

regulated articles. Plants, balled or in containers, may otherwise be certified for movement using the liquid chlorpyrifos or bifenthrin treatments described in paragraph III.C.3 of this manual, titled "Plants, Balled or in Containers." However, certification for movement under the imported-fire-ant-free nursery program will be granted only if all of the provisions of this program are followed.

**Certification Period:** Continuous as long as all provisions of the imported-fire-ant-free nursery program are followed.

5. Field-Grown Woody Ornamentals (In-Field Treatment Prior to Harvest)

**Material:** Granular chlorpyrifos (any granular formulation that is EPA registered) used in combination with:

Hydramethylnon (AMDRO®) or Fenoxycarb (AWARD®) fire ant bait.

**Dosage:** Fenoxycarb (AWARD®) or hydramethylnon (AMDRO®) at 1.5 lb (0.68 kg) bait/acre. Chlorpyrifos at 6.0 lb (2.7 kg) a.i./acre.

**Method:** Apply fenoxycarb (AWARD®) or hydramethylnon (AMDRO®) only when ants are actively foraging (follow EPA-approved label directions for use). Broadcast application with any type of equipment that can be calibrated to deliver 1.5 lb (0.68 kg) of bait per acre. Three to five days after the fenoxycarb (AWARD®) or hydramethylnon (AMDRO®) application, apply granular chlorpyrifos broadcast at 6.0 lb (2.7 kg) a.i. per acre. Treatment area must extend at least 10 feet beyond the base of all plants that are to be certified.

**Exposure Period:** 30 days. Plants can be certified 30 days after treatment.

**Certification Period:** 12 weeks.

**Special Information:** This in-field treatment is based on a sequential application of fenoxycarb (AWARD®) or hydramethylnon (AMDRO®) followed by granular chlorpyrifos. The combination treatment is necessary since broadcast application of chlorpyrifos (or other short-term residual insecticides) usually does not eliminate large, mature IFA colonies, and no bait, including fenoxycarb (AWARD®) or hydramethylnon (AMDRO®), is capable of providing a residual barrier against reinfestation by new queens. Therefore, the fenoxycarb (AWARD®) or hydramethylnon (AMDRO®) application will drastically reduce the IFA population while chlorpyrifos, applied approximately 5 days later, will destroy any remaining weakened colonies and also leave a residual barrier against reinfestation by new queens for at least 12 weeks.

6. Blueberries and Other Fruit and Nut Nursery Stocks

Certain States have special local need labeling in accordance with section 24(c) of FIFRA for D-z-n\* Diazinon AG-500 and D-z-n\* Diazinon 50W, which APHIS will recognize as a regulatory treatment for containerized nonbearing blueberries and fruit and nut plants. Follow label directions for use.

7. Plants—Greenhouse Grown

Greenhouse grown plants are certifiable without treatment if the inspector determines that the greenhouse is constructed of

fiberglass, glass, or plastic in such a way that IFA is physically excluded and cannot become established within the enclosure. No other treatment of the plants will be necessary if they are not exposed to infestation.

8. Grass—Sod

**Material**

Granular chlorpyrifos.

Material	Amount and dosage of material	Certification period
Chlorpyrifos (any granular formulation that is registered).	4.0 lb (1.8 kg) a.i./acre.	4 weeks (after exposure period has been completed).
Chlorpyrifos (any granular formulation that is registered).	6.0 lb (2.7 kg) a.i./acre.	10 weeks (after exposure period has been completed).

**Exposure Period:** 48 hours.

**Method**

1. Apply a single broadcast application of granular chlorpyrifos with ground equipment.

2. Immediately after treatment, water the treated areas with at least ½ inch of water. Chlorpyrifos wettable powder Dursban® 50-WP: Follow label directions for regulatory treatment for IFA.

9. Soil—Bulk

**Method:** Bulk soil is eligible for movement when heated either by dry or steam heat after all parts of the mass have been brought to the required temperature.

**Temperature:** 150° F (65.5° C).

**Certification Period:** As long as protected from recontamination.

10. Soil Samples

Soil samples are eligible for movement when heated or frozen as follows:

**Heat**

**Method:** Soil samples are heated either by dry heat or steam heat. All parts of the mass must be brought to the required temperature.

**Temperature:** 150° F (65.5° C).

**Certification Period:** As long as protected from recontamination.

**Cold**

**Method:** Soil samples are frozen in any commercial cold storage, frozen food locker, or home freezer capable of rapidly reducing to and maintaining required temperature. Soil samples will be placed in containers, such as plastic bags—one sample per bag. The containers will be arranged in the freezer in a manner to allow the soil samples to freeze in the fastest possible time. If desired, the frozen samples may be shipped in one carton.

**Temperature:** -10° to -20° F (-23° to -29° C) for at least 24 hours.

**Certification Period:** As long as protected from recontamination.

**D. Mitigative Measures.** The following measures are required to minimize impact on the environment and human health. Any person requesting certification to authorize the movement of regulated articles must adhere to these measures where applicable.

1. All applicable Federal, State, and local environmental laws and regulations must be followed.

2. Safety equipment and clothing, as specified by the label instructions, must be used and worn during treatments and during inspections.

3. Safety practices shall be communicated, and regulated establishment managers must require that on-the-job safety practices be followed.

4. All pesticides must be applied, handled, stored, and used in accordance with label instructions.

5. Empty pesticide containers must be disposed of in accordance with Federal and State regulations.

6. Pesticide remaining in containers after completion of an application must be retained and disposed of in accordance with label instructions and Federal and State regulations.

7. Oral or written warning must be provided to workers and the general public, indicating pesticide application areas during application and appropriate reentry periods.

8. Owners/managers of regulated properties must take precautions to limit access by the public, livestock, and wildlife to treated areas.

9. Accidental spill or water runoff of liquid or granular pesticides leading to potential contamination of ground and surface waters must be minimized by appropriate operating procedures. Catchment facilities (temporary or permanent) adequate to prevent contamination of ground and surface water are necessary in loading areas where liquid drenches and immersions are applied.

10. An environmental monitoring plan, including monitoring procedures, must be implemented by APHIS. Monitoring must be conducted to determine if additional mitigative measures are necessary.

\* \* \* \* \*

Done in Washington, DC, this 1st day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 92-29459 Filed 12-3-92; 8:45 am]

BILLING CODE 3410-34-M

9 CFR Part 75

[Docket No. 92-015-2]

Equine Infectious Anemia (Swamp Fever); Change in Official Test

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

**SUMMARY:** We are amending the regulations on communicable diseases in horses, asses, ponies, mules, and zebras to allow the use of additional

tests as official tests for the laboratory diagnosis of equine infectious anemia (EIA), also known as swamp fever. Equines that are found to be infected with EIA based on the results of an official test may be moved interstate only under certain conditions, to prevent the interstate spread of this disease. This change makes new test technology available to the industry.

**EFFECTIVE DATE:** December 4, 1992.

**FOR FURTHER INFORMATION CONTACT:** Dr. Gary S. Colgrove, Chief, Sheep, Goat, Equine, and Poultry Diseases Staff, VS, APHIS, USDA, room 702, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-6954.

**SUPPLEMENTARY INFORMATION:**

### Background

The Communicable Diseases regulations, contained in 9 CFR part 75 (referred to below as the regulations), among other things, govern the interstate movement of certain equines (horses, asses, ponies, mules, and zebras) that are subjected to an official test for equine infectious anemia (EIA) and found positive. A viral disease of equines, EIA, also known as swamp fever, is characterized by sudden fever, swelling, and anemia.

In a proposed rule published in the *Federal Register* on September 2, 1992 (57 FR 40139-40140, Docket No. 92-015-1), we proposed to expand the definition of "official test" to allow the use of products other than the Agar gel immunodiffusion (AGID) test and the Competitive Enzyme-Linked Immunosorbent Assay (C ELISA) test for the laboratory diagnosis of EIA. We proposed to allow the use of any test for the laboratory diagnosis of EIA that utilizes a diagnostic product that is: (1) Produced under license from the Secretary of Agriculture, and found to be efficacious for that diagnosis, under the Virus-Serum-Toxin Act of March 4, 1913, and subsequent amendments (21 U.S.C. 151 *et seq.*); and (2) conducted in a laboratory approved by the Administrator.

We proposed this amendment to allow persons affected by these regulations to take advantage of the many technical advances that have been made in the test kit industry, resulting in the development of new tests for the laboratory diagnosis of EIA. Further, we proposed this change to the regulations to relieve unnecessary restrictions and to encourage the development of other tests for the laboratory diagnosis of EIA.

### Comments

Our proposed rule invited the submission of comments, which were

required to be received on or before October 2, 1992. By the closing date, we received seven comments, from two veterinary diagnostics test manufacturers, a veterinarian, a veterinary continuing education company, an independent product development firm, and two national trade associations. All the comments supported the proposal rule; however, two commenters addressed related concerns. Their concerns are discussed below.

### *Impact on the National Veterinary Services Laboratories*

One commenter stated that standards for training and testing personnel in approved laboratories could be reduced in the face of expanding numbers of technologies and test protocols. Further, this commenter stated that an increased need for testing and certification in the approved laboratories might divert the resources of the National Veterinary Services Laboratories (NVSL) from current activities and would actually slow the licensing process.

The NVSL conducts or certifies the training of private, Federal, State, and university laboratory personnel to ensure their qualification to conduct official tests. The NVSL also supplies samples for periodic proficiency testing of laboratory personnel. Based upon the NVSL's evaluation of the proficiency test, laboratory personnel may be trained or retrained at NVSL. These procedures have proved sufficient in the past to ensure testing by qualified laboratory personnel. We expect the NVSL to continue its current standard for the evaluation, testing, and training of laboratory personnel in approved laboratories.

We have considered the impact that increased competition in the veterinary diagnostic products industry may have on all affected entities, including the NVSL. When equines are tested, only one test for EIA is used. Substituting one test for another will not result in increased testing in the approved laboratory. Further, given the relatively small market for EIA tests, we do not expect the number of different tests to increase to the point that NVSL would need to divert resources from its current activities. Therefore, we do not expect a substantial increase in workload for the NVSL due to this rule.

### *Impact on Quarantine Requirements for Imported Horses*

One commenter questioned whether the proposed change would apply to EIA tests performed on horses imported into the United States. Specifically, the commenter expressed a concern that

horses imported into the United States will not be quarantined for a sufficient period of time to ensure that they are free of disease. The commenter stated that Department regulations for horses not coming from Central or South American countries or from countries affected with African horse sickness require that the horse be quarantined until the results of official tests for EIA, dourine, glanders, and equine piroplasmiasis are returned. The commenter further stated that the AGID test, which is generally used by laboratories, takes about 3 days to run before results are available. The commenter expressed a concern that if new EIA test results can be obtained faster than the 3 days necessary for the AGID test results to become available, then these "3-day" horses could be released from quarantine in considerably less time. The commenter recommended that we establish a minimum quarantine time for horses entering the United States.

Our data indicate that the turn-around time for the AGID test varies from 1 day to 3 days. Turn-around time for the C ELISA test varies from 3 to 6 hours. The regulations for importing horses, contained in 9 CFR part 92, provide, among other things, that horses intended for importation into the United States shall be quarantined at the port of entry until negative results to port of entry tests are obtained and the horses are certified to be free of clinical evidence of disease (see § 92.308(a)). Paragraphs (a)(1) and (a)(2) of § 92.308 also specify minimum quarantine periods for horses imported from the Western Hemisphere and from countries affected with African horse sickness, respectively. Section 92.308 does not specify a minimum quarantine period for horses imported from other parts of the world. We are considering amending the quarantine requirements to specify a minimum time period for the quarantine of horses that are not specifically covered under paragraphs (a)(1) or (a)(2) of present § 92.308. Any proposed change to the quarantine requirements for imported horses will be published in a future issue of the *Federal Register*.

Based on the rationale set forth in the proposed rule and in this document, we are adopting the proposal to amend 9 CFR part 75, without change, as a final rule.

### *Effective Date*

The Administrator of the Animal and Plant Health Inspection Service has determined that this rulemaking proceeding should be expedited by making this rule effective upon publication. This rule relieves

restrictions on the interstate movement of horses by allowing the use of newly-developed tests that may be licensed by the Secretary of Agriculture for the laboratory diagnosis of EIA.

#### Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This rule will allow the use of additional tests for the laboratory diagnosis of EIA. Estimates of the U.S. equine population vary from 5.25 million to 6.6 million. Equine owners have suffered losses due to domestic and foreign infectious diseases. The use of diagnostic tests has substantially cut losses that result from the commingling of infected animals with healthy ones. Such has been the case with the AGID and C ELISA tests for EIA. In fiscal year 1991, 993,712 tests for EIA were conducted resulting in the identification of 2,755 reactors. Compared to 9,089 reactors out of 354,412 tests for EIA conducted in 1974,<sup>1</sup> it is clear that the incidence of EIA has declined. Between the two periods, the prevalence of infection with EIA decreased from 2.56 percent to 0.277 percent. Losses attributed to EIA declined from approximately \$271 million to \$21 million (in 1990 dollars).

Allowing other tests to be designated as official tests may not result in such a dramatic decline in losses because the present base of infected animals is smaller when compared with previous years. However, the newly-developed tests could likely continue the decline in EIA incidence and could inject competition in the EIA test market. The opportunity to develop, obtain a license for, and market a new product for the laboratory diagnosis of EIA could provide a small company the means by which to enter this industry and realize

<sup>1</sup> The first year of test reporting in the United States after the availability in the early seventies of the first test for diagnosing EIA.

a modest economic benefit. Of the dozen or so companies that manufacture veterinary diagnostic products, we are aware of only two that currently market the AGID and C ELISA tests for EIA. Neither of these companies is considered a small entity.

For these two large firms, marketing products for the laboratory diagnosis of EIA is a small fraction of their total business. Further, these sales represent a niche within a small part of a very large industry. According to USDA records, approximately 1 million tests for the laboratory diagnosis of EIA were produced in the United States in 1991. These records also indicate that during the same time period, approximately 54 million veterinary diagnostic tests were produced. Thus, the production of tests for the laboratory diagnosis of EIA equals approximately 2.0 percent of the total production of the U.S. veterinary diagnostic products.

Any increase in the production of products for the laboratory diagnosis of EIA will likely remain insignificant when compared with the total production of veterinary diagnostic products; however, increased competition could dramatically affect the test turn-around time by making available certain tests that may be less labor intensive. Additionally, designating other qualified tests as official tests will likely encourage entrepreneurs and scientists to engineer new and more powerful procedures and technology that could foster economic growth. Ultimately, costs for testing could be lowered for equine owners.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 the Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 9 CFR Part 75

Animal diseases, Horses, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 75 is amended as follows:

#### PART 75—COMMUNICABLE DISEASES IN HORSES, ASSES, PONIES, MULES, AND ZEBRAS

1. The authority citation for part 75 continues to read as follows:

Authority: 21 U.S.C. 111–113, 115, 117, 120, 121, 123–126, 134–134h; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 75.4, paragraph (a), the definition of "Official test" is revised to read as follows:

**§ 75.4 Interstate movement of equine infectious anemia reactors and approval of laboratories, diagnostic facilities, research facilities, and stockyards.**

(a) \* \* \*

\* \* \* \* \*

*Official test.* Any test for the laboratory diagnosis of equine infectious anemia that utilizes a diagnostic product that is: (1) Produced under license from the Secretary of Agriculture, and found to be efficacious for that diagnosis, under the Virus-Serum-Toxin Act of March 4, 1913, and subsequent amendments (21 U.S.C. 151 *et seq.*); and (2) conducted in a laboratory approved by the Administrator.

\* \* \* \* \*

Done in Washington, DC, this 1st day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 92-29462 Filed 12-3-92; 8:45 am]

BILLING CODE 3410-34-M

#### 9 CFR Part 94

[Docket No. 92-031-2]

#### Meat and Meat Products From Northern Ireland and the Republic of Ireland; Restrictions on Importations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final.

SUMMARY: We are affirming as final and without change an interim rule that

amended the regulations concerning the importation into the United States of meat of ruminants and swine, and certain other animal products, from Northern Ireland and the Republic of Ireland. The imposition of additional import restrictions was a necessary response to new conditions that made possible the commingling of disease-contaminated meat or meat products with disease-free meat or meat products in these countries. In Northern Ireland, conditions have changed with respect to swine vesicular disease-contamination of meat or meat products only. This action was necessary to protect against the introduction into the United States of swine vesicular disease, rinderpest, and foot-and-mouth disease.

**EFFECTIVE DATE:** January 4, 1993.

**FOR FURTHER INFORMATION CONTACT:** Dr. Harvey A. Kryder, Chief Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 756-A, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-7885.

**SUPPLEMENTARY INFORMATION:**

#### Background

In an interim rule effective and published in the *Federal Register* on August 18, 1992 (57 FR 37081-37083, Docket No. 92-031-1), we amended the animal and animal product importation regulations in 9 CFR part 94 by restricting the importation into the United States of meat of ruminants and swine, and certain other animal products, from Northern Ireland and the Republic of Ireland. This action was necessary to prevent the introduction of rinderpest, foot-and-mouth disease (FMD), and swine vesicular disease (SVD) into the United States.

Comments on the interim rule were required to be received on or before October 19, 1992. We received one comment, from a representative of the Government of Northern Ireland.

The commenter requested that we remove the special restrictions on animal products from Northern Ireland because animal products in Northern Ireland pose no disease risk to the United States. He cited the effectiveness of European Community epizootic disease control measures, and noted that most animals imported into Northern Ireland originate in the Republic of Ireland. The commenter stated that if we would not change the regulations for those reasons alone, the Government of Northern Ireland was prepared to guarantee, based on a centralized animal health computer system, that animal products exported from Northern Ireland to the United States meet all

U.S. "non-comminglement" requirements.

We are making no changes as a result of this comment. Meat and meat products of ruminants and swine from all countries listed in §§ 94.11 or 94.13 are subject to special import restrictions because of disease risk. The regulations are necessary to prevent meat and meat products from those countries from introducing rinderpest, FMD, or SVD into the United States. We can make no exception for Northern Ireland.

The facts presented in the interim rule still provide the basis for this rule.

This action also affirms the information contained in the interim rule concerning Executive Orders 12291, 12372, and 12778, the Regulatory Flexibility Act, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

#### List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, the regulations in 9 CFR part 94 are amended as follows:

#### **PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FLOW PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS**

Accordingly, we are adopting as a final rule, without change, the interim rule amending 9 CFR 94.11 and 94.13 that was published at 57 FR 37081-37083 on August 18, 1992.

**Authority:** 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC, this 1st day of December 1992.

**Lonnie J. King,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 92-29463 Filed 12-3-92; 8:45 am]

**BILLING CODE 3410-34-M**

#### **9 CFR Parts 145 and 147**

[Docket No. 91-026-2]

#### **National Poultry Improvement Plan and Auxiliary Provisions**

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

**ACTION:** Final rule.

**SUMMARY:** We are amending the National Poultry Improvement Plan (referred to below as the Plan) and its auxiliary provisions to improve its programs by isolating and testing birds from sources that do not participate in the Plan before their introduction into a Plan-participating flock, and by providing new procedures for examining and testing participating flocks. This action is necessary to increase the effectiveness of the Plan in preventing and controlling certain poultry diseases. The intended effect of these amendments is to help improve poultry breeding stock and hatchery products.

**EFFECTIVE DATE:** January 4, 1993.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Andrew Rhorer, Senior Coordinator, Poultry Improvement Staff, National Poultry Improvement Plan, VS, APHIS, USDA, room 205, Presidential Building, 6525 Belcrest Road, Hyattsville, MD 20782, (301) 436-7768.

**SUPPLEMENTARY INFORMATION:**

#### Background

The National Poultry Improvement Plan (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 to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. Participation in all the Plan programs is voluntary. However, flocks, hatcheries, and dealers must qualify as "U.S. Pullorum-Typhoid Clean" before participating in any other Plan program. Also, regulations at 9 CFR 82.33 require that no hatching eggs or newly-hatched chicks from egg-type chicken breeding flocks may be moved interstate unless they are classified "U.S. Sanitation Monitored" under the Plan, or meet the requirements of a State classification plan determined by the Administrator to be equivalent to the Plan.

The Plan identifies States, flocks, hatcheries, and dealers that meet certain disease control standards specified within the Plan's various programs. As a result, customers can buy stock 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 requirements for this program. The Animal and Plant Health Inspection Service (APHIS) amends these provisions from time to time to incorporate new scientific information and technologies within the Plan.

We published in the *Federal Register* on June 30, 1992 (57 29044-29050, Docket No. 91-026-1), a proposal to amend the regulations by making the following changes:

1. Add a definition of poultry dealer;
2. Provide for the segregation and testing of birds from sources that do not participate in the Plan before introduction into a Plan-participating flock;
3. Improve the "U.S. Sanitation Monitored" program for egg-type chicken breeding flocks by requiring 30-day culturing of the environment rather than dead-germ eggs;
4. Improve the "U.S. Sanitation Monitored" program for meat-type chicken breeding flocks by providing for environmental culturing and control efforts for flocks with certain *Salmonella* serotypes to reduce vertical transmission;
5. Provide for egg yolk monitoring test for *Mycoplasma gallisepticum* (MG) and reduced sample size for game birds to keep MG classification;
6. Improve sampling procedures for environmental sample collection for *Salmonella* testing of the breeding flock environment;
7. Provide procedures for bacteriologic examination of environmental samples for *Salmonella*; and
8. Provide procedures for drag-swab sampling for *Salmonella* testing of the breeding flock environment.

Our proposed amendments were consistent with the recommendations approved by the voting delegates to the June 1990 meeting of the Biennial Plan Conference. Participants at these meetings represented flockowners, breeders, hatcherymen, and Official State Agencies from all cooperating States.

#### Comments

Our proposed rule invited the submission of comments, which were required to be received on or before July 30, 1992. We received one comment prior to the closing date. The comment, from a State Department of Agriculture, requested that we reconsider deleting requirements for dead-germ egg culturing.

#### U.S. Sanitation Monitored—Egg Type Chicken Breeding Flocks

We proposed to amend § 145.23 to change the "U.S. Sanitation Monitored" program for egg-type chicken breeders by requiring collection of environmental samples every 30 days after the first environmental sample has been taken and by deleting the requirements for dead-germ egg culturing. Also, we proposed to require bacteriological examination of a random sample of 60 live birds if *Salmonella enteritidis* ser *enteritidis* (SE) is isolated from environmental or other specified samples. To relieve any unnecessary burden upon a producer, we proposed to provide the participant the option of requesting a new examination of an additional 60-bird sample if the bacteriological examination reveals only one positive specimen. If the new examination does not recover any SE, then the flock can be eligible for the "U.S. Sanitation Monitored" classification.

The commenter suggested that—(1) Dead-germ egg culturing be required on at least a monthly basis as long as environmental samples are SE culture positive, regardless of negative bird culture results; (2) "U.S. Sanitation Monitored" status be withheld if either the breeder flock or its progeny (dead-germ eggs or newborn chicks) are SE culture positive; and (3) dead-germ eggs in hatcheries be cultured to monitor all source flocks regardless of their respective environmental status. The commenter believes these actions are necessary because "Investigators have speculated that use of vaccine and, or antibiotics in these flocks may have precluded isolation of SE."

We agree with the commenter that positive environmental samples may call for additional samples from dead-germ eggs, meconium and other hatching debris, and newly-hatched chicks to ensure that a breeding flock is not contaminated with SE. However, we have determined that environmental testing of samples is a quicker and more reliable means of detecting SE-contaminated egg-type chicken breeding flocks than the less-sensitive dead-germ egg culturing. Although our experiences indicate that the present program as amended by this rule is a sufficient means of detecting SE, we will recommend that the General Conference Committee take action at their next scheduled meeting before the 1994 Biennial Conference if future experience shows a further change to be warranted. At this time, we are not making any changes to this rule as a result of this comment.

#### Other Changes From the Proposed Rule

We have made several changes to the proposed rule for clarification. These changes are discussed below.

#### Definition of Dealer

We proposed to amend § 145.1 by adding the following definition: "Dealer. An individual or business that deals in commerce in hatching eggs and newly-hatched poultry obtained from breeding flocks and hatcheries. This does not include an individual or business that deals in commerce in buying and selling poultry for slaughter only."

We proposed this change to eliminate confusion and misunderstandings among Plan participants. However, our proposed definition does not take into account the stage of development of poultry after newly-hatched poultry. It was our intent to include started poultry; therefore, we are adding the term "started poultry" to the definition of "dealer."

#### Use of Selenite-cystine

We proposed to amend § 147.11 by adding specific steps for conducting bacteriologic examination of environmental and other contaminated specimens. These provisions include the use of Tetrathionate Hajna selective broth, TT Mueller-Kauffmann, or selenite-cystine for culturing a representative sample at a temperature of 41-42 °C for 24 hours. The National Veterinary Services Laboratories (NVSL) have continued to work with these substances. The NVSL's recent experience indicates that the use of selenite-cystine for culturing samples preserved in double strength skim milk results in false negatives due to a precipitation reaction. Because of these recent findings, we have determined that the use of selenite-cystine may be contraindicated when double strength skim milk is used to moisten drag swabs, and we are adding a sentence to paragraph (b)(1) of § 147.11 to caution against their combined use.

#### Pooling of Composite Samples

We proposed to amend § 147.12 by allowing the pooling of composite environmental samples to not less than five samples at the laboratory. Our proposal does not address the need to maintain the proper ratio between the volume of material collected and the volume of the enrichment broth. It was our intent to allow this pooling as long as the ratio of the composite environmental samples to the enrichment broth remains approximately 1 to 10. The 1 to 10 material to broth ratio is standard

industry practice and is stipulated in similar provisions elsewhere in the regulations. Therefore, we are adding a phrase to paragraph (a)(2) of § 147.12 to provide clear and consistent guidance.

#### Miscellaneous

We have also made minor nonsubstantive editorial changes and corrections to the proposed rule.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the proposal, as changed within this document, as a final rule.

#### Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

These changes are based on the recommendations of representatives of member State, hatcheries, dealers, flock owners and breeders who were participants at the Biennial Plan Conference. Since participation in the program is voluntary, individuals are likely to continue in the program as long as the costs of implementing the program are lower than the added benefits they receive from the program.

Several of the procedures for improvement will help prevent disease. The procedure for segregating and testing of nonparticipating birds will prevent disease from spreading into the participating flock. The egg yolk monitoring test for *Mycoplasma gallisepticum* (MG), besides permitting effective identification of the disease, allows for a reduced sample (30 birds rather than 100 birds) that will result in a decreased number of tests. Together with other methods of environmental culturing, the procedure for drag-swab sampling of breeding flocks will likely strengthen the effectiveness of the disease identification procedure. Specifically, if breeders suspect the presence of disease, they will find the drag-swab sampling of the breeding flock environment more cost effective

than the previous methods. Any increased cost of these detection and prevention programs will be minor compared to the losses that each producer could bear in case of undetected disease spread. Furthermore, the number of birds required to be tested under this rule is very small compared to the size of flocks within the industry.

According to APHIS and other Federal and State Government data, there are 327 participating hatcheries with a total hatching egg capacity of approximately 490 million egg- and meat-type chickens. Hatcheries with less than a 50,000 hatching egg capacity produce only 1/10th of a percent of this total, while hatcheries with over a 500,000 hatching egg capacity account for 97 percent. Hatcheries with a 50,000 to 499,999 bird capacity account for the remaining 2.7 percent. One amendment to the "U.S. Sanitation Monitored" programs requires necropsy or culturing of 60 birds in the case of one positive sample. The additional cost of implementing this change is very minor when considered in terms of risk to the industry. In addition, the costs of conducting these tests as well as the cost of specific antigens used are modest. For example, a typical cost for performing the Pullorum-Typhoid plate test is \$15 for the first 100 birds or fraction thereof at one location, \$0.08 for each bird between 100 and 500 at the same location, and \$0.04 for each bird in excess of 500 at the same location on consecutive working days. The cost of MG plate test antigen is \$0.09 per plate test, while the cost of Pullorum-Typhoid plate test antigen is \$0.03 per plate test. Compared to the total size of the hatcheries and to the total losses that individual producers could incur due to disease incidence, the cost of testing a small fraction of birds is minor.

Although information is not available regarding the benefits of the program, implementation of these procedures will likely advance the goals of disease prevention, through early detection and control of the disease, which will result in reduced egg and chick mortality. According to the industry representativeness<sup>1</sup> contacted, the long-run losses avoided will far outweigh the cost of implementing the testing procedures. Since the additional costs and benefits are minor, the agency concludes that this rule will be unlikely to have any significant economic impact

<sup>1</sup> A list of industry representatives from whom information was collected may be obtained from the person listed under FOR FURTHER INFORMATION CONTACT within this document.

on producers, consumers, or any other small entities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will 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 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging its provisions.

#### Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this document have been submitted for approval of the Office of Management and Budget.

#### List of Subjects in 9 CFR Parts 145 and 147

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

Accordingly, we are amending 9 CFR parts 145 and 147 as follows:

#### PART 145—NATIONAL POULTRY IMPROVEMENT PLAN

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

Authority: 7 U.S.C. 429; 7 CFR 2.17, 2.51, and 371.2(d).

2. Section 145.1 is amended by adding a new definition, in alphabetical order, to read as follows:

#### § 145.1 Definitions.

\* \* \* \* \*

*Dealer.* An individual or business that deals in commerce in hatching eggs, newly-hatched poultry, and started poultry obtained from breeding flocks and hatcheries. This does not include an individual or business that deals in commerce in buying and selling poultry for slaughter only.

\* \* \* \* \*

**§ 145.3 [Amended]**

3. In § 145.3(c), the introductory text is amended by removing "NPIP Form 3B" and adding "VS Form 9-2 (formerly NPIP Form 3B)" in its place.

4. Section 145.4(d) is revised to read as follows:

**§ 145.4 General provisions for all participants.**

(d) Except as provided by this paragraph, participants in the Plan may not buy or receive products for any purpose from nonparticipants unless they are part of an equivalent program, as determined by the Official State Agency. Participants in the Plan may buy or receive products from flocks that are neither participants nor part of an equivalent program, for use in breeding flocks or for experimental purposes, under the following conditions only:

(1) With the permission of the Official State Agency and the concurrence of the Service; and

(2) By segregation of all birds before introduction into the breeding flock. Upon reaching sexual maturity, the segregated birds must be tested and found negative for pullorum-typhoid. The Official State Agency may require a second test at its discretion.

**§ 145.10 [Amended]**

5. Section 145.10(i) is amended by removing "*Mycoplasma*" in the paragraph heading and adding "U.S.M." in its place, and by adding "Figure 10" below the illustrative design.

**§ 145.14 [Amended]**

6. Section 145.14(a)(1) is amended by adding "or in literature provided by the producer" after the last word in the second sentence.

7. In § 145.14, footnote number "1" and the reference in paragraph (b)(1) are renumbered "3".

**§ 145.22 [Amended]**

8. Section 145.22(d) is amended by removing "as described in § 147.25" and adding "(see § 147.25 of this chapter)" in its place.

9. Section 145.23 is amended as follows:

a. Paragraph (d)(1)(ii)(A) is amended by removing all text following "(APPI)" and adding in its place "*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. Paragraph (d)(1)(v) is amended by adding "The authorized agent shall also collect samples every 30 days after the first sample has been collected." immediately after the first sentence.

c. Paragraph (d)(1)(vi) is amended by removing "-typhoid" in the first sentence.

d. Paragraph (d)(1)(vii) is amended by removing "as described in § 147.25(a) of this chapter" and adding "(see § 147.25 of this chapter)" in its place.

e. Paragraph (d)(1)(viii) is amended by removing "as prescribed in § 147.25 of this chapter" and adding "fumigated (see § 147.25 of this chapter)" in its place.

f. Paragraph (d)(1)(ix) is removed.

g. Paragraph (d)(2) is revised.

h. Paragraph (d)(3) is amended by revising "paragraphs (d)(1)(vi) and (d)(1)(ix)" to read "paragraph (d)(1)(vi)".

As revised § 145.23(d)(2) reads as follows:

**§ 145.23 Terminology and classification: flocks and products.**

(2) A flock shall not be eligible for this classification if *Salmonella enteritidis* ser *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 section (d)(1)(v) of this paragraph will require bacteriological examination, as described in § 147.11 of this chapter, of a random sample of 60 live birds for SE in an authorized laboratory. If only one specimen is found positive for SE, the participant may request bacteriological examination of another 60-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.

**§ 145.32 [Amended]**

10. Section 145.32(c) is amended by removing "as described in § 147.25" and adding "(see § 147.25 of this chapter)" in its place.

11. Section 145.33 is amended by revising paragraphs (d)(1)(iii), (d)(1)(iv), (d)(1)(v), and (d)(1)(vi), and by adding new paragraphs (d)(1)(vii) and (d)(1)(viii) and footnote<sup>44</sup> to read as follows:

**§ 145.33 Terminology and classification: flocks and products.**

(d) U.S. Sanitation Monitored. \* \* \* (1) \* \* \*

(iii) If pelletized feed contains animal protein, the protein products should be

purchased from participants in 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;

(iv) If mash feed contains animal protein, the protein products should be purchased from participants in the Animal Protein Products Industry (APPI) *Salmonella* Education/Reduction Program;

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

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

(vii) 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 90 days thereafter. An authorized laboratory for *Salmonella* shall examine the environmental samples bacteriologically;

(viii) Owners of flocks found infected with a paratyphoid *Salmonella* may vaccinate these flocks with an autogenous bacterin with a potentiating agent.<sup>44</sup>

**§ 145.42 [Amended]**

12. Section 147.42(c) is amended by removing "as described in § 147.25" and adding "(see § 147.25 of this chapter)" in its place.

**§ 145.43 [Amended]**

13. Section 145.43, paragraph (f)(3)(i) is amended by removing all text following "must have been" and adding in its place "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."

**§ 145.52 [Amended]**

14. Section 145.52(b) is amended by removing "as described in § 147.25" and adding "(see § 147.25 of this chapter)" in its place.

15. Section 145.53 is amended by revising paragraph (c)(1)(i), the text beginning "Provided," to read as follows:

<sup>44</sup>Preparation and use of this type of vaccine may be regulated by State statutes.

**§ 145.53 Terminology and classification; flocks and products.**

(c) *U.S.M. Gallisepticum Clean.* (1)

(i) \* \* \* *Provided*, That to retain this classification, a random sample of serum or egg yolk from at least 5 percent of the birds in the flock, but at least 30 birds, shall be tested at intervals of not more than 90 days: *And provided further*, That a sample comprised of less than 5 percent may be tested at any one time, with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 5 percent of the birds in the flock, but at least 30 birds, is tested within each 90-day period; or

16. Section 145.53(c)(1)(ii)(B) is amended by removing the "; or" at the end of the sentence and adding a "period" in its place.

**PART 147—AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN**

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

Authority: 7 U.S.C. 429; 7 CFR 2.17, 2.51, and 371.2(d).

**§ 147.5 [Amended]**

18. In § 147.5(b), footnote number "1" is amended by removing "Building 265, Beltsville Agricultural Research Center-East, Beltsville, Maryland 20705" and adding "VS, APHIS, USDA, Federal Building, Hyattsville, Maryland 20782" in its place.

19. Section 147.5(e)(4) is amended by removing "two-fold" in the first sentence and adding "twofold" in its place.

20. Section 147.5(f)(3) is amended by removing "[±]" immediately after "or vice versa" and adding "[ ∓ ]" in its place.

**§ 147.7 [Amended]**

21. Section 147.7 is amended as follows:

a. The seventh sentence of the introductory paragraph is amended by removing "any" immediately before "/ or tube antigens." and adding "and" in its place.

b. In paragraph (d)(1)(ii), the table is amended by removing "12.0" for the listing of Sodium citrate under the Grams column and adding "8.0" in its place, and by revising the entry for "Dextrose".

c. In paragraph (d)(2), the introductory paragraph is amended by removing "PBC" and adding "PBS" in its place.

d. In paragraph (e), the introductory paragraph is amended by removing

"(c)" immediately after "\$ 147.7" and adding "(d)" in its place.

e. Paragraph (e)(1)(iv) is amended by removing "paragraph (d)(1)(iv)" and adding "paragraphs (d)(1) (ii) through (v)" in its place.

f. Paragraph (e)(3)(x)(G) is amended by removing "0.05" the second time it appears and adding "0.5" in its place.

As revised, the entry for "Dextrose" in the table in paragraph (d)(1)(ii) reads as follows:

	Grams
Dextrose .....	20.5
Distilled water to make 1,000 ml	

22. Section 147.11 is amended as follows:

a. The section heading is amended by removing the word "reactors".

b. Paragraph (a) is amended by adding a new paragraph heading, and by removing "gall-bladder" in the first sentence and adding "gallbladder" in its place, and by removing "paragraph (f)" in the last sentence and adding "paragraph (g)" in its place.

c. Paragraphs (b) through (i) are redesignated as paragraphs (c) through (j) and a new paragraph (b) is added.

d. Newly-redesignated paragraph (c)(2) is amended by removing "gall bladder" and adding "gallbladder" in its place.

e. Newly-redesignated paragraph (d) is amended by removing "paragraph (b)" in the first sentence and adding "paragraph (c)" in its place.

f. Newly-redesignated paragraph (g) is amended by removing "paragraph (e)" and adding "paragraph (f)" in its place.

g. In newly-redesignated paragraph (i), footnotes 2 and 3 are redesignated as footnotes 3 and 4. Newly-redesignated footnote 3 is amended by removing "Texas A&M University, College Station, TX 77843" and adding "University of Pennsylvania, New Bolton Center, Kennett Square, Pennsylvania 19348-1692" in its place.

The additions to § 147.11 read as follows:

**§ 147.11 Laboratory procedure recommended for the bacteriological examination of Salmonella.**

(a) *Bacteriological examination of Salmonella reactors and necropsy specimens.* \* \* \*

(b) *Bacteriologic examination of environmental and other contaminated specimens.* (1) Culture a representative sample of the specimen in tetrathionate Hajna (TTH) selective broth (TT Mueller-Kauffmann or selenite-cystine is also acceptable) as a temperature of 41-42 °C for 24 hours. Note: Do not use

selenite-cystine if double strength skim milk is used as a preservative for the sample.

(2) Inoculate an agar late of brilliant green novobiocin (BGN) and an agar plate of xylose-lysine-tergitol 4 (XLT4), incubate at 37 °C for 24 hours, and retain culture tubes at room temperature for 5-7 days for possible reculturing of the negative tubes using 0.25 ml in TTH.

(3) Inoculate *Salmonella* suspect colonies to slants of triple sugar-iron (TSI) and lysine-iron (LI) agar and incubate at 37 °C for 24 hours. Five colony picks per plate should be taken unless 50 percent or more of the plates have *Salmonella*-like colonies. In that case, the number of picks may be reduced to three per plate.

(4) Conduct serologic screening of cultures revealing typical reactions of *Salmonella* on TSI and LI agar slants using somatic O-group antisera agglutination or transfer for further identification to appropriate biochemical tests such as: Dextrose, lactose, sucrose, mannitol, maltose, dulcitol, malonate, gelatin, urea broth, citrate, lysine decarboxylase, ornithine decarboxylase, methyl red and Voges-Proskauer, KCN, salicin broths, indole, and hydrogen sulfide. Motility or non-motility is demonstrated by inoculating a suitable semisolid medium. The Analytical Profile Index API 20E<sup>2</sup> for Enterobacteriaceae (APE) system may also be used for further identification if desired.

(5) Serotype all *Salmonella* group D cultures at the National Veterinary Services Laboratory.

23. Section 147.12 is amended as follows:

a. In paragraph (a)(2), the words "or house" are added after the words "the pen" in the second sentence and the words "or houses" are added after the words "from pens" in the three instances where they appear in the seventh sentence and concluding text is added at the end of paragraph (a)(2).

b. A new paragraph (c) is added. The additions to § 147.12 read as follows:

**§ 147.12 Procedures for collecting environmental samples and cloacal swabs for bacteriological examination.**

(a) \* \* \*

(2) \* \* \*

The composite samples above may be pooled to not less than five samples at

<sup>2</sup> We use trade names solely for the purpose of providing specific information. Mention of a trade name does not constitute a guarantee or warranty of the product by the U.S. Department of Agriculture or an endorsement over other products not mentioned.

the laboratory as long as the volume of material collected equals approximately 10 percent of the volume of the broth.

(c) *Drag-swabs.* Drag-swabs for bacteriological examination should involve the exposure of at least six unpooled pads per house to promote representative sampling and some element of quantification.

(1) *Drag-swab assembly.* Assemble drag-swab sampling sets from folded-once 3-by-3-inch sterile gauze pads secured with paper clips. Bend end wires of each paper clip slightly to catch into the swab fabric, thus securing the clips to the folded pads. Use two pads, assembled as described to make each drag-swab sampling set. Securely connect one pad through the free rounded end of the paper clip to a 2-ft (0.6 m) length of size 20 fibrous wrapping twine. Similarly connect the other pad to a 1-ft (0.3 m) length of twine. Then securely connect the free ends of both lengths of twine to a small loop tied at the end of a similar 5-ft length of twine. The resulting assembly resembles the letter Y with a 5-ft long vertical stem and two diagonal branches (one 1 ft long and the other 2 ft long), with a folded swab securely attached at the end of each branch. After assembly, place each two-pad drag-swab sampling set into a sterile bag.

(2) *Procedure for taking drag-swab.* (i) *Floor litter:* The Plan participants should collect two samples as follows: Drag four 3-by-3-inch sterile gauze pads premoistened with double strength skim milk<sup>1</sup> over the floor litter surface for 15 min minimally. Place the gauze pads used to collect the samples in 18-oz whirl-pack bags, two pads per bag with each bag containing 5 ml of double strength skim milk. This will maintain the moistness of the sample during transport. Mark the bags with the type of sample and the house identification.

(ii) *Nest-boxes.* The Plan participant should collect one nest-box sample by using two 3-by-3-inch sterile gauze pads premoistened with double strength skim milk. Wipe the two gauze pads used to collect the sample over assorted locations of about 10 percent of the total nesting area. Place the gauze pads used to collect the sample in an 18-oz whirl-pack bag containing 5 ml of double strength skim milk. Mark the bag with the type of sample and the house identification.

<sup>1</sup> Obtain procedure for preparing double strength skim milk from USDA-APHIS "Recommended Sample Collection Methods for Environmental Samples" available from the National Poultry Improvement Plan Staff, VS, APHIS, USDA, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782.

#### § 147.14 [Amended]

24. In § 147.14, footnote number "1" is amended by removing "Texas A&M University, College Station, TX 77843, 1975" and adding "University of Pennsylvania, New Bolton Center, Kennett Square, Pennsylvania 19348-1692, 1980" in its place.

#### § 147.15 [Amended]

25. Section 147.15(a) is amended by removing "(e)" in the fifth sentence and adding "(f)" in its place.

26. Section 147.15(b) is amended by removing "(f)" in the fifth sentence and adding "(g)" in its place.

27. Section 147.15(g) is amended by removing "18.0" after "Purified agar (g)-" and adding "12.0" in its place.

#### § 147.16 [Amended]

28. Section 147.16(c) is amended by removing "(e)" in the second sentence and adding "(f)" in its place.

29. Section 147.22(c) is amended by revising the first sentence to read as follows:

#### § 147.22 Hatching egg sanitation.

\* \* \* \* \*

(c) The visibly clean eggs should be fumigated (see § 147.25 of this chapter) or sanitized as soon as possible after collection. \* \* \*

\* \* \* \* \*

#### § 147.23 [Amended]

30. Section 147.23(d) is amended by removing "(d)" at the end of the paragraph.

#### § 147.24 [Amended]

31. Section 147.24(b)(3) is amended by removing "as described in § 147.25(e)" and adding "(see § 147.25 of this chapter)" in its place.

32. Section 147.24(c) is amended by removing "according to the procedures described in § 147.25(b) (3), (4), and (5)" and adding "(see § 147.25 of this chapter)" in its place.

#### § 147.25 [Amended]

33. Section 147.25 is amended by removing paragraphs (a) through (f).

Done in Washington, DC, this 1st day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 92-29461 Filed 12-3-92; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1240

[Docket No. 91N-0272]

#### Control of Communicable Diseases; Definition of Milk and Milk Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations established for the control of communicable disease by defining "milk" and "milk products" and by revising the regulations to clarify that the requirement for pasteurization applies to the dairy ingredients of certain dairy products, such as nonfat dry milk, cottage cheese, or butter. It was never FDA's intention to require that these finished products be subjected to the pasteurization process after their manufacture. The purpose of this technical amendment is to make explicit that which was implicit in the original rule.

**EFFECTIVE DATE:** December 4, 1992.

**FOR FURTHER INFORMATION CONTACT:** Johnnie G. Nichols, Center for Food Safety and Applied Nutrition (HFF-346), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-9175.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of January 14, 1992 (57 FR 1407), FDA proposed to amend the regulations that it promulgated under the Public Health Service Act (42 U.S.C. 264) for the control of communicable diseases by including definitions for "milk" and "milk products" among the general definitions in § 1240.3 (21 CFR 1240.3) and by clarifying when dairy ingredients must be pasteurized in accordance with § 1240.61 (21 CFR 1240.61).

Interested persons were given until March 16, 1992, to comment. FDA received three letters, each containing one or more comments, from Federal and State officials. The comments generally supported the proposal. Two comments address issues (lack of repasteurization requirements for in-process and blended dairy products and lack of standards of identity for goat milk products) that are outside the scope of the proposal and, therefore, will not be discussed here.

A summary of the remaining comments and the agency's responses follow: