January 20, 1978, regarding rates and terms for Site Option Loans.

EFFECTIVE DATE: March 17, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Paul R. Conn, 202-447-7207.

In FR Doc. 78-1475, in paragraph V of Exhibit F, page 2869, paragraph (A) was inadvertently omitted and should be inserted as follows:

V *Rates and terms.*

(A) *Interest.* Loans will be made at an interest rate of 3 percent.

* * * * *

Dated: March 2, 1978.

GORDON CAVANAUGH,
*Administrator,*
*Farmers Home Administration.*

[FR Doc. 78-7133 Filed 3-16-78; 8:45 am]

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[3410-34]

## Title 9—Animals and Animal Products

## CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

### SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

### PART 78—BRUCELLOSIS

### Swine Brucellosis

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the brucellosis regulations in regard to swine to clarify the classes of swine being restricted, and to make the language uniform in the different sections. This action is necessary to correct and clarify the intent of the prior amendment which becomes effective March 23, 1978. The intended effect of this action is to relieve certain restrictions on swine inadvertently imposed in the previous amendment.

EFFECTIVE DATE: March 23, 1978.

FOR FURTHER INFORMATION, CONTACT:

A. D. Robb, Staff Veterinarian, National Brucellosis Eradication Program, USDA, APHIS, Veterinary Services, Room 805, Federal Building, Hyattsville, Md. 20782, 301-436-8713.

SUPPLEMENTARY INFORMATION: On December 23, 1977, there was published in the FEDERAL REGISTER (42 FR 64339-64341) a notice of final rulemaking which prohibited swine from being moved interstate except in compliance with the regulations, effective March 23, 1978. The purpose of the amended regulation was to place restrictions only on certain classes of swine. However, the general restrictions inadvertently referred to all swine although the intent was only to restrict the interstate movement of swine defined as "breeding swine," "sows," "boars," "brucellosis reactor swine," and "brucellosis exposed swine." Brucellosis in swine is most prevalent in breeding swine, sows and boars, and therefore the movement of only these animals should be regulated in order to prevent the spread of brucellosis by swine.

The amendment also inadvertently placed restrictions on brucellosis reactor swine and brucellosis exposed swine which required them to be moved interstate only for immediate slaughter directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a specifically approved slaughtering establishment, or to a specifically approved stockyard for sale and shipment to such slaughtering establishment, if such swine are accompanied by a permit. The intent of the amendment was to restrict the interstate movement of brucellosis reactor swine and brucellosis exposed swine only for immediate slaughter directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a State inspected slaughtering establishment, or directly to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.), or directly to a market agency or dealer registered under said Packers and Stockyards Act, if such swine are accompanied by a permit. The references to approved stockyards or specifically approved slaughtering establishment is deleted because there are no such facilities at present to handle these swine. Therefore, the Department has determined that such reactor swine and exposed swine could be shipped directly to a slaughtering establishment operated under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a State inspected slaughtering establishment, or directly to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.) or directly to a market agency or dealer registered under said Packers and Stockyards Act, without undue risk. The procedures established at such facilities should help assure that these animals are handled in accordance with the regulations.

The correct wording appeared in § 78.30.

All of the changes in this amendment relieve restrictions under which swine may be moved interstate and it has been determined that it is necessary that these changes be made effective concurrent with the previous brucellosis regulation amendment in regard to the interstate movement of swine with the effective date of March 23, 1978.

Accordingly, 9 CFR Part 78, is amended as follows:

1. Section 78.26, is amended to read:

**§ 78.26 General restrictions**

Breeding swine, sows, boars, brucellosis reactor swine, and brucellosis exposed swine may not be moved interstate except in compliance with the regulations in this subpart.

2. In § 78.27 the introductory paragraph is amended to read:

**§ 78.27 Brucellosis reactor swine.**

Brucellosis reactor swine may only be moved interstate under this section for immediate slaughter directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a State inspected slaughtering establishment, or directly to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.) or directly to a market agency or dealer registered under said Packers and Stockyards Act, for sale to such a slaughtering establishment in accordance with the following requirements:

* * * * *

3. Section 78.28 is amended to read:

**§ 78.28 Brucellosis exposed swine.**

Brucellosis exposed swine may be moved interstate only for immediate slaughter directly to a slaughtering establishment operating under the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or directly to a State inspected slaughtering establishment, or directly to a stockyard posted under the provisions of the Packers and Stockyards Act, as amended (7 U.S.C. 181 et seq.) or directly to a market agency or dealer registered under said Packers and Stockyards Act, for sale to such a slaughtering establishment, if such swine are accompanied by a permit as defined in paragraph 78.1(v).

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1265, as amended; sec. 2, 65 Stat. 693; and secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-114a-1, 114g, 115, 117, 120, 121, 123-125, 134b, 134f); 37 FR 28464; 28477; 38 FR 19141).

The amendments clarify the classes of swine to be regulated and relax restrictions unintentionally imposed. They must be made effective concurrently with the regulations amended effective March 23, 1978, in order to avoid unnecessary restriction on the

interstate movement of swine. It does not appear that public participation in this rulemaking procedure would make additional relevant information available to the Department.

Accordingly, under the Administrative procedures provision in 5 U.S.C. 553, it is found upon good cause that further notice and other public procedure with respect to the amendment are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making the amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 13th day of March 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

J. K. ATWELL,
*Acting Deputy Administrator, Veterinary Services.*

[FR Doc. 78-7166 Filed 3-16-78; 8:45 am]

[3410-34]

SUBCHAPTER E—VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS; ORGANISMS AND VECTORS

## PART 112—PACKAGING AND LABELING

### Miscellaneous Amendments

AGENCY: Animal and Plant Health Inspection Service (APHIS).

ACTION: Final rule.

SUMMARY: This amendment permits unlabeled final containers of liquid biological products to be exported. Unlabeled desiccated products may be exported under the present regulations. This amendment relaxes the regulations by giving liquid products the same treatment as desiccated products.

EFFECTIVE DATE: This amendment becomes effective March 17, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. R. J. Price, Biologics Licensing and Standards Staff, USDA, APHIS, VS, Room 827, Federal Building, Hyattsville, Md. 20782, 301-436-8245.

SUPPLEMENTARY INFORMATION: Many licensees export biological products to foreign countries. In some cases, they are connected with firms in these foreign countries which are staffed and equipped to adequately package and label the products for consumption in those countries. In some cases, the economic advantage of having the packaging and labeling done in a foreign country is considerable.

For several years licensees have been permitted to ship desiccated products to be completed in a foreign country. This amendment would authorize them to ship liquid products as well.

Part 112 is amended by revising § 112.8(c) to read:

**§ 112.8 For export only.**

* * * * *

(c) Final containers of products, labeled or unlabeled, may be exported in sealed shipping boxes, adequately identified as to contents with an approved label, and plainly marked "For Export Only": *Provided*, That such products shall not be diverted to domestic use.

* * * * *

(21 U.S.C. 151 and 154; 37 FR 28477, 28646; 38 FR 19141.)

These amendments make administrative changes to make the packaging and labeling requirements consistent with respect to all products for export without making other substantive changes in the regulations. In order for them to be of maximum benefit, they must be made effective immediately.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure concerning these amendments are impracticable and unnecessary, and good cause is found for making these amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 13th day of March 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

J. K. ATWELL,
*Acting Deputy Administrator, Veterinary Services.*

[FR Doc. 78-7164 Filed 3-16-78; 8:45 am]

[3410-34]

## PART 113—STANDARD REQUIREMENTS

### Miscellaneous Amendments

AGENCY: Animal and Plant Health Inspection Service (APHIS).

ACTION: Final rule.

SUMMARY: This amendment codifies, in the regulations under the Virus-Serum-Toxin Act, test requirements for detection of extraneous viruses in Master Seed Virus. Purity of the Master Seed Virus is essential in the preparation of vaccines. The test methods and procedures prescribed in this amendment assures such purity with respect to extraneous viruses.

EFFECTIVE DATE: This amendment becomes effective April 17, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. R. J. Price, Biologics Licensing and Standards Staff, USDA, APHIS, VS, Room 827, Federal Building, Hyattsville, Md. 20782, 301-436-8245.

SUPPLEMENTARY INFORMATION: Seed virus derived from a Master Seed Virus (MSV) is used in the preparation of each viral vaccine. The Master Seed Virus is defined in the regulations (9 CFR 101.7(a)). Before MSV can be used for vaccine production, it must be of proven purity, safety, and antigenicity.

To meet the standards of purity established by Veterinary Services, a lot of Master Seed Virus must be free of contaminants, such as extraneous microorganisms, before it is approved for use in the preparation of viral vaccines.

The tests for such microorganisms as bacteria, fungi, or mycoplasma are prescribed in the regulations. Although the Master Seed Virus is also required to be free of extraneous viruses before it is used for the production of viral vaccines, there is no section in the present regulations specifically dealing with the detection of such viruses in the Master Seed Virus.

On November 18, 1977, a notice of proposed amendment to Part 113 was published in the FEDERAL REGISTER at 42 FR 59510.

Comments on this proposal were solicited and six responses were received. Only one response was favorable to the proposal as written.

Two responses contained comments indicating concern over having the proposed requirements apply to vaccines which cannot be evaluated by the methods proposed. Since an MSV is subject to these requirements only when prescribed in the Standard Requirement or filed Outline of Production for a product, the concern is not justified.

A suggestion in one response that all references to testing of Master Seed Virus be incorporated in § 113.55 was rejected as being impractical and cumbersome.

Suggestions received in two responses were considered appropriate and constructive. These suggestions have been incorporated in this final rule and are explained in the discussion of changes below.

After due consideration of all relevant matters, including the proposal set forth in the aforesaid notice and pursuant to the authority contained in the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151-158), the amendment of Part 113, Subchapter E, Chap-

ter I, Title 9 of the Code of Federal Regulations, as contained in the aforesaid notice is hereby adopted with the following exceptions:

Paragraph (a) is reworded to clarify the type of cell lines or cells to be used in part of the tests.

Paragraph (b) was rewritten to make the following changes:

Subculturing was reduced from three times to one time as being sufficiently sensitive, less costly, and less time consuming. Editorial changes were made as indicated.

"Hemadsorbing virus" has been inserted into the introductory portion for consistency and clarity. Printing errors have been corrected by substituting "for" for "by" and "stain" for "strain."

Paragraph (c) has been rewritten for clarification as to the cells to be used and when the monolayers are to be subcultured.

Paragraph (c) has been changed to make the time of fluorescent antibody staining consistent with the time the tests are conducted for cytopathic viruses and hemadsorbing viruses. These changes will expedite completion of these tests.

Paragraph (c)(2) has been reworded to permit the fixing of positive control monolayers that have been infected with cytopathogenic viruses before the 7 day period specified for the other monolayers, but allowing the staining of all monolayers at the same time for added convenience.

Printing errors have been corrected in paragraph (d) by changing (a) to (d) and correcting the spelling of cytopathology and hemadsorption in the lead paragraph of (d) and the spelling of uninoculated in paragraph (d)(3).

Part 113 is amended by adding a new section to read:

**§ 113.55 Detection of extraneous viruses in Master Seed Virus.**

Master Seed Virus (MSV) shall be tested and found free of extraneous viruses by the procedures provided in this section when prescribed in a Standard Requirement or the filed Outline of Production for a product.

(a) At least a 1.0 ml aliquot per cell culture of MSV shall be dispensed onto monolayers (at least 75 $cm^2$ in area) of pretested:

(1) Vero (African green monkey) cell line; and

(2) Embryonic cells, neonatal cells, or a cell line of the species for which the vaccine is recommended; and

(3) Embryonic cells, neonatal cells, or a cell line (other than Vero cell line) of the species in which the MSV is presently being propagated if different than the species for which the vaccine is recommeded.

At least one monolayer of each of these cell types shall be maintained as an uninoculated control. If the MSV is cytopathic for, or causes hemadsorption in the cells in which it is to be tested, the MSV shall be neutralized with monospecific antiserum or counteracted by a method approved by Veterinary Services.

(b) Each monolayer shall be maintained for at least 14 days and shall be subcultured at least once during the maintenance period. The monolayers shall be examined regularly throughout this period for evidence of virus induced abnormalities. At subculturing at least one inoculated monolayer and one control monolayer of each cell type shall be planted onto suitable surfaces for the tests for cytopathic viruses, hemadsorbing virus, and when applicable, for the fluorescent antibody (FA) test. At the conclusion of the maintenance period, and at least 7 days after subculturing, at least one inoculated and one uninoculated control monolayer of each cell type which are at least 90 percent confluent shall be tested for cytopathic and hemadsorbing extraneous viruses.

(1) *Test for hemadsorbing viruses.* At least one inoculated and one control monolayer of each cell type shall be washed with several changes of phosphate buffered saline. A mixed suspension of 0.2 percent guinea pig, chicken, and human "O" erythrocytes shall be added, and the cells incubated at 4° C and 25° C for an appropriate incubation period and the monolayer examined for evidence of hemadsorption.

(2) *Test for cytopathic viruses.* At least one inoculated and one control monolayer of each cell type, each with a total area of at least 8 $cm^2$, shall be stained with a suitable cytological stain and the entire monolayer examined for evidence of inclusion bodies, abnormal number of giant cells, or other cytopathology indicative of cell abnormalities attributable to an extraneous virus.

(c) Each MSV shall be tested by the FA technique for the presence of applicable extraneous viruses normally associated with those species for which the vaccine is intended and for those viruses that would not be detected by other required test methods. The most susceptible cell type, from among those inoculated with MSV shall be used for each extraneous virus. The monolayers for the FA technique shall be prepared at the time of subculturing as described in paragraph (b) of this section. Positive control monolayers shall be prepared from the innoculated cells by infecting a portion of the cells with the specific virus being tested for. The remaining uninoculated cells shall serve as negative controls. (If the MSV has been neutralized with a monospecific antiserum, the antiserum must be shown to be free of neutralizing antibody for the virus being tested for.) The test system for each extraneous virus shall consist of at least 4 MSV-inoculated monolayers, 4 positive control monolayers, and 4 negative control monolayers. Each group of 4 monolayers shall have a total area of at least 8 $cm^2$. At the conclusion of the maintenance period, and at least 7 days after subculturing, the monolayers shall be processed and stained with the appropriate antiviral fluorescein tagged antibody, and examined for the presence of specific fluorescence attributable to the virus.

(1) The viruses specified and the test conducted will depend upon the species in which the MSV was previously passed or presently propagated and upon the species for which the vaccine is intended. When applicable, reagents for the tests may be furnished by Veterinary Services.

(2) Positive control monolayers may be fixed at an earlier time if fluorescence is enhanced by so doing. Monolayers that are so treated shall be stained at the same time as the MSV-inoculated monolayers and the negative control monolayers.

(d) *Interpretation of results.* (1) If the MSV-inoculated cells show any evidence of specific cytopathology or hemadsorption attributable to an extraneous virus, the MSV is unsatisfactory and shall not be used to prepare biological products. If an extraneous virus is suspected because of cytopathology or hemadsorption and cannot be eliminated as a possibility by additional testing, the MSV is unsatisfactory, and shall not be used to prepare biological products.

(2) If the MSV-inoculated cells show any evidence of specific viral fluorescence, the MSV is unsatisfactory and shall not be used to prepare biological products: *Provided,* That, if specific fluorescence attributable to the virus is absent in more than one of the monolayers deliberately inoculated as positive controls, the test is inconclusive and may be repeated.

(3) If the fluorescence of the monolayers inoculated with the specific virus as positive controls is equivocal, or if the uninoculated monolayers show equivocal fluorescence indicating possible viral contamination, or both, the test shall be declared inconclusive and may be repeated: *Provided,* That, if the test is not repeated, the MSV shall be regarded as unsatisfactory and shall not be used to prepare biological products.

(21 U.S.C. 151 and 154; 37 FR 28477, 28646; 38 FR 19141.)

Done at Washington, D.C., this 13th day of March 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an inflation impact

statement under Executive Order 11821 and OMB Circular A-107.

J. K. ATWELL,
*Acting Deputy Administrator,*
*Veterinary Services.*

[FR Doc. 78-7163 Filed 3-16-78; 8:45 am]

[3410-37]

## CHAPTER III—FOOD SAFETY AND QUALITY SERVICE MEAT AND POULTRY INSPECTION, DEPARTMENT OF AGRICULTURE

### SUBCHAPTER B—VOLUNTARY INSPECTION AND CERTIFICATION SERVICE

### SUPPLEMENTAL RULES OF PRACTICE

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends certain regulations under the Agricultural Marketing Act of 1946, as amended, to bring such regulations into compliance with the Department's rules of practice, published January 4, 1977 (42 FR 743-749), governing, among other things, formal adjudicatory, administrative proceedings and the denial or withdrawal of voluntary inspection or certification services under the Agricultural Marketing Act of 1946, as amended.

EFFECTIVE DATE: March 17, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. W. J. Minor, Chief Staff Officer, Issuance Coordination Staff, Technical Services, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-6189.

SUPPLEMENTARY INFORMATION: On January 4, 1977, the Department of Agriculture promulgated rules of practice, published in the FEDERAL REGISTER at 42 FR 743-749, governing, inter alia, formal adjudicatory, administrative proceedings under the regulations promulgated under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.), for the denial or withdrawal of voluntary inspection or certification service. The Department's rules of practice (7 CFR 1.130 et seq.) became effective on February 1, 1977, and superseded all rules of practice and regulations which were in conflict with such rules. The Department's rules of practice require the Administrator of each agency administering the programs involved to publish documents revoking any rules or regulations superseded by the new rules and promulgating new or additional and supplemental rules and regulations relating to particular circumstances arising in connection with proceedings under the statutes and regulations administered by them, pursuant to such new rules. Supplemental rules of practice and revised regulations governing some programs formerly administered by the Animal and Plant Health Inspection Service have previously been published in the FEDERAL REGISTER in separate documents (42 FR 10959, 10962). However, those supplemental rules of practice and regulations did not amend certain regulations (9 CFR Parts 350, 351, 354, 355, and 362) under the Agricultural Marketing Act of 1946, as amended, formerly administered by the Animal and Plant Health Inspection Service and now administered by the Food Safety and Quality Service.

Those regulations in 9 CFR, Parts 350, 354, and 355 authorize the "Administrator" to withdraw or deny inspection service under certain specified circumstances. The regulations in this respect are inconsistent with the Department's rules of practice which authorize such actions, after opportunity for a hearing, by an Administrative Law Judge, and, upon appeal from a decision of such Judge, by the Judicial Officer of this Department. Accordingly, the regulations are being amended to provide for such actions by those officials in accordance with the Department's rules of practice. Pending final determination in such matters, the Administrator or other specified officials of the Food Safety and Quality Service will still have authority to suspend, deny, or withdraw inspection service as provided in the regulations (9 CFR 350.6, 351.20, 354.45, and 355.38). With repect to such actions, regulations are being issued to provide for notification to the affected parties with respect to the determination of the Administrator or other specified officials. The regulations in 9 CFR Part 362, concerning Voluntary Poultry Inspection, are also being amended, for clarification purposes, to specify the applicability of the Department's rules of practice and supplemental rules of practice to certain proceedings under those regulations.

The regulations are amended as follows:

## PART 350—SPECIAL SERVICES RELATING TO MEAT AND OTHER PRODUCTS

1. A new § 350.2(k) is added to Subchapter B, Chapter III, Title 9 of the Code of Federal Regulations (9 CFR 350.2(k)), to define the term "Secretary" as follows:

**§ 350.2 Definitions.**

* * * * *

(k) Secretary. The Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or may hereafter be delegated, to act in his stead in connection with the function involved.

2. Section 350.6(b) of Subchapter B, Chapter III, Title 9 of the Code of Federal Regulations (9 CFR 350.6(b)), is amended by deleting the term "Administrator" in the first sentence of said section and inserting in lieu thereof the term "Secretary," and by deleting the second sentence of said section and inserting the following in lieu thereof:

**§ 350.6 Denial or withdrawal of service.**

* * * * *

(b) * * *. When the Administrator determines that the public interest so requires, he may deny or withdraw service provided for in this Part, without a hearing, pending final determination of the matter. The applicant or recipient of service involved shall be notified of the Administrator's decision to deny or suspend service and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to deny or suspend the service shall be effective upon such oral or written notification, whichever is earlier, to the applicant or recipient of service. If such notification is oral, the Administrator shall confirm such decision and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient of service, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)).

3. A new § 350.8 is added to Subchapter B, Chapter III, Title 9 of the Code of Federal Regulations (9 CFR 350.8), to read as follows:

**§ 350.8 Scope and applicability of rules of practice.**

The rules of practice of the Department of Agriculture in subpart H of Part I, Subtitle A, Title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR Part 350).

## PART 351—CERTIFICATION OF TECHNICAL ANIMAL FATS FOR EXPORT

4. Section 351.20 of Subchapter B, Chapter III, Title 9 of the Code of Federal Regulations (9 CFR 351.20), is amended by adding three new sentences to the end of paragraph (b) and by adding a new paragraph (c) to read as follows: