criteria for determining whether a bird is infected with H5/H7 LPAI. With one exception they are consistent with the OIE guidelines regarding NAI that were discussed earlier in this document. The OIE definition of NAI, which includes both HPAI and H5/H7 LPAI, mentions detecting the virus or viral antigens or RNA in products derived from poultry. However, only HPAI virus has been found in products derived from poultry; research indicates that live LPAI virus is not found in poultry meat or from other products derived from poultry. Therefore, we have not included that part of the OIE definition in our definition of H5/H7 LPAI infection.

Official State Agency. The State authority recognized by the Department to cooperate in the administration of the Plan.

Plan. The provisions of the National Poultry Improvement Plan contained in part 146.

<u>Poultry</u>. Domesticated chickens and turkeys that are bred for the primary purpose of producing eggs or meat.

The definition of <u>poultry</u> is similar to the definitions of that term in § 145.1 but has been adapted to refer specifically to the types of poultry included in part 146.

Administration

⁶ See David E. Swayne and Joan R. Beck, "Experimental Study to Determine if Low-Pathogenicity and High-Pathogenicity Avian Influenza Viruses Can Be Present in Chicken Breast and Thigh Meat Following Intranasal Virus Inoculation," <u>Avian Diseases</u> 49:81-85, 2005.

Section 146.2 sets out the conditions under which the provisions of part 146 are administered. These conditions are substantively identical to those under which the Plan's provisions in part 145 for breeding poultry are administered; we believe they will be effective for commercial poultry as well.

Paragraph (a) of this section states that the Department cooperates through a Memorandum of Understanding with Official State Agencies in the administration of the Plan.

Paragraph (b) of this section states that the administrative procedures and decisions of the Official State Agency are subject to review by the Service (i.e., APHIS) and that the Official State Agency shall carry out the administration of the Plan within the State according to the applicable provisions of the Plan and the Memorandum of Understanding.

Paragraph (c)(1) of this section allows an Official State Agency to accept for participation a commercial table-egg layer flock or a commercial meat-type flock (including an affiliated flock) located in another participating State under a mutual understanding and agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision. If a flock is located in a State that does not participate in the Plan, paragraph (c)(2) provides that such a flock may participate with a participating State under a mutual understanding and agreement, in writing, between the owner of the flock and the Official State Agency regarding conditions of participation and supervision. These provisions ensure that flocks are able to participate in the Plan in States other than the State in which they are located when such participation is desirable to facilitate participation in the Plan. In particular, these provisions allow affiliated flocks that are located in a State other than the one in which the

slaughter plant with which they are participating is located to participate in the Plan in the State in which the slaughter plant is located.

The Plan does not provide for slaughter plants to participate in a State other than the State in which they are located, because the sample collection that may take place at slaughter plants must be overseen by the local Official State Agency.

Paragraph (d) of this section allows the Official State Agency of any State to adopt regulations applicable to the administration of the Plan in that State that further define the provisions of the Plan or establish higher standards that are compatible with the Plan.

Paragraph (e) of this section requires that an authorized laboratory of the NPIP follow the laboratory protocols outlined in 9 CFR part 147 when determining the status of a participating flock with respect to an official Plan classification.

Paragraph (f) of this section states that the Official State Agency will be responsible for making the determination to request Federal assistance under 9 CFR part 56 in the event of an outbreak of H5/H7 LPAI. While the provisions of 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 (and described in further detail later in this document) 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 regulations in 9 CFR part 56, by contrast, provide that APHIS may pay indemnity for destroyed birds and eggs and for certain other activities; because indemnity may be paid from Federal funds under these regulations, all actions taken under part 56 are subject to APHIS review and approval. Given this administrative structure, some Official State Agencies

may prefer to eradicate outbreaks of H5/H7 LPAI without invoking APHIS assistance when it is feasible for them to do so. With this provision and a similar provision in § 56.2(c), the new H5/H7 LPAI control and indemnity regulations allow for this flexibility. If a State decides that APHIS assistance is necessary, we will support that State to the greatest extent our resources allow.

Participation

Section 146.3 sets out the conditions under which commercial table-egg producers and commercial meat-type chicken and meat-type turkey flocks and slaughter plants may participate in the Plan. These provisions ensure that participants in the Plan comply with Plan requirements.

For commercial meat-type chickens and meat-type turkeys, the control program in part 146 is organized around the participation of slaughter plants. This is because slaughter plants for commercial meat-type chickens and meat-type turkeys are typically owned by the same entity that owns the birds themselves. Thus, when slaughter plants participate in the Plan, the owners of those slaughter plants are able to ensure that the flocks from which meat-type chickens and meat-type turkeys are sent to the slaughter plants meet the testing requirements of the control program. Under the surveillance programs for meat-type chickens and meat-type turkeys, slaughter plants have the option to conduct surveillance either at the slaughter plant or in the flocks that will eventually be sent to the slaughter plant.

Independently owned meat-type flocks may participate in the Plan by becoming affiliated with a slaughter plant that participates in the Plan. Owners of independently owned flocks participating in this manner would have to either allow surveillance to be conducted at the

slaughter plant or conduct surveillance themselves in the flocks, depending on how the slaughter plant participates in the Plan.

Since commercial table-egg layers are organized for production purposes at the flock level, the control program provides for their participation at the flock level.

Paragraph (a) of this section states that any table-egg producer and any meat-type chicken or meat-type turkey producer or slaughter plant may participate in the Plan when the producer or plant has demonstrated, to the satisfaction of the Official State Agency, that its facilities, personnel, and practices are adequate for carrying out the relevant special provisions of this part and has signed an agreement with the Official State Agency to comply with the relevant special provisions in subparts B, C, or D of part 146. (We use the phrase "relevant special provisions" because some commercial poultry flocks and slaughter plants that may participate in the Plan are not required to comply with the special provisions due to size requirements. These provisions are discussed in greater detail later in this document.)

Paragraph (b) of this section requires that each participant comply with the Plan throughout the operating year, or until released by the Official State Agency.

Paragraph (c) of this section requires that a participating slaughter plant participate with all of the meat-type chicken and/or meat-type turkey flocks that are processed at the facility, including affiliated flocks. Only if all the flocks participating at a slaughter plant have been produced under Plan-approved biosecurity controls and surveillance programs can the plant be considered to be participating in the Plan, according to the OIE guidelines. It also requires that affiliated flocks participate through a written agreement with a participating slaughter plant that is approved by the Official State Agency. This requirement ensures that the Official State

Agency is aware of all the flocks participating with any slaughter plant and has an opportunity to approve the terms of their participation.

Paragraph (d) of this section states that participation in the Plan shall entitle the participant to use the Plan participant emblem. The Plan participant emblem is often used as a marketing tool by participants, so it is important to include a statement in the regulations specifically allowing its use only by Plan participants.

Paragraph (e) of this section states that participation in the NPIP by commercial table-egg layers is limited to 2 years after the effective date of this interim rule unless the majority of the commercial table-egg layer delegates vote to continue the program in accordance with subpart E of 9 CFR part 147 at the National Plan Conference. We have included this provision because, at the July 2004 NPIP meeting in San Francisco, CA, the commercial table-egg layer industry indicated that it wanted to make its participation in the Plan conditional. If that industry decides at a National Plan Conference after the publication of this interim rule that it wants to continue its participation in the NPIP, we will remove paragraph § 146.3(e) from the regulations. If that industry decides that it does not want to continue its participation, we will amend part 146 to remove the special provisions for table-egg layers in subpart B of that part and will remove references to table-egg layers in subpart A. We would then evaluate the available regulatory options to ensure that the voluntary control program could continue to provide an adequate level of surveillance for H5/H7 LPAI.

General Provisions for All Participating Flocks and Slaughter Plants

Section 146.4 sets out general provisions with which all flocks and slaughter plants that participate in the Plan must comply.

Paragraph (a) of this section requires that records that establish the identity of products handled be maintained in a manner satisfactory to the Official State Agency. Adequate recordkeeping will allow any necessary investigations to be conducted more efficiently.

Paragraph (b) of this section states that material that is used to advertise products shall be subject to inspection by the Official State Agency at any time. Paragraph (c) states that advertising must be in accordance with the Plan and applicable rules and regulations of the Official State Agency and the Federal Trade Commission. Paragraph (c) further states that a participant advertising products as being of any official classification may include in their advertising reference to associated or franchised slaughter or production facilities only when such facilities produce products of the same classification. These provisions ensure that Plan participation is not misrepresented for marketing purposes.

Paragraph (d) states that each Plan participant shall be assigned a permanent approval number by APHIS. This number, prefaced by the numerical code of the State, will be the official approval number of the participant and may be used on each certificate, invoice, shipping label, or other document used by the participant in the sale of the participant's products. Each Official State Agency which requires an approval number for out-of-State participants to ship into its State shall honor this number. The assignment of a permanent approval number helps in tracking Plan participation. In addition, the requirement that Official State Agencies honor the permanent approval numbers assigned to participants when administering State import requirements helps simplify the interstate movement process for producers.

Specific Provisions for Participating Flocks

Section 146.5 requires that:

- Participating flocks, and all equipment used in connection with the flocks, be separated from non-participating flocks in a manner acceptable to the Official State Agency; and
- Poultry equipment, and poultry houses and the land in the immediate vicinity thereof, be
 kept in sanitary condition as recommended in § 147.21(c).

These requirements are similar to requirements in § 145.5(a). The provision requiring that participating flocks be separated from non-participating flocks ensures that participating flocks are not subject to the higher risks of disease presence associated with non-participating flocks. The requirement that poultry equipment, and poultry houses and the land in the immediate vicinity thereof, be kept in sanitary condition will help to mitigate any risks of disease for participating flocks.

Specific Provisions for Participating Slaughter Plants

Section 146.6 sets out specific provisions for participating slaughter plants. These provisions are:

- Only meat-type chicken and meat-type turkey slaughter plants that are under continuous
 inspection by the Food Safety and Inspection Service of the U.S. Department of
 Agriculture or under State inspection that the Food Safety Inspection Service has
 recognized as equivalent to federal inspection may participate in the Plan.
- To participate in the Plan, meat-type chicken and meat-type turkey slaughter plants must follow the relevant special provisions for sample collection and flock monitoring in §§ 146.33(a) and 146.43(a), respectively, unless they are exempted from the special provisions under §§ 146.32(b) or 146.42(b), respectively. The specific provisions require routine monitoring for H5/H7 LPAI of all flocks slaughtered at the slaughter plants.

Testing for meat-type chickens and meat-type turkeys may be performed either at the slaughter plant or at the flock level. As discussed earlier in this document, slaughter plants for commercial meat-type chickens and meat-type turkeys are typically owned by the same entity that owns the birds themselves; thus, when slaughter plants participate in the Plan, the owners of those slaughter plants are able to ensure that the flocks from which meat-type chickens and meat-type turkeys are sent to the slaughter plants meet the testing requirements in §§ 146.33(a) and 146.43(a). Affiliated flocks that are not owned by the slaughter plant with which they participate will agree on how testing is to be conducted in the written agreement between the affiliated flock and the slaughter plant. On the other hand, table-egg layers are tested at the flock level either within 30 days of disposal or once every 12 months. (The provisions for monitoring of table-egg layer flocks are described in more detail under the heading "Subpart B-Special Provisions for Commercial Table-Egg Layer Flocks" later in this document.)

Terminology and Classification

Section 146.7 states that classification terms and illustrative designs associated with those terms may only be used by participants in the Plan and may only be used to describe products that have met all the specific requirements of those classifications. Section 146.8 states that participating slaughter plants shall be designated as "U.S. H5/H7 Avian Influenza Monitored," and all Official State Agencies shall be notified by APHIS of additions, withdrawals, and changes in classification. Section 146.9 sets out the various classifications that may be earned by participating flocks (including affiliated flocks), products produced from those flocks, and States, and provides illustrative designs corresponding to those classifications that may be used by those

flocks and States. The organization, language, and designs in these sections are modeled on those contained in similar provisions in §§ 145.8 through 145.10.

The specific testing requirements for each type of poultry in 9 CFR part 146 are discussed in detail later in this document.

Supervision

Section 146.10 authorizes the Official State Agency to designate qualified persons as Authorized Agents to do the sample collecting provided for in § 146.13, which sets out sample collection procedures for the blood test for AI. It also states that the Official State Agency may employ or authorize qualified persons as State Inspectors to perform the selecting and testing of participating flocks and to perform the official inspections necessary to verify compliance with the requirements of the Plan. Under this section, the authorities issued to Authorized Agents and State Inspectors are subject to cancellation by the Official State Agency on the grounds of incompetence or failure to comply with the provisions of the Plan or regulations of the Official State Agency. Such actions shall not be taken until thorough investigation has been made by the Official State Agency and the authorized person has been given notice of the proposed action and the basis thereof and an opportunity to present his or her views. These provisions allow the Official State Agency to designate persons to administer the various provisions of the Plan and to withdraw that designation on the grounds of incompetence or failure to comply with the provisions of the Plan or regulations of the Official State Agency.

<u>Inspections</u>

All slaughter plants and flocks of commercial poultry that participate in the Plan must comply with the inspection requirements of § 146.11. The requirements are:

- Each participating slaughter plant shall 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.
- On-site inspections of flocks and premises will be conducted if a State Inspector determines that a breach of testing has occurred for the Plan programs for which the flocks are certified.
- The official H5/H7 LPAI testing records of all participating flocks and slaughter plants shall be examined annually by a State Inspector. Official H5/H7 LPAI testing records shall be maintained for 3 years.

Compliance with these auditing and inspection requirements will serve to establish that the participating flock or slaughter plant is complying with the surveillance requirements of the Plan. These requirements are also important because, as discussed earlier in this document, participating table-egg layer premises with fewer than 75,000 birds and participating slaughter plants that slaughter fewer than 200,000 meat-type chickens per week or 2 million meat-type turkeys per year are exempt from the special provisions, including the active surveillance requirements, for table-egg layer premises, meat-type chicken slaughter plants, and meat-type turkey slaughter plants in subparts B, C, and D, respectively, of part 146. However, participating table-egg layer premises with fewer than 75,000 birds and participating slaughter plants that slaughter fewer than 200,000 meat-type chickens per week or 2 million meat-type turkeys per year must be audited and, if necessary, inspected according to this section in order to participate in the Plan, which will help to ensure that they are complying with the requirements of subpart A of part 146.

Debarment From Participation

Section 146.12 describes the procedures by which participants in the Plan may be debarred from participation. Under this section, participants in the Plan who, after investigation by the Official State Agency or its representative, are notified in writing of their apparent noncompliance with the Plan provisions or regulations of the Official State Agency shall be afforded a reasonable time, as specified by the Official State Agency, within which to demonstrate or achieve compliance. If compliance is not demonstrated or achieved within the specified time, the Official State Agency may debar the participant from further participation in the Plan for such period, or indefinitely, as the Official State Agency may deem appropriate. The debarred participant shall be afforded notice of the bases for the debarment and opportunity to present his or her views with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order, requests the Administrator of APHIS to determine the eligibility of the debarred participant for participation in the Plan. In such an event, the Administrator shall determine the matter de novo in accordance with the rules of practice in 7 CFR part 50.

Testing

Section 146.13 sets out requirements relating to testing samples for H5/H7 LPAI. Either egg yolk or blood samples may be used for testing.

Paragraph (a) of this section contains requirements for sample collection and preparation.

Paragraph (a)(1) requires that egg yolk samples be collected and prepared in accordance with the

requirements in § 147.8. Prior to the publication of this interim rule, § 147.8, "Procedures for preparing egg yolk samples for diagnostic tests," had referred only to testing for Mycoplasma gallisepticum and M. synoviae. We believe the procedures for preparation of egg yolk samples in this section will work equally well for preparing egg yolk samples for testing for H5/H7 LPAI. Accordingly, we are amending the introductory text of § 147.8 to indicate that the procedure may be used for preparing samples for testing for the U.S. H5/H7 AI Monitored Classifications in part 146. We are also amending paragraph (b)(7) of that section to indicate that subsequent testing for H5/H7 LPAI must be performed in accordance with the requirements in paragraph (b) of § 146.13.

Paragraph (a)(2) contains specific requirements for collection and storage of blood samples to be tested for LPAI, including when and how blood should be collected from birds, when and how the sample should be refrigerated, and what measures should be taken to ensure that the sample can be reliably tested. It also states that blood samples must be drawn by an Authorized Agent or State Inspector, as designated in accordance with § 146.10. The details of these requirements are set out in the rule portion of this document.

Paragraph (b) of § 146.13 sets out the requirements for testing for AI. Under this paragraph, the official tests for AI are the agar gel immunodiffusion (AGID) test and the enzyme-linked immunosorbent assay (ELISA). Both tests can be used on either egg yolk or blood samples. The procedures for testing for avian influenza using AGID and ELISA are set out in § 147.9.

The ELISA, a rapid, sensitive test, is typically used to perform initial testing on samples.

Any samples that are found to be positive using ELISA must be confirmed using the AGID test,

which is more time-consuming but provides more accurate results. Any samples that are found to be positive by AGID must be further tested and subtyped by Federal Reference Laboratories using the hemagglutination inhibition test, which can provide a definitive diagnosis. Final judgment as to whether a sample is positive for H5/H7 LPAI may be based upon further sampling or culture results. The official determination of a flock as positive for H5/H7 LPAI may be made only by the National Veterinary Services Laboratories in Ames, IA (NVSL).

The AGID and ELISA tests must be conducted using antigens or test kits approved by APHIS. Test kits must be licensed by APHIS and approved by the Official State Agency and must be used in accordance with the recommendations of the producer or manufacturer.

Diagnostic Surveillance Program for H5/H7 LPAI

Section 146.14 provides for the diagnostic surveillance program mentioned above under the heading "Overall Approach of Voluntary Control and Indemnity Program." It requires the Official State Agency to develop a diagnostic surveillance program for H5/H7 LPAI for all poultry (not just commercial poultry) in the State. The exact provisions of the program are at the discretion of the States. APHIS will use the standards below in assessing individual State plans for adequacy, including the specific provisions that the State developed. The standards should be used by States in developing those plans.

The regulations in this section require that AI 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/H7 LPAI directly to APHIS) 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.

We believe any plan that adequately fulfills these guidelines will ensure that possible infections of H5/H7 LPAI are promptly reported to responsible State authorities, which can then take any further action that may be required.

The diagnostic surveillance plan performance standards specifically mention that H5/H7 LPAI should be reported directly to APHIS. APHIS is the governmental organization authorized to represent the United States to the OIE; we have included this provision to ensure that only APHIS, rather than any individual State, makes a report of H5/H7 LPAI to the OIE.

Subpart B–Special Provisions for Commercial Table-Egg Layer Flocks

Subpart B (§§ 146.21 through 146.24) of part 146 provides special provisions of the Plan with which participating table-egg layer flocks and States must comply in order to be eligible for the U.S. Avian Influenza Monitored classification.

Section 146.21, "Definitions," sets out a definition of <u>table-egg layer</u> that reads: "A domesticated chicken grown for the primary purpose of producing eggs for human consumption."

Section 146.22, "Participation," states that participating flocks of table-egg layers must comply both with the applicable general provisions of subpart A of part 146 and the special

provisions of subpart B of part 146. However, the section exempts participating table-egg laying premises with fewer than 75,000 birds from the special provisions of subpart B.

Section 146.23, "Terminology and classification; flocks and products," sets out the active surveillance requirements for participating commercial table-egg layer flocks. The active surveillance requirements in § 146.23(a) are intended for table egg-laying premises of 75,000 birds or more. However, producers of smaller table-egg layer flocks may wish to participate in the NPIP to use its seal of approval as a marketing tool. Therefore, smaller table-egg layer flocks are eligible to participate in the NPIP. We believe that diagnostic surveillance in accordance with § 146.14 and inspections in accordance with § 146.11, which are required in the general provisions in subpart A, are adequate to determine whether H5/H7 LPAI is present on such premises.

The indemnity provisions we are establishing in part 56 provide authority to pay indemnity for only 25 percent of costs to any table-egg layer premises that has 75,000 or more birds and that does not participate in the active surveillance described in § 146.23(a). As discussed earlier, the 75,000-bird standard is consistent with the American Egg Board's definition of commercial egg producers and will concentrate resources on testing flocks that comprise a relatively high percentage of the total U.S. population of commercial table-egg layers.

Under paragraph (a) of § 146.23, a table egg-layer flock is eligible for the U.S. H5/H7 Avian Influenza Monitored designation if it meets one of the following requirements:

- \$ It is a table-egg layer flock in which a minimum of 11 birds or egg samples from the same flock have been tested negative for antibodies to the H5/H7 subtypes of avian influenza within 30 days prior to disposal;
- \$ It is a table-egg layer flock in which a minimum of 11 birds or egg samples from the same flock have been tested negative for antibodies to the H5/H7 subtypes of avian influenza within a 12-month period; or
- \$ The flock has an ongoing active and diagnostic surveillance program for H5/H7 LPAI in which the number of birds or egg samples tested is equivalent to the number required by one of the first two options. Such a program must be approved by the Official State Agency and APHIS.

Both of the first two testing requirements are sufficient to establish commercial table-egg layer flocks as free of H5/H7 LPAI at a 95 percent confidence interval for a 25 percent infection rate, and both are consistent with the new OIE guidelines for surveillance of NAI that were discussed earlier in this document. These testing requirements are designed to ensure that participating flocks are tested at least once each operating year. Most laying flocks are in lay for almost 2 years and are then disposed of; the first testing requirement ensures that if a participating flock is tested once and then disposed of prior to the passing of a second 12-month period, it will be tested again prior to disposal.

⁷ This plan, as well as the plans for meat-type chickens and meat-type turkeys discussed later in this document, was developed in accordance with the OIE guidelines in the Terrestrial Animal Health Code Chapter 3.8.9, "Guidelines for surveillance of avian influenza," and in accordance with Dr. Victor Beal's reference <u>Regulatory Statistics</u> (sixth edition, June 1983). For details of the testing plan, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

Any ongoing active and diagnostic surveillance program that is approved by the Official State Agency and APHIS would have to test a number of birds or egg samples equivalent to the other two options, but this by itself would not be sufficient to secure approval for the program; the Official State Agency and APHIS would have to agree that the detailed testing plan for the alternate program is sufficient to establish a level of confidence for the detection of AI that is equivalent to that of the other two options. Allowing owners of participating flocks to develop an alternative ongoing active and diagnostic surveillance program of equivalent efficacy will give the flock owners some flexibility.

Section 146.24, "Terminology and classification; States," sets out the requirements for States to be eligible for the U.S. H5/H7 Avian Influenza Monitored State, Layers classification. These requirements are contained in paragraph (a)(1) of § 146.24. The requirements are:

- \$ All table-egg layer flocks in production within the State that are not exempt from the special provisions of subpart B under § 146.22 are classified as U.S. H5/H7 Avian Influenza Monitored under § 146.23(a);
- \$ All egg-type chicken breeding flocks in production within the State are classified as U.S. Avian Influenza Clean under § 145.23(h);
- \$ All persons performing poultry disease diagnostic service within the State must be required to report to the Official State Agency, within 24 hours, the source of all table-egg layer specimens that were deemed positive on an official test for AI, as designated in § 146.13(a);
- \$ All table-egg layer specimens that were deemed positive on an official test for AI, as designated in § 146.13(a) must be sent to an authorized laboratory for subtyping; and

- \$ All table-egg layer flocks within the State found to be infected with H5/H7 LPAI must be quarantined, in accordance with an initial State response and containment plan as described in 9 CFR part 56 and under the supervision of the Official State Agency.

 APHIS may revoke this classification if:
- \$ There is a discontinuation of any of the above conditions;
- \$ Repeated outbreaks of H5/H7 LPAI occur in table-egg layer flocks; or
- \$ An infection spreads from the originating premises.

APHIS will not revoke a classification until a thorough investigation has been made by APHIS and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator, as described in § 146.12. (The language governing revocation of classification is similar to language used to describe revocation of State classifications in part 145.)

It should be noted that participation in the U.S. H5/H7 Avian Influenza Monitored State, Layers program is not a precondition for State participation in the Plan; rather, it is an optional program that States may pursue if an Official State Agency and the table-egg layer owners in that State wish to use the designation of U.S. H5/H7 Avian Influenza Monitored State, Layers. Subpart C–Special Provisions for Meat-Type Chicken Slaughter Plants

Subpart C (§§ 146.31 through 146.33) of part 146 provides special provisions of the Plan with which participating meat-type chicken slaughter plants must comply in order to be eligible for the U.S. H5/H7 Avian Influenza Monitored classification. We do not believe it is necessary to provide for a U.S. H5/H7 Avian Influenza Monitored State classification for meat-type chickens at this time. However, 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.

Section 146.31, "Definitions," sets out a definition of <u>meat-type chicken</u> that reads: "A domesticated chicken grown for the primary purpose of producing meat, including but not limited to broilers, roasters, fryers, and cornish" and a definition of <u>meat-type chicken slaughter plant</u> that reads: "A meat-type chicken slaughter plant that is federally inspected or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection." It also defines <u>shift</u> as: "The working period of a group of employees who are on duty at the same time."

Section 146.32, "Participation," states that participating meat-type chicken slaughter plants shall comply with applicable general provisions of subpart A of part 146 and the special provisions of subpart C. However, the section exempts participating meat-type chicken slaughter plants that slaughter fewer than 200,000 meat-type chickens in an operating week from the special provisions of subpart C.

Section 146.33, "Terminology and classification; meat-type chicken slaughter plants," sets out the active surveillance requirements for participating commercial meat-type chicken slaughter plants. The active surveillance requirements in § 146.33 are intended for meat-type chicken slaughter plants that slaughter 200,000 or more meat-type chickens in an operating week. However, smaller meat-type chicken slaughter plants are eligible to participate in the NPIP. We believe that diagnostic surveillance in accordance with § 146.14 and inspections in accordance with § 146.11, which are required in the general provisions in subpart A, are adequate to determine whether H5/H7 LPAI is present on such premises.

The indemnity provisions we are establishing in part 56 provide authority to pay indemnity for only 25 percent of costs to owners of meat-type chicken flocks that participate in the Plan through a meat-type chicken slaughter plant that slaughters 200,000 or more meat-type chickens in an operating week and that does not participate in the active surveillance described in § 146.33(a). As discussed earlier, the standard of slaughtering 200,000 or more meat-type chickens in an operating week is consistent with Watt Publishing Companies' listing of commercial meat-type chicken slaughter operations and will concentrate resources on testing meat-type chickens associated with slaughter plants that slaughter a relatively high percentage of the total U.S. population of commercial meat-type chickens.

Under paragraph (a) of § 146.33, a meat-type chicken slaughter plant is eligible for the U.S. H5/H7 Avian Influenza Monitored designation if it meets one of the following requirements:

- \$ A minimum of 11 birds per shift are tested negative for antibodies to H5/H7 LPAI at slaughter. However, with the approval of the Official State Agency, fewer than 11 birds per shift may be tested for any given shift if the total number of birds tested during the operating month is equivalent to testing 11 birds per shift;
- \$ The plant accepts only meat-type chickens from flocks where a minimum of 11 birds have been tested negative for antibodies to H5/H7 LPAI no more than 21 days prior to slaughter; or
- \$ The plant has an ongoing active and diagnostic surveillance program for H5/H7 LPAI in which the number of birds tested is equivalent to the number required by one of the first two options. Such a program must be approved by the Official State Agency and APHIS.

Both of the first two of these testing requirements are sufficient to establish the commercial meat-type chicken slaughter plants as free of H5/H7 LPAI at a 95 percent confidence interval for a 25 percent infection rate, and both are consistent with the new OIE guidelines for surveillance of NAI that were discussed earlier in this document. Allowing participating slaughter plants to choose between them will give the slaughter plants some flexibility. The first option provides for occasional variances below 11 birds per shift because occasional sample collection problems are likely to arise at slaughter plants; as long as the Official State Agency approves, testing more birds during other shifts so that the number of birds tested per month is equivalent to testing 11 birds per shift will provide adequate surveillance.

Any ongoing active and diagnostic surveillance program that is approved by the Official State Agency and APHIS would have to test a number of birds equivalent to the other two options, but this by itself would not be sufficient to secure approval for the program; the Official State Agency and APHIS would have to agree that the detailed testing plan for the alternate program is sufficient to establish a level of confidence for the detection of AI that is equivalent to that of the other two options. Allowing participating slaughter plants to develop an alternative ongoing active and diagnostic surveillance program of equivalent efficacy will give the plants some additional flexibility.

Subpart D–Special Provisions for Meat-Type Turkeys

Subpart D (§§ 146.41 through 146.44) of part 146 provides special provisions of the Plan with which participating producers and States must comply in order to be eligible for the U.S. H5/H7 Avian Influenza Monitored classification.

Section 146.41, "Definitions," sets out a definition of <u>meat-type turkey</u> that reads: "A domesticated turkey grown for the primary purpose of producing meat." It also sets out a definition of <u>meat-type turkey slaughter plant</u> that reads: "A meat-type turkey slaughter plant that is federally inspected or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection."

Section 146.42, "Participation," states that participating meat-type turkey slaughter plants shall comply with applicable general provisions of subpart A of part 146 and the special provisions of subpart D. However, the section exempts meat-type turkey slaughter plants that slaughter fewer than 2 million meat-type turkeys in a 12-month period from the special provisions of subpart D.

Section 146.43, "Terminology and classification; meat-type turkey slaughter plants," sets out the active surveillance requirements for participating commercial meat-type turkey slaughter plants. The active surveillance requirements in § 146.43 are intended for meat-type turkey slaughter plants that slaughter 2 million or more meat-type turkeys in a 12-month period. However, smaller meat-type turkey slaughter plants are eligible to participate in the NPIP. We believe that diagnostic surveillance in accordance with § 146.14 and inspections in accordance with § 146.11, which are required in the general provisions in subpart A, are adequate to determine whether H5/H7 LPAI is present on such premises.

The indemnity provisions we are establishing in part 56 provide authority to pay indemnity for only 25 percent of costs to owners of meat-type turkey flocks that participate in the Plan through a meat-type turkey slaughter plant that slaughters 2 million or more meat-type turkeys in a 12-month period and that does not participate in the active surveillance described in

§ 146.33(a). As discussed earlier, the standard of slaughtering 2 million or more meat-type turkeys in a 12-month period is consistent with Watt Publishing Companies' listing of commercial meat-type turkey slaughter operations and will concentrate resources on testing meat-type turkeys associated with slaughter plants that slaughter a relatively high percentage of the total U.S. population of commercial meat-type turkeys.

Under paragraph (a)(1) of § 146.43, a meat-type turkey slaughter plant is eligible for the U.S. H5/H7 Avian Influenza Monitored designation if it meets one of the following requirements:

- It is a meat-type turkey slaughter plant at which a sample of a minimum of 60 birds has tested negative each month for antibodies to type A avian influenza virus. Positive samples shall be further tested by an authorized laboratory using the hemagglutination inhibition test to detect antibodies to the hemagglutinin subtypes H5 and H7 when more than 4 months of age and prior to the onset of production. It is recommended that samples be collected from flocks over 10 weeks of age with respiratory signs such as coughing, sneezing, snicking, sinusitis, or rales; depression; or decreases in food or water intake; or
- The plant has an ongoing active and diagnostic surveillance program for H5/H7 LPAI in
 which the number of birds tested is equivalent to the number required by the option
 directly above. Such a program must be approved by the Official State Agency and
 APHIS.

Under the first testing requirement, turkeys may be tested either on the flock level or at the slaughter plant; existing State LPAI control programs, which may be used as a basis for

meeting the requirements of this program, typically require testing in one location or the other. If turkeys are tested at the slaughter plant, it may be more difficult to determine whether they have clinical symptoms that can indicate the presence of AI, although it is still possible. To accommodate testing at both locations, we have indicated that turkeys with clinical symptoms should be tested if possible; however, if no turkeys can be determined to have clinical symptoms, any turkeys may be tested to fulfill the requirement.

The first testing requirement is sufficient to establish the meat-type turkey slaughter plants as free of H5/H7 LPAI at a 95 percent confidence interval for a 25 percent infection rate and is consistent with the new OIE guidelines for surveillance of NAI that were discussed earlier in this document. In addition, the recommendation that turkeys with clinical symptoms, rather than turkeys selected at random, be tested for H5/H7 LPAI could further improve the results of the testing.

Any ongoing active and diagnostic surveillance program that is approved by the Official State Agency and APHIS would have to test a number of birds equivalent to the first requirement, but this by itself would not be sufficient to secure approval for the program; the Official State Agency and APHIS would have to agree that the detailed testing plan for the alternate program is sufficient to establish a level of confidence for the detection of AI that is equivalent to that of the first requirement. Allowing participating slaughter plants to develop an alternative ongoing active and diagnostic surveillance program of equivalent efficacy will give the plants some flexibility.

Section 146.44, "Terminology and classification; States," sets out the requirements for States to be eligible for the U.S. H5/H7 Avian Influenza Monitored State, Turkeys classification. These requirements are contained in paragraph (a)(1) of § 146.44. The requirements are:

- \$ All meat-type turkey slaughter plants within the State that are not exempt from the special provisions of subpart D under § 146.42 are classified as U.S. H5/H7 Avian Influenza Monitored under § 146.43(a);
- \$ All turkey breeding flocks in production within the State are classified as U.S. H5/H7

 Avian Influenza Clean under § 145.43(g);
- \$ All persons performing poultry disease diagnostic service within the State must be required to report to the Official State Agency, within 24 hours, the source of all meat-type turkey specimens that were deemed positive on an official test for AI, as designated in § 146.13(a);
- \$ All meat-type turkey specimens that were deemed positive on an official test for AI, as designated in § 146.13(a), must be sent to an authorized laboratory for subtyping; and
- \$ All meat-type turkey flocks within the State that are found to be infected with the H5/H7 subtypes of avian influenza must be quarantined, in accordance with an initial State response and containment plan as described in part 56 and under the supervision of the Official State Agency.

APHIS may revoke this classification if:

- \$ There is a discontinuation of any of the above conditions;
- \$ Repeated outbreaks of the H5/H7 subtypes of avian influenza occur in meat-type turkey flocks; or

\$ An infection spreads from the originating premises.

The conditions under which APHIS will revoke a classification are identical to those in § 146.24(b) for revoking the classification of U.S. H5/H7 Avian Influenza Monitored State, Layers.

It should be noted that participation in the U.S. H5/H7 Avian Influenza Monitored State, Turkeys program is not a precondition for State participation in the Plan; rather, it is an optional program that States may pursue if an Official State Agency and the meat-type turkey slaughter plants in that State wish to use the designation of U.S. H5/H7 Avian Influenza Monitored State, Turkeys.

Emergency Response and Compensation Provisions in 9 CFR Part 56

Definitions

Section 56.1 sets out definitions for the terms Animal and Plant Health Inspection Service (APHIS), classification, commercial meat-type flock, commercial table-egg layer flock, commercial table-egg layer premises, Department, domesticated, H5/H7 low pathogenic avian influenza (LPAI), H5/H7 LPAI virus infection (infected), meat-type chicken, meat-type turkey, Official State Agency, State, table-egg layer, and United States that are identical to the definitions of those terms in part 146.

The definition of <u>Administrator</u> in part 56 reads: "The Administrator, Animal and Plant Health Inspection Service, or any other employee of the Animal and Plant Health Inspection Service delegated to act in the Administrator's stead." The definition of <u>Administrator</u> in part 146 does not limit the people who may be delegated to act in the Administrator's stead to employees of APHIS. We have included this limitation in part 56 because the Administrator is

authorized to pay compensation under § 56.3, and APHIS must have the final authority to make a decision on whether to pay compensation. The definition of <u>Plan</u> in part 56 refers to the provisions of the NPIP in parts 145, 146, and 147.

The definition of <u>poultry</u> in part 56 reads: "Domesticated fowl, including chickens, turkeys, ostriches, emus, rheas, cassowaries, waterfowl, and game birds, except doves and pigeons, which are bred for the primary purpose of producing eggs or meat." For reasons discussed earlier in this document, this definition includes poultry for which NPIP AI control programs do not exist in parts 145 or 146.

The following definitions are unique to part 56:

Breeding flock. A flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing chicks for the ultimate production of eggs or meat for human consumption. (Section 145.1 includes definitions of primary breeding flock and multiplier breeding flock; for the purposes of determining eligibility for compensation, it is not necessary to make such a distinction, although whether a bird is a member of a primary or multiplier breeding flock would be taken into account when determining its fair market value through appraisal.)

<u>Cooperating State Agency</u>. Any State authority recognized by the Department to cooperate in the administration of the provisions of this part 56. This may include the State animal health authority or the Official State Agency. We are including this definition because part 56 contains 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 would cooperate with the State animal health authority to eradicate an H5/H7 LPAI outbreak and pay indemnity under part 56.

Flock plan. A written flock management agreement developed by APHIS and the Official State Agency with input from the flock owner and other affected parties. Under this definition, 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. (This definition is adapted from the definition of herd plan in the chronic wasting disease control and indemnity regulations in 9 CFR part 55.)

<u>H5/H7 LPAI exposed</u>. At risk of developing H5/H7 LPAI because of association with birds or poultry infected with H5/H7 LPAI, excrement from birds or poultry infected with H5/H7 LPAI, or other material touched by birds or poultry infected with H5/H7 LPAI, or because there is reason to believe that association has occurred with H5/H7 LPAI or vectors of H5/H7 LPAI, as determined by the Cooperating State Agency and confirmed by APHIS.

We are requiring that the determination that poultry are H5/H7 LPAI exposed be made by the Cooperating State Agency in order to be consistent with the other provisions of the NPIP, including the new provisions for commercial poultry, which require State Inspectors and Authorized Agents designated by the Official State Agency to collect and test samples. (As noted earlier, eradication efforts for poultry not included in the NPIP could be conducted in

cooperation with the State animal health authority.) However, since the final determination on whether to pay indemnity for birds destroyed due to H5/H7 LPAI will be made by the APHIS Administrator, we are requiring that this determination be confirmed by APHIS.

Mortgage. Any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity for the destruction of poultry or eggs due to H5/H7 LPAI.

Official appraiser (APHIS official appraiser, State official appraiser). A person authorized by APHIS to appraise poultry for the purposes of this part. A State official appraiser is selected by a State and authorized by APHIS.

<u>Secretary</u>. The Secretary of the United States Department of Agriculture, or any officer or employee of the Department delegated to act in the Secretary's stead.

Cooperation with States

Section 56.2 states that the Administrator of APHIS has been delegated the authority to cooperate with Cooperating State Agencies in the eradication of LPAI. The section provides that cooperation may include, but is not necessarily limited to, the following activities:

- Payment to Cooperating State Agencies for surveillance and monitoring associated with poultry that have been infected with or exposed to H5/H7 LPAI;
- Transfer of vaccine for H5/H7 LPAI to Cooperating State Agencies, if provided for in the initial State response and containment plan developed by the Official State Agency and approved by APHIS under § 56.10; and
- Payment for vaccine administration by Cooperating State Agencies, if provided for in the initial State response and containment plan.

APHIS is authorized to transfer vaccine for disease control purposes, but current regulations do not provide for payment of compensation to Cooperating State Agencies for their use of vaccine. However, any costs Cooperating State Agencies incur in administering the transferred vaccine, such as labor on the part of Cooperating State Agency employees to give the vaccine to poultry, will be eligible for payment by APHIS.

Paragraph (b) of this section sets out conditions for payment and vaccine transfer under § 56.2. Paragraph (b)(1) requires that any payment made to Cooperating State Agencies for surveillance, monitoring, and vaccine administration after detection of H5/H7 LPAI be made through a cooperative agreement between the Cooperating State Agency and APHIS. It further states that the payment for which the Cooperating State Agency is eligible will be determined in the cooperative agreement.

Paragraph (b)(1)(i) provides that, for any State that participates in the diagnostic surveillance program for H5/H7 LPAI in part 146 and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS, the cooperative agreement will provide that the Cooperating State Agency is eligible for payment of 100 percent of the costs of surveillance and monitoring and 100 percent of the costs of vaccine administration, as determined in the cooperative agreement. Paragraph (b)(1)(ii) provides that, for States that do not meet those criteria, the cooperative agreement will provide that the Cooperating State Agency is eligible for payment of 25 percent of the costs of surveillance and monitoring and 25 percent of the costs of vaccine administration, as determined in the cooperative agreement.

The reasons why we believe 100 percent payment for eligible costs is appropriate for participating States are discussed in detail earlier in this document under the heading

"Differences Between This Approach and the Approach Used in Virginia and Texas in 2002." We are providing 25 percent of eligible costs for nonparticipating States in order to provide an additional incentive for States to participate while continuing to provide some relief for costs associated with outbreaks of H5/H7 LPAI.

Paragraph (b)(2) provides that transfer of vaccine must be accomplished through a cooperative agreement between the Cooperating State Agency and APHIS.

Paragraph (c) of this section states that States will be responsible for making the determination to request Federal assistance in the event of an outbreak of H5/H7 LPAI. This provision is also included in § 146.2, and is discussed in more detail under the heading "Administration" earlier in this document; we have included it in § 56.2 to further indicate that it is a State decision to invoke the regulations in part 56.

Payment of Indemnity

Section 56.3 sets out the costs for which indemnity may be paid under the indemnity program for H5/H7 LPAI and the percentage of those costs that are eligible for indemnity.

Paragraph (a) of this section sets out 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.

Paragraph (b) of § 56.3 sets out the percentage of these costs for which the Administrator is authorized to pay indemnity for participants and nonparticipants in the voluntary AI control programs in 9 CFR parts 145 and 146. Under this paragraph, the Administrator is authorized to pay indemnity for 100 percent of eligible costs related to infected or exposed poultry, unless the poultry meet any of the conditions listed below. If the poultry meet any of those conditions, the Administrator is authorized to pay indemnity for only 25 percent of eligible costs:

- The poultry are breeding table egg-layers, meat-type chickens, or meat-type turkeys from a flock that participates in at least one disease control program in the Plan for breeding poultry flocks in 9 CFR part 145 but does not participate in the Plan AI control program for table egg-layer, meat-type chicken, or meat-type turkey breeding flocks;
- The poultry are commercial table-egg layers from a premises that has 75,000 or more birds and that does not participate in the U.S. H5/H7 Avian Influenza Monitored program for commercial table-egg layer flocks described earlier in this document;
- The poultry are commercial meat-type chickens that are associated with a slaughter plant that slaughters 200,000 or more meat-type chickens per operating week and that does not participate in the U.S. H5/H7 Avian Influenza Monitored program for commercial meat-type chicken slaughter plants described earlier in this document;
- The poultry are commercial meat-type turkeys that are associated with a slaughter plant that slaughters 2 million or more meat-type turkeys in a 12-month period and that does

- not participate in the U.S. H5/H7 Avian Influenza Monitored program for commercial meat-type turkey slaughter plants described earlier in this document; or
- The infected or exposed poultry are associated with a flock or slaughter plant that participates in the relevant Plan AI control program, but the State in which they participate does not participate in the NPIP diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14, or does not have an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS, as described in § 56.10. However, if the poultry participate in the Plan with another State that does participate in the National Poultry Improvement Plan diagnostic surveillance program for H5/H7 LPAI, as described in § 146.14, and has an initial State response and containment plan for H5/H7 LPAI that is approved by APHIS, they would be eligible for 100 percent indemnity.

The reasons why we believe 100 percent indemnity for eligible costs is appropriate for most poultry are discussed in detail earlier in this document under the heading "Differences Between This Approach and the Approach Used in Virginia and Texas in 2002." We are providing the authority to pay 25 percent indemnity for eligible costs for nonparticipants in order to provide an additional incentive for owners of commercial enterprises and owners of breeding poultry that participate in the Plan to participate in the AI surveillance programs, while continuing to provide some relief for costs associated with outbreaks of H5/H7 LPAI.

Under paragraph (b) of § 56.3, table-egg layer flocks and meat-type chicken and meat-type turkey slaughter plants that are smaller than the size standards in part 146 are always eligible to receive indemnity for 100 percent of the costs listed in paragraph (a). We are not

providing owners of those smaller flocks and slaughter plants with an incentive to participate in an active surveillance program because these programs described in part 146 are designed for large commercial flocks and slaughter plants. (Owners of smaller flocks and slaughter plants may participate in the Plan without participating in the active surveillance programs and thus receive the Plan seal of approval to use as a marketing tool.)

As discussed earlier in this document, many States conduct AI surveillance programs, some of which are designed for table-egg layer flocks and meat-type chicken and meat-type turkey slaughter plants that are smaller than the size standards in paragraph (b), as well as for meat-type poultry that do not have an association with a slaughter plant and for other types of poultry. These programs may have testing requirements that are equivalent to those in the active surveillance programs in part 146 if those testing requirements are sufficient to detect a 25 percent or greater prevalence of H5/H7 LPAI at a confidence interval of 95 percent or greater.

Although we have provided in this interim rule that all poultry associated with table-egg layer flocks and meat-type chicken and meat-type turkey slaughter plants that are smaller than these size standards and from flocks of other types of poultry will be eligible to receive 100 percent indemnity, it may 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 could encourage owners of smaller flocks to participate in the State AI testing programs designed for those flocks. For example, we could add provisions to the regulations specifying that if infected or exposed poultry are eligible to participate in an active surveillance program whose testing requirements have been recognized by APHIS as equivalent

to the testing requirements for the H5/H7 LPAI surveillance programs in part 146, but do not participate in that program, their owner would be eligible to receive indemnity for less than 100 percent of costs related to an H5/H7 LPAI outbreak. We invite 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.

Paragraph (c) of this section indicates that if the recipient of indemnity for any of the activities listed in paragraph (a) also receives payment for any of those activities from a State or from other sources, the indemnity provided under 9 CFR part 56 will be reduced by the total amount of payment received from the State or other sources. This provision ensures that recipients of indemnity will not receive payment twice for the same loss.

Determination of Indemnity Amounts

Section 56.4 sets out requirements related to the determination of the amount of indemnity that may be paid with regard to each category of cost for which indemnity may be paid under § 56.3. These include provisions for the appraisal and destruction of poultry eligible for indemnity; provisions for the appraisal of eggs destroyed during testing for H5/H7 LPAI during an outbreak of H5/H7 LPAI; and provisions for providing evidence of actual costs for cleaning and disinfection and undertaking cleaning and disinfection under a compliance agreement, 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, indemnity for the materials to be destroyed and disposed.

Paragraph (a)(1) of this section states that indemnity for poultry infected with or exposed to H5/H7 LPAI and subject to destruction will be based on the fair market value of the poultry, as determined by an appraisal. Poultry infected with or exposed to H5/H7 LPAI that are removed by APHIS or a Cooperating State Agency from a flock for testing will be appraised by an APHIS official appraiser and a State official appraiser jointly, or, if APHIS and State authorities agree, by either an APHIS official appraiser or a State official appraiser alone. The use of multiple appraisers will provide maximum assurance that an appropriate fair market value will be determined for the poultry subject to destruction, while the provision that allows appraisers to act singly upon agreement of APHIS and State authorities will ensure that an adequate number of appraisers are available for fast-moving outbreaks.

Appraisals for commercial poultry differ somewhat from appraisals for other livestock. In a typical livestock appraisal, an animal's value is determined by finding sale prices for comparable animals. This method is unworkable for commercial poultry, because the poultry are not sold at market but rather are owned by the same entity throughout the production process; the first price data available for poultry are often wholesale prices for carcasses or eggs. Therefore, APHIS economists have developed means to determine the fair market value of commercial poultry at various stages of production by examining the costs involved in the production of the poultry and the wholesale prices of the resulting carcasses or eggs. These means have been used to determine compensation in poultry disease eradication efforts such as the effort to eradicate

H5/H7 LPAI in Virginia and Texas in 2002.⁸ If we use these means to value commercial poultry in an H5/H7 LPAI outbreak, we would also require State official appraisers to use them whenever applicable.

APHIS would appraise poultry outside of this framework if circumstances warrant. For example, breeding poultry with exceptional genetics might need to be appraised independently in order to arrive at their fair market value. For poultry sold in the live bird marketing system, market price data might be available to provide an appraisal.

Paragraph (a)(1) further requires that appraisals of poultry must be reported on forms furnished by APHIS and signed by the appraisers and that the appraisals must be signed by the owners of the poultry to indicate agreement with the appraisal amount. Appraisals of poultry must be signed by the owners of the poultry prior to the destruction of the poultry, unless the owners, APHIS, and the Cooperating State Agency agree that the poultry may be destroyed immediately. Reports of appraisals must show the number of birds and the value per head.

Paragraph (a)(2) of this section states that indemnity for disposal of poultry infected with or exposed to H5/H7 LPAI will be based on receipts or other documentation maintained by the claimant verifying expenses for disposal activities authorized by part 56. Under this paragraph, any disposal of poultry infected with or exposed to H5/H7 LPAI for which compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for disposal to ensure that all expenditures relate directly to activities described in § 56.5 and in the

⁸ A more detailed description of the process we would use to appraise commercial poultry can be found in the economic analysis prepared for this interim rule. For information on how to obtain

initial State response and containment plan described in § 56.10. The compliance agreement and the APHIS review will help to ensure that APHIS does not pay disposal costs in excess of what is necessary; the fact that the disposal requirements are based on the guidelines in § 56.5 and the initial State response and containment plan means that they will ensure that cleaning and disinfection is conducted properly while taking into account local conditions. If disposal is performed by the Cooperating State Agency, paragraph (a)(2) provides that APHIS will indemnify the Cooperating State Agency for disposal under a cooperative agreement.

Paragraph (a)(3) requires 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, as described in § 56.10. As discussed earlier in this document, the initial State response and containment plan is a requirement for any State that wishes to participate in a cooperative agreement with APHIS and be eligible to receive 100 percent of its costs and ensure that poultry owners in that State are eligible to receive 100 percent indemnification.

Paragraph (b) of this section states that indemnity for eggs destroyed during an outbreak for testing for H5/H7 LPAI will be based on the fair market value of the eggs, as determined by an appraisal. Eggs destroyed for testing for H5/H7 LPAI will be appraised by an APHIS official appraiser and a State official appraiser jointly, or, if APHIS and State authorities agree, by either an APHIS official appraiser or a State official appraiser alone. Appraisals of eggs must be reported on forms furnished by APHIS and signed by the appraisers and must be signed by the owners of the eggs to indicate agreement with the appraisal amount. Appraisals of eggs must be signed by the owners of the eggs prior to the destruction of the poultry, unless the owners,

this analysis, see the section headed "Executive Order 12866 and Regulatory Flexibility Act"

APHIS, and the Cooperating State Agency agree that the eggs may be destroyed immediately. Reports of appraisals must show the number of eggs and the value per egg. It is not necessary to include disposal requirements for eggs destroyed during testing because testing will in all cases be conducted in sanitary conditions.

Paragraph (c)(1) of this section states that indemnity for cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that are infected with or exposed to H5/H7 LPAI will be based on receipts or other documentation maintained by the claimant verifying expenditures for cleaning and disinfection activities authorized by part 56. 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. 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. The compliance agreement and the APHIS review will help to ensure that APHIS does not pay cleaning and disinfection costs in excess of what is necessary; the fact that the cleaning and disinfection requirements are based on the provisions of § 56.5 and the initial State response and containment plan means that they will ensure that cleaning and disinfection is conducted properly while taking into account local conditions.

Paragraph (c)(2) of this section states that 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, indemnity for the destruction of the materials will be based on the

later in this document.

fair market value of those materials, as determined by an appraisal. Materials will be appraised by an APHIS official appraiser and a State official appraiser jointly, or, if APHIS and State authorities agree, by either an APHIS official appraiser or a State official appraiser alone. Indemnity for disposal of the materials will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by part 56. Any disposal of materials for which indemnity is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for disposal 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.

<u>Destruction and Disposal of Poultry and Cleaning and Disinfection of Premises, Conveyances,</u> and Materials

Section 56.5 sets out requirements for the destruction and disposal of poultry, the cleaning and disinfection of premises, conveyances, and materials, and the destruction and disposal of materials.

Paragraph (a) of § 56.5 states that poultry that are infected with or exposed to H5/H7

LPAI may be required to be destroyed at the discretion of the Cooperating State Agency and

APHIS and in accordance with the initial State response and containment plan. The Cooperating

State Agency and APHIS will select a method to use for the destruction of such poultry based on the following factors:

- \$ 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 speed with which destruction must be conducted.

This will ensure that the Cooperating State Agency and APHIS take into consideration all relevant issues when selecting an appropriate method for destruction of poultry.

Paragraph (b) of § 56.5 states that carcasses of poultry that have died from H5/H7 LPAI infection or poultry that have been humanely slaughtered to fulfill depopulation requirements must be disposed of promptly and efficiently in accordance with the initial State response and containment plan to prevent the spread of H5/H7 LPAI infection. Disposal methods will be selected by the Cooperating State Agency and APHIS and may include one or more of the following: Burial, incineration, composting, or rendering. Paragraph (b) additionally states that, regardless of the disposal method used, strict biosecurity procedures must be implemented and enforced for all personnel and vehicular movement into and out of the area in accordance with the initial State response and containment plan to prevent dissemination of the H5/H7 LPAI virus.

Paragraph (c) of § 56.5 addresses controlled marketing. Under § 56.5(c), at the discretion of the Cooperating State Agency and APHIS, poultry that are infected with or exposed to H5/H7

LPAI may be allowed to move for controlled marketing in accordance with the initial State response and containment plan and 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 in § 56.10; and
- 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. Although poultry are likely to be free of the virus 21 days after the acute phase of the infection has been concluded, they are not certain to be free of it; the additional test helps reduce the risk that controlled marketing could spread H5/H7 LPAI.

This paragraph allows controlled marketing for both flocks that have been infected with and flocks that have been exposed to H5/H7 LPAI. As noted previously in this document, LPAI infection in poultry is typically not fatal; if a flock is infected with LPAI, the infection will eventually cease, and the flock will then test negative for LPAI. In addition, LPAI virus is not found in poultry products, meaning that products from an infected flock can be safely marketed. If a State wishes to allow controlled marketing of infected flocks, the conditions specified in that document under which controlled marketing would be allowed must be approved by APHIS; in addition, any controlled marketing must take place under the conditions described above, which are consistent with the OIE guidelines for NAI that were discussed earlier in this document. Therefore, we believe that controlled marketing of an infected flock and its products under the

conditions described above and in accordance with the initial State response and containment plan would not pose a risk of spreading H5/H7 LPAI to uninfected poultry.

APHIS will not pay claims for indemnity for infected or exposed poultry that are allowed to move for controlled marketing; the regulations in part 56 only authorize payment for poultry infected with or exposed to H5/H7 LPAI that are destroyed and disposed according to the regulations in part 56, which means that poultry moved for slaughter and sale are ineligible for indemnity.

Paragraph (d) of § 56.5 sets out guidelines for performing cleaning and disinfection of premises, conveyances, and materials. Premises, conveyances, and materials that came into contact with poultry infected with or exposed to H5/H7 LPAI must be cleaned and disinfected, except that materials for which the cost of cleaning and disinfection would exceed the value of the materials or for which cleaning and disinfection would be impracticable for any reason may be destroyed and disposed. All cleaning and disinfection of premises, conveyances, and materials must be performed in accordance with the initial State response and containment plan. The guidelines in paragraph § 56.5(d) will help States develop cleaning and disinfection plans. The guidelines address preparation for cleaning and disinfection, conducting the cleaning and disinfection, and activities to be performed after cleaning and disinfection. Within the cleaning and disinfection guidelines, four areas are specifically addressed:

- \$ Disposal of manure, debris, and feed;
- \$ Cleaning of premises and materials;
- \$ Disinfection of premises and materials; and
- \$ Cleaning and disinfection of conveyances.

The specific, detailed provisions of these guidelines can be found in the rule portion of this document. Paragraph (d) also indicates that, in the case of materials for which the cost of cleaning and disinfection would exceed the value of the materials or for which cleaning and disinfection would be impracticable for any reason, the destruction and disposal of the materials must be conducted in accordance with the initial State response and containment plan described in § 56.10.

Presentation of Claims for Indemnity

Section 56.6 addresses claims for the following costs, which will be paid by APHIS should they be approved:

- The value of poultry to be destroyed due to infection with H5/H7 LPAI;
- The value of eggs to be destroyed during testing for H5/H7 LPAI; and
- The cost of cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry 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 cost of destruction and disposal for the materials.

The section requires that claims for these costs must be documented on a form furnished by APHIS and presented to an APHIS employee or the State representative authorized to accept the claims.

Mortgage Against Poultry or Eggs

Section 56.7 requires that when poultry or eggs have been destroyed under part 56, any claim for indemnity be presented on forms furnished by APHIS. The owner of the poultry or

eggs must certify on the forms that the poultry or eggs covered are, or are not, subject to any mortgage as defined in § 56.1. If the owner states there is a mortgage, the owner and each person holding a mortgage on the poultry or eggs must sign, consenting to the payment of indemnity to the person specified on the form.

Conditions for Payment

As mentioned earlier in this document under the heading "Differences Between This Approach and the Approach Used in Virginia and Texas in 2002," this indemnity program contains provisions specifically ensuring that contract growers, or anyone else providing services related to the growing and care of the birds, receive payment for their services when indemnity is provided for birds destroyed under their care. Just as in the Virginia and Texas outbreaks, we believe it is important to ensure that all participants in the poultry industry with a stake in the continued health of the U.S. poultry stock are compensated for costs associated with the eradication of outbreaks of H5/H7 LPAI.

Therefore, § 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 this section, 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. For example, suppose a meat-type chicken flock belonging to an owner who participated in the Plan is destroyed and disposed of under this part, and the flock was appraised at \$1,000. The flock was being grown by a contractor with a \$500 contract; half of the contract's duration had elapsed. The contractor would be eligible to receive \$250 in indemnity, and the owner would be eligible to receive the difference, \$750.

For losses resulting from the H5/H7 LPAI outbreak in Virginia and Texas, the Administrator was authorized to pay 100 percent of the costs contract growers incurred and up to 75 percent of the total costs poultry owners incurred related to destruction and disposal of poultry affected by H5/H7 LPAI. This section does not structure indemnity payments in this manner. Under paragraph (b) of § 56.8, the Administrator is authorized to pay contract growers and other parties with contractual claims 100 percent of eligible costs related to the destruction and disposal of poultry infected with or exposed to H5/H7 LPAI, and 100 percent of eligible costs related to the destruction of eggs during testing of commercial poultry for H5/H7 LPAI during outbreaks, unless the producer of the poultry or eggs is a commercial poultry producer that does not participate in the LPAI control program or a breeding poultry producer that participates in the Plan but not in the AI control program. In the latter case, the Administrator is

authorized to pay contract growers and other parties with contractual claims 25 percent of eligible costs.

Paragraph (c) of this section explicitly states that if indemnity is paid to a contractor 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.

Paragraph (d) of this section provides that in the event that determination of indemnity to a party with which the owner of destroyed poultry or eggs has entered into a contract for the growing or care of the poultry or eggs as described in paragraph (a) is determined to be impractical or inappropriate, APHIS may use any other method that the Administrator deems appropriate to make that determination. This provision provides APHIS with flexibility in the event that the formula described previously does not result in an appropriate distribution of indemnity.

Claims Not Allowed

Section 56.9 states that the Department will not allow the following claims:

- \$ Claims arising out of the destruction of poultry unless the poultry have been appraised as prescribed in § 56.4 and the owners have signed the appraisal form indicating agreement with the appraisal amount as required by § 56.4(a)(1).
- 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. Persons who do not maintain their poultry and premises in accordance with this written agreement will not be eligible to receive indemnity under this part.

Claims arising out of the destruction of poultry unless the poultry have been moved or handled by the owner in accordance with an agreement for the control and eradication of H5/H7 LPAI and in accordance with part 56, for any progeny of any poultry unless the poultry have been moved or handled by the owner in accordance with an agreement for the control and eradication of H5/H7 LPAI and in accordance with part 56, or for any poultry that become or have become infected with or exposed to H5/H7 LPAI because of actions not in accordance with an agreement for the control and eradication of H5/H7 LPAI or a violation of part 56.

These provisions are consistent with the relevant provisions of the Animal Health Protection Act, which are found at 7 U.S.C. 8306(d)(3).

Initial State Response and Containment Plan

Section 56.10 states that, in order for poultry owners within a State to be eligible for 100 percent indemnity under paragraph § 56.3(b)(1), the State in which the poultry owners participate in the NPIP must have in place an initial State response and containment plan that has been approved by APHIS. The plan must be developed by the Official State Agency and administered by the Cooperating State Agency of the relevant State. Section 56.10 also sets out the elements that this plan must include:

\$ Provisions for a standing emergency disease management committee, regular meetings, and exercises, including coordination with any tribal governments that may be affected;

- \$ A minimum biosecurity plan followed by all poultry producers;
- \$ Provisions for adequate diagnostic resources;
- \$ Detailed, specific procedures for initial handling and investigation of suspected cases of H5/H7 LPAI;
- \$ Detailed, specific procedures for reporting test results to APHIS. These procedures must be developed after appropriate consultation with poultry producers in the State and must provide for the reporting only of confirmed cases of H5/H7 LPAI in accordance with 9 CFR 146.13;
- \$ Detailed, strict quarantine measures for presumptive and confirmed index cases;
- \$ Provisions for developing flock plans for infected and exposed flocks;
- Detailed plans for disposal of infected flocks, including preexisting agreements with regulatory agencies and detailed plans for carcass disposal, disposal sites, and resources for conducting disposal, and detailed plans for disposal of materials that come into contact with poultry infected with or exposed to H5/H7 LPAI;
- \$ Detailed plans for cleaning and disinfection of premises, repopulation, and monitoring after repopulation;
- \$ Provisions for appropriate control/monitoring zones, contact surveys, and movement restrictions;
- \$ Provisions for monitoring activities in control zones;
- \$ If vaccination is considered as an option, a written plan for use in place with proper controls and provisions for APHIS approval of any use of vaccine;

- \$ Plans for H5/H7 LPAI-negative flocks that provide for quarantine, testing, and controlled marketing; and
- \$ Public awareness and education programs regarding avian influenza.

We believe that any State with a plan that includes all these elements is fully capable of determining whether H5/H7 LPAI is present in flocks that participate in the Plan within that State and taking action to respond to any outbreaks of H5/H7 LPAI that may occur. A model initial State response and containment plan is available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov). APHIS plans to distribute the model initial State response and containment plan as a guide to help States develop initial State response and containment plans for approval by APHIS; the model plan sets out what would typically be considered to be provisions that would satisfy the requirements for an initial State response and containment plan in this interim rule. We invite public comment on the model initial State response and containment plan.

Section 56.10 also provides that if a State has U.S. Avian Influenza Monitored status under § 146.24(a) or § 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. If a State completes the actions required by the initial State response and containment plan, 90 days will provide adequate time to complete the post-outbreak surveillance necessary to establish that the State is free of H5/H7 LPAI. As discussed earlier in this document in the context of the special provisions for table-egg layers and meat-type turkeys, APHIS reserves the right to remove U.S. Avian Influenza Monitored status

from a State entirely if there is a discontinuation of any of the conditions required to attain that status, if repeated outbreaks of the H5/H7 subtypes of avian influenza occur in table-egg layer or meat-type turkey flocks, or if an infection spreads from the originating premises in a State.

Miscellaneous Changes

The new part 146 is titled "National Poultry Improvement Plan for Commercial Poultry." The title of part 145 has been "National Poultry Improvement Plan." Prior to the publication of this interim rule, the only poultry included in the Plan (and, thus, in part 145) had been breeding poultry. To ensure clarity, we are amending the title of part 145 to read "National Poultry Improvement Plan for Breeding Poultry."

Section 147.45 of the auxiliary provisions of the NPIP provides that each cooperating State is entitled to one official delegate at Plan conferences for each of the programs prescribed in subparts B, C, D, E, and F of 9 CFR part 145 in which it has one or more participants at the time of the Plan conference. We are amending this section to accommodate the addition of the new programs in 9 CFR part 146 by stating that each cooperating State is also entitled to one official delegate for each of the programs prescribed in subparts B, C, and D of 9 CFR part 146. We are also amending § 147.46(a) by providing for the establishment of committees to give preliminary consideration to the proposed changes falling in their respective fields for egg-type commercial chickens, meat-type commercial chickens, and meat-type commercial turkeys.

Immediate Action

We believe that it is necessary to establish a voluntary LPAI control program and an LPAI indemnity program in an interim rule in order to proactively address the increasing threat of mutation to HPAI posed by outbreaks of H5/H7 LPAI, including the H7N2 LPAI virus

present in New York and New Jersey, and thus mitigate the potential poultry and human health threat of an H5/H7 HPAI virus. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 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 rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The 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.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an initial regulatory flexibility analysis that 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.

Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

Under the interim rule, the U.S. Department of Agriculture (USDA) will compensate both owners and growers for losses arising from depopulation of birds affected with H5/H7 LPAI.

In general, benefits of depopulating birds affected with H5/H7 LPAI come from containing the spread of the disease. Benefits of containing disease spread fall into three general categories: (1) Avoided owner and grower losses from disease morbidity and mortality; (2) avoided consumer price increases resulting from decreased supplies; and (3) avoided trade bans (State, regional, or national) that result when trading partners close markets during or after a disease outbreak.

The groups who enjoy the primary benefit of a disease eradication campaign are consumers and those owners/growers whose flocks have remained healthy. The group who bears the primary burden of the eradication effort is the owners and/or growers whose flocks are depopulated. 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 are derived from avoiding costs incurred when an outbreak occurs. Evidence of types of benefits gained from control of avian influenza is found in the USDA-Economic Research Service study of a 1983-84 outbreak (summarized in the full economic analysis). Also, the 2002 outbreak in Virginia provides evidence of the costs incurred due to an avian influenza incident. This evidence shows that the costs of an avian influenza outbreak can be substantial.

To the extent that the interim 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 avoiding LPAI outbreaks and losses should an outbreak occur, exceed the cost to producers and States of participating in disease prevention efforts. Under the rule, producers would be required to keep flocks and facilities clean, slaughter plants would be required to conduct sampling, and States would be required to conduct annual inspections and develop response and containment plans. As the Federal part of the control program, APHIS would provide full indemnity for specific costs to participating producers and States should an outbreak occur. Related to, but separate from, this LPAI rule, APHIS received about \$14 million in fiscal year 2006 appropriations for LPAI efforts, including almost \$2 million in NPIP cooperative agreements to 24 States for ongoing surveillance.

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 7 CFR part 3015, subpart V.)

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.

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.

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 proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

Lists of Subjects

9 CFR Part 53

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

9 CFR Part 56

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

9 CFR Parts 145, 146, and 147

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

Accordingly, we are amending 9 CFR chapter I as follows:

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

1. The authority citation for 9 CFR part 53 continues to read as follows:

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

§ 53.4 [Amended]

- 2. Section 53.4 is amended as follows:
- a. In paragraph (a), by removing the third sentence.
- b. In paragraph (a), in the fourth sentence, by removing the words "or poultry."
- c. By removing and reserving paragraph (b).

§ 53.8 [Amended]

- 3. Section 53.8 is amended as follows:
- a. In paragraph (a), in the first sentence, by removing the words "Except for claims made under § 53.11, claims" and adding the word "Claims" in their place.
 - b. By removing and reserving paragraph (b) and removing paragraph (c).

§ 53.11 [Removed]

- 4. Section 53.11 is removed.
- 5. A new part 56 is added to read as follows.

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

Sec.

- 56.1 Definitions.
- 56.2 Cooperation with States.
- 56.3 Payment of indemnity.
- 56.4 Determination of compensation amounts.
- 56.5 Destruction and disposal of poultry and cleaning and disinfection of premises, conveyances, and materials.

56.6 Presentation of claims for indemnity.

56.7 Mortgage against poultry or eggs.

56.8 Conditions for payment.

56.9 Claims not allowed.

56.10 Initial State response and containment plan.

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

§ 56.1 <u>Definitions</u>.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any other employee of the Animal and Plant Health Inspection Service delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Breeding flock. A flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing chicks for the ultimate production of eggs or meat for human consumption.

<u>Classification</u>. A designation earned by participation in a Plan program.

<u>Commercial meat-type flock</u>. All of the meat-type chickens or meat-type turkeys on one farm. However, at the discretion of the Official State Agency, 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 may be considered as a separate flock.

<u>Commercial table-egg layer flock</u>. All table-egg layers of one classification in one barn or house.

<u>Commercial table-egg layer premises</u>. A farm containing contiguous flocks of commercial table-egg layers under common ownership.

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

<u>Department</u>. The U.S. Department of Agriculture.

<u>Domesticated</u>. Propagated and maintained under the control of a person.

Flock plan. 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.

H5/H7 low pathogenic avian influenza (LPAI). An infection of poultry caused by an influenza A virus of H5 or H7 subtype that has an intravenous pathogenicity index test in 6-week-old chickens less than 1.2 or any infection with influenza A viruses of H5 or H7 subtype for which nucleotide sequencing has not demonstrated the presence of multiple basic amino acids at the cleavage site of the hemagglutinin.

<u>H5/H7 LPAI exposed</u>. At risk of developing H5/H7 LPAI because of association with birds or poultry infected with H5/H7 LPAI, excrement from birds or poultry infected with H5/H7

LPAI, or other material touched by birds or poultry infected with H5/H7 LPAI, or because there is reason to believe that association has occurred with H5/H7 LPAI or vectors of H5/H7 LPAI, as determined by the Cooperating State Agency and confirmed by APHIS.

H5/H7 LPAI virus infection (infected). 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
- (2) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry; or
- (3) 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.

Meat-type chicken. A domesticated chicken grown for the primary purpose of producing meat including but not limited to broilers, roasters, fryers, and cornish.

Meat-type turkey. A domesticated turkey grown for the primary purpose of producing meat.

Mortgage. Any mortgage, lien, or other security or beneficial interest held by any person other than the one claiming indemnity for the destruction of poultry or eggs due to H5/H7 LPAI.

Official appraiser (APHIS official appraiser, State official appraiser). A person authorized by APHIS to appraise poultry for the purposes of this part. A State official appraiser is selected by a State and authorized by APHIS.

Official State Agency. The State authority recognized by the Department to cooperate in the administration of the Plan.

<u>Plan</u>. The provisions of the National Poultry Improvement Plan contained in parts 145, 146, and 147 of this chapter.

<u>Poultry</u>. Domesticated fowl, including chickens, turkeys, ostriches, emus, rheas, cassowaries, waterfowl, and game birds, except doves and pigeons, which are bred for the primary purpose of producing eggs or meat.

<u>Secretary</u>. The Secretary of the United States Department of Agriculture, or any officer or employee of the Department delegated to act in the Secretary's stead.

State. Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands of the United States, or any territory or possession of the United States.

<u>Table-egg layer</u>. A domesticated chicken grown for the primary purpose of producing eggs for human consumption.

United States. All of the States.

§ 56.2 <u>Cooperation with States</u>.

(a) The Administrator has been delegated the authority to cooperate with Cooperating State Agencies in the eradication of H5/H7 LPAI. This cooperation may include, but is not necessarily limited to, the following activities:

- (1) Payment to Cooperating State Agencies for surveillance and monitoring associated with poultry that have been infected with or exposed to H5/H7 LPAI;
- (2) Transfer of vaccine for H5/H7 LPAI to Cooperating State Agencies if provided for in the initial State response and containment plan developed by the Official State Agency and approved by APHIS under § 56.10; and
- (3) Payment for vaccine administration by Cooperating State Agencies, if provided for in the initial State response and containment plan developed by the Official State Agency and approved by APHIS under § 56.10
- (b) (1) Any payment made to a State or an Official State Agency for the activities listed in paragraphs (a)(1) and (a)(3) of this section must be made through a cooperative agreement between the Cooperating State Agency and APHIS. The payment for which the Cooperating State Agency is eligible will be determined in the cooperative agreement.
- (i) For any Cooperating State Agency that participates in the National Poultry Improvement Plan 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, as described in § 56.10 of this part, the cooperative agreement will provide that the Cooperating State Agency is eligible for payment of 100 percent of the costs of surveillance and monitoring and 100 percent of the costs of vaccine administration, as determined in the cooperative agreement.
- (ii) For any Cooperating State Agency that does not meet the criteria in paragraph (b)(1)(i) of this section, the cooperative agreement will provide that the Cooperating State

Agency is eligible for payment of 25 percent of the costs of surveillance and monitoring and 25 percent of the costs of vaccine administration, as determined in the cooperative agreement.

- (2) Transfer of vaccine under paragraph (a)(2) of this section must be accomplished through a cooperative agreement between the Cooperating State Agency and APHIS.
- (c) States will be responsible for making the determination to request Federal assistance under this part in the event of an outbreak of H5/H7 LPAI.

§ 56.3 Payment of indemnity.

- (a) <u>Activities eligible for indemnity</u>. The Administrator may pay indemnity for the activities listed in paragraphs (a)(1) through (a)(3) of this section, as provided in paragraph (b) of this section:
- (1) Destruction and disposal of poultry that were infected with or exposed to H5/H7 LPAI;
- (2) Destruction of any eggs destroyed during testing of poultry for H5/H7 LPAI during an outbreak of H5/H7 LPAI; and
- (3) 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.
- (b) <u>Percentage of costs eligible for indemnity</u>. Except for poultry that are described by the categories in paragraphs (b)(1) through (b)(7) of this section, the Administrator is authorized to pay 100 percent of the costs, as determined in accordance with § 56.4, of the activities

described in paragraphs (a)(1) through (a)(3) of this section, regardless of whether the infected or exposed poultry participate in the Plan. For infected or exposed poultry that are described by the categories in paragraphs (b)(1) through (b)(7) of this section, the Administrator is authorized to pay 25 percent of the costs of the activities described in paragraphs (a)(1) through (a)(3) of this section:

- (1) The poultry are egg-type breeding chickens from a flock that participates in any Plan program in part 145 of this chapter but that does not participate in the U.S. Avian Influenza Clean program of the Plan in § 145.23(h) of this chapter; or
- (2) The poultry are meat-type breeding chickens from a flock that participates in any Plan program in part 145 of this chapter but that does not participate in the U.S. Avian Influenza Clean program of the Plan in § 145.33(l) of this chapter; or
- (3) The poultry are breeding turkeys from a flock that participates in any Plan program in part 145 of this chapter but that does not participate in the U.S. H5/H7 Avian Influenza Clean program of the Plan in § 145.43(g) of this chapter; or
- (4) The poultry are commercial table-egg layers from a premises that has 75,000 or more birds and that does not participate in the U.S. H5/H7 Avian Influenza Monitored program of the Plan in § 146.23(a) of this chapter; or
- (5) The poultry are commercial meat-type chickens that are associated with a slaughter plant that slaughters 200,000 or more meat-type chickens per operating week and that does not participate in the U.S. H5/H7 Avian Influenza Monitored program of the Plan in § 146.33(a) of this chapter; or

- (6) The poultry are commercial meat-type turkeys that are associated with a slaughter plant that slaughters 2 million or more meat-type turkeys in a 12-month period and that does not participate in the U.S. H5/H7 Avian Influenza Monitored program of the Plan in § 146.43(a) of this chapter; or
- (7) The poultry 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 National Poultry Improvement Plan 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, unless such poultry participate in the Plan with another State that does participate in the National Poultry Improvement Plan 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.
- (c) Other sources of payment. If the recipient of indemnity for any of the activities listed in paragraphs (a)(1) through (a)(3) of this section 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.

§ 56.4 Determination of indemnity amounts.

(a) <u>Destruction and disposal of poultry</u>. (1) Indemnity for the destruction of poultry infected with or exposed to H5/H7 LPAI will be based on the fair market value of the poultry, as determined by an appraisal. Poultry infected with or exposed to H5/H7 LPAI that are removed by APHIS or a Cooperating State Agency from a flock will be appraised by an APHIS official appraiser and a State official appraiser jointly, or, if APHIS and State authorities agree, by either

an APHIS official appraiser or a State official appraiser alone. For laying hens, the appraised value should include the hen's projected future egg production. Appraisals of poultry must be reported on forms furnished by APHIS and signed by the appraisers and must be signed by the owners of the poultry to indicate agreement with the appraisal amount. Appraisals of poultry must be signed by the owners of the poultry prior to the destruction of the poultry, unless the owners, APHIS, and the Cooperating State Agency agree that the poultry may be destroyed immediately. Reports of appraisals must show the number of birds and the value per head.

- (2) Indemnity for disposal of poultry infected with or exposed to H5/H7 LPAI will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by this part. Any disposal of poultry infected with or exposed to H5/H7 LPAI for which compensation is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for disposal 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. If disposal is performed by the Cooperating State Agency, APHIS will indemnify the Cooperating State Agency for disposal under a cooperative agreement.
- (3) The destruction and disposal of the indemnified poultry must be conducted in accordance with the initial State response and containment plan for H5/H7 LPAI, as described in § 56.10.
- (b) <u>Destruction of eggs</u>. Indemnity for eggs destroyed during an outbreak for testing for H5/H7 LPAI will be based on the fair market value of the eggs, as determined by an appraisal. Eggs destroyed for testing for H5/H7 LPAI will be appraised by an APHIS official appraiser and

a State official appraiser jointly, or, if APHIS and State authorities agree, by either an APHIS official appraiser or a State official appraiser alone. Appraisals of eggs must be reported on forms furnished by APHIS and signed by the appraisers and must be signed by the owners of the eggs to indicate agreement with the appraisal amount. Appraisals of eggs must be signed by the owners of the eggs prior to the destruction of the poultry, unless the owners, APHIS, and the Cooperating State Agency agree that the eggs may be destroyed immediately. Reports of appraisals must show the number of eggs and the value per egg.

- (c) <u>Cleaning and disinfection</u>. (1) Indemnity for cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry that are infected with or exposed to H5/H7 LPAI will be based on receipts or other documentation maintained by the claimant verifying expenditures for cleaning and disinfection activities authorized by this part. 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. 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.
- (2) 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, indemnity for the destruction of the materials will be based on the fair market value of those materials, as determined by an appraisal. Materials will be appraised by an APHIS official appraiser and a State official appraiser jointly, or, if APHIS and State authorities agree, by either an APHIS official appraiser or a State official appraiser alone. Indemnity for disposal of the

materials will be based on receipts or other documentation maintained by the claimant verifying expenditures for disposal activities authorized by this part. Any disposal of materials for which indemnity is requested must be performed under a compliance agreement between the claimant, the Cooperating State Agency, and APHIS. APHIS will review claims for compensation for disposal 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.

- § 56.5 <u>Destruction and disposal of poultry and cleaning and disinfection of premises</u>, conveyances, and materials.
- (a) <u>Destruction of poultry</u>. Poultry that are infected with or exposed to H5/H7 LPAI may be required to be destroyed at the discretion of the Cooperating State Agency and APHIS and in accordance with the initial State response and containment plan described in § 56.10. The Cooperating State Agency and APHIS will select a method to use for the destruction of such poultry based on the following factors:
 - (1) The species, size, and number of the poultry to be destroyed;
 - (2) The environment in which the poultry are maintained;
 - (3) The risk to human health or safety of the method used;
 - (4) Whether the method requires specialized equipment or training;
 - (5) The risk that the method poses of spreading the H5/H7 LPAI virus;
 - (6) Any hazard the method could pose to the environment;
- (7) The degree of bird control and restraint required to administer the destruction method; and
 - (8) The speed with which destruction must be conducted.

- (b) <u>Disposal of poultry</u>. Carcasses of poultry that have died from H5/H7 LPAI infection or poultry that have been humanely slaughtered to fulfill depopulation requirements must be disposed of promptly and efficiently in accordance with the initial State response and containment plan described in § 56.10 to prevent the spread of H5/H7 LPAI infection. Disposal methods will be selected by the Cooperating State Agency and APHIS and may include one or more of the following: Burial, incineration, composting, or rendering. Regardless of the method used, strict biosecurity procedures must be implemented and enforced for all personnel and vehicular movement into and out of the area in accordance with the initial State response and containment plan to prevent dissemination of the H5/H7 LPAI virus.
- (c) <u>Controlled marketing</u>. (1) At the discretion of the Cooperating State Agency and APHIS, poultry that has been infected with or exposed to H5/H7 LPAI may be allowed to move for controlled marketing in accordance with the initial State response and containment plan described in § 56.10 and in accordance with the following requirements:
- (i) 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; and
- (ii) 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.
- (2) Poultry moved for controlled marketing will not be eligible for indemnity under § 56.3.

- (d) Cleaning and disinfection of premises, conveyances, and materials. Premises, conveyances, and materials that came into contact with poultry infected with or exposed to H5/H7 LPAI must be cleaned and disinfected; Provided, that materials for which the cost of cleaning and disinfection would exceed the value of the materials or for which cleaning and disinfection would be impracticable for any reason may be destroyed and disposed. 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. This paragraph (d) provides guidelines for the development of a cleaning and disinfection plan for a premises and for the materials and conveyances on that premises.
- (1) <u>Preparation for cleaning and disinfection</u>. Following the depopulation or controlled marketing of all poultry infected with or exposed to H5/H7 LPAI on a premises, the following procedures should be completed prior to cleaning and disinfection:
- (i) 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;
- (ii) Apply insecticides and rodenticides immediately after the removal of the birds, before the house cools:
- (iii) Close the house in which the poultry were held, maintaining just enough ventilation to remove moisture. 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.
 - (iv) Heat the house to 100 °F for the 72 hours prior to cleaning and disinfection.

- (2) <u>Cleaning and disinfection</u>. All premises, conveyances, and materials that came into contact with poultry that were infected with or exposed to H5/H7 LPAI must be cleaned and disinfected. Cleaning and disinfection must be performed on all buildings that came into contact with poultry that were infected with or exposed to H5/H7 LPAI within a premises, including pumphouses and service areas. To accomplish cleaning and disinfection, the following procedures should be completed:
- (i) <u>Disposal of manure, debris, and feed</u>. Clean up all manure, debris, and feed. Compost manure, debris, and feed in the house if possible. If this is not possible, set up a system for hauling manure, debris, and feed to an approved site for burial, piling, or composting. Do not clean out the house or move or spread litter until any H5/H7 LPAI virus that may have contaminated the manure and litter is dead, as determined by the Cooperating State Agency and in accordance with the initial State response and containment plan described in § 56.10. If composting is used as a disposal method, manure and litter should be composted in accordance with State and local regulations. If litter is piled, the litter pile must be covered and allowed to sit undisturbed for an amount of time approved by the Cooperating State Agency and APHIS and in accordance the initial State response and containment plan described in § 56.10. Drying and heat in situ over time are effective and may be used in place of composting if weather conditions or conditions in the building are favorable. After use, equipment used to clean out manure, debris, and feed must be washed, disinfected, and inspected at the site to which the manure and litter was transported. In the case of inclement weather, the equipment may be washed, disinfected, and inspected at off-site wash stations at the discretion of the Cooperating State Agency and APHIS.

- (ii) <u>Cleaning of premises and materials</u>. 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 soap and water to knock dust down to the floor, using no more water than necessary. Wash equipment and houses with soap 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 cleaning. Inspect houses and equipment to ensure that cleaning has removed all contaminated materials or substances and let houses and equipment dry completely before applying disinfectant.
- (iii) <u>Disinfection of premises and materials</u>. When cleaning has been completed and all surfaces are dry, all interior surfaces of the structure should be saturated with a disinfectant authorized in § 71.10(a) of this chapter. A power spray unit should be used to spray the disinfectant on all surfaces, making sure that the disinfectant gets into cracks and crevices. Special attention should be given to automatic feeders and other closed areas to ensure adequate disinfection.
- (vi) Cleaning and disinfection of conveyances. Clean and disinfect all trucks and vehicles used in transporting affected poultry or materials before soil dries in place. Both exterior, including the undercarriage, and interior surfaces, including truck cabs, must be cleaned. The interior of the truck cabs should be washed with clean water and sponged with a disinfectant authorized in § 71.10(a) of this chapter. Manure and litter removed from these vehicles should be handled in a manner similar to that described in paragraph (d)(2)(i) of this section.

- (3) Activities after cleaning and disinfection. Premises should be checked for virus before repopulation in accordance with the initial State response and containment plan described in § 56.10. The premises may not be restocked with poultry until after the date specified in the initial State response and containment plan described in § 56.10.
- (4) <u>Destruction and disposal of materials</u>. In the case of materials for which the cost of cleaning and disinfection would exceed the value of the materials or for which cleaning and disinfection would be impracticable for any reason, the destruction and disposal of the materials must be conducted in accordance with the initial State response and containment plan described in § 56.10.

§ 56.6 Presentation of claims for indemnity.

Claims for the following must be documented on a form furnished by APHIS and presented to an APHIS employee or the State representative authorized to accept the claims:

- (a) Compensation for the value of poultry to be destroyed due to infection with or exposure to H5/H7 LPAI;
- (b) Compensation for the value of eggs to be destroyed during testing for H5/H7 LPAI; and
- (c) Compensation for the cost of cleaning and disinfection of premises, conveyances, and materials that came into contact with poultry 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 cost of destruction and disposal for the materials.

§ 56.7 Mortgage against poultry or eggs.

When poultry or eggs have been destroyed under this part, any claim for indemnity must be presented on forms furnished by APHIS. The owner of the poultry or eggs must certify on the forms that the poultry or eggs covered are, or are not, subject to any mortgage as defined in this part. If the owner states there is a mortgage, the owner and each person holding a mortgage on the poultry or eggs must sign the APHIS-furnished form, consenting to the payment of indemnity to the person specified on the form.

§ 56.8 Conditions for payment.

- (a) When poultry or eggs have been destroyed pursuant to this part, 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. The indemnity the Administrator may pay to such a party or parties shall be determined as follows:
- (1) Divide the value of the contract the owner of the poultry or eggs entered into with another party for the growing and care of the poultry or eggs in dollars by the duration of the contract as it was signed prior to the H5/H7 LPAI outbreak in days;
- (2) Multiply this figure 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.
- (b) (1) If indemnity for the destroyed poultry or eggs is being provided for 100 percent of eligible costs under § 56.3(b), the Administrator may pay contractors eligible for compensation under this section 100 percent of the indemnity determined in paragraph (a) of this section.

- (2) If indemnity for the destroyed poultry or eggs is being provided for 25 percent of eligible costs under § 56.3(b), the Administrator may pay contractors eligible for compensation under this section 25 percent of the indemnity determined in paragraph (a) of this section.
- (c) If indemnity is paid to a contractor under this section, 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.
- (d) In the event that determination of indemnity to a party with which the owner of destroyed poultry or eggs has entered into a contract for the growing or care of the poultry or eggs using the method described in paragraph (a) of this section is determined to be impractical or inappropriate, APHIS may use any other method that the Administrator deems appropriate to make that determination.

§ 56.9 Claims not allowed.

- (a) The Department will not allow claims arising out of the destruction of poultry unless the poultry have been appraised as prescribed in this part and the owners have signed the appraisal form indicating agreement with the appraisal amount as required by § 56.4(a)(1).
- (b) The Department 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. Persons who do not maintain their poultry and premises in accordance with this written agreement will not be eligible to receive indemnity under this part.

(c) The Department will not allow claims arising out of the destruction of poultry unless the poultry have been moved or handled by the owner in accordance with an agreement for the control and eradication of H5/H7 LPAI and in accordance with part 56, for any progeny of any poultry unless the poultry have been moved or handled by the owner in accordance with an agreement for the control and eradication of H5/H7 LPAI and in accordance with part 56, or for any poultry that become or have become infected with or exposed to H5/H7 LPAI because of actions not in accordance with an agreement for the control and eradication of H5/H7 LPAI or a violation of this part.

§ 56.10 <u>Initial State response and containment plan</u>.

- (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 and administered by the Cooperating State Agency of the relevant State. This plan must include:
- (1) Provisions for a standing emergency disease management committee, regular meetings, and exercises, including coordination with any tribal governments that may be affected;
 - (2) A minimum biosecurity plan followed by all poultry producers;
 - (3) Provisions for adequate diagnostic resources;
- (4) Detailed, specific procedures for initial handling and investigation of suspected cases of H5/H7 LPAI;

- (5) Detailed, specific procedures for reporting test results to APHIS. These procedures must be developed after appropriate consultation with poultry producers in the State and must provide for the reporting only of confirmed cases of H5/H7 LPAI in accordance with § 146.13 of this chapter;
 - (6) Detailed, strict quarantine measures for presumptive and confirmed index cases;
 - (7) Provisions for developing flock plans for infected and exposed flocks;
- (8) Detailed plans for disposal of infected flocks, including preexisting agreements with regulatory agencies and detailed plans for carcass disposal, disposal sites, and resources for conducting disposal, and detailed plans for disposal of materials that come into contact with poultry infected with or exposed to H5/H7 LPAI;
- (9) Detailed plans for cleaning and disinfection of premises, repopulation, and monitoring after repopulation;
- (10) Provisions for appropriate control/monitoring zones, contact surveys, and movement restrictions;
 - (11) Provisions for monitoring activities in control zones;
- (12) If vaccination is considered as an option, a written plan for use in place with proper controls and provisions for APHIS approval of any use of vaccine;
- (13) Plans for H5/H7 LPAI-negative flocks that provide for quarantine, testing, and controlled marketing; and
 - (14) Public awareness and education programs regarding avian influenza.
- (b) If a State is designated a U.S. Avian Influenza Monitored State, Layers under \$ 146.24(a) of this chapter or a U.S. Avian Influenza Monitored State, Turkeys under \$ 146.44(a)

of this chapter, 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.

PART 145-NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

6. The authority citation for part 145 continues to read as follows:

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

- 7. The part heading for part 145 is revised to read as set forth above.
- 8. A new part 146 is added to read as follows.

PART 146-NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL

POULTRY

Subpart A–General Provisions

Sec.

- 146.1 Definitions.
- 146.2 Administration.
- 146.3 Participation.
- 146.4 General provisions for all participating flocks and slaughter plants.
- 146.5 Specific provisions for participating flocks.
- 146.6 Specific provisions for participating slaughter plants.
- 146.7 Terminology and classification; general.
- 146.8 Terminology and classification; slaughter plants.
- 146.9 Terminology and classification; flocks, products, and States.
- 146.10 Supervision.

146.11 Inspections.

146.12 Debarment from participation.

146.13 Testing.

146.14 Diagnostic surveillance program for H5/H7 low pathogenic avian influenza.

Subpart B-Special Provisions for Commercial Table-Egg Layer Flocks

Sec.

146.21 Definitions.

146.22 Participation.

146.23 Terminology and classification; flocks and products.

146.24 Terminology and classification; States.

Subpart C-Special Provisions for Meat-Type Chicken Slaughter Plants

146.31 Definitions.

146.32 Participation.

146.33 Terminology and classification; meat-type chicken slaughter plants.

Subpart D–Special Provisions for Meat-Type Turkey Slaughter Plants

146.41 Definitions.

146.42 Participation.

146.43 Terminology and classification; meat-type turkey slaughter plants.

146.44 Terminology and classification; States.

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

Subpart A–General Provisions

§ 146.1 <u>Definitions</u>.

Except where the context otherwise requires, for the purposes of this subpart the following terms shall be construed, respectively, to mean:

<u>Administrator</u>. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Affiliated flock. A meat-type flock that is owned by or has an agreement to participate in the Plan with a slaughter plant and that participates in the Plan through that slaughter plant.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

<u>Authorized Agent</u>. Any person designated under § 146.10(a) to perform functions under this part.

Authorized laboratory. An authorized laboratory designated by an Official State Agency, subject to review by the Service, to perform the diagnostic assays. The Service's review will include, but will not necessarily be limited to, checking records, laboratory protocol, check-test proficiency, periodic duplicate samples, and peer review. A satisfactory review will result in the authorized laboratory being recognized by the Service as a national approved laboratory qualified to perform the diagnostic assays provided for in this part.

<u>Classification</u>. A designation earned by participation in a Plan program.

<u>Commercial meat-type flock</u>. All of the meat-type chickens or meat-type turkeys on one farm. However, at the discretion of the Official State Agency, 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 may be considered as a separate flock.

<u>Commercial table-egg layer flock</u>. All table-egg layers of one classification in one barn or house.

<u>Commercial table-egg layer premises</u>. A farm containing contiguous flocks of commercial table-egg layers under common ownership.

<u>Department</u>. The U.S. Department of Agriculture.

<u>Domesticated</u>. Propagated and maintained under the control of a person.

Equivalent. Requirements which are equal to the program, conditions, criteria, or classifications with which compared, as determined by the Official State Agency and with the concurrence of the Service.

H5/H7 low pathogenic avian influenza (LPAI). An infection of poultry caused by an influenza A virus of H5 or H7 subtype that has an intravenous pathogenicity index test in 6-week-old chickens less than 1.2 or any infection with influenza A viruses of H5 or H7 subtype for which nucleotide sequencing has not demonstrated the presence of multiple basic amino acids at the cleavage site of the hemagglutinin.

H5/H7 LPAI virus infection (infected). 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
- (2) Viral antigen or viral RNA specific to the H5 or H7 subtype of AI virus has been detected in poultry; or
- (3) 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.

Official State Agency. The State authority recognized by the Department to cooperate in the administration of the Plan.

Person. A natural person, firm, or corporation.

<u>Plan</u>. The provisions of the National Poultry Improvement Plan contained in this part.

<u>Poultry</u>. Domesticated chickens and turkeys that are bred for the primary purpose of producing eggs or meat.

<u>Program.</u> Management, sanitation, testing, and monitoring procedures which, if complied with, will qualify, and maintain qualification for, designation of a flock, a slaughter plant, or a State by an official Plan classification and illustrative design, as described in § 146.9 of this part.

<u>Service</u>. The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

State. Any of the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands of the United States, or any territory or possession of the United States.

<u>State Inspector</u>. Any person employed or authorized under § 146.10(b) to perform functions under this part.

United States. All of the States.

§ 146.2 Administration.

- (a) The Department cooperates through a Memorandum of Understanding with the Official State Agency in the administration of the Plan.
- (b) The administrative procedures and decisions of the Official State Agency are subject to review by the Service. The Official State Agency shall carry out the administration of the Plan within the State according to the applicable provisions of the Plan and the Memorandum of Understanding.
- (c) (1) An Official State Agency may accept for participation a commercial table-egg layer flock or a commercial meat-type flock (including an affiliated flock) located in another participating State under a mutual understanding and agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision.
- (2) An Official State Agency may accept for participation a commercial table-egg layer flock or a commercial meat-type flock (including an affiliated flock) located in a State that does not participate in the Plan under a mutual understanding and agreement, in writing, between the owner of the flock and the Official State Agency regarding conditions of participation and supervision.
- (d) The Official State Agency of any State may adopt regulations applicable to the administration of the Plan in such State further defining the provisions of the Plan or establishing higher standards, compatible with the Plan.
- (e) An authorized laboratory will follow the laboratory protocols outlined in part 147 of this chapter when determining the status of a participating flock with respect to an official Plan classification.

(f) States will be responsible for making the determination to request Federal assistance under part 56 of this chapter in the event of an outbreak of H5/H7 LPAI. § 146.3 Participation.

(a) Any table-egg producer and any meat-type chicken or meat-type turkey slaughter plant, including its affiliated flocks, may participate in the Plan when the producer or plant has demonstrated, to the satisfaction of the Official State Agency, that its facilities, personnel, and practices are adequate for carrying out the relevant special provisions of this part and has signed an agreement with the Official State Agency to comply with the relevant special provisions of this part.

- (b) Each participant shall comply with the Plan throughout the operating year, or until released by the Official State Agency.
- (c) A participating slaughter plant shall participate with all of the meat-type chicken and/or meat-type turkey flocks that are processed at the facility, including affiliated flocks.

 Affiliated flocks must participate through a written agreement with a participating slaughter plant that is approved by the Official State Agency.
- (d) Participation in the Plan shall entitle the participant to use the Plan emblem reproduced as follows:

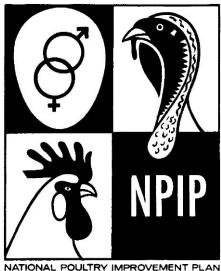


FIGURE 1.

(e) Participation in the NPIP by commercial table-egg layers will cease after [Insert date 2 years after effective date of interim rule] unless the majority of the commercial table-egg layer delegates vote to continue the program in accordance with subpart E of part 147 of this chapter at a National Plan Conference.

§ 146.4 General provisions for all participating flocks and slaughter plants.

- (a) Records that establish the identity of products handled shall be maintained in a manner satisfactory to the Official State Agency.
- (b) Material that is used to advertise products shall be subject to inspection by the Official State Agency at any time.
- (c) Advertising must be in accordance with the Plan, and applicable rules and regulations of the Official State Agency and the Federal Trade Commission. A participant advertising products as being of any official classification may include in their advertising reference to associated or franchised slaughter or production facilities only when such facilities produce products of the same classification.

(d) Each participant shall be assigned a permanent approval number by the Service. This number, prefaced by the numerical code of the State, will be the official approval number of the participant and may be used on each certificate, invoice, shipping label, or other document used by the participant in the sale of the participant's products. Each Official State Agency which requires an approval number for out-of-State participants to ship into its State shall honor this number.

§ 146.5 Specific provisions for all participating flocks.

- (a) Participating flocks, and all equipment used in connection with the flocks, shall be separated from non-participating flocks in a manner acceptable to the Official State Agency.
- (b) Poultry equipment, and poultry houses and the land in the immediate vicinity thereof, shall be kept in sanitary condition as recommended in § 147.21(c) of this subchapter. § 146.6 Specific provisions for participating slaughter plants.
- (a) Only meat-type chicken and meat-type turkey slaughter plants that are under continuous inspection by the Food Safety and Inspection Service of the Department or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection may participate in the Plan.
- (b) To participate in the Plan, meat-type chicken and meat-type turkey slaughter plants must follow the relevant special provisions in §§ 146.33(a) and 146.43(a), respectively, for sample collection and flock monitoring, unless they are exempted from the special provisions under §§ 146.32(b) or 146.42(b), respectively.

§ 146.7 Terminology and classification; general.

The official classification terms defined in §§ 146.8 and 146.9 and the various designs illustrative of the official classifications reproduced in §146.9 may be used only by participants and to describe products that have met all of the specific requirements of such classifications.

Participating slaughter plants shall be designated as "U.S. H5/H7 Avian Influenza Monitored." All Official State Agencies shall be notified by the Service of additions, withdrawals, and changes in classification.

§ 146.9 Terminology and classification; flocks, products, and States.

§ 146.8 Terminology and classification; slaughter plants.

Participating flocks (including affiliated flocks), products produced from them, and States which have met the respective requirements specified in subparts B, C, or D of this part may be designated by the following terms or illustrative designs:

(a) <u>U.S. H5/H7 Avian Influenza Monitored</u>. (See §§ 146.23(a), 146.33(a), and 146.43(a).)



Figure 2.

(b) <u>U.S. H5/H7 Avian Influenza Monitored State, Layers</u>. (See § 146.24.)



Figure 3.

(c) U.S. H5/H7 Avian Influenza Monitored State, Turkeys. (See § 146.44.)

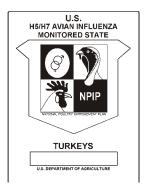


Figure 4.

§ 146.10 Supervision.

- (a) The Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting provided for in § 146.13 of this part.
- (b) The Official State Agency shall employ or authorize qualified persons as State

 Inspectors to perform the selecting and testing of participating flocks and to perform the official inspections necessary to verify compliance with the requirements of the Plan.
- (c) Authorities issued to Authorized Agents or State Inspectors under the provisions of this section shall be subject to cancellation by the Official State Agency on the grounds of incompetence or failure to comply with the provisions of the Plan or regulations of the Official State Agency. Such actions shall not be taken until thorough investigation has been made by the Official State Agency and the authorized person has been given notice of the proposed action and the basis thereof and an opportunity to present his or her views.

§ 146.11 Inspections.

- (a) Each participating slaughter plant shall 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 this part.
- (b) On-site inspections of any participating flocks and premises will be conducted if a State Inspector determines that a breach of testing has occurred for the Plan programs for which the flocks are certified.
- (c) The official H5/H7 LPAI testing records of all participating flocks and slaughter plants shall be examined annually by a State Inspector. Official H5/H7 LPAI testing records shall be maintained for 3 years.

§ 146.12 <u>Debarment from participation</u>.

Participants in the Plan who, after investigation by the Official State Agency or its representative, are notified in writing of their apparent noncompliance with the Plan provisions or regulations of the Official State Agency shall be afforded a reasonable time, as specified by the Official State Agency, within which to demonstrate or achieve compliance. If compliance is not demonstrated or achieved within the specified time, the Official State Agency may debar the participant from further participation in the Plan for such period, or indefinitely, as the Official State Agency may deem appropriate. The debarred participant shall be afforded notice of the bases for the debarment and opportunity to present his or her views with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order,

requests the Administrator to determine the eligibility of the debarred participant for participation in the Plan. In such an event, the Administrator shall determine the matter de novo in accordance with the rules of practice in 7 CFR part 50, which are herby made applicable to proceedings before the Administrator under this section. The definitions in 7 CFR 50.10 and the following definitions shall apply with respect to terms used in such rules of practice:

- (a) <u>Administrator</u> means the Administrator, Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, or any officer or employee to whom authority has heretofore been delegated or to who authority may hereafter be delegated to act in his or her stead.
 - (b) [Reserved]

§ 146.13 <u>Testing</u>.

- (a) <u>Samples</u>. Either egg or blood samples may be used for testing. Samples must be collected in accordance with the following requirements:
- (1) <u>Egg samples</u>. Egg samples must be collected and prepared in accordance with the requirements in § 147.8 of this subchapter.
- (2) <u>Blood samples</u>. Blood samples obtained in the slaughter plant should be collected after the kill cut with birds remaining on the kill line. Hold an open 1.5 mL snap cap microcentrifuge tube under the neck of the bird directly after the kill cut and collect drips of blood until the tube is half full. Keep the blood tubes at room temperature for the clot to form, which should require a minimum of 4 hours and a maximum of 12 hours. Refrigerate the tube after the clot has formed. Put tubes in a container and label it with plant name, date, shift (A.M. or Day, P.M. or Night), and flock number. After the clot is formed, the clot should be removed by the

Authorized Agent in order to ensure good-quality sera. Prepare a laboratory submission form and ship samples with submission forms to the laboratory in a polystyrene foam cooler with frozen ice packs. Submission forms and the manner of submission must be approved by the Official State Agency and the authorized laboratory to ensure that there is sufficient information to identify the samples and that the samples are received in an acceptable condition for further tests to be reliably performed. Blood samples should be shipped routinely to the laboratory. Special arrangements should be developed for samples held over the weekend to ensure that the samples can be reliably tested. Blood samples for official tests shall be drawn by an Authorized Agent or State Inspector.

- (b) Avian influenza. The official tests for avian influenza are the agar gel immunodiffusion (AGID) test and the enzyme-linked immunosorbent assay (ELISA). These tests may be used on either egg yolk or blood samples. Standard test procedures for the AGID test for avian influenza are set forth in § 147.9 of this subchapter.
- (1) The AGID test must be conducted on all ELISA-positive samples. Any samples that are found to be positive by AGID must be further tested and subtyped by Federal Reference Laboratories using the hemagglutination inhibition test. Final judgment may be based upon further sampling or culture results.
- (2) The tests must be conducted using antigens or test kits approved by the Service. Test kits must be licensed by the Service and approved by the Official State Agency, and tests must be performed in accordance with the recommendations of the producer or manufacturer.
- (3) The official determination of a flock as positive for the H5 or H7 subtypes of low pathogenic avian influenza may be made only by the National Veterinary Services Laboratories.

- § 146.14 Diagnostic surveillance program for H5/H7 low pathogenic avian influenza.
- (a) The Official State Agency must develop a diagnostic surveillance program for H5/H7 low pathogenic avian influenza for all poultry in the State. The exact provisions of the program are at the discretion of the States. The Service will use the standards in paragraph (b) of this section in assessing individual State plans for adequacy, including the specific provisions that the State developed. The standards should be used by States in developing those plans.
- (b) Avian influenza 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 avian influenza 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 low pathogenic avian influenza 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 avian influenza.

Subpart B-Special Provisions for Commercial Table-Egg Layer Flocks

§ 146.21 Definitions.

<u>Table-egg layer</u>. A domesticated chicken grown for the primary purpose of producing eggs for human consumption.

§ 146.22 Participation.

- (a) Participating commercial table-egg layer flocks shall comply with the applicable general provisions of subpart A of this part and the special provisions of subpart B of this part.
- (b) Commercial table-egg laying premises with fewer than 75,000 birds are exempt from the special provisions of subpart B of this part.

§ 146.23 Terminology and classification; flocks and products.

Participating flocks which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 146.9 of this part:

- (a) <u>U.S. H5/H7 Avian Influenza Monitored</u>. This program is intended to be the basis from which the table-egg layer industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in table-egg layers through routine serological surveillance of each participating commercial table-egg layer flock. A flock will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:
- (1) It is a commercial table-egg layer flock in which a minimum of 11 birds or egg samples have been tested negative for antibodies to the H5/H7 subtypes of avian influenza within 30 days prior to disposal;
- (2) It is a commercial table-egg layer flock in which a minimum of 11 birds or egg samples have been tested negative for antibodies to the H5/H7 subtypes of avian influenza within a 12-month period; or
- (3) It is a commercial table-egg layer flock that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds or

egg samples tested is equivalent to the number required in paragraph (a)(1) or (a)(2) and that is approved by the Official State Agency and the Service.

- (b) [Reserved]
- § 146.24 <u>Terminology and classification; States.</u>
- (a) <u>U.S. H5/H7 Avian Influenza Monitored State, Layers</u>. (1) A State will be declared a U.S. H5/H7 Avian Influenza Monitored State, Layers when it has been determined by the Service that:
- (i) All commercial table-egg layer flocks in production within the State that are not exempt from the special provisions of this subpart B under § 146.22 are classified as U.S. H5/H7 Avian Influenza Monitored under § 146.23(a) of this part;
- (ii) All egg-type chicken breeding flocks in production within the State are classified as U.S. Avian Influenza Clean under § 145.23(h) of this subchapter;
- (iii) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency, within 24 hours, the source of all table-egg layer specimens that were deemed positive on an official test for avian influenza, as designated in § 146.13(a) of this chapter;
- (iv) All table-egg layer specimens that were deemed positive on an official test for avian influenza, as designated in § 146.13(a) of this chapter, are sent to an authorized laboratory for subtyping; and
- (v) All table-egg layer flocks within the State that are found to be infected with the H5/H7 subtypes of avian influenza are quarantined, in accordance with an initial State response

and containment plan as described in part 56 of this chapter and under the supervision of the Official State Agency.

(2) If there is a discontinuation of any of the conditions described in paragraph (a)(1) of this section, or if repeated outbreaks of the H5/H7 subtypes of avian influenza occur in commercial table-egg layer flocks as described in paragraph (a)(1)(i) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has been made by the Service and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

(b) [Reserved]

Subpart C–Special Provisions for Meat-Type Chicken Slaughter Plants § 146.31 Definitions.

Meat-type chicken. A domesticated chicken grown for the primary purpose of producing meat, including but not limited to broilers, roasters, fryers, and cornish.

Meat-type chicken slaughter plant. A meat-type chicken slaughter plant that is federally inspected or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection.

Shift. The working period of a group of employees who are on duty at the same time. § 146.32 <u>Participation</u>.

(a) Participating meat-type chicken slaughter plants shall comply with applicable general provisions of subpart A of this part and the special provisions of this subpart C.

(b) Meat-type chicken slaughter plants that slaughter fewer than 200,000 meat-type chickens in an operating week are exempt from the special provisions of this subpart C. § 146.33 Terminology and classification; meat-type chicken slaughter plants.

Participating meat-type chicken slaughter plants that have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 146.9 of this part:

- (a) <u>U.S. H5/H7 Avian Influenza Monitored</u>. This program is intended to be the basis from which the meat-type chicken industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of the H5/H7 subtypes of avian influenza in meat-type chickens through routine surveillance of each participating meat-type chicken slaughter plant. A meat-type chicken slaughter plant will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:
- (1) It is a meat-type chicken slaughter plant where a minimum of 11 birds per shift are tested negative for antibodies to the H5/H7 subtypes of avian influenza at slaughter; <u>Provided</u>, that with the approval of the Official State Agency, fewer than 11 birds per shift may be tested on any given shift if the total number of birds tested during the operating month is equivalent to testing 11 birds per shift; or
- (2) It is a meat-type chicken slaughter plant which accepts only meat-type chickens from flocks where a minimum of 11 birds have been tested negative for antibodies to the H5/H7 subtypes of avian influenza no more than 21 days prior to slaughter; or

(3) It is a meat-type chicken slaughter plant that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(1) or (a)(2) and that is approved by the Official State Agency and the Service.

(b) [Reserved]

Subpart D–Special Provisions for Meat-Type Turkey Slaughter Plants

§ 146.41 <u>Definitions</u>.

Meat-type turkey. A domesticated turkey grown for the primary purpose of producing meat.

Meat-type turkey slaughter plant. A meat-type turkey slaughter plant that is federally inspected or under State inspection that the Food Safety Inspection Service has recognized as equivalent to federal inspection.

§ 146.42 Participation.

- (a) Participating meat-type turkey slaughter plants shall comply with applicable general provisions of subpart A of this part and the special provisions of this subpart D.
- (b) Meat-type turkey slaughter plants that slaughter fewer than 2 million meat-type turkeys in a 12-month period are exempt from the special provisions of this subpart D. § 146.43 Terminology and classification; meat-type turkey slaughter plants.

Participating meat-type turkey slaughter plants which have met the respective requirements specified in this section may be designated by the following terms and the corresponding designs illustrated in § 146.9 of this part:

- (a) <u>U.S. H5/H7 Avian Influenza Monitored</u>. This program is intended to be the basis from which the meat-type turkey industry may conduct a program to monitor for the H5/H7 subtypes of avian influenza. It is intended to determine the presence of avian influenza in meat-type turkeys through routine surveillance of each participating meat-type turkey slaughter plant. A participating meat-type turkey slaughter plant will qualify for this classification when the Official State Agency determines that it has met one of the following requirements:
- (1) It is a meat-type turkey slaughter plant at which a sample of a minimum of 60 birds has tested negative each month for antibodies to type A avian influenza virus. Positive samples shall be further tested by an authorized laboratory using the hemagglutination inhibition test to detect antibodies to the hemagglutinin subtypes H5 and H7. It is recommended that samples be collected from flocks over 10 weeks of age with respiratory signs such as coughing, sneezing, snicking, sinusitis, or rales; depression; or decreases in food or water intake.
- (2) It is a meat-type turkey slaughter plant that has an ongoing active and diagnostic surveillance program for the H5/H7 subtypes of avian influenza in which the number of birds tested is equivalent to the number required in paragraph (a)(1) and that is approved by the Official State Agency and the Service.

(b) [Reserved]

- § 146.44 Terminology and classification; States.
- (a) <u>U.S. H5/H7 Avian Influenza Monitored State, Turkeys</u>. (1) A State will be declared a U.S. H5/H7 Avian Influenza Monitored State, Turkeys when it has been determined by the Service that:

- (i) All meat-type turkey slaughter plants within the State that are not exempt from the special provisions of this subpart D under § 146.42 are classified as U.S. H5/H7 Avian Influenza Monitored under § 146.43(a) of this part;
- (ii) All turkey breeding flocks in production within the State are classified as U.S. H5/H7 Avian Influenza Clean under § 145.43(g) of this subchapter;
- (iii) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency, within 24 hours, the source of all meat-type turkey specimens that were deemed positive on an official test for avian influenza, as designated in § 146.13(a) of this chapter;
- (iv) All meat-type turkey specimens that were deemed positive on an official test for avian influenza, as designated in § 146.13(a) of this chapter, are sent to an authorized laboratory for subtyping; and
- (v) All meat-type turkey flocks within the State that are found to be infected with the H5/H7 subtypes of avian influenza are quarantined, in accordance with an initial State response and containment plan as described in part 56 of this chapter, and under the supervision of the Official State Agency.
- (2) If there is a discontinuation of any of the conditions described in paragraph (a)(1) of this section, or if repeated outbreaks of the H5/H7 subtypes of avian influenza occur in meat-type turkey flocks as described in paragraph (a)(1)(i) of this section, or if an infection spreads from the originating premises, the Service shall have grounds to revoke its determination that the State is entitled to this classification. Such action shall not be taken until a thorough investigation has

been made by the Service and the Official State Agency has been given an opportunity for a hearing in accordance with rules of practice adopted by the Administrator.

PART 147-AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

9. The authority citation for part 147 continues to read as follows:

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

- 10. Section 147.8 is amended as follows:
- a. In the introductory text, by removing the words ", and for" and adding the word "; for" in its place; and by adding the words "; and for retaining the classification U.S. H5/H7 Avian Influenza Monitored under § 146.23(a), § 146.33(a), and § 146.44(a)" before the words "of this chapter".
 - b. By revising paragraph (b)(7) to read as set forth below.
- § 147.8 <u>Procedures for preparing egg yolk samples for diagnostic tests</u>.
- * * * * *
 - (b) * * *
- (7) (i) For egg yolk samples being tested to retain the U.S. M. Gallisepticum Clean and U.S. M. Synoviae Clean classifications, test the resultant supernatant for M. gallisepticum and M. synoviae by using test procedures specified for detecting IgG antibodies set forth for testing serum in §147.7 (for these tests the resultant supernatant would be substituted for serum); except that a single 1:20 dilution hemagglutination inhibition (HI) test may be used as a screening test in accordance with the procedures set forth in § 147.7.

(ii) For egg yolk samples being tested to retain the U.S. H5/H7 Avian Influenza Monitored classification, test the resultant supernatant in accordance with the requirements in § 146.13(b).

Note: For evaluating the test results of any egg yolk test, it should be remembered that a 1:2 dilution of the yolk in saline was made of the original specimen.

* * * * *

§ 147.45 [Amended]

- 11. Section 147.45 is amended by adding the words "and for each of the programs prescribed in subparts B, C, and D of part 146 of this chapter" after the word "chapter".
 - 12. In § 147.46, paragraph (a) is revised to read as follows:

§ 147.46 Committee consideration of proposed changes.

- (a) The following committees shall be established to give preliminary consideration to the proposed changes falling in their respective fields:
 - (1) Egg-type breeding chickens.
 - (2) Meat-type breeding chickens.
 - (3) Breeding turkeys.
 - (4) Breeding waterfowl, exhibition poultry, and game birds.
 - (5) Breeding ostriches, emus, rheas, and cassowaries.

| | (6) Egg-type commercial chickens. |
|-----|-------------------------------------|
| | (7) Meat-type commercial chickens. |
| | (8) Meat-type commercial turkeys. |
| * * | * * * |
| | Done in Washington, DC, this day of |
| | |
| | |

Under Secretary, Marketing and Regulatory Programs.

04-111-1.wpd ALM 6/3/05 revised version to OGC ALM 8/26/05 second revised version to OGC ALM 10/18/05 OGC changes 10/31/05 ALM final OGC changes and paperwork statement 11/17/05 DA changes 11/23/05 ALM controlled marketing changes 11/30/05 ALM initial changes based on OBPA questions and Andy input 12/20/05 ALM updated paperwork info 12/23/05 ALM addtl changes 2/9/06 ALM final econ edits 2/14/06 ALM new version with many changes 3/2/06 ALM added affected paperwork sections boilerplate 3/13/06 ALM new vn to re-enter clearance 3/24/06 ALM OGC changes 4/10/06 ALM OBPA changes 5/2/06 and 5/8/06 ALM Initial responses to preliminary OMB comments 8/11/06 ALM