

assignee with the Treasurer, CCC, at the address specified in the Contacts P/R.

(3) Receipt of the notice of assignment will ordinarily be acknowledged to the exporter and its assignee in writing by an officer of CCC. In cases where a financial institution is determined to be ineligible to receive an assignment, in accordance with paragraph (b) of this section, CCC will provide notice thereof, to the financial institution and to the exporter issued the payment guarantee, in lieu of an acknowledgment of assignment.

(4) The name and address of the assignee must be included on the written notice of assignment.

(b) *Ineligibility of financial institutions to receive an assignment.* A financial institution will be ineligible to receive an assignment of proceeds which may become payable under a payment guarantee if, at the time of assignment, such financial institution:

(1) Is not in sound financial condition, as determined by the Treasurer of CCC;

(2) Owns or controls the entity issuing the importer obligation; or

(3) Is owned or controlled by an entity that owns or controls the entity issuing the importer obligation.

(c) *Ineligibility of financial institutions to receive proceeds.* A financial institution will be ineligible to receive proceeds payable under a payment guarantee approved by CCC if such financial institution:

(1) At the time of assignment of a payment guarantee, is not in sound financial condition, as determined by the Treasurer of CCC;

(2) Owns or controls the entity issuing the importer obligation; or

(3) Is owned or controlled by an entity that owns or controls the entity issuing the importer obligation.

(d) *Alternative satisfaction of payment guarantees.* CCC may, with the agreement of the exporter (or if the right to proceeds payable under the payment guarantee has been assigned, with the agreement of the exporter's assignee), establish procedures, terms and/or conditions for the satisfaction of CCC's obligations under a payment guarantee other than those provided for in this subpart if CCC determines that those alternative procedures, terms, and/or conditions are appropriate in rescheduling the debts arising out of any transaction covered by the payment guarantee and would not result in CCC paying more than the amount of CCC's obligation.

(e) *Maintenance of records and access to premises.* (1) For a period of five years after the date of expiration of the coverage of a payment guarantee, the

exporter or the exporter's assignee, as applicable, must maintain and make available all records pertaining to sales and deliveries of and extension of credit for agricultural commodities exported in connection with a payment guarantee, including those records generated and maintained by agents, intervening purchasers, and related companies involved in special arrangements with the exporter. The Secretary of Agriculture and the Comptroller General of the United States, through their authorized representatives, must be given full and complete access to the premises of the exporter or the exporter's assignee, as applicable, during regular business hours from the effective date of the payment guarantee until the expiration of such five-year period to inspect, examine, audit, and make copies of the exporter's, exporter's assignee's, agent's, intervening purchaser's, or related company's books, records and accounts concerning transactions relating to the payment guarantee, including, but not limited to, financial records and accounts pertaining to sales, inventory, processing, and administrative and incidental costs, both normal and unforeseen. During such period, the exporter or the exporter's assignee may be required to make available to the Secretary of Agriculture or the Comptroller General of the United States, through their authorized representatives, records that pertain to transactions conducted outside the program, if, in the opinion of the GSM, such records would pertain directly to the review of transactions undertaken by the exporter in connection with the payment guarantee.

(2) The exporter must maintain the proof of entry required by § 1493.490(b), and must provide access to such documentation if requested by the Secretary of Agriculture or his authorized representative for the five-year period specified in paragraph (e)(1) of this section.

(f) *Responsibility of program participants.* It is the responsibility of all program participants to review, and fully acquaint themselves with, all regulations, Program Announcements, and Notices to Participants issued pursuant to this subpart. Applicants for payment guarantees are hereby on notice that they will be bound by any terms contained in applicable Program Announcements or Notices to Participants issued prior to the date of approval of a payment guarantee.

(g) *Submission of documents by principal officers.* All required submissions, including certifications, applications, reports, or requests (i.e.,

requests for amendments), by exporters or exporters' assignees under this subpart must be signed by a principal or officer of the exporter or exporter's assignee or their authorized designee(s). In cases where the designee is acting on behalf of the principal or the officer, the signature must be accompanied by: Wording indicating the delegation of authority or, in the alternative, by a certified copy of the delegation of authority; and the name and title of the authorized person or officer. Further, the exporter or exporter's assignee must ensure that all information/reports required under these regulations are submitted within the required time limits. If requested in writing, CCC will acknowledge receipt of a submission by the exporter or the exporter's assignee. If acknowledgment of receipt is requested, the exporter or exporter's assignee must submit an extra copy of each document and a stamped self-addressed envelope for return by U.S. mail. If courier services are desired for the return receipt, the exporter or exporter's assignee must also submit a self-addressed courier service order which includes the recipient's billing code for such service.

(h) *Officials not to benefit.* No member of or delegate to Congress, or Resident Commissioner, shall be admitted to any share or part of the payment guarantee or to any benefit that may arise therefrom, but this provision shall not be construed to extend to the payment guarantee if made with a corporation for its general benefit.

(i) *OMB control number assigned pursuant to the Paperwork Reduction Act.* The information requirements contained in this part (7 CFR part 1493, subpart D) have been approved by the Office of Management and Budget (OMB) in accordance with the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB Control Number 0551-0037.

Signed this 25th day of June 1996 at Washington, DC.

Mary T. Chambliss,

Acting General Sales Manager, Foreign Agricultural Service and Acting Vice President, Commodity Credit Corporation.  
[FR Doc. 96-16674 Filed 6-28-96; 8:45 am]

BILLING CODE 3410-10-P

## Animal and Plant Health Inspection Service

### 9 CFR Parts 112 and 113

[Docket No. 94-046-2]

### Viruses, Serums, Toxins, and Analogous Products; Marek's Disease Vaccines

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

**ACTION:** Final rule.

**SUMMARY:** We are amending the standard requirements for Marek's disease vaccines by including vaccines prepared from any of the three Marek's disease virus serotypes, and by defining the identity, safety, and efficacy requirements for vaccines prepared from each serotype or combinations of serotypes. We are also amending the requirements for labeling Marek's disease vaccines. These amendments are necessary based on the evolution of virus serotypes in the field, advances in the development of vaccines that are currently prepared to prevent the disease, and advances in the methods for evaluating such vaccines. The effect of this rule will be to save license applicants time by clarifying and codifying the guidelines developed for licensing these products over the past several years.

**EFFECTIVE DATE:** July 31, 1996.

**FOR FURTHER INFORMATION CONTACT:** Dr. David Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD, 20737-1237, (301) 734-8245.

#### SUPPLEMENTARY INFORMATION:

##### Background

Veterinary biologics are regulated under the Virus-Serum-Toxin Act of 1913, as amended by the Food Security Act of 1985 (21 U.S.C. 151-159, hereinafter referred to as the Act). In accordance with the Act, the Animal and Plant Health Inspection Service (APHIS) promulgates standard requirements that establish the purity, safety, potency, and efficacy requirements for these products.

The current standard requirements in § 113.330 (hereinafter referred to as the regulations) for licensing Marek's disease vaccines were promulgated at a time when only Serotype 3 Marek's disease vaccines were prepared. Also, the standard requirements did not include the evaluation of vaccine efficacy. Since that time, vaccines for Serotypes 1 and 2 have been developed, very virulent forms of the field virus have emerged, and other advances in

our understanding of this virus have occurred. In response to these changes, APHIS has developed guidelines over the past several years for licensing these products.

On May 9, 1995, we published in the Federal Register (60 FR 24584-24587, Docket No. 94-046-1) a proposal to amend the standard requirement for Marek's disease vaccines to include Serotypes 1 and 2, and to codify appropriate efficacy standards and guidelines which license applicants have utilized.

We solicited comments concerning our proposal for 60 days ending July 10, 1995. We received two comments by that date. They were from an association of poultry producers and a poultry producer. Both commenters agreed with the need for the establishment of standard requirements for vaccines prepared from any of the three Marek's disease virus serotypes. Both commenters were in favor of the rule as proposed.

In preparing the final rule, APHIS observed that it is necessary to clarify the appropriate use of the group 4 controls in § 113.330, paragraphs (c)(1)(4) and (c)(4), to assess the severity of serotype 1 virus challenge in an immunogenicity test. The proposed rule specified that "at least" (i.e., "greater than or equal to") 20 percent of the birds in group 4 must have lesions for a valid test after serotype 1 virus challenge in birds vaccinated with a serotype 3 vaccine (see § 113.330, paragraph (c)(4)). For a satisfactory serotype 3 vaccine immunogenicity test, the proposed rule specified that 80 percent of vaccinated birds must be free of lesions (see § 113.330, paragraph (c)(5)). Stated another way, 20 percent of the vaccinated birds may have lesions for a satisfactory serotype 3 vaccine immunogenicity test.

When the severity of virulence of the challenge virus for a serotype 1 or 2 vaccine in group 4 controls is equal to that for serotype 3 vaccine, the result would be inconsistent with a claim to aid in the prevention of disease against a very virulent serotype 1 virus (see § 113.330(c)(5)). If the birds in group 4 show 20 percent or fewer lesions, the challenge virus is deemed not sufficiently virulent and the test is declared invalid.

Therefore, proposed § 113.330(c)(4) is amended to read "greater than" (in place of "at least") 20 percent of vaccinated birds in group 4 controls must have lesions for a valid immunogenicity test after challenge with more virulent serotype 1 virus. The amendment to proposed § 113.330(c)(4) should not hold the vaccine producer to

a higher standard than was originally proposed. This is because the proposed rule specified that the group 4 control would not apply to the case of a serotype 3 vaccine challenge virus that requires that 20 per cent of the vaccinated birds have lesions (see § 113.330(c)(1)(iv)). Thus, the amendment to § 113.330(c)(4) is consistent with APHIS' original intent that immunogenicity tests for serotype 1 and 2 vaccines be based on challenge viruses more virulent than that for serotype 3 vaccines.

Therefore, based on the rationale set forth in the proposed rule and this document, we are adopting the provisions of the proposal as a final rule with the change discussed in this document.

#### Executive Order 12866 and Regulatory Flexibility Act

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

The amendments to the standard requirements for Marek's disease vaccines codify guidelines developed for licensing these products over the past several years. These amendments affect all (currently a total of eight) manufacturers of Marek's disease vaccines, some of which may be small businesses. By clarifying licensing requirements for Marek's disease vaccines, the rule will save time during the application process and will not cause an adverse economic impact on industry.

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. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures that must be exhausted prior

to a judicial challenge to the provisions of this rule.

#### Paperwork Reduction Act

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

#### List of Subjects

##### 9 CFR Part 112

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

##### 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 112 and 113 are amended as follows:

### PART 112—PACKAGING AND LABELING

1. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 112.7 is amended by adding paragraph (m) to read as follows:

#### § 112.7 Special additional requirements.

\* \* \* \* \*

(m) In the case of biological products containing Marek's disease virus, all labels shall specify the Marek's disease virus serotype(s) used in the product.

### PART 113—STANDARD REQUIREMENTS

3. The authority citation for part 113 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

4. Section 113.330 is revised to read as follows:

#### § 113.330 Marek's Disease Vaccines.

Marek's disease vaccine shall be prepared from virus-bearing tissue culture cells. Only Master Seed Virus which has been established as pure, safe, and immunogenic shall be used for preparing the production seed virus for vaccine production.

(a) The Master Seed Virus shall meet the applicable requirements prescribed in § 113.300, and the requirements prescribed in this section. The identity test required in § 113.300(c) shall be conducted in a serotype-specific manner by a method acceptable to APHIS. Each lot of Master Seed Virus shall also be tested for pathogens by the chicken embryo inoculation test prescribed in

§ 113.37, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(b) *Safety test.* The Master Seed Virus shall be nonpathogenic for chickens as determined by the following procedure:

(1) Specific pathogen free chickens or embryos, negative for Marek's disease virus antibodies, and from the same source, shall be isolated into the following groups:

(i) *Group 1.* At least 50 test subjects shall be inoculated with 10 times as much viable virus as will be contained in one dose of vaccine, by the route recommended for vaccination.

(ii) *Group 2.* At least 50 test subjects shall be injected with a very virulent Marek's disease virus provided or approved by APHIS, at a dosage level that will cause gross lesions of Marek's disease in at least 80 per cent of the chickens within 50 days.

(iii) *Group 3.* Fifty uninoculated controls. For *in ovo* studies, this group should receive a sham inoculation of diluent.

(iv) *Group 4.* For studies evaluating Serotype 1 Master Seed Viruses, a group of 50 uninoculated control chickens shall be housed in contact with the group 1 vaccinated chickens.

(2) At least 40 chickens in each group shall survive to 5 days of age. All chickens that die shall be necropsied and examined for lesions of Marek's disease and cause of death. The test shall be judged according to the following criteria:

(i) At 50 days of age, the remaining chickens in group 2 shall be killed and examined for gross lesions of Marek's disease. If at least 80 percent of this group do not develop Marek's disease, the test is inconclusive and may be repeated.

(ii) At 120 days of age, the remaining chickens in groups 1, 3, and 4 shall be weighed, killed, and necropsied. If less than 30 of the chickens in group 3 survive the 120 day period, or if any of the chickens in group 3 have gross lesions of Marek's disease at necropsy, the test is declared inconclusive. If less than 30 chickens in groups 1 and 4 survive the 120 day period; or if any of the chickens in groups 1 and 4 have gross lesions of Marek's disease at necropsy; or if the average body weight of the chickens in groups 1 or 4 is significantly (statistically) different from the average in group 3 at the end of the 120 days, the lot of Master Seed Virus is unsatisfactory.

(3) For tests involving *in ovo* inoculation, hatchability results shall also be reported for each group.

(c) *Immunogenicity.* Each lot of Master Seed Virus used for vaccine production shall be tested for immunogenicity at the highest passage level allowed for the product, and the virus dose to be used shall be established as follows:

(1) Specific pathogen free chickens or embryos, negative for Marek's disease antibodies, and from the same source, shall be isolated into the following groups:

(i) *Group 1.* A minimum of 35 test subjects shall be inoculated with the vaccine, using the recommended route, at 1 day of age for chicks or 18 days of embryonation for embryos. The dose used shall be established by 5 replicate virus titrations conducted by a cell culture system or other titration method acceptable to APHIS.

(ii) *Group 2.* A minimum of 35 nonvaccinated test subjects shall be held as challenge controls.

(iii) *Group 3.* A minimum of 25 nonvaccinated test subjects shall be held as nonchallenge controls.

(iv) *Group 4.* Except for studies evaluating vaccines which contain only a Serotype 3 virus as the Marek's disease fraction, a minimum of 35 chicks shall be vaccinated at 1 day of age with a licensed Serotype 3 vaccine, in order to document the severity of the very virulent challenge.

(2) At least 30 chickens in groups 1, 2, and 4, and at least 20 chickens in group 3, shall survive to 5 days of age. All chickens in groups 1, 2, and 4 shall be challenged at 5 days of age in the following manner:

(i) For studies evaluating vaccines which contain only a Serotype 3 virus as the Marek's disease fraction, groups 1 and 2 shall be inoculated with a standard virulent challenge virus provided or approved by APHIS.

(ii) For all other Marek's disease vaccines, groups 1, 2, and 4 shall be inoculated with a very virulent challenge virus provided or approved by APHIS.

(3) All chickens shall be observed until 7 weeks of age, necropsied, and examined for grossly observable lesions consistent with Marek's disease. All chickens dying before the end of the 7 week observation period shall be necropsied and evaluated for gross lesions of Marek's disease. Any chickens not so examined shall be scored as positive for Marek's disease.

(4) For a valid test, at least 80 percent of the chickens in group 2 must develop grossly observable lesions, none of the chickens in group 3 shall develop

grossly observable lesions, and (when included) greater than 20 percent of the chickens in group 4 must develop grossly observable lesions.

(5) For a valid test to be considered satisfactory, at least 80 percent of the chickens in group 1 must remain free of grossly observable lesions. The appropriate product claim resulting from a satisfactory test would be to aid in the prevention of Marek's disease, for vaccines containing only a Serotype 3 virus as the Marek's disease fraction, or to aid in the prevention of very virulent Marek's disease, for all other vaccines.

(d) *Test requirements for release.* Each serial and subserial shall meet the applicable requirements prescribed in § 113.300. The identity test required in § 113.300(c) shall be conducted in a serotype-specific manner by a method acceptable to APHIS. Final container samples of completed product shall also meet the requirements in paragraphs (d) (1), (2), and (3) of this section. Any serial or subserial found unsatisfactory by a prescribed test shall not be released.

(1) *Purity test.* The chicken embryo inoculation test prescribed in § 113.37 shall be conducted, except that, if the test is inconclusive because of a vaccine virus override, the chicken inoculation test prescribed in § 113.36 may be conducted and the virus judged accordingly.

(2) *Safety test.* At least 25 one-day-old, specific pathogen free chickens shall be injected, by the subcutaneous route, with the equivalent of 10 chicken doses of virus (vaccine concentrated 10X). The chickens shall be observed each day for 21 days. Chickens dying during the period shall be examined, cause of death determined, and the results recorded.

(i) If at least 20 chickens do not survive the observation period, the test is inconclusive.

(ii) If lesions of any disease or cause of death are directly attributable to the vaccine, the serial is unsatisfactory.

(iii) If less than 20 chicks survive the observation period and there are no deaths or lesions attributable to the vaccine, the test may be repeated one time, *Provided*, that if the test is not repeated, the serial shall be declared unsatisfactory.

(3) *Potency test.* The samples shall be titrated using a cell culture system or other titration method acceptable to APHIS. For vaccines composed of more than one Marek's disease virus serotype, each fraction shall be titrated in a serotype-specific manner.

(i) Samples of desiccated vaccine shall be incubated at 37°C for 3 days before preparation for use in the

potency test. Samples of desiccated or frozen vaccine shall be reconstituted in diluent according to the label recommendations, and held in an ice bath at 0°C to 4°C for 2 hours prior to use in the potency test.

(ii) For a serial or subserial to be eligible for release, each serotype contained in the vaccine shall have a virus titer per dose which is at least 3 times greater than the number of plaque forming units (pfu) used in the immunogenicity test prescribed in paragraph (c) of this section, but not less than 1000 pfu per dose.

(iii) When tested (without the pretest incubation of desiccated products) at any time within the expiration period, each serotype contained in the vaccine shall have a virus titer per dose which is at least 2 times the number of pfu used in the immunogenicity test, but not less than 750 pfu per dose.

Done in Washington, DC, this 25th day of June 1996.

Donald W. Luchsinger,  
*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 96-16710 Filed 6-28-96; 8:45 am]

BILLING CODE 3410-34-P

## FEDERAL DEPOSIT INSURANCE CORPORATION

### 12 CFR Part 324

RIN 3067-AB77

### Agricultural Loan Loss Amortization

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Final rule.

**SUMMARY:** As part of the FDIC's systematic review of its regulations and written policies under section 303(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (CDRI), the FDIC is removing its regulation governing agricultural loan loss amortization. This action is needed to eliminate the regulation when it becomes obsolete on January 1, 1999.

**EFFECTIVE DATE:** January 1, 1999.

#### FOR FURTHER INFORMATION CONTACT:

Robert W. Walsh, Manager, Planning and Program Development, (202) 898-6896, Division of Supervision; Susan van den Toorn, Counsel, (202) 898-8707, Legal Division, FDIC, 550 17th Street, N.W., Washington, D.C. 20429.

**SUPPLEMENTARY INFORMATION:** The FDIC is conducting a systematic review of its regulations and written policies. Section 303(a) of the CDRI (12 U.S.C. 4803(a)) requires each federal banking agency to streamline and modify its regulations

and written policies in order to improve efficiency, reduce unnecessary costs, and eliminate unwarranted constraints on credit availability. Section 303(a) also requires each federal banking agency to remove inconsistencies and outmoded and duplicative requirements from its regulations and written policies.

As part of this review, the FDIC is removing 12 CFR part 324. This action is appropriate because the regulation implemented legislation which permitted agricultural banks to amortize qualified agricultural loan losses incurred only between 1984 and 1991 with a resulting amortization period not to exceed seven years. Consequently, this regulation will become obsolete at the end of the permissible amortization period. Therefore, the FDIC is eliminating the rule effective January 1, 1999. The Office of the Comptroller of the Currency (OCC), as part of its Regulation Review Program, has previously reviewed its regulation on Agricultural Loan Loss Amortization, 12 CFR part 35, and determined that the regulation becomes obsolete on January 1, 1999. The OCC issued a proposed rule on February 8, 1995 (60 FR 7467) and a final rule on May 24, 1995 (60 FR 27401) to remove its regulation on January 1, 1999. The Federal Reserve Board (FRB) has under consideration a similar proposal with regard to 12 CFR 208.15.

Title VIII of the Competitive Equality Banking Act of 1987 (Act), Pub. L. 100-86, 101 Stat. 635 (1987), added 12 U.S.C. 1823(j) in an attempt to alleviate some of the financial pressures then facing agricultural banks. In particular, 12 U.S.C. 1823(j) permits an agricultural bank to amortize over a period not to exceed seven years: (1) Any loss on a qualified agricultural loan that the bank would otherwise be required to show on its annual financial statement for any year between December 31, 1983, and January 1, 1992; and (2) any loss resulting from the reappraisal of property that the bank owned or acquired between January 1, 1983, and January 1, 1992, in connection with a qualified agricultural loan. The FDIC implemented this statutory provision by promulgating 12 CFR part 324 with a final rule published on November 2, 1987 (52 FR 41968). Pursuant to section 1823(j)(3) of the Act, the OCC and the FRB issued substantively similar regulations. See, 12 CFR part 35 and 12 CFR 208.15 respectively.

Because the statute requires that a loss occur on or before December 31, 1991, to qualify, and that the amortization period may not exceed seven years, the program becomes obsolete on January 1,