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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 405

[Amendment No. 3; Doc. No. 7756S]

Apple Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) amends the Apple Crop Insurance Regulations (7 CFR part 405), effective for the 1990 and succeeding crop years, by changing the policy to provide that premium reduction gained by insureds through good insuring experience will extend beyond the present 1990 crop year expiration. The intended effect of this rule is to allow a continuation of good experience discount for all present policyholders who are eligible for a premium reduction while FCIC reviews the entire good experience discount issue.

EFFECTIVE DATE: October 1, 1990.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC, 20250, telephone (202) 447–3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512–1. This action does not constitute a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is April 1, 1990.

David W. Gabriel, Acting Manager, FCIC, (1) Has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons and will not have a significant economic impact on a substantial number of small entities.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Under the provisions of subsection 5.c. of the Apple Crop Insurance Regulations (7 CFR part 405), an insured may be eligible for a premium reduction in excess of 5 percent based on that individual's insuring experience through the 1984 crop year under the terms and conditions contained in the apple crop insurance policy in effect for the 1985 crop year. The insured will continue to receive the benefit of such reduction subject to several conditions, one of which being that no premium reduction will be retained after the 1991 crop year.

The FCIC Board of Directors has suggested that the present premium reduction be continued, and directed that a study be made of the entire premium reduction for good experience issue as it might apply to all policyholders.

On Tuesday, November 21, 1989, FCIC published a notice of proposed rulemaking in the **Federal Register** at 54 FR 48109, to change the policy to provide that premium reduction gained by insureds through good insuring experience will extend beyond the present 1990 crop year expiration. The intended effect of this rule is to allow a continuation of good experience discount for all present policyholders who are eligible for a premium reduction while FCIC reviews the entire good experience discount issue for all policyholders.

The public was given 30 days in which to submit written comments, data, and opinions on the proposed rule, but none were received. Therefore, the proposed rule published at 54 FR 48109 is hereby adopted as a final rule.

List of Subjects in 7 CFR Part 405

Crop insurance, Apples.

Final Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation amends the Apple Crop Insurance Regulations (7 CFR part 405), effective for the 1991 and succeeding crop years, as follows:

PART 405—[AMENDED]

1. The authority citation for 7 CFR part 405 is amended to read as follows:

Authority: 7 U.S.C. 1506, 1516.

2. 7 CFR § 405.7.(d) is amended by revising subsection 5.c.(1) to read as follows:

§ 405.7 The application and policy.

* * * * *

(d) * * *

5. * * *

c. * * *

(1) No premium reduction will be retained after the 1991 crop year;

* * * * *

Done in Washington, DC, on August 23, 1990.

David W. Gabriel,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 90–20558 Filed 8–30–90; 8:45 am]

BILLING CODE 3410-08-M

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 89-151]

Viruses, Serums, Toxins, and Analogous Products; Standard Requirements for Certain Specified Animal Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to add standard requirements for evaluating Bovine Virus Diarrhea Vaccine, Chlamydia Psittaci Vaccine, Bovine Rhinotracheitis Vaccine, Pasteurella Haemolytica Vaccine (Bovine Isolate), Pasteurella Multocida Vaccine (Bovine Isolate), and Pasteurella Multocida Vaccine (Avian Isolate). The purpose of this rule is to codify uniform standard requirements and test methods for use by any producers making the products concerned. Certain section designations are changed to allow for the addition of the new standard requirements.

EFFECTIVE DATE: October 1, 1990.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8245.

SUPPLEMENTARY INFORMATION:

Background

Standard requirements consist of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service (APHIS) for evaluating biological products for purity, safety, potency, and efficacy. Until such standard requirements for a given biological product are codified in the regulations (9 CFR part 113), the test methods, procedures, and criteria to be used in the evaluation of a product are developed by the licensees and are written into an Outline of Production which is required to be filed with APHIS for each veterinary biological product. Outlines of Production are required to be approved by APHIS as a prerequisite to the licensing of a product.

When standard requirements for a biological product have been developed and approved by APHIS for general use, they are proposed for codification in the regulations. Each of the standard requirement test methods in these amendments has been successfully used in the evaluation of at least two currently licensed products. Development of such requirements is accomplished through cooperative efforts involving academic institutions, research organizations, licensees and applicants, and the National Veterinary Services Laboratories. Codification assures uniformity and general availability of the standard requirements to producers making the products concerned.

These amendments contain the standard requirements for products containing live and modified live pasteurella haemolytica bacteria and pasteurella multocida bacteria, live chlamydia psittaci, killed bovine virus diarrhea virus and bovine rhinotracheitis virus.

To allow for the addition to the standards of the proposed requirements for killed virus vaccines, and new standard requirements in the future, certain sections in this Part have been redesignated.

Comments Received

On December 9, 1988, we published a proposed rule in the **Federal Register** (53 FR 49669-49674, Docket No. 87-185) discussing this revision. The proposed rule provided that comments would be accepted for 30 days, until January 9, 1989. The industry association and others requested that we extend the comment period to provide interested persons adequate time to prepare comments. A Notice was published in the **Federal Register** (54 FR 5939, Docket No. 88-211) reopening and extending the comment period by 45 days, until February 23, 1989.

We received comments from 12 licensed manufacturers and 1 national trade association representing major research-based U.S. manufacturers of animal health products. While generally accepting the proposed rule, all those commenting suggested certain changes to one or more of the standard requirements as proposed.

One commenter requested that the term "susceptible animal" be defined. For the purpose of determining the immunogenicity of a viral Master Seed, animals shall be considered susceptible if the results of a virus plaque reduction method performed on individual prevaccination sera are negative at a 1:2 final serum dilution. This procedure for determining susceptible animals appears in the current Standard Requirements and is not intended to exclude other approved means of determining susceptibility of test animals. However, the procedure in the standards is widely accepted for use in studies designed to show efficacy of veterinary biological products of viral origin. Other methods equally as sensitive and approved by APHIS may also be used to establish susceptibility.

In the case of bacterial Master Seeds, a standard uniform procedure such as the procedure used for viral Master Seeds is not available at this time. Therefore, susceptibility of animals used in immunogenicity studies is demonstrated on an individual basis by an approved test procedure on file with APHIS. As acceptable procedures are developed and approved, these procedures are made available for individual bacterial Master Seeds in the Supplemental Assay Method (SAM) in accordance with 9 CFR 113.2—Testing aids.

Two commenters suggested that in evaluating the Master Seed in §§ 113.68 and 113.69, we specify that "clinical signs and/or lung lesions" can be used to determine if a Master Seed is satisfactory. The lungs of all calves which are used in the test must be examined. Those calves which survive challenge must be euthanized so that a proper examination may be made. Examination of the lungs using an acceptable scoring system and demonstrating a significant difference in lung lesion scores is a more accurate method of valuation than relying only on clinical signs. Therefore, this recommendation is not accepted. It was also suggested that the methods for assessing lung lesions be specified in §§ 113.68 and 113.69. When proven procedures are developed, which are acceptable for general use, the Agency publishes such procedures in the Supplemental Assay Method (SAM) in accordance with § 113.2(a). Until procedures are published, manufacturers must utilize methods which are developed and approved for testing each particular product. It was also suggested that in paragraph (b)(3) of §§ 113.68 and 113.69 the intrathoracic route of administering the challenge be added in addition to the respiratory route. The respiratory route of administering the virulent challenge organisms includes the intrathoracic route. The virulent organisms must be introduced into the lungs to produce the desired lesions. It was further suggested that the period of observation following challenge be changed from 5-7 days to 4-7 days in § 113.68 and from 7-10 days to 4-10 days in § 113.69. The Agency does not object, and appropriate changes have been made in the final rule. Corresponding changes have been made in paragraph (b)(5) in these sections. Two firms suggested that paragraph (c)(2) in these sections contain provisions for a second stage

test as described in § 113.8—In vitro tests in lieu of host animal tests for immunogenicity. Section 113.8(b) describes the method for doing a second stage potency test for live products and § 113.8(b)(4) describes the criteria for acceptance in a second stage test for live bacterial products. Although this provision is applicable to all the Standard Requirements for live bacterial products, reference to § 113.8 is added to paragraph (c) of §§ 113.68 and 113.69 to clarify the standard requirements.

Several commenters recommended that the interval between the original Master Seed immunogenicity tests and the repeat Master Seed immunogenicity tests for live viral and bacterial vaccines be extended from 3 to 5 years. Several reasons were offered in support of this recommendation including the observation that the first serial of product may be offered to the market 2 years after the original Master Seed test. The requirement to conduct a repeat immunogenicity test 3 years after the original immunogenicity test was codified in the regulations on January 24, 1985 (50 FR 431). Prior to that time, the regulations required a repeat immunogenicity test at 3 years and then every 5 years thereafter. This change represented a significant relaxation in the regulations. However, the Agency believed that experience justified the relaxation. The repeat immunogenicity test was established at 3 years to allow for early detection of any change that may occur in the Master Seed and to correct as early as possible any unexpected or adverse reaction caused by the licensed product that can be traced back to the Master Seed. In most cases, the repeat immunogenicity is conducted with less than half the number of animals used in the initial test, which significantly reduces the expense of conducting the repeat test. The Agency believes that conducting the repeat immunogenicity test at 3 years rather than at 5 years has good scientific merit. Therefore, this suggestion is not adopted.

With regards to § 113.70, Pasteurella Multocida Vaccine, Avian Isolate, it was suggested that specifying the intramuscular route for administering the challenge is too restrictive. In light of newer test methods reported in the literature, the Agency agrees, and § 113.70(b)(3) has been changed to allow for the use of other challenge methods acceptable to APHIS. Objection was also expressed regarding the use of four vials of final container samples in a repeat test when only two vials are required in the initial potency test. As noted earlier, the provisions of § 113.8 are applicable when doing a repeat in vitro test of live products. Those provisions require the use of double the number of samples in a repeat test. Such requirement is deemed appropriate for the test and is not being amended by this rulemaking. In the final rule, paragraph (c)(2) has been edited to provide for consistency in wording of the Standard Requirements for live bacterial vaccines and a reference to § 113.8 has been included in paragraph (c). This is an editorial rather than a substantive change because the testing requirement remains the same.

With regard to § 113.71, Chlamydia Psittacine Vaccine, Live Chlamydia, one commenter suggested that both the Master Seed and Working Seed be tested in accordance with § 113.37. The Agency feels that testing only the Master Seed and each serial of completed product according to § 113.37 is adequate for this purpose. Another firm suggested that the vaccinates and controls be challenged at 14 or more days rather than 21 or more days after the final dose of vaccine. The Agency does not object and the appropriate change has been made in the final rule. It was also recommended that the number of controls showing clinical signs for a valid challenge be changed from less than 8 of 10 controls to less than 7 of 10 controls and that the scoring system use clinical signs or chlamydia shedding. The challenge culture furnished by APHIS has been shown to consistently produce clinical signs in unvaccinated controls. Therefore, the Agency does not agree with reducing the number of controls which must show clinical signs for a valid challenge but will permit the demonstration of a significant difference in clinical signs other than fever as the criteria for a satisfactory Master Seed.

With regard to the proposed rule for the inactivated viral vaccines, most comments referred to both §§ 113.215 and 113.216. One commenter suggested that a range of 100–500 TCID50 of virus be permitted in the virus neutralization test. Using the proposed range of 50–300 TCID50 of the test virus increases the sensitivity of the neutralization test in determining susceptibility of test animals. This range also provides for flexibility in conducting the test. Therefore, the Agency does not agree with the recommended change. The Agency has proposed to use serological evaluation of sera of animals used in the firm's potency test. This would not only decrease the time required for serial release but would make it unnecessary for the Agency to repeat the potency test using additional host animals. In the proposed rule, paragraph (c)(2)(vii) in §§ 113.215 and 113.216 requires that the prevaccination and postvaccination sera from a satisfactory potency test be submitted to the National Veterinary Services Laboratories for confirmatory testing. Several of those commenting recommended deleting or changing this paragraph to permit the submission of prevaccination and postvaccination sera from the firm's satisfactory potency tests only for those serials which will be tested at the National Veterinary Services Laboratories prior to release. The Agency utilizes a computer generated random selection method for selecting serials to be tested. Using this method, the Agency is currently testing between 17 percent and 20 percent of all serials presented for release. The recommendation would compromise the random selection method of testing serials prior to release. Therefore, it cannot be adopted.

A recommendation was also made that in §§ 113.215 and 113.216, a paragraph (c)(2)(viii) be added to allow in the Outline of Production a provision for alternate potency tests acceptable to APHIS. When uniform and acceptable potency tests are developed, they will be codified in the regulations in accordance with § 113.9, New Potency Test. Until such methods are codified, firms that have developed potency tests acceptable to the Agency may request approval of such tests. One commenter stated that serum from animals used in the firm's potency test does not meet the definition of a sample of a prerelease biological product according to § 113.3. Such samples are still required to be submitted prior to serial release. A predetermined serological response is an acceptable and satisfactory index of immunity and that is why it appears in these standards.

Other commenters requested reducing the number of animals used in the potency test from eight animals to either five or six animals, i.e., four or five vaccinates and one control. Eight animals is the least number required in a test to enable a statistical analysis of the challenge results in comparing vaccinates and controls, i.e., five vaccinates and three controls. Other responses suggested that requiring four of the five vaccinates in a valid potency test to develop 50 percent endpoint titers of 1:8 or greater is sufficient for a satisfactory potency test. The Agency agrees and has deleted the requirement that the fifth animal must develop an endpoint titer of 1:4. Another commenter recommended that it is not necessary to require both a temperature rise to 104.5 °F and clinical signs for a valid

challenge potency test. The Agency disagrees with this suggestion. Respiratory and clinical signs confirm that the temperature rise is due to the virulent challenge and not another cause.

Several commenters suggested that requiring animals used in the potency test be at the minimum age recommended for vaccination is too restrictive since the immunogenicity was done using animals at the minimum age and the difficulty in obtaining and maintaining seronegative animals. The Agency agrees and appropriate changes have been made in the final rule.

Based on the rationale set forth in the proposal and in this document, we are adopting the provisions of the proposal with changes as a final rule.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291 and Departmental Regulation 1512-1 and have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this action 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. Its purpose is to publish in the regulations the test methods and procedures currently used by manufacturers to evaluate certain animal biologics.

Pursuant to requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601), the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not result in adverse economic impact on a substantial number of small entities. Its purpose is to codify in the regulations standard requirements for veterinary biological products.

Paperwork Reduction Act

The regulations in this rule contain no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

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.)

List of Subjects in 9 CFR Part 113

Animal biologics.

PART 113—STANDARD REQUIREMENTS

Accordingly, 9 CFR part 113 is amended as follows:

1. The authority citation for part 113 is revised to read as follows:

Authority: 21 U.S.C. 151–159; 37 FR 28477, 28646; 38 FR 19141.

2. In 9 CFR part 113—Standard Requirements, certain sections, footnotes, and references thereto, are redesignated and for the convenience of the user the table of contents is revised to read as follows:

PART 113—STANDARD REQUIREMENTS

Applicability

Sec.

Standard Procedures

Sec.

Ingredient Requirements

Live Bacterial Vaccines

Inactivated Bacterial Products

Sec.

Killed Virum Vaccines

Live Virus Vaccines

Diagnostics and Reagents

Sec.

Blood Origin Products

3. 9 CFR part 113, under the heading "Live Bacterial Vaccines," is amended by adding new §§ 113.68 through 113.71 to read as follows:

§ 113.68 Pasteurella Haemolytica Vaccine, Bovine.

Pasteurella Haemolytica Vaccine, Bovine, shall be prepared as a desiccated live culture bacterial vaccine of an avirulent or modified strain of *Pasteurella haemolytica*, identified as serotype 1. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.64 and the requirements in this section.

(b) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity. The immunogenicity of a selected bacterial count from the lot of Master Seed shall be established as follows:

(1) Fifteen *Pasteurella haemolytica* susceptible calves shall be used as test animals (10 vaccinates and 5 controls) for each route of administration recommended on the label.

(2) An arithmetic mean count of the colony forming units from vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The 10 calves to be used as vaccinates shall be injected as recommended on the label with a predetermined quantity of vaccine bacteria. The five control calves shall be held separately from the vaccinates. To confirm the dosage calculation, five replicate titrations on a sample of the bacterial vaccine used. Only plates containing between 30 and 300 colonies shall be considered a valid test.

(3) The vaccinates and controls shall be examined and their average body temperature determined prior to challenge. Fourteen to twenty-one days post vaccination, the vaccinates and controls shall each be challenged by the respiratory route with a (virulent) pneumonia producing *Pasteurella haemolytica* culture and observed for 4 to 7 days. The challenge culture and instructions for preparation for use shall be furnished or approved by the Animal and Plant Health Inspection Service.

(4) A satisfactory challenge shall be evidenced in the controls by progression of clinical signs consistent with respiratory system infection following challenge, including but not limited to lacrimation, mucoid nasal exudates, expiratory dyspnea, tachypnea, pulmonary rales, and cough possibly terminating in death; moribundity, depression with anorexia, diarrhea with substantial weight loss; or any combination of these symptoms.

(5) Lung lesion response to challenge will be assessed in all calves. Lung lesions will be assessed at necropsy in calves that succumb to challenge. Surviving calves will be euthanized on day 4 to 7 following challenge and lung lesions assessed at necropsy. Lung lesion scores will be used in the assessment of the response to challenge exposure. If a significant difference in lung lesion scores cannot be demonstrated between vaccinates and controls using a scoring system approved by the Animal and Plant Health Inspection Service, the Master Seed is unsatisfactory.

(6) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest: *Provided*, that, at least four of five vaccinates and four of five controls shall meet the criteria prescribed in paragraphs (b)(4) and (b)(5) of this section.

(7) An Outline of Production change must be made before authority for use of a new lot of Master Seed is granted by the Animal and Plant Health Inspection Service.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in §§ 113.8 and 113.64 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* Samples of completed product from each serial or first subserial shall be tested for safety in calves as provided in §§ 113.41(a) and 113.41(b) except, that the equivalent of two doses of vaccine shall be used and administered in the manner recommended on the label.

(2) *Bacterial count requirements.* Final container samples of completed product shall be tested for bacterial count using the method used in paragraph (b)(2) of

this section. Two replicate titrations shall be conducted on each serial and subserial. Each sample shall be rehydrated with accompanying sterile diluent to the volume indicated on the label. To be eligible for release, each serial and subserial shall have a bacterial count sufficiently greater than that of the vaccine used in the immunogenicity test to assure that, when tested at any time within the expiration period, each serial and subserial shall have a bacterial count at least two times greater than that used in the immunogenicity test.

§ 113.69 Pasteurella Multocida Vaccine, Bovine.

Pasteurella Multocida Vaccine, Bovine, shall be prepared as a desiccated live culture bacterial vaccine of an avirulent or modified strain of *Pasteurella multocida*, of bovine origin. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.64 and the requirements in this section.

(b) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity. The immunogenicity of a selected bacterial count from the lot of Master Seed shall be established as follows:

(1) Fifteen *Pasteurella multocida* susceptible calves shall be used as test animals (10 vaccinates and 5 controls) for each route of administration recommended on the label.

(2) An arithmetic mean count of the colony forming units from vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The 10 calves to be used as vaccinates shall be injected as recommended on the label with a predetermined quantity of vaccine bacteria. The five control calves shall be held separately from the vaccinates. To confirm the dosage calculation, arithmetic mean count shall be established by conducting five replicate titrations on a sample of the bacterial vaccine used. Only plates containing between 30 and 300 colonies shall be considered a valid test.

(3) The vaccinates and controls shall be examined and their average body temperature determined prior to challenge. Fourteen to twenty-one days post vaccination, the vaccinates and controls shall each be challenged by the respiratory route with a (virulent) pneumonia producing *Pasteurella multocida* culture and observed for 4 to 10 days. The challenge culture and instructions for preparation for use shall be furnished or approved by the Animal and Plant Health Inspection Service.

(4) A satisfactory challenge shall be evidenced in the controls by progression of clinical signs consistent with respiratory system infection following challenge, including but not limited to acute illness with higher body temperature and respiration rate, lacrimation, mucoid nasal exudate, expiratory dyspnea, tachypnea, pulmonary rales, and cough, possibly terminating in death; moribundity, depression with anorexia; diarrhea with substantial weight loss; or any combination of these symptoms.

(5) Lung lesion response to challenge will be assessed in all calves. Lung lesions will be assessed at necropsy in calves that succumb to challenge. Surviving calves will be euthanized on day 4 to 10 following challenge and lung lesions assessed at necropsy. Lung lesion scores will be used in the assessment of the response to challenge exposure. If a significant difference in lung lesion scores cannot be demonstrated between vaccinates and controls using a scoring system approved by the Animal and Plant Health Inspection Service, the Master Seed is unsatisfactory.

(6) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Only five vaccinates and five controls need to be used in the retest: *Provided*, that, at least four of five vaccinates and four of five controls shall meet the criteria prescribed in paragraphs (b)(4) and (b)(5) of this section.

(7) An Outline of Production change must be made before authority for use of a new lot of Master Seed is granted by the Animal and Plant Health Inspection Service.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in §§ 113.8 and 113.64 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety Test.* Samples of completed product from each serial or first subserial shall be tested for safety in calves as provided in §§ 113.41(a) and 113.41(b), except that the equivalent of two doses of vaccine shall be used and administered in the manner recommended on the label.

(2) *Bacterial count requirements.* Final container samples of completed product shall be tested for bacterial count using the method used in paragraph (b)(2) of this section. Two replicate titrations shall be conducted on each serial and subserial. Each sample shall be rehydrated with accompanying sterile diluent to the volume indicated on the label. To be eligible for release, each serial and subserial shall have a bacterial count sufficiently greater than that of the vaccine used in the immunogenicity test count per dose established to assure that, when tested at any time within the expiration period, each serial and subserial shall have a bacterial count at least two times greater than that used in the immunogenicity test.

§ 113.70 Pasteurella Multocida Vaccine, Avian Isolate.

Pasteurella Multocida Vaccine, Avian Isolate, shall be prepared as a desiccated live culture of an avirulent or modified strain of Pasteurella Multocida. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.64 and the requirements in this section.

(b) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity in each species and for each serotype for which the Master Seed is claimed to give protection.

(1) Thirty Pasteurella Multocida susceptible birds shall be used as test animals (20 vaccinates and 10 controls) for each bird species, route of administration, and serotype for which protection is claimed on the label.

(2) An arithmetic mean count of colony forming units from vaccine produced from the highest passage of Master Seed shall be established before the immunogenicity test is conducted. The 20 birds to be used as vaccinates shall be inoculated, as recommended on the label with a predetermined quantity of vaccine bacteria. The 10 control birds shall be held separately from the vaccinates. To confirm the dosage calculation, an arithmetic mean count shall be established by conducting five replicate titrations on a sample of the bacterial vaccine used. Only plates containing between 30 and 300 colonies shall be considered in a valid test.

(3) Not less than 14 days after vaccination, each of 20 vaccinates and each of 10 unvaccinated controls shall be challenged intramuscularly or by other methods acceptable to the Animal and Plant Health Inspection Service with a virulent Pasteurella multocida

strain, for which protection is claimed, and observed daily for a 14 day post-challenge period.

(4) Eight or more of the unvaccinated controls must die for the test to be valid. If at least 14 of 20 of the vaccinates do not survive the 14-day post challenge period, the Master Seed is unsatisfactory at the selected bacterial count.

(5) The Master Seed shall be retested for immunogenicity in 3 years and shall meet the criteria prescribed in paragraph (b)(4) of this section.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable requirements in §§ 113.8 and 113.64 and the requirements in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety test.* Samples of completed product from each serial or first subserial shall be tested for safety.

(i) Ten birds of a species for which the vaccine is recommended shall be given the equivalent of 10 doses each of the vaccine and observed for 10 days. If the vaccine is recommended for more than one species, only one species needs to be tested.

(ii) If unfavorable reactions attributable to the vaccine occur during the observation period in two or more of the test birds, the serial is unsatisfactory.

(iii) If unfavorable reactions occur which are not attributable to the test vaccine, the test is inconclusive and may be repeated. If the results of the next test are not satisfactory, or if the test is not repeated, the serial shall be considered unsatisfactory.

(2) *Bacterial count requirements.* Final container samples of completed product shall be tested for bacterial count using the method used in paragraph (b)(2) of this section. Two replicate titrations shall be conducted on each serial and subserial. Each sample shall be rehydrated with accompanying sterile diluent to the volume indicated on the label. To be eligible for release, each serial and subserial shall have a bacterial count sufficiently greater than that of the vaccine used in the immunogenicity test count per dose established to assure that, when tested at any time within the expiration period, each serial and subserial shall have a bacterial count at least two times greater than that used in the immunogenicity test.

§ 113.71 Chlamydia Psittaci Vaccine (Feline Pneumonitis), Live Chlamydia.

Chlamydia Psittaci Vaccine (Feline Pneumonitis), Live Chlamydia, shall be prepared from chlamydia-bearing cell culture fluids or embryonated chicken eggs. Only Master Seed which has been established as pure, safe, and immunogenic shall be used for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable requirements prescribed in § 113.300 and the requirements in this section. Master Seed propagated in chicken embryos shall be tested for pathogens by the chicken embryo test prescribed in § 113.37. If found unsatisfactory by any prescribed test, the Master Seed shall not be used.

(b) Each lot of Master Seed used for vaccine production shall be tested for immunogenicity. The immunogenicity of a selected dose from the lot of Master Seed shall be established as follows:

(1) Thirty feline pneumonitis susceptible cats shall be used as test animals (20 vaccinates and 10 controls). Blood samples shall be drawn and individual serum samples tested. The cats shall be considered suitable for use if all serums are negative for pneumonitis antibody in a complement fixation test or other test of equal sensitivity.

(2) A geometric mean titer of the dried vaccine produced from the highest passage of the Master Seed shall be established before the immunogenicity test is conducted. The 20 cats used as vaccinates shall be administered a predetermined quantity of vaccine by the method to be recommended on the label and the remaining 10 cats shall be held as controls. To confirm the dosage calculations, five replicate titrations shall be conducted on a sample of the vaccine dilution used. If two doses are used, five replicate confirming titrations shall be conducted on each dose.

(3) Fourteen or more days after the final dose of vaccine, the vaccinates and controls shall each be challenged intranasally with a minimum of 10,000 yolk sac LD50 of virulent feline pneumonitis furnished or approved by the Animal and Plant Health Inspection Service and observed each day for 28 days postchallenge. The rectal temperature of each animal shall be taken and the presence or absence of clinical signs noted and recorded each day.

(i) If less than 8 of 10 controls show clinical signs of feline pneumonitis infection other than fever, the test is inconclusive and may be repeated.

(ii) If a significant difference in clinical signs other than fever or chlamydia shedding cannot be demonstrated between vaccinates and controls using a scoring system approved by the Animal and Plant Health Inspection Service, the Master Seed is unsatisfactory.

(4) The Master Seed shall be retested for immunogenicity in 3 years unless use of the lot previously tested is discontinued. Either 10 vaccinates and 6 controls or 5 vaccinates and 3 controls shall be used in the retest.

(i) If less than five of six or three of three of the controls in the retest show clinical signs of feline pneumonitis infection other than fever, the test is inconclusive and may be repeated.

(ii) A significant difference in clinical signs shall be demonstrated between vaccinates and controls in a valid test as prescribed in paragraph (c)(3)(ii) of this section.

(5) An Outline of Production change must be made before authority for use of a new lot of Master Seed is granted by the Animal and Plant Health Inspection Service.

(c) *Test requirements for release:* Except for § 113.300(a)(3)(ii), each serial and subserial shall meet the requirements prescribed in § 113.135 and in this paragraph. Final container samples of completed product shall be tested. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) The test for pathogens prescribed in § 113.37 shall be conducted on each serial or one subserial of avian origin vaccine.

(2) *Chlamydia titer requirements.* Final container samples of completed product shall be tested for chlamydia titer using the titration method used in paragraph (b)(2) of this section. To be eligible for release, each serial and each subserial shall have a titer sufficiently greater than the titer of vaccine used in the immunogenicity test prescribed in paragraph (b) of this section to assure that when tested at any time within the expiration period, each serial and subserial shall have a titer 0.7 greater than that used in such immunogenicity test but not less than 2.5 ID50 per dose.

4. In 9 CFR part 113, the following sections are redesignated as follows:

§§ 113.250–113.255 [Redesignated as §§ 113.450–113.455]

a. Sections 113.250–113.255, "Blood Origin Products," are redesignated as §§ 113.450–113.455;

§§ 113.200–113.203 [Redesignated as §§ 113.400–113.409]

b. Sections 113.200–113.203, "Diagnostics and Reagents," are redesignated as §§ 113.400–113.409;

§§ 113.135–113.167 [Redesignated as §§ 113.300–113.332]

c. Sections 113.135–113.167, "Live Virus Vaccine," are redesignated as §§ 113.300–113.332, and "Vaccine" is changed to "Vaccines;"

§§ 113.120–113.134 [Redesignated as §§ 113.200–113.216]

d. Sections 113.120–113.134, "Killed Virus Vaccines," are redesignated as §§ 113.200–113.216; and

§§ 113.85–113.108 [Redesignated as §§ 113.100–113.123]

e. Sections 113.85–113.108, "Inactivated Bacterial Products," are redesignated as §§ 113.100–113.123.

5. 9 CFR part 113, under the heading "Killed Virus Vaccines," is amended to add new §§ 113.215 and 113.216 to read as follows:

§ 113.215 Bovine Virus Diarrhea Vaccine, Killed Virus.

Bovine Virus Diarrhea Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master Seed virus which has been established as pure, safe, and immunogenic shall be used for preparing seed cultures for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.200 and the requirements of this section.

(b) The immunogenicity of vaccine prepared from the Master Seed in accordance with the Outline of Production shall be established by a method acceptable to the Animal and Plant Health Inspection Service. Vaccine used for this test shall be at the highest passage from the Master Seed and at the minimum preinactivation titer provided in the Outline of Production.

(c) *Test requirements for release.* Each serial and subserial shall meet the applicable general requirements prescribed in § 113.200 and the special requirements provided in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety.* Vaccinates used in the potency test in paragraph (c)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions occur, including respiratory signs, which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated one time. If results of the second test are not satisfactory, or if the test is not repeated, the serial is unsatisfactory.

(2) *Potency.* Bulk or final container samples of completed product shall be tested for potency using the method described in this paragraph.

(i) Eight bovine virus diarrhea susceptible calves (five vaccinates and three controls) shall be used as test animals. Individual serum samples shall be collected, inactivated, and individually tested for neutralizing antibody.

(ii) A constant virus decreasing serum neutralization test in cell culture using 50–300 TCID50 of virus shall be used. Calves shall be considered susceptible if there is no neutralization at 1:2 final serum dilution. Other tests of equal sensitivity approved by the Animal and Plant Health Inspection Service may be used.

(iii) The five calves used as vaccinates shall be administered one dose of vaccine as recommended on the label. If two doses are recommended, the second dose shall be given according to the interval recommended on the label.

(iv) Fourteen days or more after the last vaccination, blood samples shall be drawn and the individual serum samples inactivated and tested for bovine virus diarrhea virus neutralizing antibody by the same method used to determine susceptibility.

(v) *Test interpretation.* If the controls have not remained seronegative at 1:2, the test is a No Test (NT) and may be repeated. If at least four of the five vaccinates in a valid test have not developed 50 percent endpoint titers of 1:8 or greater, the serial is unsatisfactory, except as provided in paragraph (c)(2)(vi) of this section.

(vi) *Virus Challenge Test.* If the results of a valid serum neutralization test are unsatisfactory, the vaccinates and controls may be challenged with virulent bovine virus diarrhea virus furnished or approved by the Animal and Plant Health Inspection Service. The animals shall be observed for 14 days post-challenge. If two of the three control calves do not show a temperature rise to 104.5 °F and develop respiratory or clinical signs of bovine virus diarrhea, the test is inconclusive and may be repeated one time. If two or more vaccinates show a temperature of 104.0 °F for 2 or more days and develop respiratory or clinical or other signs, the serial is unsatisfactory.

(vii) The prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the National Veterinary Services Laboratories for confirmatory testing.

§ 113.216 Bovine Rhinotracheitis Vaccine, Killed Virus.

Infectious Bovine Rhinotracheitis Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master Seed virus which has been established as pure, safe, and immunogenic shall be used for preparing seed cultures for vaccine production. All serials of vaccine shall be prepared from the first through the fifth passage from the Master Seed.

(a) The Master Seed shall meet the applicable general requirements prescribed in § 113.200 and the requirements of this section.

(b) The immunogenicity of vaccine prepared in accordance with the Outline of Production shall be established by a method acceptable to the Animal and Plant Health Inspection Service. Vaccine used for this test shall be at the highest passage from the Master Seed and at the minimum preinactivation titer provided in the Outline of Production.

(c) *Test requirements for release.* Each serial and subserial shall meet the requirements prescribed in § 113.120 and the special requirements provided in this paragraph. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Safety.* Vaccinates used in the potency test in paragraph (c)(2) of this section shall be observed each day during the prechallenge period. If unfavorable reactions occur, which are attributable to the vaccine, the serial is unsatisfactory. If unfavorable reactions occur which are not attributable to the vaccine, the test is inconclusive and may be repeated one time. If the results of the second test are not satisfactory, or if the test is not repeated, the serial is unsatisfactory.

(2) *Potency.* Bulk or final container samples of completed product shall be tested for potency using the method described in this paragraph.

(i) Eight infectious bovine rhinotracheitis susceptible calves (five vaccinates, three controls) shall be used as test animals. Individual serum samples shall be collected, inactivated, and individually tested for neutralizing antibody.

(ii) A constant virus decreasing serum neutralization test in cell culture using 50–300 TCID50 of virus shall be used. Calves shall be considered susceptible if there is no neutralization at 1:2 final serum dilution. Other tests of equal sensitivity acceptable to the Animal and Plant Health Inspection Service may be used.

(iii) The five calves used as vaccinates shall be administered one dose of vaccine as recommended on the label. If

two doses are recommended, the second dose shall be given according to the interval recommended on the label.

(iv) Fourteen or more days after the last vaccination, blood samples shall be drawn and the individual serum samples inactivated and tested for infectious bovine rhinotracheitis virus neutralizing antibody by the same method used to determine susceptibility.

(v) *Test interpretation.* If the three controls have not remained seronegative at 1:2, the test is a No Test (NT) and may be repeated. If at least four of the five vaccinates in a valid test have not developed 50 percent endpoint titers of 1:8, the serial is unsatisfactory, except as provided in paragraph (c)(2)(vi) of this section.

(vi) *Virus Challenge Test.* If the results of a valid serum neutralization test are unsatisfactory, the vaccinates and controls may be challenged with virulent infectious bovine rhinotracheitis virus furnished or approved by the Animal and Plant Health Inspection Service. The animals shall be observed each day for 14 days post-challenge. If two of the three control calves do not show a temperature rise to 104.5 °F and develop respiratory or other clinical signs of infectious bovine rhinotracheitis, the test is a No Test (NT) and may be repeated one time. If more than one of the vaccinates shows a temperature of 104.0 °F for 2 or more days or if more than one of the vaccinates develops respiratory or clinical or other signs, the serial is unsatisfactory.

(vii) The prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the National Veterinary Services Laboratories for testing by the Animal and Plant Health Inspection Service.

Done in Washington, DC, the 24th day of August 1990.

Robert Melland,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-20545 Filed 8-30-90; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

RIN 3150-AD72

Fingerprint Cards: Increase in Fee

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to reflect an administrative change pertaining to an increase in the fee that is charged for processing nuclear power plant fingerprint cards which are associated with granting unescorted access to an operating reactor site, or access to Safeguards Information. This amendment is necessary to reflect a fee schedule change imposed by the FBI.

EFFECTIVE DATE: October 1, 1990.

FOR FURTHER INFORMATION CONTACT: R.B. Manili, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492-0940.

SUPPLEMENTARY INFORMATION:

Background

On June 29, 1990, the FBI's Identification Division notified the Nuclear Regulatory Commission that there would be an increase of three dollars in the use-fee charge for fingerprint cards submitted by the NRC effective October 1, 1990. The increase from $20 to $23 in the user-fee charged NRC by the FBI was necessitated primarily by the rising personnel costs of operating the FBI's central fingerprint repository. The amended rule is needed to adjust the fee each licensee pays for the FBI criminal history checks so that the NRC can process and submit the fingerprint cards in conjunction with the effective date of the FBI's rate change. The NRC handling charge is included in the new $23.00 charge.

Because this amendment solely deals with a fee schedule change ordered by the FBI, the notice and comment provisions of the Administrative Procedure Act are impracticable and unnecessary. This amendment is effective 30 days after publication in the **Federal Register**. The increased fee applied to applications received by the NRC on or after October 1, 1990.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in a categorical exclusion 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environment assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget under control number 3150-0002.

Backfit Analysis

The Backfit rule, 10 CFR 50.109, does not apply to the action taken in this final rulemaking. Therefore, no backfit analysis has been prepared.

List of Subjects in 10 CFR Part 73

Hazardous materials-transportation, Incorporated by reference, Nuclear materials, Nuclear power plants and reactors, Penalty, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 73.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

1. The authority citation for part 73 continues to read in part as follows:

Authority: Secs. 53, 161, 68 Stat. 930, 948, as amended, sec. 147, 94 Stat. 780 (42 U.S.C. 2073, 2167, 2201); sec. 201, as amended, 204, 88 Stat. 1242, as amended, 1245 (42 U.S.C. 5841, 5844).* * *

§ 73.57 [Amended]

2. In § 73.57(d)(3), the rate of payment in the second sentence which currently reads "$21" is revised to read "$23."

Dated at Rockville, Maryland this 21st day of August, 1990.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 90-20611 Filed 8-30-90; 8:45am]

BILLING CODE 7590-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 389

Receivership Rules

CFR Correction

In title 12 of the Code of Federal Regulations, parts 300 to 499, revised as of January 1, 1990, on page 506 §§ 389.7-1 and 389.8-1, were inadvertently dropped when part 389 was redesignated from part 569c at 54 FR 42801, October 8, 1989. These sections had originally been added to 12 CFR as § 569c.7-1 at 54 FR 6112, February 7, 1989 and § 569c.8-1 at 54 FR 19156, May 4, 1989.

These missing sections read as follows: