the committee ultimately determined that exempting handlers of less than 5,000 pounds of assessed weight pistachios was prudent because only 14 additional handlers would be affected, and the total volume of exempted pistachios handled is relatively insignificant (less than 0.02 percent of total production). Thus, exempting an estimated total of 28 handlers with less than 5,000 pounds of assessed weight pistachios would not affect the overall quality of the pistachios handled as those pistachios are likely to be for home or personal use and will not compete in traditional markets.

Both the subcommittee and the committee noted that spot-checks on small handlers would be continued to ensure compliance with order requirements.

This action would reduce reporting requirements for pistachio handlers who fall below the 5,000 pound threshold. Such handlers would also be exempt from most of the other regulatory requirements imposed under the authority.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection requirements that are contained in this rule have previously been approved by the Office of Management and Budget (OMB), and have been assigned OMB No. 0581–0215.

AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule.

Further, the committee’s meetings are widely publicized throughout the pistachio industry and all interested persons are encouraged to attend the meetings and participate in the committee’s deliberations. In this respect, the March 1, 2006, subcommittee and committee meetings regarding the handler exemption were public meetings and all entities, both large and small, were encouraged to express their views on this issue.

The committee recommendation on March 1, 2006, resulted from deliberations of its Technical Subcommittee, which is charged with compliance, quality, and inspection issues under the marketing order. During the subcommittee meeting, the opinions and concerns of industry representatives were solicited, openly discussed, and deliberated at some length. The subcommittee made its unanimous recommendation to the committee, who agreed with the recommendation unanimously, as well.

Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: http://www.ams.usda.gov/fv/moab.html. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the FOR FURTHER INFORMATION CONTACT section.

A 20-day comment period is provided to allow interested persons to respond to this proposal. Twenty days is deemed appropriate because this rule should be in place by September 1, 2006, the beginning of the crop year, and is a relaxation of current handling requirements. All written comments received by the end of the comment period will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 983

Marketing agreements, Pistachios, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 983 is proposed to be amended as follows:

PART 983—PISTACHIOS GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 983 continues to read as follows:


2. In §983.143, revise paragraph (b)(2) to read as follows:

§983.143 Reinspection.  
* * * * *

(b) * * * *

(2) Handlers exempted from order requirements under §983.170 are exempt from all reinspection requirements.

3. In §983.147, paragraphs (c) and (g) are revised to read as follows:

§983.147 Reports.  
* * * * *

(c) ACP–4, Federal Marketing Order Exempt Handler Notification. Each handler who handles less than 5,000 pounds of assessed weight pistachios in a production year shall complete and furnish this report to the committee no later than November 15 of each production year.

* * * * *
lower “Search Regulations and Federal Actions” 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-2006–0008 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–2006–0008, 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–2006–0008.

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 for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. Participation in all Plan programs is voluntary, but flocks, hatcheries, and dealers must first qualify as “U.S. Pullorum-Typhoid Clean” as a condition for participating in the other Plan programs.

The Plan identifies States, flocks, hatcheries, and dealers that meet certain disease control standards specified in the Plan’s various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR parts 145 and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS, also referred to as “the Service”) of the U.S. Department of Agriculture (USDA, also referred to as “the Department”) amends these provisions from time to time to incorporate new scientific information and technologies within the Plan.

The proposed amendments discussed in this document are consistent with the recommendations approved by the voting delegates to the National Plan Conference that was held from July 8 to July 10, 2004. Participants in the 2004 National Plan Conference represented flockowners, breeders, hatcherymen, and Official State Agencies from all cooperating States. The proposed amendments are discussed in detail below.

New Definition of Authorized Testing Agent

The regulations in § 145.11(a) state that the Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting and blood testing provided for in § 145.14 and the selecting required for the U.S. Approved classification in § 145.53(a). The term Authorized Agent in the definitions in § 145.1 simply refers to any person authorized under § 145.11(a) to perform functions under 9 CFR part 145. Thus, the term Authorized Agent as it is currently used in the regulations refers to persons with different tasks and capabilities, which could cause confusion. For example, Authorized Agents who may be authorized to collect blood samples should not be allowed to perform blood testing unless they have been specifically authorized to perform both duties.

To address this problem, we are proposing to establish a new term, “Authorized Testing Agent,” that would refer to persons authorized to perform blood testing and collect samples, and use the existing term “Authorized Agent” to refer to persons only authorized to collect samples. We would amend § 145.11(a) to state that the Official State Agency may designate Authorized Agents to do the sample collecting provided for in § 145.14 and may designate qualified persons as Authorized Agents to do the sample collecting and blood testing provided for in § 145.14. We would also add a new definition to § 145.1 of the term Authorized Testing Agent that would read “Any person designated under § 145.11(a) to collect official samples for submission to an authorized laboratory as described in §§ 147.1(a) and 147.12 of this subchapter to perform the stained antigen, rapid whole blood test for pullorum typhoid.”

The definition of Authorized Agent would be revised to read “Any person designated under § 145.11(a) to collect official samples for submission to an authorized laboratory as described in §§ 147.1(a) and 147.12 of this subchapter.”

To accomplish this change, we would change references to “Authorized Agent” when the term specifically designates a person who performs blood testing for pullorum typhoid to instead refer to “Authorized Testing Agent.” These references occur in §§ 145.14, 145.23(b)(2)(iii), 145.33(b)(2)(iii), 145.43(b)(2)(iii), and 145.53(b)(2)(iii).

We are also proposing to remove the reference in § 145.11(a) to the U.S. Approved classification in § 145.53(a), as this classification no longer exists.

A related change we are proposing concerns the U.S. Sanitation Monitored, Turkeys program. Paragraph (f)(2) of § 145.43 requires that the pouls for a breeding flock that is a candidate for this classification must be “placed in a building that has been cleaned, disinfected, and examined bacteriologically for the presence of Salmonella by an Authorized Agent, as described in § 147.12 of this chapter.”

As indicated in the discussion above, the Authorized Agent’s role is to collect samples for bacteriological examination for Salmonella, not to perform the bacteriological examination. Accordingly, we would amend this requirement to read: “The pouls for the candidate breeding flock are placed in a building that has been cleaned and disinfected. An Authorized Agent must collect environmental samples from the building and submit them to an authorized laboratory for a bacteriological examination for the presence of Salmonella, as described in § 147.12 of this chapter.”

Clarification of Supervisory Role in Selecting and Testing of Participating Flocks

In § 145.11, paragraph (b) states: “The Official State Agency shall employ or authorize qualified persons as State Inspectors to perform or supervise the performance of the selecting and testing of participating flocks, and to perform the official inspection necessary to verify compliance with the requirements of the Plan.” We would
amend this paragraph to remove the reference to supervising the performance of selecting and testing. In addition, to improve clarity, we would indicate that the testing that State Inspectors should perform is qualification testing, referring to testing undertaken to determine whether a flock meets the criteria for participation in a Plan program. These changes would have the effect of requiring that a State Inspector perform the selecting and qualification testing of flocks that apply for participation in the Plan.

Most Official State Agencies already require that State Inspectors perform selecting and qualification testing in order to ensure that a State representative is involved in NPIP testing at least once in the life of a participating flock. Subsequent testing is typically performed by Authorized Agents, who are typically employees of the company that owns the poultry. Foreign governments have also encouraged us to make this change in order to increase governmental involvement in NPIP testing. This proposed requirement would increase governmental oversight of participating flocks in States where such oversight is not already required.

Requiring That Participating Hatcheries Be Audited at Least Once Annually

The regulations in § 145.12(a) require that each participating hatchery be inspected a sufficient number of times each year to satisfy the Official State Agency that the operations of the hatchery are in compliance with the provisions of the Plan. We are proposing to change this requirement to indicate that participating hatcheries must be audited, rather than inspected. As the regulations in § 145.12(b) state, on-site inspections of flocks and premises are conducted only if the State inspector determines that a breach of sanitation, blood testing, or other provisions has occurred for Plan programs for which the flocks have been or are being licensed. In order for the State inspector to determine that a breach of Plan provisions has occurred, the inspector first examines records submitted to the Official State Agency. We believe “audit” is a better term to describe this process than “inspect,” as inspections are typically presumed to take place on-site.

In addition, the phrase “a sufficient number of times each year” does not establish a minimum number of times a participating hatchery must be inspected. We are proposing to add a requirement that participating hatcheries be audited a minimum of one time annually. This change would ensure that participating hatcheries are audited at regular intervals while allowing the Official State Agency to audit more often if the Official State Agency determines that more audits are necessary to establish that the operations of the hatchery are in compliance with the provisions of the Plan.

Approved Tests

In order to establish and maintain eligibility for classifications under the Plan, poultry flocks must be tested regularly for various diseases. Descriptions of how to conduct some bacteriological tests are provided in 9 CFR part 147. Other acceptable tests using veterinary biologics are licensed by APHIS’ Center for Veterinary Biologics (CVB) according to the testing and licensing procedure described in 9 CFR part 113. Tests produced by CVB also may be used.

Diagnostic test kits, such as polymerase chain reaction (PCR) and other bacteriological culturing test kits, are also a useful tool for performing tests. The NPIP has approved a procedure for testing diagnostic test kits and approving them for use by Plan participants, and this procedure has already been used to approve one test kit. However, we have not previously included this procedure in the Plan regulations. This proposal would establish a new section, § 145.15, “Approved tests,” setting out this procedure.

Paragraph (a) of proposed § 145.15 would read as follows: “The procedures for the bacteriological examination of poultry and poultry environments described in part 147 of this subchapter are approved tests for use in the NPIP. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in part 147 of this subchapter are approved for use in the NPIP.” The regulations currently do not explicitly state that veterinary biologics licensed or produced by the Service and used as described in part 147 are approved for use in Plan testing; this proposed new language would correct that oversight.

Proposed paragraph (b) would set out a procedure by which diagnostic test kits that are not licensed by the Service could be approved for use in the NPIP. The required steps in this procedure would be as follows:

• The sensitivity of the kit would be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in 9 CFR part 147. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples would be included so that the magnitude and significance of the effect(s) can be evaluated.

• The specificity of the kit would be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by the official NPIP procedures found in 9 CFR part 147. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples would be included so that the magnitude and significance of the effect(s) can be evaluated.

• The kit would be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories would perform the assay exactly as stated in the supplied instructions. Each laboratory would test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory would be asked to test 50 known negative clinical samples obtained from several sources to provide a representative sampling of the general population. The identity of the samples would be coded so that the cooperating laboratories are blinded to identity and classification. Each sample would have to be provided in duplicate or triplicate, so that error and repeatability data could be generated.

• Cooperating laboratories would submit to the kit manufacturer all raw data regarding the assay response. Each sample tested would be reported as positive or negative and the official NPIP procedure used to classify the sample would be submitted in addition to the assay response value.

• The findings of the cooperating laboratories would be evaluated by the NPIP technical committee and the technical committee would make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the technical committee recommends approval, the final approval would be granted in accordance with the procedures described in §§ 147.46 and 147.47.

We believe this procedure would be sufficient for determining whether a test kit is accurate and, if it is accurate, for approving it for use in the NPIP.

Separation of Provisions for Primary and Multiplier Breeding Flocks of Egg-Type and Meat-Type Chickens

Within 9 CFR part 145, the regulations in subpart B (§§ 145.21...
primary breeding flocks participating in NPIP programs are free of disease; therefore, the program requirements for primary breeding flocks in these subparts are generally more stringent than the program requirements for multiplier breeding flocks. In addition, some programs in these subparts are only intended for use by either primary breeding flocks or multiplier breeding flocks. Listing both sets of program requirements in the same section, with what are, in some cases, ambiguous indications regarding whether they are intended for use by primary or multiplier breeding flocks within the text describing the programs, could lead to confusion.

Therefore, we are proposing to establish new subparts G and H in 9 CFR part 145 for primary egg-type chicken breeding flocks and primary meat-type chicken breeding flocks, respectively. We are also proposing to remove provisions in subparts B and C of 9 CFR part 145 that are specific to primary breeding flocks. The changes we would make to accomplish this are summarized in the four tables that follow.

### TABLE 1.—PROPOSED CHANGES TO AND DELETIONS FROM THE PROVISIONS IN SUBPART B OF 9 CFR PART 145

<table>
<thead>
<tr>
<th>Program (if applicable)</th>
<th>Location</th>
<th>Proposed change</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Gallisepticum Clean</td>
<td>§ 145.23(b)(2)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. M. Gallisepticum Clean</td>
<td>§ 145.23(b)(5)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. M. Synoviae Clean</td>
<td>§ 145.23(c)(1)(i)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. M. Synoviae Clean</td>
<td>§ 145.23(c)(2)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. Avian Influenza Clean</td>
<td>§ 145.23(h)(1)</td>
<td>Remove</td>
</tr>
</tbody>
</table>

### TABLE 2.—PROPOSED CHANGES TO AND DELETIONS FROM THE PROVISIONS IN SUBPART C OF 9 CFR PART 145

<table>
<thead>
<tr>
<th>Program (if applicable)</th>
<th>Location</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Pullorum—Typhoid Clean</td>
<td>§ 145.32 introductory text</td>
<td>Indicate that multiplier flocks participate in this subpart.</td>
</tr>
<tr>
<td>U.S. M. Gallisepticum Clean</td>
<td>§ 145.32(b)</td>
<td>Make existing requirement for primary flocks apply to multiplier flocks (see discussion later under this heading).</td>
</tr>
<tr>
<td>U.S.M. Gallisepticum Clean</td>
<td>§ 145.33(b)(5)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. M. Synoviae Clean</td>
<td>§ 145.33(c)(1)(i)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. M. Synoviae Clean</td>
<td>§ 145.33(c)(2)</td>
<td>Remove</td>
</tr>
<tr>
<td>U.S. Avian Influenza Clean</td>
<td>§ 145.33(e)(1)(i)</td>
<td>Remove</td>
</tr>
</tbody>
</table>
TABLE 2.—PROPOSED CHANGES TO AND DELETIONS FROM THE PROVISIONS IN SUBPART C OF 9 CFR PART 145—Continued

<table>
<thead>
<tr>
<th>Program (if applicable)</th>
<th>Location</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. S. Enteritidis Clean</td>
<td>§ 145.33(h)</td>
<td>Remove.</td>
</tr>
<tr>
<td>U.S. Salmonella Monitored</td>
<td>§ 145.33(i)</td>
<td>Remove.</td>
</tr>
<tr>
<td>U.S. Avian Influenza Clean</td>
<td>§ 145.33(l)(1)</td>
<td>Remove.</td>
</tr>
</tbody>
</table>

§ 145.72 would read: “Provided, That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1)(i) or (ii) of this section are set”.

TABLE 3.—DERIVATION OF PROPOSED SUBPART G OF 9 CFR PART 145

<table>
<thead>
<tr>
<th>Program (if applicable)</th>
<th>Proposed new section or paragraph</th>
<th>Based on</th>
<th>Copied or moved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Pulmonary-Typhoid Clean</td>
<td>§ 145.73(b)(1)</td>
<td>§ 145.21 and new definition of primary breeding flock.</td>
<td>Copied.</td>
</tr>
<tr>
<td>U.S. M. Gallisepticum Clean</td>
<td>§ 145.73(b)(2)</td>
<td>§ 145.22 and new language indicating that the subpart applies to primary breeding flocks.</td>
<td>Copied.</td>
</tr>
<tr>
<td>U.S. S. Enteritidis Clean</td>
<td>§ 145.73(c)(1)(i)</td>
<td>§ 145.23(c)(1)(i)</td>
<td>Moved.</td>
</tr>
<tr>
<td>U.S. M. Synoviae Clean</td>
<td>§ 145.73(c)(2)</td>
<td>Language in § 145.23(c)(2) and new language.</td>
<td>Moved and changed (see discussion later under this heading).</td>
</tr>
<tr>
<td>U.S. Avian Influenza Clean</td>
<td>§ 145.73(e)(3)</td>
<td>§ 145.23(e)(3)</td>
<td>Copied.</td>
</tr>
<tr>
<td>§ 145.72(l)(1)</td>
<td>§ 145.23(f)(1)</td>
<td>Moved.</td>
<td></td>
</tr>
</tbody>
</table>

TABLE 4.—DERIVATION OF PROPOSED SUBPART G OF 9 CFR PART 145

<table>
<thead>
<tr>
<th>Program (if applicable)</th>
<th>Proposed new section or paragraph</th>
<th>Based on</th>
<th>Copied or moved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Pulmonary-Typhoid Clean</td>
<td>§ 145.81</td>
<td>§ 145.31 with primary definition</td>
<td>Copied.</td>
</tr>
<tr>
<td>§ 145.82</td>
<td>§ 145.32 and very little new language</td>
<td>Copied.</td>
<td></td>
</tr>
<tr>
<td>§ 145.83(b)(1)</td>
<td>§ 145.33(b)(1)</td>
<td>Copied.</td>
<td></td>
</tr>
<tr>
<td>§ 145.83(b)(2)</td>
<td>§ 145.33(b)(2) through (b)(5)</td>
<td>Copied.</td>
<td></td>
</tr>
<tr>
<td>U.S. M. Gallisepticum Clean</td>
<td>§ 145.83(c)(1)(i)</td>
<td>§ 145.33(c)(1)(i)</td>
<td>Moved.</td>
</tr>
<tr>
<td>§ 145.83(c)(2)</td>
<td>Language in § 145.33(c)(2) and new language.</td>
<td>Moved and changed (see discussion later under this heading).</td>
<td></td>
</tr>
<tr>
<td>U.S. M. Synoviae Clean</td>
<td>§ 145.83(c)(3)</td>
<td>§ 145.33(c)(3)</td>
<td>Copied.</td>
</tr>
<tr>
<td>§ 145.83(d)(2)</td>
<td>Language in § 145.33(e)(2) and new language.</td>
<td>Moved and changed (see discussion later under this heading).</td>
<td></td>
</tr>
<tr>
<td>U.S. S. Enteritidis Clean</td>
<td>§ 145.83(e)</td>
<td>§ 145.33(h)</td>
<td>Moved.</td>
</tr>
<tr>
<td>U.S. Salmonella Monitored</td>
<td>§ 145.83(f)</td>
<td>§ 145.33(i)</td>
<td>Moved and changed (see discussion later under this heading).</td>
</tr>
<tr>
<td>U.S. Avian Influenza Clean</td>
<td>§ 145.83(g)</td>
<td>§ 145.33(l)</td>
<td>Copied.</td>
</tr>
<tr>
<td>§ 145.83(g)(1)</td>
<td>§ 145.33(l)(1)</td>
<td>Moved.</td>
<td></td>
</tr>
</tbody>
</table>

The new definition of primary egg-type chicken breeding flocks in § 145.71 would read: “Foundation flocks that are composed of pedigreed, great-grandparent, and grandparent stock that has been developed for egg production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce table egg layers.” The new definition of primary meat-type chicken breeding flocks in § 145.81 would read: “Foundation flocks that are composed of pedigreed, great-grandparent, and grandparent stock that has been developed for meat production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce commercial broilers.”

As mentioned previously, for meat-type chickens, the U.S. Sanitation Monitored program in § 145.33(d) and the U.S. M. Synoviae Monitored program in § 145.33(k) would not be
Finally, we are proposing to make two changes to the regulations for egg-type and meat-type chickens:

- The regulations in §§145.22(b) and 145.32(b) currently require hatching eggs produced by primary breeding flocks of egg-type and meat-type chickens, respectively, to be fumigated in accordance with §147.25 or otherwise sanitized. This requirement should apply to both primary and multiplier breeding flocks. Accordingly, we are proposing to extend it to multiplier breeding flocks in §§145.22(b) and 145.32(b).

- The regulations in §§145.23(b)(2) and 145.33(b)(2) refer to a testing program for either multiplier breeding flocks or “a breeding flock composed of progeny of a primary breeding flock which is intended solely for the purpose of production of multiplier breeding flocks.” Such a flock would normally be classified as a multiplier flock, and it is treated identically to a multiplier flock in these regulations. Accordingly, we are proposing to delete the quoted language to eliminate the possibility of confusion.

We would also make minor editorial changes to the new primary breeding flock subparts to improve clarity and consistency.

**Testing in U.S. Avian Influenza Clean Programs for Egg-Type and Meat-Type Chickens**

In the current regulations, the U.S. Avian Influenza Clean programs for egg-type and meat-type chicken breeding flocks and products are set out at §§145.23(h) and 145.33(i), respectively. As discussed earlier in this document, we would move the requirements for primary breeding flocks to new subparts for primary egg-type and meat-type chicken breeding flocks; the provisions of the U.S. Avian Influenza Clean programs that relate to primary breeding flocks of egg-type and meat-type chickens would be found at §§145.73(f) and 145.83(g), respectively, under this proposal. The provisions of the U.S. Avian Influenza Clean programs for multiplier breeding flocks of egg-type and meat-type chickens would remain at §§145.23(h) and 145.33(i). We are proposing to make several changes to the provisions of the U.S. Avian Influenza Clean programs for both primary and multiplier breeding flocks of egg-type and meat-type chickens.

The U.S. Avian Influenza Clean programs for primary breeding flocks of egg-type and meat-type chickens presently require that a sample of at least 30 birds be tested negative at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period. The programs for multiplier breeding flocks are the same except that the relevant interval is 180 days.

We are proposing to require for egg-type chickens that, in addition to the current testing requirements, primary and multiplier spent fowl be tested within 30 days prior to movement to disposal. Similarly, we would require for meat-type chickens that, in addition to the current testing requirements, primary and multiplier spent fowl be tested within 30 days prior to movement to slaughter. (We would use different terms—i.e., disposal and slaughter—because the economic value of a spent table-egg laying hen has eliminated slaughter as a viable option in many parts of the country.) This requirement would ensure that the samples taken from spent fowl are tested in a timely fashion for the presence of avian influenza, which would help prevent further spread of the virus within and outside the flock if it is present.

For meat-type chickens, we are also proposing to require that the 30 birds tested for avian influenza be tested prior to the onset of egg production. If infected birds produce eggs, the eggs can serve as fomites for the transmission of the disease. This requirement would ensure that, if any avian influenza virus is present in a meat-type chicken flock, it is not spread from the flock to a hatchery by the movement of eggs.

**Sample Sizes and Procedures for M. Gallisepticum and M. Synoviae in Primary Breeding Flocks of Meat-Type Chickens**

In the current regulations, the U.S. Gallisepticum Clean and U.S. M. Synoviae Clean programs for meat-type chicken breeding flocks and products set out testing requirements for primary meat-type chicken breeding flocks in §§145.33(c)(1)(i) and 145.33(e)(1)(i), respectively. As discussed earlier in this document, we would move these requirements to a new subpart for primary meat-type chicken breeding flocks; these requirements would be found at §§145.83(d)(1)(i) and 145.83(d)(3)(1)(i), respectively, under this proposal.

We are additionally proposing to change these testing requirements as they apply to primary breeding flocks. Currently, paragraph (c)(1)(i) of §145.33 requires that primary breeding flocks demonstrate freedom from M. gallisepticum by testing all birds or a sample of at least 300 birds for M. gallisepticum when more than 4 months of age. To retain this classification, a
minimum of 150 birds must be tested at intervals of not more than 90 days; a sample of fewer than 150 birds may be tested at any one time if all pens are equally represented and a total of 150 birds is tested within each 90-day period. Paragraph (e)(1)(i) of § 145.33 sets out a similar requirement relating to testing for *M. synoviae*.

The requirement that 150 birds be tested at intervals of not more than 90 days provides an adequate indication that the birds they are producing and marketing are free of *M. gallisepticum* and *M. synoviae*, but it is not mandatory. Therefore, we are proposing to require that, for a meat-type chicken primary breeding flock to retain the classification U.S. M. Gallisepticum Clean or U.S. M. Synoviae Clean, a minimum of 40 birds must be tested at intervals of not more than 28 days, with a total of at least 150 birds tested within each 90-day period. We believe this change would provide greater assurance for primary breeders that their flocks are free of *M. gallisepticum* and *M. synoviae* while still allowing for some flexibility in the testing plan.

**Sample Types in U.S. Sanitation Monitored Program for Turkeys**

The U.S. Sanitation Monitored Program for turkey breeding flocks, as provided in § 145.43(f), requires in paragraph (f)(1) that hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), a sample of the pouls that died within 10 days after hatching, or both, from each candidate breeding flock produced by a primary breeder must be examined bacteriologically at an authorized laboratory for *Salmonella*. If the candidate flock is approved for the U.S. Sanitation Monitored classification, paragraph (f)(7) requires that hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), a sample of the pouls that died within 10 days after hatching, or both, be cultured from pouls produced from hatching eggs from each flock as a means of evaluating the effectiveness of the control procedures.

We are proposing to add swabs collected from hatch debris in the hatch trays as material that can be sampled for testing for *Salmonella* in paragraphs (f)(1) and (f)(7) of § 145.43. Testing swabs collected from hatch debris can be a very effective way to determine whether *Salmonella* is present in the hatchery. Because the current regulations provide that a combination of hatchery debris and poult samples may be used in *Salmonella* testing, we would amend the regulations to indicate that hatchery debris, swabs collected from hatch debris in the hatch trays, and poult samples, either alone or in combination, may be used for *Salmonella* testing.

We are also proposing to require that the sample of pouls that died within 10 days of hatching consist of all of those pouls, up to a maximum of 10. If more than 10 pouls died within 10 days of hatching, a sample of 10 pouls would be adequate for testing purposes; this change would ensure that adequate samples are available for testing without placing an unnecessary burden on owners of turkey breeding flocks.

**Testing in U.S. Avian Influenza Clean Program for Turkeys**

The U.S. H5/H7 Avian Influenza Clean Program for breeding turkeys, whose provisions are set out in § 145.43(g), contains testing requirements for both primary and multiplier breeding flocks in order to determine their freedom from the H5 and H7 subtypes of avian influenza. We are proposing to make three changes to these testing requirements for both primary and multiplier breeding flocks. In order for either a primary or a multiplier turkey breeding flock to be eligible for the U.S. H5/H7 Avian Influenza Clean classification, the regulations currently require that a minimum of 30 birds from the flock has been tested negative for antibodies to the H5 and H7 subtypes of avian influenza by the agar gel immunodiffusion (AGID) test specified in § 147.9.

We are proposing to instead require that a minimum of 30 birds from the flock be tested for antibodies to type A avian influenza virus (a larger category that includes the H5 and H7 subtypes) by AGID. Positive samples would be required to be tested by an authorized laboratory (as defined in § 145.1) using the hemagglutination inhibition test to detect antibodies to the hemagglutinin subtypes H5 and H7. Requiring the use of the hemagglutination inhibition test would provide more certainty as to whether any avian influenza virus detected in turkey breeding flocks is H5 or H7 subtype avian influenza.

Similarly, we are proposing to amend § 145.43(g)(1) regarding turkey breeding flock requirements to require that the 30 birds tested for H5 and H7 avian influenza be tested prior to the onset of egg production. If infected birds produce eggs, the eggs can serve as fomites for the transmission of the disease. This requirement would ensure that, if any H5 or H7 avian influenza virus is present in a turkey flock, it is not spread from the flock to a hatchery by the movement of eggs.

**Limiting the Avian Influenza Program for Waterfowl, Game Birds, and Exhibition Poultry Breeding Flocks to the H5/H7 Subtypes of Avian Influenza**

In § 145.53, paragraph (e) sets out the provisions of the U.S. Avian Influenza Clean program for waterfowl, game bird, and exhibition poultry breeding flocks. That program currently does not distinguish among the subtypes of avian influenza. Most avian influenza virus strains are low pathogenic and cause few or no clinical signs in infected birds. However, the H5 and H7 subtypes of low pathogenic avian influenza are considered the most dangerous, as they have the ability to mutate into highly pathogenic avian influenza. Wild waterfowl, shorebirds, and gulls serve as natural hosts and reservoirs for avian influenza viruses, and all subtypes of avian influenza can typically be found in the waterfowl population. Because the domestic waterfowl population is essentially an extension of the wild waterfowl population, it is unrealistic to expect owners of waterfowl breeding flocks to be able to demonstrate complete freedom from avian influenza in their flocks. Concentrating their efforts on preventing the occurrence of the two strains of low pathogenic avian influenza that can mutate into viruses that are dangerous would be a more effective use of their resources.

Therefore, we are proposing to amend the U.S. Avian Influenza Clean program
for waterfowl, game bird, and exhibition poultry breeding flocks in §145.53(e) to indicate that it applies to the H5 and H7 subtypes of avian influenza only. The testing requirements would remain unchanged. This proposed change would more effectively use the resources of waterfowl, exhibition poultry, and game bird breeding flock owners while allowing them to demonstrate freedom from the two most dangerous subtypes of avian influenza.

Sample Size in U.S. Pullorum-Typhoid Clean Program for Ostrich, Emu, Rhea, and Cassowary Breeding Flocks

The U.S. Pullorum-Typhoid Clean program for ostrich, emu, rhea, and cassowary breeding flocks, whose provisions are set out in §145.63(a), requires that either participating flocks either be officially blood tested within the past 12 months with no reactors or that samples from the flock be tested for pullorum-typhoid according to the size of the flocks:

• In flocks of 30 or fewer birds, each bird must be tested.
• In flocks of 30 to 300 birds, a minimum of 30 birds must be tested; and
• In flocks of more than 300 birds, 10 percent of all birds must be tested.

Most of the flocks that participate in the U.S. Pullorum-Typhoid Clean program for ostrich, emu, rhea, and cassowary breeding flocks, however, consist of fewer than 30 birds. This means that all the birds must be tested in order to maintain U.S. Pullorum-Typhoid Clean status. The costs associated with testing every bird in their flocks have discouraged many owners of ostrich, emu, rhea, and cassowary breeding flocks from participating in the NPIP.

Therefore, we are proposing to require that, for breeding flocks of ostrich, emu, rhea, or cassowary with fewer than 300 birds, either 10 percent of the birds or 1 bird from each pen, whichever is greater, must be tested for pullorum-typhoid. We believe samples of this proportion would provide adequate information regarding the pullorum-typhoid status of such flocks. The requirement that at least one bird from each pen be tested would ensure that the disease is not present in any part of the production facility.

In addition, we are proposing to require that a minimum of 30 birds be sampled from flocks of 300 or more birds. This would represent a reduction in the number of birds required to be sampled and tested; for example, an owner of a 400-bird flock is presently required to sample and test a minimum of 10 percent of its birds, or 40 birds, while under this requirement the owner would be required to sample and test a minimum of 30 birds. However, we believe that 30 birds is a sufficient sample size to determine whether an ostrich, emu, rhea, or cassowary breeding flock is free of pullorum-typhoid.

The introductory text of §145.14 currently requires that a minimum of 30 birds (regardless of type of poultry) be tested for pullorum-typhoid, and that if a house contains fewer than 30 birds, all the birds in the house must be tested. To accommodate the proposed change to the ostrich, emu, rhea, or cassowary testing requirements, we are also proposing to modify the requirements in §145.14 to exclude ostriches, emus, rheas, and cassowaries.

Laboratory Procedure Recommended for the Bacteriological Examination of Salmonella in Turkeys

The regulations in §147.11(a) set out a recommended laboratory procedure for the bacteriological examination of Salmonella in egg- and meat-type chickens, waterfowl, exhibition poultry, and game birds. The regulations in §147.11(b) set out a procedure to accomplish the same examination in turkeys. However, the procedures in §147.11(a) and §147.11(b) are nearly identical, and there is no reason the procedure in §147.11(a) could not be effectively used for the bacteriological examination of Salmonella in turkeys.

Therefore, we are proposing to remove and reserve paragraph §147.11(b) and add turkeys to the list of poultry for which the procedure in §147.11(a) may be used.

Besides adding turkeys to the list of poultry in the paragraph heading in §47.11(a), this change would require one additional amendment to the regulations. The introductory text of paragraph (a) currently recommends that all reactors to the pullorum-typhoid tests, up to 25 birds, and birds from Salmonella enteridis-positive environments be cultured in accordance with both the direct and selective enrichment procedures described in §147.11(a). However, §145.14(a)(6)(ii) requires that if a flock has more than four reactors to the standard tube agglutination test or the microagglutination test, a minimum of four reactors must be submitted to an authorized laboratory for bacteriological examination. Testing turkeys for pullorum-typhoid tends to result in a higher rate of false positives than testing other types of poultry; thus, we would add language to the introductory text of §147.11(a) indicating that turkeys would be tested in the numbers specified in §145.14(a)(6)(ii). This proposed language would provide that the number of turkeys tested complies with the regulations without placing an undue burden on participating turkey flocks.

Select Enrichment in Approved Rapid Detection Method for Salmonella

The regulations in §147.12 set out procedures for collection, isolation, and identification of Salmonella from environmental samples, cloacal swabs, chick box papers, and meconium samples. Paragraph (b) of §147.12 describes methods for the isolation and identification of Salmonella from such samples. Paragraph (b)(3) sets out an approved rapid detection method for such isolation and identification.

We are proposing to amend §147.12(b)(3) by adding a requirement that selective enrichment be performed using a PCR-based assay approved by the NPIP. Currently, the regulations state that the rapid detection method should be used following selective enrichment, but they do not provide any instructions as to how selective enrichment should be accomplished. By specifically referring to an NPIP-approved PCR-based assay, we would ensure that selective enrichment was performed in a manner that ensures that the rest of the approved rapid detection method can be used.

As described earlier in this document, we are proposing to establish new standards by which the NPIP would approve certain PCR tests in proposed §145.15. We would add that citation to the proposed requirement that a PCR-based assay be used in §147.12(b)(3) in order to ensure clarity.

Laboratory Procedure Recommended for the Bacteriological Examination of Poults for Salmonella

The regulations in §147.17 set out a recommended procedure for the bacteriological examination of cull chicks for Salmonella. The U.S. Sanitation Monitored program for meat-type turkeys in §145.43(f) requires that pouls that die within 10 days of hatching be examined bacteriologically at an authorized laboratory for Salmonella. However, there currently exists in the regulations no recommended procedure for the bacteriological examination of pouls for Salmonella. Since the procedure for the bacteriological examination of cull chicks for Salmonella in §147.17 can be used effectively for pouls as well, we are proposing to amend the regulations to indicate that the procedure may be used for pouls.
As discussed earlier in this document, we are proposing to amend the U.S. Sanitation Monitored program for turkeys to require that 10 poults be sampled and bacteriologically examined if poults are used as a sample type. The testing procedure in §147.17 for cull chicks requires that 15 pools (5 organ pools, 5 yolk pools, and 5 intestinal pools) be generated from 25 randomly selected 1-to 5-day-old cull chicks. One cull chick can provide material for each of the pool types, but each pool is required to be created from 5 cull chicks. This would be impossible to accomplish with a 10-poult sample size. Accordingly, we would indicate that, if poults are tested, two poults should be used to generate each of the five organ pools, yolk pools, and intestinal pools. We would make other similar amendments to accommodate the addition of poults as well. However, we would not make any changes to the steps required by the procedure for either cull chicks or poults.

**PCR Test for M. gallisepticum and M. synoviae**

The regulations in 9 CFR part 147 currently do not contain any molecular examination procedures. However, since PCR testing is now routinely used for diagnosing *M. gallisepticum* and *M. synoviae*, we believe it would be useful to include a recommended laboratory procedure for performing such PCR testing in the Plan. Therefore, we are proposing to establish a new subpart D in 9 CFR part 147, called “Molecular Examination Procedures,” in order to differentiate the PCR test from the blood testing procedures, bacteriological examination procedures, and sanitation procedures contained elsewhere in 9 CFR part 147. Section 147.30 in the new subpart D would set out the recommended laboratory procedure for the PCR test for *M. gallisepticum* and *M. synoviae*. A detailed description of the procedure can be found in the rule portion of this document.

**Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to amend the Plan and its auxiliary provisions by providing new or modified sampling and testing procedures for Plan participants and participating flocks. The proposed changes were voted on and approved by the voting delegates at the Plan’s 2004 National Plan Conference. These changes would keep the provisions of the Plan current with changes in the poultry industry and provide for the use of new sampling and testing procedures.

The poultry industry plays an important role in the U.S. economy. The industry directly employs about 240,000 workers. The poultry industry is comprised of highly integrated companies that combine breeding, hatching, and growing functions. The primary breeder companies are responsible for the development of genetic lines of poultry for commercial companies that market the product to final consumers. They maintain and expand pure designated blood lines and supply breeding stock to commercial broiler and turkey industries all over the globe. Improved genetic products are multiplied through the hatchery system. The hatcheries, in turn, supply these more efficient birds to producers and growers in nearby States. Hatcheries incubate and hatch eggs and sell chicks to the commercial producer when they are 1 day old. The commercial producers grow the chicks either for meat production or as egg-laying varieties. The genetic lines of both egg-laying varieties and meat-producing chickens are carefully controlled by primary breeding companies.

Almost all birds are produced on a contractual basis between the company and growers. In such arrangements, the grower normally supplies the poultry house, land, labor, litter, equipment, taxes, utilities, and insurance, while the company provides the chicks, feed, necessary medications, and supervision. Labor and equipment for catching and hauling the birds to market are also provided by the company. The company retains title to the birds, and in return farmers are paid according to the amount produced (pounds of birds or dozens of eggs).

Currently, there are three major firms that produce primary breeding stock of egg-type chickens, three breeders of meat-type chickens, two breeders of turkey, and one firm producing both egg-type and meat-type chickens. All of these are large facilities headquartered in the United States, and all of them operate in domestic and international markets. Other multinational organizations headquartered in Europe, Israel, and Japan produce several varieties of breeding stock offered to commercial facilities around the globe.

U.S. broiler production totaled 8.5 billion in 2003. Ten States (listed in table 5) accounted for over 79 percent of broilers in the United States. U.S. turkey production in 2003 totaled 274 million birds. The top 10 turkey-producing States accounted for 82 percent of total production. A total of 87.2 billion eggs were produced in 2003. Ten States accounted for 62 percent of total production. Approximately 85 percent of egg production was for human consumption (the table-egg market), while the remainder of production was for the hatching market.

### TABLE 5.—BROILERS, EGG-LAYING CHICKENS, AND TURKEYS: VALUE BY MAJOR STATES, 2003

<table>
<thead>
<tr>
<th>Broilers</th>
<th>Egg-laying chickens</th>
<th>Turkeys</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>State</td>
<td>Value in millions of dollars</td>
</tr>
<tr>
<td>Georgia</td>
<td>$2,143</td>
<td>Iowa</td>
</tr>
<tr>
<td>Arkansas</td>
<td>1,987</td>
<td>Georgia</td>
</tr>
<tr>
<td>Alabama</td>
<td>1,838</td>
<td>Ohio</td>
</tr>
<tr>
<td>North Carolina</td>
<td>1,512</td>
<td>Pennsylvania</td>
</tr>
<tr>
<td>Mississippi</td>
<td>1,424</td>
<td>Arkansas</td>
</tr>
<tr>
<td>Texas</td>
<td>1,032</td>
<td>Texas</td>
</tr>
<tr>
<td>Delaware</td>
<td>543</td>
<td>Indiana</td>
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<tr>
<td>Kentucky</td>
<td>507</td>
<td>Alabama</td>
</tr>
<tr>
<td>Maryland</td>
<td>495</td>
<td>California</td>
</tr>
<tr>
<td>Virginia</td>
<td>442</td>
<td>North Carolina</td>
</tr>
</tbody>
</table>

1 USDA/FA, Export Promotion Increase

Cash receipts from sales of poultry and eggs (broilers, farm chickens, eggs, turkey, ducks, and other poultry) were about $23.9 billion in 2003. Of this total, 64 percent was from broilers, 22 percent from eggs, 11 percent from turkeys, and 3 percent from other poultry. In terms of tonnage, poultry production and trade exceeds that of beef or pork. For instance, in 2003, the United States produced 38.4 billion pounds of poultry meat, compared with 26.2 billion pounds of beef and 19.9 billion pounds of pork. Additionally, the United States also produced 87.2 billion pounds of pork. Furthermore, the United States exported more poultry meat (5.404 million pounds) than beef and veal (2.518 million pounds) or pork (1.717 million pounds) during the same period.

The United States is a major exporter of poultry and poultry products. It exported poultry and poultry products valued at $2,287 million in 2003. The major importers are Russia ($384 million), Canada ($346 million), Mexico ($293 million), Hong Kong ($236 million), China ($177 million), Japan ($83 million), South Korea ($56 million), European Union ($126 million), Turkey ($42 million), and Taiwan ($37 million). These countries altogether accounted for a total of $1,720 million worth of exports of U.S. poultry. U.S. imports of poultry and products totaled $307 million. Of this total, $135 million was from Canada, $113 million from China, $19 million from Taiwan, and $16 million from France.

Impact on Small Entities

The Regulatory Flexibility Act requires that agencies consider the economic impact of their rules on small entities. The Small Business Administration has established guidelines for determining which types of firms are to be considered small under the Regulatory Flexibility Act. The main entities that would be affected by this proposal are those engaged in production of breeding stock. Currently there are three major firms that produce primary breeding stock of egg-type chickens, three breeders of meat-type chickens, two breeders of turkeys, and one firm producing both egg-type and meat-type chickens. All of these are large facilities headquartered in the United States and operating in domestic and international markets. Additionally, broker operations (North American Industry Classification System [NAICS] 112320), hatcheries (NAICS 112340) and other poultry operations (NAICS 112390) would be positively, at least qualitatively, affected as they would benefit from the supply of improved and healthy breeding stock. There were a total of 79,600 commercial growers with sales in 2002. Nearly 100 percent of broiler operations, 70 percent of turkey operations, and about 43 percent of layer operations produce poultry through production contracts. All of these farms are considered to be small if they have annual sales of $750,000 or less. About 93 percent of these farms are small, while the rest are large. Commercial egg producers (NAICS 112310) are considered small if they have annual sales of less than $10.5 million.

This proposed rule would introduce a series of minor changes to the NPIP and would not involve significant changes in program operations. Most of the changes involve clarifications, rearrangements of procedures, and definitions of terms. These changes are in line with the industry’s best practices and would likely involve no additional costs in order to meet these requirements. Additionally, the NPIP is a voluntary program established between the industry and State and Federal governments. Any person producing or dealing in products may participate in the NPIP when he or she has demonstrated that his or her facilities, personnel, and practices are adequate for carrying out the applicable provisions of the NPIP. Since most countries will not accept hatching eggs or live birds from a producer unless it can be shown to be a NPIP participant, being a member of the NPIP allows greater ease in moving hatching eggs or live birds within States, across State lines, and into other countries. The poultry industry plays a very important role in the U.S. economy, and the proposed amendments would help to ensure the safety of the industry and benefit the economy.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 9 CFR Parts 145 and 147

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

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Accordingly, we propose to amend 9 CFR parts 145 and 147 as follows:

**PART 145—NATIONAL POULTRY IMPROVEMENT PLAN**

1. The authority citation for part 145 would continue to read as follows:

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

2. Section 145.1 would be amended as follows:
   a. By revising the definition of *Authorized Agent* to read as set forth below.
   b. By adding, in alphabetical order, a new definition of *Authorized Testing Agent* to read as set forth below.

   **§ 145.1 Definitions.**

   * * * * *

   **Authorized Agent.** Any person designated under § 145.11(a) to collect official samples for submission to an authorized laboratory as described in §§ 147.1(a) and 147.12 of this subchapter.

   * * * * *

   **Authorized Testing Agent.** Any person designated under § 145.11(a) to collect official samples for submission to an authorized laboratory as described in §§ 147.1(a) and 147.12 of this subchapter and to perform the stained antigen, rapid whole-blood test for pullorum-typhoid.

   * * * * *

3. In § 145.11, paragraphs (a) and (b) would be revised to read as follows:

   **§ 145.11 Supervision.**

   (a) The Official State Agency may designate qualified persons as Authorized Agents to do the sample collecting provided for in § 145.14 and may designate qualified persons as Authorized Testing Agents to do the sample collecting and blood testing provided for in § 145.14.

   (b) The Official State Agency shall employ or authorize qualified persons as State Inspectors to perform the qualification testing of participating flocks, and to perform the official inspections necessary to verify compliance with the requirements of the Plan.

   * * * * *

   **§ 145.12 [Amended]**

   4. In § 145.12, paragraph (a), the word “inspected” would be removed and the words “audited at least one time annually or” would be added in its place.

   5. In § 145.14, in the introductory text of the section, the second, third, and fifth sentences would be revised to read as follows:

   **§ 145.14 Blood testing.**

   * * * Blood samples for official tests shall be drawn by an Authorized Agent, Authorized Testing Agent, or State Inspector and tested by an authorized laboratory, except that the stained antigen, rapid whole-blood test for pullorum-typhoid may be conducted by an Authorized Testing Agent or State Inspector. For Plan programs in which a representative sample may be tested in lieu of an entire flock, except the ostrich, emu, rhea, and cassowary program in § 145.63(a), the minimum number tested shall be 30 birds per house, with at least 1 bird taken from each pen and unit in the house. * * *

   In houses containing fewer than 30 birds other than ostriches, emus, rheas, and cassowaries, all birds in the house must be tested.

   * * * * *

   5a. A new § 145.15 would be added to subpart A to read as follows:

   **§ 145.15 Approved tests.**

   (a) The procedures for the bacteriological examination of poultry and poultry environments described in part 147 of this subchapter are approved tests for use in the NPIP. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in part 147 of this subchapter are approved for use in the NPIP.

   (b) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

   (1) The sensitivity of the kit will be estimated in at least 3 authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in part 147 of this subchapter. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

   (2) The specificity of the kit will be estimated in at least 3 authorized laboratories selected by the Service by testing known negative samples, as determined by the official NPIP procedures found in part 147 of this subchapter. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

   * * *

   The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

   (4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

   (5) The findings of the cooperating laboratories will be evaluated by the NPIP technical committee, and the technical committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the technical committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47 of this subchapter.

   6. In subpart B, the subpart heading would be revised to read as follows:

   **Subpart B—Special Provisions for Multiplier Egg-Type Chicken Breeding Flocks and Products**

   **§ 145.22 [Amended]**

   7. Section 145.22 would be amended as follows:

   a. In the introductory text, by adding the word “multiplier” before the words “egg type”.

   b. In paragraph (b), by removing the word “primary” and adding the word “multiplier” in its place.

   **§ 145.23 [Amended]**

   8. Section 145.23 would be amended as follows:

   a. In paragraph (b)(2), in the introductory text, by removing the words “or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks”.

   b. In paragraph (b)(2)(iii), by adding the word “Testing” after the word “Authorized”.

   c. By removing paragraph (b)(5).

   d. By removing and reserving paragraph (c)(1)(ii).
e. In paragraph (c)(2), by removing the words "Provided, That U.S. M. Gallisepticum Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set".

f. By removing and reserving paragraph (e)(1)(i).

g. In paragraph (e)(2), by removing the words "Provided, That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1)(i) or (ii) of this section are set".

h. By removing and reserving paragraph (h)(1).

i. In paragraph (h)(2)(i), by adding the words "Provided: That multiplier spent fowl must be tested within 30 days prior to movement to disposal" after the words "180 days."

§ 145.24 [Amended]

9. Section 145.24 would be amended as follows:

a. In paragraph (a)(1)(i), by removing the word "and" and adding the words ", §145.73(b)(2)(i) and §145.83(b)(2)(i)" before the period.

b. By adding and reserving paragraph (b).

10. In subpart C, the subpart heading would be revised to read as follows:

Subpart C—Special Provisions for Multiplier Meat-Type Chicken Breeding Flocks and Products

§ 145.32 [Amended]

11. Section 145.32 would be amended as follows:

a. In the introductory text, by adding the word "multiplier" before the words "meat type".

b. In paragraph (b), by removing the word "primary" and adding the word "multiplier" in its place.

§ 145.33 [Amended]

12. Section 145.33 would be amended as follows:

a. In paragraph (b)(2), in the introductory text, by removing the words "or a breeding flock composed of progeny of a primary breeding flock which is intended solely for the production of multiplier breeding flocks."

b. In paragraph (b)(2)(iii), by adding the word "Testing" after the word "Authorized".

c. By removing paragraph (b)(5).

d. By removing and reserving paragraph (c)(1)(i).

e. In paragraph (c)(2), by removing the words "Provided, That U.S. M. Gallisepticum Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (c)(1)(i) of this section are set".

f. By removing and reserving paragraph (e)(1)(i).

g. In paragraph (e)(2), by removing the words "Provided, That U.S. M. Synoviae Clean chicks from primary breeding flocks shall be produced in incubators and hatchers in which only eggs from flocks qualified under paragraph (e)(1)(i) or (ii) of this section are set".

h. By removing and reserving paragraphs (h) and (i).

i. In paragraph (i)(1), in the introductory text, by adding the words "and prior to the onset of egg production" after the word "age."

j. In paragraph (i)(2)(i), by adding the words "Provided: That multiplier spent fowl must be tested within 30 days prior to movement to slaughter" after the words "180 days."

§ 145.34 [Amended]

Section 145.34 would be amended as follows:

a. In paragraph (a)(1)(i), by removing the word "and", and by adding the words ", §145.73(b)(2)(i), and §145.83(b)(2)(i)" before the period.

b. In paragraph (b)(1)(i), by adding the words "in accordance with §§1A145.33(c) and 145.83(c)" after the word "Clean".

14. Section 145.43 would be amended as follows:

a. In paragraph (b)(2)(iii), by adding the word "Testing" after the word "Authorized".

b. By revising paragraphs (f)(1)(i), (f)(2), (f)(7), (g)(1) introductory text, (g)(1)(i), (g)(2) introductory text, and (g)(2)(i) to read as set forth below.

§ 145.43 Terminology and classification; flocks and products.

(1) Hatchery debris (dead germ hatching eggs, fluff, and meconium collected by sexors), swabs collected from hatch debris in hatcher trays, a sample of all the poult's that died within 10 days after hatching up to 10 poult's, or a combination of 2 or all 3 of the above, shall be cultured as a means of evaluating the effectiveness of the control procedures.

(2) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative for antibodies to type A avian influenza virus by the agar gel immunodiffusion test specified in §147.9 of this chapter. 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 egg production. To retain this classification:

(a) A sample of at least 30 birds must be tested negative at intervals of 90 days; Provided, that primary spent fowl be tested within 30 days prior to movement to disposal; or

(b) It is a multiplier breeding flock in which a minimum of 30 birds has been tested negative for antibodies to type A avian influenza virus by the agar gel immunodiffusion test specified in §147.9 of this chapter. 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 egg production. To retain this classification:

(1) A sample of at least 30 birds must be tested negative at intervals of 180 days; Provided, that multiplier spent fowl be tested within 30 days prior to movement to disposal; or

§ 145.53 [Amended]

15. Section 145.53 would be amended as follows:

a. In paragraph (b)(2)(iii), by adding the word "Testing" after the word "Authorized".

b. In paragraph (e), in the paragraph heading, by adding the words "H5/H7" before the words "Avian Influenza".
145.73 Terminology and classification; flocks and products.

(a) [Reserved]

(b) Egg-type chicken breeding flocks and products.

145.72 Participation.

145.71 Definitions.

Emergency slaughter of poultry is authorized by the Service in accordance with the procedures of this subpart.

145.73 Terminology and classification; flocks and products.

(a) [Reserved]

(b) U.S. Pullorum-Typhoid Clean. A flock in which freedom from pullorum and typhoid has been demonstrated by an official blood test of at least 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with no reactors; or

(b) It is a multiplier or primary breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors.

(i) It is a breeding flock that meets one of the following criteria:

(ii)(A) It is a multiplier or primary breeding flock of fewer than 300 birds in which a sample of 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with no reactors; or

(B) It is a multiplier or primary breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors.

(ii) It is a flock that has already been designated U.S. Pullorum-Typhoid Clean and uses a subsequent bacteriological examination monitoring program of hatchery debris or eggs for S. pullorum, S. gallinarum, or S. typhimurium acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

(iii) It is a multiplier breeding flock located in a State that has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time the isolation of pullorum or typhoid has been made that can be traced to a source in that State, that uses a bacteriological examination monitoring program of hatchery debris or eggs for S. pullorum, S. gallinarum, or S. typhimurium acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

17. A new Subpart G would be added to read as follows:

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

Sec.

145.71 Definitions.

145.72 Participation.

145.73 Terminology and classification; flocks and products.

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

§ 145.71 Definitions.

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

Chicks. Newly hatched chickens.

Primary egg-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for egg production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce table egg layers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§ 145.72 Participation.

Participating flocks of primary egg-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart G.

(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(b) Hatching eggs produced by primary breeding flocks shall be fumigated (see § 147.25 of this chapter) or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in § 145.10.

§ 145.73 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) U.S. Pullorum-Typhoid Clean. A flock in which freedom from pullorum and typhoid has been demonstrated by an official blood test of at least 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with no reactors; or

(d) It is a multiplier breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors.

(ii) It is a flock that has already been designated U.S. Pullorum-Typhoid Clean and uses a subsequent bacteriological examination monitoring program of hatchery debris or eggs for S. pullorum, S. gallinarum, or S. typhimurium acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

(iii) It is a multiplier breeding flock located in a State that has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time the isolation of pullorum or typhoid has been made that can be traced to a source in that State, that uses a bacteriological examination monitoring program of hatchery debris or eggs for S. pullorum, S. gallinarum, or S. typhimurium acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

17. A new Subpart G would be added to read as follows:

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

Sec.

145.71 Definitions.

145.72 Participation.

145.73 Terminology and classification; flocks and products.

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

§ 145.71 Definitions.

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

Chicks. Newly hatched chickens.

Primary egg-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for egg production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce table egg layers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§ 145.72 Participation.

Participating flocks of primary egg-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart G.

(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in § 145.5(a).

(b) Hatching eggs produced by primary breeding flocks shall be fumigated (see § 147.25 of this chapter) or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially represented in the Plan disease classifications listed in § 145.10.

§ 145.73 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in § 145.10:

(a) [Reserved]

(b) U.S. Pullorum-Typhoid Clean. A flock in which freedom from pullorum and typhoid has been demonstrated by an official blood test of at least 10 percent of the birds in a flock or at least 1 bird from each pen, whichever is more, has been officially tested for pullorum-typhoid within the past 12 months with no reactors; or

(d) It is a multiplier breeding flock of 300 birds or more in which a sample of a minimum of 30 birds has been officially tested for pullorum-typhoid within the past 12 months with no reactors.

(ii) It is a flock that has already been designated U.S. Pullorum-Typhoid Clean and uses a subsequent bacteriological examination monitoring program of hatchery debris or eggs for S. pullorum, S. gallinarum, or S. typhimurium acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

(iii) It is a multiplier breeding flock located in a State that has been deemed to be a U.S. Pullorum-Typhoid Clean State for the past 3 years, and during which time the isolation of pullorum or typhoid has been made that can be traced to a source in that State, that uses a bacteriological examination monitoring program of hatchery debris or eggs for S. pullorum, S. gallinarum, or S. typhimurium acceptable to the Official State Agency and approved by the Service in lieu of annual blood testing.

17. A new Subpart G would be added to read as follows:

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

Sec.

145.71 Definitions.

145.72 Participation.

145.73 Terminology and classification; flocks and products.

Subpart G—Special Provisions for Primary Egg-Type Chicken Breeding Flocks and Products

§ 145.71 Definitions.

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

Chicks. Newly hatched chickens.

Primary egg-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and grandparent stock that has been developed for egg production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce table egg layers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.
revoke its determination that such conditions and procedures have been met or complied with. 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 to present its views; and

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: Provided, That a bacteriological examination monitoring program acceptable to the Official State Agency and approved by the Service may be used in lieu of blood testing.

(c) U.S. Gallisepticum Clean. (1) A flock maintained in compliance with the provisions of §147.26 of this chapter and in which freedom from M. gallisepticum has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for M. gallisepticum as provided in §145.14(b) when more than 4 months of age: Provided, That to retain this classification, a minimum of 150 birds shall be tested at intervals of not more than 90 days: And provided further. That a flock comprised of fewer than 150 birds may be tested at any one time, if all pens are equally represented and a total of 150 birds is tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Gallisepticum Clean products shall handle only products of equivalent status.

(3) U.S. M. Gallisepticum Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in §147.24(a) of this chapter.

(d) U.S. S. Enteritidis Clean. This classification is intended for primary egg-type breeders wishing to assure their customers that the hatching eggs and multiplier chicks produced are certified free of Salmonella enteritidis.

(1) A flock and the hatching eggs and chicks produced from it which have met the following requirements as determined by the Official State Agency:

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or meconium from the chick boxes and a sample of chicks that died within 7 days after hatching are examined bacteriologically for salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped.

(ii) All feed fed to the flock shall meet the following requirements:

(A) Pelletized feed shall contain either no animal protein or only animal protein products produced under the Animal Protein Products Industry (APPI) Salmonella Education/Reduction Program. The protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F, or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process.

(B) Mash feed may contain no animal protein other than an APPI animal protein product supplement manufactured in pellet form and crumbled: Provided, That mash feed may contain nonpelleted APPI animal protein product supplements if the finished feed is treated with a salmonella control product approved by the Food and Drug Administration.

(C) Feed shall include at least 8 ounces of meat or bone meal from U.S. M. Gallisepticum Clean sources, and 1/4 ounce of U.S. M. Synoviae Clean.

(D) Feed shall be stored and transported in such a manner as to prevent possible contamination.

(E) The flock is maintained in compliance with §§147.21, 147.24(a), and 147.26 of this chapter. Rodents and other pests should be effectively controlled.

(v) Environmental samples shall be collected from the flock by an Authorized Agent, as described in §147.12 of this chapter, when the flock is 2 to 4 weeks of age. The samples shall be examined bacteriologically for group D salmonella at an authorized laboratory. Cultures from positive samples shall be serotyped. The Authorized Agent shall also collect samples every 30 days after the first sample has been collected.

(vi) If a Salmonella vaccine is used that causes positive reactions with pullorum-typhoid antigen, one of the following options must be utilized:

(A) Administer the vaccine after the pullorum-typhoid testing is done as described in paragraph (d)(1)(vii) of this section.

(B) An injectable bacterin or live vaccine that does not spread is used, keep a sample of 350 birds unvaccinated and banded for identification until the flock reaches at least 4 months of age. Following negative serological and bacteriological examinations as described in paragraph (d)(1)(vii) of this section, vaccinate the banded, nonvaccinated birds.

(vii) Blood samples from 300 nonvaccinated birds as described in paragraph (d)(1)(vii) of this section shall be tested with either pullorum antigen or by a licensed Salmonella enteritidis enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella, as described in §147.11 of this chapter. Cultures from positive samples shall be serotyped.

(viii) Hatching eggs are collected as quickly as possible and are handled as described in §147.22 of this chapter and are sanitized or fumigated (see §147.25 of this chapter).

(ix) Eggs produced by the flock are incubated in a hatchery that is in compliance with the recommendations in §§147.23 and 147.24(b) of this chapter, and sanitized either by a procedure approved by the Official State Agency or fumigated (see §147.25 of this chapter).

(2) A flock shall not be eligible for this classification if Salmonella enteritidis serotype enteritidis (SE) is isolated from a specimen taken from a bird in the flock. Isolation of SE from an environmental or other specimen, as described in paragraph (d)(1)(v) of this section, will require bacteriological examination for SE in an authorized laboratory, as described in §147.11(a) of this chapter, of a random sample of 60 live birds from a flock of 5,000 birds or more, or 30 live birds from a flock with fewer than 5,000 birds. If only one specimen is found positive for SE, the participant may request bacteriological examination of a second sample, equal in size to the first sample, from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification.

(3) A non-vaccinated flock shall be eligible for this classification if SE is isolated from an environmental sample collected from the flock in accordance with paragraph (d)(1)(v) of this section: Provided, That testing is conducted in accordance with paragraph (d)(1)(vii) of this section each 30 days and no positive samples are found.

(4) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(5) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures. The Official State Agency shall not revoke the participant’s classification until the participant has been given an opportunity for a hearing in accordance with rules of practice adopted by the Official State Agency.

(e) U.S. M. Synoviae Clean. (1) A flock maintained in compliance with the
provisions of §147.26 of this chapter and in which freedom from M. synoviae has been demonstrated under the criteria specified in paragraph (e)(1)(i) of this section.

(i) It is a flock in which a minimum of 300 birds has been tested for M. synoviae as provided in §145.14(b) when more than 4 months of age: Provided, That to retain this classification, a sample of at least 150 birds shall be tested at intervals of not more than 90 days: And provided further, That a sample comprised of fewer than 150 birds may be tested at any one time if all pens are equally represented and a total of 150 birds is tested within each 90-day period.

(ii) [Reserved]

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in §147.24(a) of this chapter.

(f) U.S. Avian Influenza Clean. This program is intended to be the basis from which the breeding-hatchery industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in primary breeding chickens through routine serological surveillance of each participating breeding flock. A flock and the holding eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza when more than 4 months of age. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days: Provided, That primary spent fowl must be tested within 30 days prior to movement to disposal; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period.

(2) [Reserved]

18. A new subpart H would be added to read as follows:

Subpart H—Special Provisions for Primary Meat-Type Chicken Breeding Flocks and Products

§145.81 Definitions.

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

Chicks. Newly hatched chickens.

Primary meat-type chicken breeding flocks. Foundation flocks that are composed of pedigree, great-grandparent, and great-grandparent stock that has been developed for meat production and are maintained for the principal purpose of producing multiplier breeding chicks used to produce commercial broilers.

Started chickens. Young chickens (chicks, pullets, cockerels, capons) which have been fed and watered and are less than 6 months of age.

§145.82 Participation.

Participating flocks of primary meat-type chickens, and the eggs and chicks produced from them, shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart H.

(a) Started chickens shall lose their identity under Plan terminology when not maintained by Plan participants under the conditions prescribed in §145.5(a),

(b) Hatching eggs produced by primary breeding flocks shall be fumigated (see §147.25 of this chapter) or otherwise sanitized.

(c) Any nutritive material provided to chicks must be free of the avian pathogens that are officially recognized in the Plan disease classifications listed in §145.10.

§145.83 Terminology and classification; flocks and products.

Participating flocks, and the eggs and chicks produced from them, which have met the respective requirements specified in this section, may be designated by the following terms and the corresponding designs illustrated in §145.10:

(a) [Reserved]

(b) U.S. Pullorum-Typhoid Clean. A flock in which freedom from pullorum and typhoid has been demonstrated to the Official State Agency under the criteria in paragraph (b)(1) or (b)(2) of this section: Provided, That a flock qualifying by means of a blood test shall be tested within the past 12 months, except that the retesting of a participating flock which is retained for more than 12 months shall be conducted a minimum of 4 weeks after the induction of molt. (See §145.14 relating to the official blood test where applicable.)

(1) It has been officially blood tested with no reactors.

(2) It is a primary breeding flock that meets the following criteria:

(i) The primary breeding flock is located in a State in which pullorum disease or fowl typhoid is not known to exist nor to have existed in hatchery supply flocks within the State during the preceding 12 months and in which it has been determined by the Service that:

(A) All hatcheries within the State are qualified as “National Plan Hatcheries” or have met equivalent requirements for pullorum-typhoid control under official supervision;

(B) All hatchery supply flocks within the State, are qualified as U.S. Pullorum-Typhoid Clean or have met equivalent requirements for pullorum-typhoid control under official supervision: Provided, That if other domesticated fowl, except waterfowl, are maintained on the same premises as the participating flock, freedom from pullorum-typhoid infection shall be demonstrated by an official blood test of each of these fowl;

(C) All shipments of products other than U.S. Pullorum-Typhoid Clean, or equivalent, into the State are prohibited;

(D) All persons performing poultry disease diagnostic services within the State are required to report to the Official State Agency within 48 hours the source of all poultry specimens from which S. pullorum or S. gallinarum is isolated;

(E) All reports of any disease outbreak involving a disease covered under the Plan are promptly followed by an investigation by the Official State Agency to determine the origin of the infection; Provided, That if the origin of the infection involves another State, or if there is exposure to poultry in another State from the infected flock, then the National Poultry Improvement Plan will conduct an investigation;

(F) All flocks found to be infected with pullorum or typhoid are quarantined until marketed or destroyed under the supervision of the Official State Agency, or until subsequently blood tested following the procedure for reacting flocks as contained in §145.14(a)(5) of this chapter, and all birds fail to demonstrate pullorum or typhoid infection;

(G) All poultry, including exhibition, exotic, and game birds, but excluding waterfowl, going to public exhibition shall come from U.S. Pullorum-Typhoid Clean or equivalent flocks, or have had a negative pullorum-typhoid test within
90 days of going to public exhibition; and

(H) Discontinuation of any of the conditions or procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section, or the occurrence of repeated outbreaks of pullorum or typhoid in poultry breeding flocks within or originating within the State shall be grounds for the Service to revoke its determination that such conditions and procedures have been met or complied with. 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 to present its views; and

(ii) In the primary breeding flock, a sample of 300 birds from flocks of more than 300, and each bird in flocks of 300 or less, has been officially tested for pullorum-typhoid with no reactors: Provided, That a bacteriological examination monitoring program acceptable to the Official State Agency or by fumigation. Provided, That to retain this classification, a flock maintained in compliance with the provisions of §147.26 of this chapter and in which freedom from _M. gallisepticum_ has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for _M. gallisepticum_ as provided in §145.14(b) of this chapter when more than 4 months of age: Provided, That to retain this classification, a minimum of 40 birds shall be tested at intervals of not more than 28 days, and a total of at least 150 birds shall be tested within each 90-day period.

(ii) [Reserved]

(ii) A participant handling U.S. M. Gallisepticum Clean products must handle only products of equivalent status.

(iii) U.S. M. Gallisepticum Clean flocks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in §147.24(a) of this chapter.

(c) U.S. M. Gallisepticum Clean. (1) A flock maintained in compliance with the provisions of §147.26 of this chapter and in which freedom from _M. gallisepticum_ has been demonstrated under the criteria specified in paragraph (c)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for _M. gallisepticum_ as provided in §145.14(b) of this chapter when more than 4 months of age: Provided, That to retain this classification, a minimum of 40 birds shall be tested at intervals of not more than 28 days, and a total of at least 150 birds shall be tested within each 90-day period.

(ii) [Reserved]

(ii) A participant handling U.S. M. Gallisepticum Clean products must handle only products of equivalent status.

(iii) U.S. M. Gallisepticum Clean flocks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in §147.24(a) of this chapter.

(d) U.S. M. Synoviae Clean. (1) A flock maintained in compliance with the provisions of §147.26 of this chapter and in which freedom from _M. synoviae_ has been demonstrated under the criteria specified in paragraph (d)(1)(i) of this section.

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for _M. synoviae_ as provided in §145.14(b) of this chapter when more than 4 months of age: Provided, That to retain this classification, a sample of at least 150 birds shall be tested within 90 days of going to public exhibition; and

(ii) There shall be no reactors in a sample of 300 birds selected live birds from the flock and/ or 500 cloacal swabs collected in accordance with §147.12(a) of this chapter, or

(iii) The flock met or complied with the conditions and procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section.

(2) A participant handling U.S. M. Synoviae Clean products shall handle only products of equivalent status.

(3) U.S. M. Synoviae Clean chicks shall be boxed in clean boxes and delivered in trucks that have been cleaned and disinfected as described in §147.24(a) of this chapter.

(e) U.S. S. Enteritidis Clean. This classification is intended for primary meat-type breeders wishing to assure their customers that the chicks produced are certified free of _Salmonella enteritidis_.

(1) A flock and the hatching eggs and chicks produced from it shall be eligible for this classification if they meet the following requirements, as determined by the Official State Agency:

(i) The flock originated from a U.S. S. Enteritidis Clean flock, or one of the following samples has been examined bacteriologically for _S. enteritidis_ at an authorized laboratory and any group D _Salmonella_ samples have been serotyped:

(A) A 25-gram sample of meconium from the chicks in the flock collected and cultured as described in §147.12(a)(5) of this chapter; or

(B) A sample of chick papers collected and cultured as described in §147.12(c) of this chapter; or

(C) A sample of 10 chicks that died within 7 days after hatching.

(ii) All feed fed to the flock meets the following requirements:

(A) Pelleted feed must have a minimum moisture content of 14.5 percent and must have been heated for this classification if the flock is 90 days of going to public exhibition; and

(B) Mash feed may contain animal manufacturing process;

(C) All feed is stored and transported with a salmonella control product approved by the Food and Drug Administration.

(3) U.S. S. Enteritidis Clean chicks produced from it shall be eligible for this classification if the flock is maintained in compliance with the conditions and procedures described in paragraphs (b)(2)(i)(A) through (b)(2)(i)(G) of this section.

(iv) Environmental samples are collected from the flock by or under the supervision of an Authorized Agent, as described in §147.12 of this chapter, when the flock reaches 4 months of age and cultured as described in §147.24(b) of this chapter.

(v) Blood samples from 300 birds from the flock are officially tested with pullorum antigen when the flock is at least 4 months of age. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D salmonella in accordance with §§147.10 and 147.11 of this chapter. Cultures from group D positive samples shall be serotyped.

(vi) Hatching eggs produced by the flock are collected as quickly as possible and are handled as described in §147.22 of this chapter.

(vii) Hatching eggs produced by the flock are incubated in a hatchery that is in compliance with the recommendations in §§147.23 and 147.24(b) of this chapter, and the hatchery must have been sanitized either by a procedure approved by the Official State Agency or by fumigation.

(2) If _Salmonella enteritidis_ serotype _enteritidis_ (SE) is isolated from a specimen taken from a bird in the flock, except as provided in paragraph (e)(3) of this section, the flock shall not be eligible for this classification.

(3) If SE is isolated from an environmental sample collected from the flock in accordance with paragraph (e)(1)(iv) of this section, 25 randomly selected live birds from the flock and/or 500 cloacal swabs collected in accordance with §147.12(a)(2) of this chapter must be bacteriologically examined for SE as described in §147.11 of this chapter. If only 1 bird from the 25-bird sample is found positive for SE, the participant may request bacteriological examination of a second 25-bird sample from the flock. If no SE is recovered from any of the specimens in the second sample, the flock will be eligible for the classification and will remain eligible for this classification if the flock is tested in accordance with paragraph (e)(1)(v) of this section each 30 days and no positive samples are found.

(4) In order for a hatchery to sell products of this classification, all products handled by the hatchery must meet the requirements of this paragraph.

(5) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures. The Official State Agency shall not revoke the participant’s classification until the participant has been given an opportunity for a hearing in accordance with rules of practice adopted by the Official State Agency.
(6) A pedigree, experimental, or great-grandparent flock that is removed from the U.S. S. Enteritidis Clean program may be reinstated whenever the following conditions are met:

(i) The owner attests that corrective measures have been implemented, which may include one or more of the following:

(A) Test and slaughter infected birds based on blood tests of every bird in the flock, with either pullorum antigen or by a federally licensed Salmonella enteritidis enzyme-linked immunosorbent assay (ELISA) test when the flock is more than 4 months of age.

(B) Perform other corrective actions including, but not limited to, vaccination, medication, cleaning and disinfection of houses, rodent control, and movement of uninfected birds to premises that have been determined to be environmentally negative for S. enteritidis as described in §147.12(a) of this chapter.

(C) One hundred percent of blood samples from the birds moved to the clean premises are tested negative for Salmonella pullorum and group D Salmonella. All birds with positive or inconclusive reactions, up to a maximum of 25 birds, shall be submitted to an authorized laboratory and examined for the presence of group D Salmonella, as described in §147.11 of this chapter. Cultures from positive samples shall be serotyped.

(D) Two consecutive environmental drag swabs taken at the clean premises collected as specified in §147.12(a) of this chapter 4 weeks apart are negative for S. enteritidis.

(E) Other corrective measures at the discretion of the Official State Agency.

(ii) Following reinstatement, a flock will remain eligible for this classification if the flock is tested in accordance with paragraph (e)(1)(v) of this section every 30 days and no positive samples are found and the flock meets the requirements set forth in §145.83(e).

(f) U.S. Salmonella Monitored. This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of salmonellosis. It is intended to reduce the incidence of Salmonella organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. This will afford other segments of the poultry industry an opportunity to reduce the incidence of Salmonella in their products. The following requirements, as determined by the Official State Agency:

(i) The flock is maintained in compliance with §§147.21, 147.24(a), and 147.26 of this chapter;

(ii) If feed contains animal protein, the protein products must have a minimum moisture content of 14.5 percent and must have been heated throughout to a minimum temperature of 190 °F or above, or to a minimum temperature of 165 °F for at least 20 minutes, or to a minimum temperature of 184 °F under 70 lbs. pressure during the manufacturing process;

(iii) Feed shall be stored and transported in a manner to prevent possible contamination;

(iv) Chicks shall be hatched in a hatchery meeting the requirements of §§147.23 and 147.24(b) of this chapter and sanitized or fumigated (see §147.25 of this chapter).

(v) An Authorized Agent shall take environmental samples from the hatchery every 30 days; i.e., meconium or chick papers. An authorized laboratory for Salmonella shall examine the samples bacteriologically;

(vi) An Authorized Agent shall take environmental samples as described in §147.12 of this chapter from each flock at 4 months of age and every 30 days thereafter. An authorized laboratory for Salmonella shall examine the environmental samples bacteriologically;

(vii) Owners of flocks may vaccinate with a paratyphoid vaccine: Provided, That a sample of 350 birds, which will be banded for identification, shall remain unvaccinated until the flock reaches at least 4 months of age.

(2) The Official State Agency may use the procedures described in §147.14 of this chapter to monitor the effectiveness of the egg sanitation practices.

(3) In order for a hatchery to sell products of this classification, all products handled shall meet the requirements of the classification.

(4) This classification may be revoked by the Official State Agency if the participant fails to follow recommended corrective measures.

(g) U.S. Avian Influenza Clean. This program is intended to be the basis from which the breeding-hatching industry may conduct a program for the prevention and control of avian influenza. It is intended to determine the presence of avian influenza in primary breeding chickens through routine serological surveillance of each participating breeding flock. A flock and the hatching eggs and chicks produced from it will qualify for this classification when the Official State Agency determines that they have met the following requirements:

(1) It is a primary breeding flock in which a minimum of 30 birds have been tested negative for antibodies to avian influenza when more than 4 months of age and prior to the onset of egg production. To retain this classification:

(i) A sample of at least 30 birds must be tested negative at intervals of 90 days; Provided, that primary spent flock be tested within 30 days prior to movement to slaughter; or

(ii) A sample of fewer than 30 birds may be tested, and found to be negative, at any one time if all pens are equally represented and a total of 30 birds is tested within each 90-day period.

|§147.7 [Amended] |

20. In §147.7, paragraph (b)(1)(vii), the citation “§147.6” would be removed and the citation “§147.6(a)” would be added in its place.

21. Section 147.11 would be amended as follows:

a. In paragraph (a), the introductory text would be revised to read as set forth below.

b. Paragraph (b) would be removed and reserved.

§147.11 Laboratory procedure recommended for the bacteriological examination of salmonella.

(a) For egg- and meat-type chickens, turkeys, waterfowl, exhibition poultry, and game birds. All reactors to the pullorum-typhoid tests, up to 25 birds, and birds from Salmonella enteritidis (SE) positive environments should be cultured in accordance with both the direct enrichment (paragraph (a)(1)) and selective enrichment (paragraph (a)(2)) procedures described in this section: Provided, that in turkeys, if there are more than 4 reactors to the pullorum-typhoid tests in the flock, a minimum of 4 reactors as provided for in §145.14(a)(6)(ii) of this subchapter shall be submitted to the authorized laboratory for bacteriological examination. Careful aseptic technique should be used when collecting all tissue samples.

§147.12 [Amended] |

22. In §147.12, paragraph (b)(3) would be amended by adding the words...
“using a PCR-based assay approved by the NPIP under § 145.15” after the word “enrichment.”

23. Section 147.17 would be amended as follows:

a. The section heading, the introductory text of the section, and paragraphs (a) and (c) would be revised to read as set forth below.

b. In paragraph (d), the number “15” would be removed.

§ 147.17 Laboratory procedure recommended for the bacteriological examination of cull chicks and poults for salmonellosa.

The laboratory procedure described in this section is recommended for the bacteriological examination of cull chicks from egg-type and meat-type chicken flocks and waterfowl, exhibition poultry, and game bird flocks and poults from turkey flocks for salmonellosa.

(a) For cull chicks, from 25 randomly selected 1- to 5-day-old chicks that have not been placed in a brooding house, prepare 5 organ pools, 5 yolk pools, and 5 intestinal tissue pools as follows. For poults, from a sample of 10 poults that died within 10 days after hatching, prepare organ pools, yolk pools, and intestinal pools as follows:

MG–F 5' GAG CTA ATC TGT AAA
MG–R 5' GCT TCC TCG CGG TTA

(2) M. synoviae. The primer for M. synoviaeae should consist of the following sequences:

MS–F 5' GAG AAG CAA AAT AGT GAT ATC A
MS–R 5' CAG GAG AAG CAA AAT AGT GAT ATC A

(c) Polymerase chain reaction. (1) Treat each sample (100 to 2000 ng/5 μl) with one of the following 45 μl PCR cocktails:

(i) 5 μl 10x PCR buffer, 1 μl dNTP (10 mM), 1 μl of Reverse primer (50 μM), 1 μl of Forward primer (50 μM), 4 μl MgCl₂ (25 mM), 1 μl taq-polymerase (5 U), 32 μl DEP water.

(ii) 18 μl water, 25 μl PCR mix (Promega), 1 μl Reverse primer (50 μM), 1 μl Forward primer (50 μM).

(2) Perform DNA amplification in a Perkin-Elmer 9600 thermocycler or in a Hybaid PCR Express thermocycler.24

The optimized PCR program is as follows:

(1) Organ pool: From each of five chicks or two poults, composite and mince 1- to 2-gram samples of heart, lung, liver, and spleen tissues. Include the proximal wall of the bursa of Fabricius for chicks only.

(2) Yolk pool: From each of five chicks or two poults, composite and mince 1- to 2-gram samples of the unabsorbed yolk sac or, if the yolk sac is essentially absent, the entire yolk stalk remnant.

(3) Intestinal pool: From each of five chicks or two poults, composite and mince approximately 0.5 cm² sections of the crop wall and 5-mm-long sections of the duodenum, cecum, and ileocecal junction.

* * * * *

(c) For cull chicks, repeat the steps in paragraphs (a) and (b) of this section for each 5-chick group until all 25 chicks have been examined, producing a total of 15 pools (5 organ, 5 yolk, and 5 intestinal). For poults, repeat the steps in paragraphs (a) and (b) of this section for each two-poul group until all the poults in the sample have been examined.

* * * * *

24. A new subpart D would be added to read as set forth below.

§ 147.30 Laboratory procedure recommended for the polymerase chain reaction (PCR) test for Mycoplasma gallisepticum and M. synoviae.

(a) DNA isolation. Isolate DNA from 1 mL of eluate from tracheal swabs in PBS or 1 mL of broth culture by a non-phenolic procedure. Centrifuge samples at 14,000 x g for 5 to 10 minutes. Decant supernatant and wash the pellet with 1 mL of PBS. Centrifuge as above and resuspend the pellet in 25–50 μl of 0.1 percent DEP (Diethyl Pyrocarbonate; Sigma) water. Boil at 120 °C for 10 minutes followed by 10 minutes incubation at 4 °C. Centrifuge as above and transfer the supernatant DNA to a nuclease-free tube. Estimate the DNA concentration and purity by spectrophotometric reading at 260 nm and 280 nm.

(b) Primer selection—(1) M. gallisepticum. The primer for M. gallisepticum should consist of the following sequences:

MS–F 5' GAG AAG CAA AAT AGT GAT ATC A
MS–R 5' CAG GAG AAG CAA AAT AGT GAT ATC A

(d) Electrophoresis. Mix PCR products (5 to 10 μl) with 2 μl loading buffer (Sigma) and electrophorese on a 2 percent agarose gel containing 0.5 μg/mL ethidium bromide in TAE buffer (40 mM tris; 2 mM EDTA; pH 8.0 with glacial acetic acid) for 30 minutes at 80 °C. M. gallisepticum (185 bp) and M. synoviae (214 bp) amplicons can be visualized under an ultraviolet transilluminator along with the PCR marker (50 to 2000 bp; Sigma).

Subpart D—Molecular Examination Procedures

§ 145.30 Laboratory procedure recommended for the polymerase chain reaction (PCR) test for Mycoplasma gallisepticum and M. synoviae.

(a) DNA isolation. Isolate DNA from 1 mL of eluate from tracheal swabs in PBS or 1 mL of broth culture by a non-phenolic procedure. Centrifuge samples at 14,000 x g for 5 to 10 minutes. Decant supernatant and wash the pellet with 1 mL of PBS. Centrifuge as above and resuspend the pellet in 25–50 μl of 0.1 percent DEP (Diethyl Pyrocarbonate; Sigma) water. Boil at 120 °C for 10 minutes followed by 10 minutes incubation at 4 °C. Centrifuge as above and transfer the supernatant DNA to a nuclease-free tube. Estimate the DNA concentration and purity by spectrophotometric reading at 260 nm and 280 nm.

(b) Primer selection—(1) M. gallisepticum. The primer for M. gallisepticum should consist of the following sequences:

MS–F 5' GAG AAG CAA AAT AGT GAT ATC A
MS–R 5' CAG GAG AAG CAA AAT AGT GAT ATC A

(d) Electrophoresis. Mix PCR products (5 to 10 μl) with 2 μl loading buffer (Sigma) and electrophorese on a 2 percent agarose gel containing 0.5 μg/mL ethidium bromide in TAE buffer (40 mM tris; 2 mM EDTA; pH 8.0 with glacial acetic acid) for 30 minutes at 80 °C. M. gallisepticum (185 bp) and M. synoviae (214 bp) amplicons can be visualized under an ultraviolet transilluminator along with the PCR marker (50 to 2000 bp; Sigma).

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