agreement, and upon the American Short Line Railroad Association; and that notice of this amendment be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-23083 Filed 10-29-73;8:45 am]

[S.O. 1112, Amdt. 4]

PART 1033—CAR SERVICE

Railroad Operating Regulations for Freight Car Movement

At a session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 19th day of October 1973.

Upon further consideration of Service Order No. 1112 (37 FR 21153, 23728, 23840; 38 FR 7332), and good cause appearing therefor:

It is ordered, That § 1033.1112 *Service Order No. 1112* (Railroad operating regulations for freight car movement) be, and it is hereby, amended by substituting the following paragraph (d) for paragraph (d) thereof:

(d) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., April 30, 1974, unless otherwise modified, changed, or suspended by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., October 31, 1973.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended (49 U.S.C. 1, 12, 15, and 17(2)). Interprets or applies secs. 1(10-17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911 (49 U.S.C. 1(10-17), 15(4), and 17(2).)

It is further ordered, That a copy of this amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this amendment be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73-23084 Filed 10-29-73;8:45 am]

[S. O. 1149, Amdt. 1]

PART 1033—CAR SERVICE

Fort Worth and Denver Railway Co.

At a session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 19th day of October 1973.

Upon further consideration of Service Order No. 1149 (38 FR 23793), and good cause appearing therefor:

It is ordered, That: § 1033.1149 *Service Order No. 1149* (Fort Worth and Denver Railway Company authorized to operate over tracks of Quanah, Acme & Pacific Railway Company and over tracks of the Atchison, Topeka and Santa Fe Railway Company) Service Order No. 1149 be, and it is hereby, amended by substituting the following paragraph (e) for paragraph (e) thereof:

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., April 30, 1974, unless otherwise modified, changed, or suspended by order of this Commission.

Effective date. This amendment shall become effective at 11:59 p.m., October 31, 1973.

(Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 384, as amended; (49 U.S.C. 1, 12, 15, and 17(2)). Interprets or applies secs. 1(10-17), 15(4), and 17(2), 40 Stat. 101, as amended, 54 Stat. 911; (49 U.S.C. 1(10-17), 15(4), and 17(2)).)

It is further ordered, That a copy of this amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this amendment be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.73—23085 Filed 10-29-73;8:45 am]

Title 9—Animals and Animal Products

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

SUBCHAPTER D—EXPORTATION AND IMPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS: INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

Relief of Restrictions on Importation of Birds

Statement of considerations. On January 26, 1973, there were published in the FEDERAL REGISTER (38 FR 2463-2464) proposed amendments of the regulations in 9 CFR Part 92 which would allow the importation of commercial birds under specified conditions, including a requirement of quarantine in facilities approved by an inspector of Veterinary Services and a requirement that the birds be handled during quarantine in accordance with procedures prescribed by the Deputy Administrator, Veterinary Services. A period of 30 days was allowed for submission of comments by interested persons. On March 2, 1973, there were published in the FEDERAL REGISTER (38 FR 5641-5642) proposed amendments of the regulations in 9 CFR Part 92 which would prescribe facilities, standards and handling procedures to implement the amendments as proposed January 26, 1973 (38 FR 2463-2464). A period of 30 days was allowed for submission of comments by the March 2, 1973, notice and the period for comments on the proposal published January 26, 1973 (38 FR 2463-2464) was extended to coincide with the expiration of the comment period on the March 2, 1973, notice.

In response to the proposed amendments published January 26, 1973 (38 FR 2463-2464), nearly 200 comments were received from various sources including representatives of State government agencies, zoological parks, and pet shops, individual aviculturists, bird importers, researchers, and various segments of the poultry industry. Thirty percent of comments received favored the proposal and requested publication without change, 55 percent supported the proposal but suggested revisions or exceptions, and 15 percent opposed the proposal, requesting that the prohibition against importation of commercial birds be permanently maintained or that such importations be allowed without restrictions.

Among comments received was a request that special procedures be provided for importation of birds by zoological parks and that such birds be quarantined at destination in such parks. Suggestions were made that additional ports of entry be provided; that birds be permitted to transit certain ports before being inspected; that veterinary inspection at ports of entry be eliminated; that a provision be made for the quarantine of the birds at any point in the United States; that health certification be limited to inspection made at the time of export; that exceptions to the requirements be made for certain avian species; and that birds from any part of the world be permitted entry at any port of entry designated for the importation of commercial birds.

Twenty-one written comments were received in response to the proposal published March 2, 1973 (38 FR 5641-5642), about half of which were favorable. Objections posed by the remaining comments received were: That standards as proposed were too stringent; that cost of providing facilities would be prohibitive; that handling procedures as proposed were not practical for certain avian species; that quarantine facilities should be established overseas in lieu of the United States; that the provision for quarantine on an "all-in, all-out" basis should be eliminated and that disposal of waste from quarantine facilities should be permitted in public facilities after birds held in facilities were released from quarantine.

After due consideration of all relevant material, including that submitted in

connection with such notices, the proposals are hereby adopted without substantive change, except that the following additional ports of entry have been added to the list of such ports in § 92.8 (b): Tampa, Florida; Chicago, Illinois; San Francisco, California; Boston, Massachusetts; and New Orleans, Louisiana; and the provision whereby birds imported from Canada and Mexico would enter through specific ports has been changed to permit entry of birds from those countries through any port designated for the importation of commercial birds. Various other changes are made to clarify and coordinate the provisions contained in the notices. It has been determined that the provisions adopted are necessary and adequate to prevent the introduction or dissemination of poultry diseases into the United States.

Therefore, pursuant to section 2 of the Act of February 2, 1903, as amended, and sections 2, 3, 4, and 11 of the Act of July 2, 1962 (21 U.S.C. 111, 134a, 134b, 134c, and 134f), Part 92, Title 9, Code of Federal Regulations is hereby amended in the following respects:

1. In § 92.1 paragraph (j)(2) is amended by adding new subdivisions (i) and (ii) to read as follows:

§ 92.1 Definitions.

* * * * *

(j) * * *

(2) * * *

(i) *Pet birds.* Birds which are imported for the personal pleasure of their individual owners and are not intended for resale, research, breeding, or public display.

(ii) *Commercial birds.* Birds which are imported for the purpose of resale, research, breeding, or public display.

* * * * *

2. In § 92.2, in paragraph (b) the last clause "except as provided in paragraph (c) or (d) of this section." is amended to read "except as provided in paragraph (c), (d), or (f) of this section."

3. In § 92.2, a new paragraph (f) is added to read as follows:

§ 92.2 General prohibitions; exceptions.

* * * * *

(f) Commercial birds may be imported into the United States if they meet the requirements of §§ 92.3(f), 92.4, 92.5(c), 92.8(b), and 92.11(e) which specifically apply to commercial birds and the requirement of all other sections in this part that are applicable to poultry or to animals generally.

4. In § 92.3, a new paragraph (f) is added to read:

§ 92.3 Ports designated for the importation of animals.

* * * * *

(f) Notwithstanding any other provisions of this section, all commercial birds shall be imported only at a port of entry specified in § 92.8(b).

§ 92.4 [Amended]

5. In § 92.4, a reference to a new footnote [6] is added after the section heading and a new footnote [6] is added to the regulations to read as follows:

6. In § 92.5, the section heading is amended and a new paragraph (c) is added to read:

§ 92.5 Certificate of ruminants, swine, poultry, and commercial birds.

* * * * *

(c) *Birds.* All commercial birds offered for importation from any country of the world shall be accompanied by a certificate issued by a full-time salaried veterinary officer of the National Government of the country from which the birds are to be exported, stating that all birds covered by the certificate have been inspected by him and that no evidence of Newcastle disease, ornithosis, or other communicable disease of poultry was found among the birds and insofar as has been possible to determine, they were not exposed to any such disease during the 90 days immediately preceding their exportation; that such birds were individually identified by serially numbered legbands (or by other suitable means of identification approved by the Deputy Administrator, Veterinary Services, upon request to him) and such birds were placed into new containers at the premises from which the birds are to be exported; that such birds have not been vaccinated with Newcastle disease vaccine; that Newcastle disease did not occur anywhere on the premises from which the birds are to be exported or on adjoining premises during the 90 days immediately preceding the exportation of such birds and that these premises are not located in any area under quarantine for poultry diseases at any time during such preceding 90 days.

7. In § 92.8, a new paragraph (b) is added to read:

§ 92.8 Inspection at port of entry.

* * * * *

(b) All commercial birds imported from any part of the world shall be subjected to inspection at the Customs port of entry by a veterinary inspector of Veterinary Services and such birds shall be permitted entry only at the following ports of entry: Boston, Massachusetts; New York, New York; Miami, Florida; Tampa, Florida; New Orleans, Louisiana; Brownsville, Texas; El Paso, Texas; San Ysidro, California; Los Angeles, California; San Francisco, California; Honolulu, Hawaii; Seattle, Washington; Chicago, Illinois, and Detroit, Michigan.

8. In § 92.11, in paragraph (c)(1) the reference to "§ 92.26(a)" is changed to "§ 92.26" and the phrase "and § 92.38 (a)" is deleted; and the section heading is changed and new paragraphs (e) and (f) are added to read:

§ 92.11 Quarantine requirements.

* * * * *

(e) *Birds.* Each lot of commercial birds imported from any part of the world shall be quarantined for a minimum of 30 days, and for such longer period as may be required by the Deputy Administrator, Veterinary Services, in any specific case, on an "all-in, all-out" basis, at one of the ports of entry specified in § 92.8(b) in facilities which are provided by the importer and which have been approved by the Deputy Administrator as provided in paragraph (f) of this section, prior to the issuance of the import permit described in § 92.4. During the quarantine period, the importer shall comply with handling procedures, (including inspection and testing) as provided in paragraph (f) of this section. If the birds are found free of evidence of communicable diseases of poultry during quarantine, then the port veterinarian shall issue an agriculture release for entry through U.S. Customs. If the birds are found during port of entry inspection or during quarantine, to be infected with or exposed to a communicable disease of poultry, such birds shall be refused entry or shall be held for an additional period in quarantine until determined to be free of evidence of any communicable disease, or shall be otherwise disposed of as directed by the Deputy Administrator, Veterinary Services, in accordance with the provisions of section 2 of the Act of July 2, 1962 (21 U.S.C. 134a). See also paragraph (f)(3)(ii)(E) of this section.

(f) *Standards for approved quarantine facilities and handling procedures for importation of birds.* To qualify for designation as an approved quarantine facility [7] and to retain such approval, the facility and its maintenance and operation must meet the minimum requirements of subparagraphs (1) through (6) of this paragraph (f). The cost of the facility and all costs associated with the maintenance and operation of such facility shall be borne by the importer.

(1) *Supervision of the facility.* The facility shall be maintained under the supervision of the Veterinary Services port veterinarian at one of the ports listed in § 92.8(b).

(2) *Physical plant requirements.* The facility shall comply with the following requirements:

(i) *Location.* The quarantine facility shall be located:

(A) Within the immediate area of the port of entry to curtail to a minimum the possibility of introduction and dissemination of poultry diseases by the imported birds, while in transit from the point of entry to the quarantine facility;

(B) At least one-half mile from any concentration of avian species, such as, but not limited to, poultry processing

[6] For other permit requirements for birds, the regulations issued by the U.S. Department of the Interior (Part 17, Title 50, Code of Federal Regulations) and the regulations issued by the U.S. Department of Health, Education, and Welfare (Subpart J-1 of Part 71, Title 42, Code of Federal Regulations) should be consulted.

[7] Information as to the identity of such facilities may be obtained from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

plants, poultry or bird farms, pigeon lofts, or other approved quarantine facilities. Factors such as prevailing winds, possible exposure to poultry or birds moving in local traffic, etc., shall be taken into consideration. If the quarantine facility consists of multiple units for handling separate lots of birds, the individual units shall be located at least one-half mile from each other with separate personnel working as handlers in each unit.

(ii) *Construction.* The unit or units making up the quarantine facility shall each consist of a building or buildings which shall:

(A) Be constructed only with materials that can withstand continued cleaning and disinfection. (All solid walls, floors, and ceilings shall be constructed of impervious material; all screening shall be metal; all openings to the outside shall be double-screened.);

(B) Have a bird holding area of sufficient size to prevent overcrowding of the birds in quarantine. (All access into this holding area shall be from within the building and each entryway into such area shall be equipped with self-closing, double doors; *Provided*, That emergency exits to the outside may exist in the bird holding area if required by local fire ordinances. Such emergency exits shall be constructed so as to permit their opening from the inside of the facility only.);

(C) Have a ventilation capacity sufficient to control moisture and odor at levels that are not injurious to the health of the birds in quarantine;

(D) Have a vermin-proof feed storage area;

(E) Have office space for recordkeeping;

(F) Have a separate necropsy room which shall have refrigerated storage space for carcasses retained for laboratory examination and facilities adequate for specimen preparation and carcass disposal;

(G) Have a separate area for washing facility equipment;

(H) Have a shower at the entrance into the area comprised of the bird holding and necropsy rooms and a clothes storage and change area at each end of the shower area;

(I) Have a storage area for equipment necessary for quarantine operations;

(J) Have equipment necessary to maintain the facility in clean and sanitary condition, including insect and pest control equipment;

(K) Have a receptable for soiled and contaminated clothing in the clothes change area located nearest the entrance to the bird holding area.

(iii) *Sanitation and security.* Arrangements shall exist for:

(A) A supply of water adequate to meet all watering and cleaning needs.

(B) Disposal of wastes by incineration or a public sewer system which meets all applicable environmental quality control standards;

(C) Control of surface drainage onto or from the facility to prevent any disease agent from entering or escaping;

(D) Protective clothing and footwear adequate to insure that workers at the facility have clean clothing and footwear at the start of each workday and at any time such articles become soiled or contaminated;

(E) Power cleaning and disinfecting equipment with adequate capacity to disinfect the facility and equipment;

(F) Sufficient stocks of a disinfectant authorized in § 71.10(a)(5) of this chapter;

(G) A security system which prevents contact of birds in quarantine with persons not authorized entry to the facility and with other birds and animals. Such a system shall include a daily log to record the entry and exit of all persons entering the facility and controls at all doorways and other openings to the facility to prevent escape or accidental entry of birds.

(3) *Operational procedures.* To retain designation as an approved quarantine facility, the following procedures shall be observed at the facility at all times.

(i) *Personnel.* Access to the facility shall be granted only to persons working at the facility or to persons specifically granted such access by the Veterinary Services port veterinarian.

(A) All personnel granted access to the bird holding area shall:

(*1*) Wear clean protective clothing and footwear upon entering the bird holding area;

(2) Change protective clothing and footwear when they become soiled or contaminated;

(3) Shower when entering or leaving the bird holding and necropsy areas.

(B) The operator of the facility shall handle soiled clothing worn within the quarantine unit in a manner approved by the Veterinary Services port veterinarian as adequate to preclude transmission of a poultry disease agent from the facility.

(ii) *Handling of the birds in quarantine.* The birds shall be kept in the quarantine facility for a minimum of 30 days and while in quarantine shall be handled in compliance with the following requirements:

(A) Each lot of birds to be quarantined shall be placed in the facility on an "all-in, all-out" basis. No birds shall be taken out of the lot while it is in quarantine except for diagnostic purposes and if additional birds are added to a lot, the total quarantine period for that lot shall be extended so that all birds will have completed at least 30 consecutive days of quarantine before release for entry into the commerce of the United States. The quarantine period may be extended as provided in paragraph (e) of this section;

(B) The birds shall not be vaccinated prior to release from the quarantine;

(C) Birds of the psittacine family shall receive treatment as a precautionary measure against ornithosis (psittacosis), in accordance with the guidelines of the United States Public Health Service; *

(D) The facility operator shall immediately collect all birds which die in quarantine and hold them under refrigeration, within the facility, shall account for all birds in the shipment, and shall not dispose of any carcass or parts thereof unless authorized to do so by a Veterinary Medical Officer of Veterinary Services of the Department. Birds that die enroute to the United States or while in quarantine shall be made available at the port of entry for necropsy by a Department poultry disease diagnostician who may submit specimens from such birds for laboratory examination.

(E) During the period of quarantine, the birds shall be subjected to such tests and procedures as are required in specific cases by the Veterinary Services port veterinarian, to determine whether the birds are free from communicable diseases of poultry. Such procedures may include requiring that sentinel birds be placed in the facility to detect the presence of exotic Newcastle disease. Such sentinel birds shall be provided by the importer from a source approved by the Deputy Administrator as adequate to supply birds meeting the requirements of Part 90 of this chapter. If frank or clinical Newcastle disease occurs among any commercial or sentinel birds in quarantine, all birds in the facility shall be destroyed or refused entry and the entire facility shall be thoroughly cleaned and then disinfected as directed under the supervision of a Veterinary Services inspector.

(F) The quarantine facility from which a lot of birds has been released shall be thoroughly cleaned and disinfected with a disinfectant authorized in § 71.10(a)(5) of this chapter, under supervision of a Veterinary Services inspector before a new lot is placed in the facility.

(iii) *Records.* It shall be the responsibility of the operator of the facility to maintain a current daily log for each lot of birds, recording such information as the general condition of the birds each day, source of origin of the birds in the lot, total number of birds in the lot when imported, number of dead birds when lot arrived, date lot was placed into the facility, number of deaths each day in the lot during the quarantine period, necropsy results, and laboratory findings on birds that died during the quarantine, date of prescribed tests and results, Department import permit numbers of each lot, date lot was removed from the facility, and any other observations pertinent to the general health of the birds in the lot. The daily log shall be maintained for one calendar year following the date of release of the birds from quarantine and shall be made available to Veterinary Services personnel upon request.

* Such guidelines may be obtained from the Director, Center for Disease Control, U.S. Public Health Service, Atlanta, Georgia 30333, or the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

(4) Additional requirements as to location, security, physical plant and facilities, sanitation, and other items may be imposed by the Deputy Administrator, Veterinary Services, in each specific case in order to assure that the quarantine of the birds in such facility will be adequate to enable determination of their health status, prevent spread of disease among birds in quarantine, and prevent escape of poultry disease agents from the facility.

(5) Requests for approval and plans for proposed facilities shall be submitted to the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Center Building, Hyattsville, Maryland 20782.

(6) Before a decision is made with respect to the eligibility of any facility for initial approval, a personal inspection of the facility shall be made by a Veterinary Medical Officer of Veterinary Services, to determine whether it complies with the standards outlined in this section. Approval of any facility may be refused and approval of any approved quarantine facility may be withdrawn at any time by the Deputy Administrator, Veterinary Services, upon his determination that any requirement of this section is not being met. Before such action is taken, the operator of the facility will be informed of the reasons for the proposed action and afforded opportunity to present his views thereon.

Requirements of other Federal laws and regulations, such as the Department's Animal Welfare Regulations in Subchapter A of this chapter shall also apply as applicable to the quarantine facilities.

9. Section 92.38 is deleted and § 92.26 is amended to read:

§ 92.26 Poultry from Canada.

Poultry imported from Canada is not required to meet the requirements of § 92.11(c) but shall meet all other requirements of this Part applicable to poultry or to animals generally.

§ 92.38 [Deleted]

(Sec. 2, 32 Stat. 792, as amended; secs. 2, 3, 4, and 11, 76 Stat. 129, 130, 132; 21 U.S.C. 111, 134a, 134b, 134c, 134f; 37 FR 28464, 28477; 38 FR 19141.)

NOTE.—The recordkeeping and reporting requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.

Effective date. The foregoing amendments shall become effective October 30, 1973.

Insofar as the amendments impose restrictions necessary in order to prevent further introduction or dissemination of poultry diseases from foreign countries into the United States, and in order to protect the gains made in the exotic Newcastle disease eradication program they must be made effective as soon as possible in order to accomplish these objectives.

Insofar as the amendments relieve certain restrictions no longer deemed necessary to prevent the introduction and spread of poultry disease, they must be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that further public participation in rulemaking proceedings concerning the amendments would make additional relevant information available to the Department.

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

Done at Washington, D.C., this 24th day of October 1973.

G. H. WISE,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc.73-23096 Filed 10-29-73;8:45 am]

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

PART 113—STANDARD REQUIREMENTS

Miscellaneous Amendments

On June 12, 1973, there was published in the FEDERAL REGISTER (FR Doc. 73-15450) a notice of proposed rulemaking with respect to proposed amendments to the regulations relating to viruses, serums, toxins, and analogous products in Part 113 of Title 9, Code of Federal Regulations, issued pursuant to the provisions of the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151-158).

These amendments shall make more readily available to the general public some of the requirements to be complied with when preparing biological products, including acceptable test methods and procedures by publishing such requirements, methods, and procedures in the regulations instead of administrative memorandums.

Nine basic tests, requirements for selection of cells for cell cultures and purity requirements for some ingredients of biological products would be codified in 12 new sections which would be added to Part 113. Section 113.2 is redesignated as § 113.50; § 113.33 as proposed is deleted; and 14 sections are reserved for future use.

The basic tests and the requirements included in these amendments have been developed over a period of years in cooperation with interested members of the scientific society and, for the most part, have been utilized by industry either as accepted requirements or as proposals under development. The test shall be conducted on samples of each serial produced when such tests are prescribed in a Standard Requirement or in a filed Outline of Production for the product. If the results of such tests are unsatisfactory, the serial will not be released for market.

After due consideration of all relevant matters, including the proposals set forth in the aforesaid notice of rulemaking, and the comments and views submitted by interested persons, and pursuant to the authority contained in the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151-158), the amendments of Part 113 of Subchapter E, Chapter I, Title 9 of the Code of Federal Regulations, as contained in the aforesaid notice are hereby adopted and are set forth herein, subject to the following noted modifications:

Conforming changes have been made in the proposal to be consistent with the processing of Outlines of Production as prescribed in § 114.8 of this subchapter. The word "approved" has been changed to "filed" in the lead paragraphs of §§ 113.30, 113.32, 113.34, 113.35, 113.36, and 113.37.

"Standard Requirement" has been capitalized in the lead paragraphs of §§ 113.34, 113.35, 113.36, and 113.37.

In § 113.28, the M-96 test has been deleted at this time; minor adjustments and corrections have been made in the heart infusion test; paragraph (g) has been rewritten for clarity and redesignated as paragraph (e).

The lead paragraph in § 113.29 has been rewritten and § 113.29(d) deleted to conform with other tests.

Corrected spelling of "monometer" and "mg" in § 113.29(b)(2) and (3), respectively; corrected temperature in § 113.29 (c)(1) to "100° C or higher;" reworded § 113.29(c)(6), (7), (9), and (10) for clarity.

§ 113.30(a) has been rewritten to provide for tissue culture products; the choice of mediums has been changed in § 113.30(b); and "Salmonella" has been capitalized in two places in § 113.30(d) and (e).

The lead paragraph in § 113.31 has been rewritten to limit the test to virus products of chicken origin and provide for exemption of certain inactivated products. The word "if" has been deleted from the first line of § 113.31(a)(1) and "the same week" has been inserted in the tenth line for clarification. Grammar in § 113.31(b)(1) has been corrected by inserting "and."

§ 113.32 has been rewritten for clarification.

The proposed § 113.33 has been withheld at this time and § 113.33 has been reserved.

§ 113.34(a) has been reworded to provide for combination products containing Newcastle Disease Vaccine. In § 113.34 (c), "post-inoculation" has been hyphenated.

§ 113.34(e) is reworded for clarification.

§ 113.35 has been rewritten for clarification.

The words "at least" have been inserted in § 113.36(b) to make the test more flexible.

The phrase "up to" has been inserted in § 113.37(b) to make the test more flexible.

"Chorio-allantoic membrane (CAM)" has been inserted instead of "CAM" in § 113.37(c)(1) for completeness and § 113.37(c)(2) has been reworded for clarification; spelling of "embryos" has been corrected; and "post-inoculation" has been hyphenated. A comma has been inserted in § 113.37(d).

The lead paragraph of § 113.51, § 113.51(a), § 113.51(b), and the first sentence of § 113.51(c) have been reworded for clarification of intent. Reference to § 113.27 in § 113.51(b) has been corrected to read "§ 113.26." § 113.51(c)(2) has been reworded for clarity. The tenth line in § 113.51(c)(3) which was printed upside down in the proposal has been corrected.

The first sentence in the lead paragraph of § 113.51(d) is rewritten for clarification. The word "glass" is deleted from the second sentence as being unnecessarily restrictive and the word "deliberately" deleted from the fifth sentence as superfluous.

The phrase "any of" has been deleted from the first line of § 113.51(d)(1) and § 113.51(d)(2) has been rewritten for clarity.

§ 113.51 (e) and (f) have been rewritten for clarity.

§ 113.52(a)(2) "Master Cell Stock" has been capitalized.

§ 113.52(a)(5) "Veterinary Services" has been capitalized.

The lead paragraph of § 113.52(d) has been changed for accuracy of wording and to provide for 28 days instead of 14 days.

Grammatical correction has been made in § 113.52(d)(1).

Reference has been corrected in § 113.52(d)(2).

The word "methodically" has been deleted from § 113.52(d)(3) as superfluous. § 113.52(d)(4) (iv) and (v) has been reworded and (v) changed from (vi) for accuracy. Reference is corrected in § 113.52(d)(5). The word "of" has been inserted in the second sentence of § 113.52(d)(6) as a grammatical correction. Wrong reference has been corrected in § 113.52(e) and in two places in § 113.52(f). "Veterinary Services" has been capitalized in § 113.52(f) and the spelling of "positive" has been corrected.

The word "harmful" has been deleted from the third line and "consists" changed to "consist" in the sixth line of § 113.52(g) for clarity.

§ 113.52(g)(3)(i) has been reworded for accuracy and clarity. "Post-inoculation" has been hyphenated in § 113.52(g)(3)(ii). The word "foreign" has been deleted from § 113.52(g)(3)(iii) in two places for accuracy.

Punctuation has been corrected in § 113.52(g)(4)(i) by adding commas in two places. Also, the phrase "progressively proliferating" has been substituted for "progressive proliferation" as being a better choice of words. Spelling of "or" has been corrected.

The phrase "disrupted completely" has been substituted for "rendered free of intact cells" for accuracy in § 113.52(g)(4)(ii).

The word "glass" has been deleted from the lead paragraph of § 113.52(g)(5) as being unnecessarily restrictive and reworded to include the use of a specific conjugate for completion of the test. "Veterinary Services" has been capitalized in § 113.52(g)(5)(iii).

The lead paragraph of § 113.53 has been changed to exempt material which has been heat sterilized. Requirement for mycoplasma test in § 113.53(a)(1) has been reworded according to changes made in § 113.28.

§ 113.53(b)(2) has been reworded to correct references, for clarification, and permit use of all cells.

§ 113.53(b)(3) has been reworded to limit abnormalities to those that are virus induced.

§ 113.53(b)(4) has been reworded to permit subculturing and to use a test specified by reference. § 113.53(b)(6) has been corrected by inserting "and" in the last sentence.

§ 113.53(b)(7) has been corrected by substituting "into" for "onto a rack."

The word "additionally" has been inserted for clarity in § 113.53(b)(8).

§ 113.53(b)(8)(i) has been reworded for clarity and "post-inoculation" has been hyphenated in § 113.53(b)(8)(ii).

A statement has been added in a new § 113.53(b)(9) to be used in judging results of the tests.

Licensees and permittees have been operating under currently effective sample requirements which have been prescribed in administrative memorandums by the Deputy Administrator in accordance with § 113.3 in the number needed to conduct required tests. The revisions being made by these amendments merely codify in § 113.3 the basic sample requirements in such memorandums. The changes in § 113.4 are merely conforming and editorial in nature in that § 113.4 is amended to make the heading consistent with the content and further amended to conform with § 114.8 of this subchapter by substituting "filed Outline of Production for the product" for "approved outline" in § 113.4(a) and editorial changes in § 113.4(b).

Therefore, it is found upon good cause that notice and other public procedure concerning the sample requirements in § 113.3 and the conforming and editorial changes in § 113.4 are impractical and unnecessary.

1. §§ 113.3 and 113.4 are amended by revising the lead paragraph of § 113.3; by revising § 113.3(a); by revising § 113.3(b) and redesignating it as § 113.3(c); by adding a new § 113.3(b); and by revising § 113.4., §§ 113.3, and 113.4 are amended to read:

§ 113.3 Sampling of biological products.

Each licensee and permittee shall furnish representative samples of each serial or subserial of a biological product manufactured in the United States or imported into the United States as prescribed in this section. Additional samples may be purchased in the open market by a Veterinary Services representative.

(a) An employee of the Department, of the licensee, or of the permittee, as designated by the Deputy Administrator shall select prerelease samples of biological product to be tested by Veterinary Services. Such samples shall be forwarded to the place designated by the Deputy Administrator and in the number prescribed in paragraph (b) of this section.

(1) Selection shall be made as follows:

(i) Nonviable liquid biological products—either bulk or final container samples of completed product shall be selected for purity, safety, or potency tests. Biological product in final container shall be selected to test for viable bacteria and fungi.

(ii) Viable liquid biological products; samples shall be in final containers and shall be randomly selected at the end of the filling operation. Bulk containers of completed product may be sampled when authorized by the Deputy Administrator.

(iii) Desiccated biological products; samples shall be in final containers and shall be randomly selected if desiccated in the final container. Biological products desiccated in bulk shall be sampled at the end of the filling operation.

(iv) Representative samples of each serial or subserial in each shipment of imported biological products shall be selected.

(2) Comparable samples shall be used by Veterinary Services, the licensee, and the permittee for similar tests.

(b) Unless otherwise prescribed by the Deputy Administrator, the number of final container samples to be selected from each serial and subserial shall be:

(1) *Vaccines:*

(i) Twelve single-dose or six multiple-dose samples of live bacterial vaccines;

(ii) Thirty single-dose or 20 multiple-dose samples of equine encephalomyelitis vaccine (killed);

(iii) Eighteen samples of live virus rabies vaccine;

(iv) Six samples of coccidiosis vaccine;

(v) Sixteen samples of all other vaccines.

(2) *Bacterins:*

(i) Twelve samples of single-fraction bacterins;

(ii) Thirteen samples of double-fraction bacterins;

(iii) Fourteen samples of triple-fraction bacterins;

(iv) Fifteen samples of bacterins containing more than three fractions.

(3) *Antiserums:* Twelve samples of antiserum recommended for large animals or 14 samples of antiserum recommended for small animals or the number of reagent serum samples prescribed in the filed Outline of Production for the product.

(4) *Antitoxins:* Twelve samples of tetanus antitoxin or 11 samples of all other antitoxins.

(5) *Toxoids and Bacterin-Toxoids:* Sixteen single-dose samples or 13 multiple-dose samples of tetanus toxoid or 12 samples of all other toxoids or bacterin-toxoids.

(6) *Antigens:* Twelve samples of poultry antigens or 20 samples of tuberculin or four samples of all other diagnostic antigens.

(7) *Miscellaneous:* The number of samples from products not in the categories provided for in subparagraphs (1), (2), (3), (4), (5), or (6) of this paragraph shall be prescribed in the filed Outline of Production for the product.

(8) *Prelicensing:* The number of samples for prelicensing tests of a biological product shall be double the number prescribed in this section for such product.

(c) Reserve samples shall be selected from each serial and subserial of every biological product. Such samples shall be selected at random from finished product by an employee of the Department, of the licensee, or of the permittee, as designated by the Deputy Administrator.

Each sample shall:

(1) Consist of 5 single dose or 2 multiple dose packages as the case may be;

(2) Be adequate in quantity for appropriate examination and testing;

(3) Be truly representative and in final containers;

(4) Be held in a special compartment or equivalent set aside by the licensee or permittee, for holding these samples under refrigeration at the storage temperature recommended on the labels for 6 months after the expiration date stated on the labels. These samples shall be stored in this manner and shall be delivered to Veterinary Services upon request.

§ 113.4 Exemptions to tests.

(a) The test methods and procedures contained in all applicable Standard Requirements shall be complied with unless otherwise exempted by the Deputy Administrator and provided that such exemption is noted in the filed Outline of Production for the product.

(b) Test methods and procedures by which the biological products shall be evaluated shall be designated in the Outline of Production for such products.

2. "Part 113—Standard Requirements" is amended by deleting § 113.33 as proposed and adding nine new sections to read:

§ 113.28 Detection of mycoplasma contamination.

The heart infusion test, using heart infusion broth and heart infusion agar, provided in this section shall be conducted when a test for mycoplasma contamination is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Media additives provided in this paragraph shall be prepared as follows:

(1) DPN-Cysteine Solution:

(i) Use Nicotinamide adenine dinucleotide (oxidized) and L-Cysteine hydrochloride.

(ii) Prepare 1 gram/100 milliliters (ml) distilled water (1 percent solution) of each. Mix the solutions together; the cysteine reduces the DPN. Filter sterilize, dispense in appropriate amounts and store frozen at —20° C.

(2) Inactivated horse serum—horse serum which has been inactivated at 56° C for 30 minutes.

(b) Heart infusion broth shall be prepared as provided in this paragraph.

(1) Dissolve in 970 ml of distilled water the following:

Heart infusion broth	grams	25
Yeast autolysate	do	5
Proteose peptone No. 3	do	10

(2) Add the following:

1 percent tetrazolium chloride	ml	5.5
1 percent thallium acetate	ml	25
Penicillin	units	500,000
Inactivated horse serum	ml	100

(3) Adjust pH to 7.9 with NaOH, filter sterilize, and dispense 100 ml aliquots into 125 ml flasks and store until needed.

(4) Add 2 ml of DPN-Cysteine solution to each 100 ml of broth on day of use.

(c) Heart Infusion Agar shall be prepared as provided in this paragraph.

(1) Dissolve in 900 ml of distilled water by boiling the following:

Heart infusion agar	grams	25
Heart infusion broth	do	10
Proteose peptone No. 3	do	10
1 percent thallium acetate	ml	25

(2) Cool the medium and adjust pH to 7.9 with NaOH.

(3) Autoclave the medium.

(4) Cool the medium 30 minutes in a 56° C waterbath.

(5) Dissolve 5 grams of yeast autolysate in 100 ml of distilled water, filter sterilize, and add to the medium.

(6) Add to the medium:

126 ml of inactivated horse serum
21 ml of DPN-Cysteine solution
525,000 units of Penicillin.

Dispense 10 ml aliquots into 60×15 mm disposable culture dishes or petri dishes.

(d) The test procedure provided in this paragraph shall be followed when conducting the mycoplasma detection test.

(1) Preparation of inoculum. Immediately prior to starting the test, frozen liquid vaccine shall be thawed, and lyophilized vaccine shall be rehydrated to the volume recommended on the label with mycoplasma medium. In the case of a lyophilized biological product, e.g., 1,000 dose vial of poultry vaccine to be administered via the drinking water, the vaccine shall be rehydrated to 30 ml with mycoplasma medium. In the case of a cell line or a sample of primary cells, the inoculum shall consist of the resuspended cells. Control tests shall be established as provided in subparagraph (4) of this paragraph.

(2) Inoculation of plate. Plate 0.1 ml of inoculum on an agar plate and make a short, continuous streak across the plate with a pipet. Tilt the plate to allow the inoculum to flow over the surface.

(3) Inoculation of flask of medium. Transfer 1 ml of the inoculum into a flask containing 100 ml mycoplasma medium and mix thoroughly. Incubate the flask at 33 to 37° C for 14 days during which time, one of four agar plates shall be streaked with 0.1 ml of material from the incubating flask of inoculated medium on the 3d day, one on the 7th day, one on the 10th day, and one on the 14th day post-inoculation.

(4) Control tests shall be conducted simultaneously with the detection test using techniques provided in subparagraphs (2) and (3) of this paragraph, except the inoculum for the positive control test shall be selected mycoplasma cultures and the negative control test shall be uninoculated medium from the same lot used in the detection test.

(5) All plates shall be incubated in a high humidity, 4–6 percent CO_2 atmosphere at 33° to 37° C for 10–14 days and examined with a stereoscopic microscope at 35x to 100x or with a regular microscope at 100x.

(e) Interpretation of test results.

(1) If growth appears on at least one of the plates in the positive control test and does not appear on any of the plates in the negative control test, the test is valid.

(2) If mycoplasma colonies are found on any of the plates inoculated with material being tested, the results are positive for mycoplasma contamination.

§ 113.29 Determination of moisture content in desiccated biological products.

Methods provided in this section shall be used when a determination of moisture content in desiccated biological products is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Final container samples of completed product shall be tested. Individual samples having a low net weight shall be pooled at the time of testing in order to attain a minimum of 100 milligrams of dried product.

(b) The weight loss of the sample(s) due to drying to a constant weight in a vacuum oven shall be determined. The recommended equipment is as follows:

(1) Numbered, low-form, flat-bottom weighing dishes with tight-fitting lids.

(2) Vacuum oven equipped with a vacuum pump, accurate thermometer, vacuum gage, and thermostat. A suitable drying device shall be attached to the inlet valve of the oven. The vacuum system shall have a manometer and flowmeter for proper regulation of flow and pressure.

(3) Balance, accurate to 0.1 mg (rated precision ±0.01 mg.

(4) Dry box or hood equipped with a suitable drying device and hygrometer to assure a relative humidity of 0 to 10 percent. The box should be sufficient in size to allow for the convenient transfer of samples and, if possible, incorporation of the balance and vacuum oven.

(5) If needed, a desiccator jar equipped with P_2O_5 plus $CaSO_4$ or $CaCl_2$ drying agent with indicator.

(c) Test procedure:

(1) Thoroughly cleaned weighing dishes shall be dried approximately 3 hours at 60° C under vacuum or for 1 hour at 100° C or higher in a drying oven. Immediately upon removal, the dishes shall be placed in a dry atmosphere and allowed to cool to room temperature. The tare weight of each weighing dish shall be determined as rapidly as possible. All manipulations of weighing dishes shall be made with tongs or while wearing gloves.

(2) The relative humidity of the dry box shall be reduced to 0 to 10 percent to assure a low level of moisture in the box during the time of transfer of the sample to the weighing dish.

(3) After the sample container has equilibrated in the dry atmosphere, the vacuum shall be released slowly allowing dry air to enter the bottle.

(4) The stopper shall be removed and the sample plug broken up with a spatula.

(5) The sample shall be rapidly transferred to a previously weighed and marked weighing dish and covered with its lid.

(6) After transfer has been completed, the weighing dish with its contents shall be weighed immediately giving the gross weight of the dish and sample. This weight minus the tare weight of the weighing dish is the sample weight.

(7) The lids shall be removed and placed with their matched weighing dishes in the vacuum oven. The pressure in the oven shall be reduced to 1 millimeter of mercury or less and the thermostat set at 60° C. A small amount of dry air shall be allowed to bleed into the oven during the drying period and the reduced pressure maintained by continuous operation of the vacuum pump.

(8) After 24 hours of drying time, the vacuum pump shall be stopped and dry air allowed to continually bleed into the oven with an increased flow rate until the pressure inside of the oven has been equalized with the atmosphere.

(9) The lids shall be immediately replaced in the normal closed position and the dishes placed in an efficient desiccator and allowed to cool to room temperature.

(10) Immediately upon reaching ambient temperature, each weighing dish containing the sample shall be removed from the desiccator and weighed as rapidly as possible. This weight subtracted from the gross weight obtained in accordance with subparagraph (6) of this paragraph gives the equivalent weight of moisture lost upon drying.

(11) The steps prescribed in subparagraphs (8), (9), and (10) of this paragraph may be repeated if experience has indicated that the particular product will not dry to a constant weight in the first 24 hours.

(12) Refer to subparagraphs (6) and (10) of this paragraph. The equivalent weight of moisture divided by the sample weight times 100 equals the percentage of moisture in the original sample.

§ 113.30 Detection of Salmonella contamination.

The test for detection of Salmonella contamination provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Samples shall be collected from the bulk suspension before bacteriostatic or bactericidal agents have been added. When tissue culture products are to be tested, 1 ml of tissue extract used as the source of cells or 1 ml of the minced tissue per se shall be tested.

(b) Five ml of the liquid vaccine suspension shall be used to inoculate each 100 ml of liquid broth medium (tryptose and either selenite F or tetrathionate). The inoculated media shall be incubated 18–24 hours at 35–37° C.

(c) Transfers shall be made to either MacConkey agar or Salmonella-Shigella agar, incubated for 18–24 hours and examined.

(d) If no growth typical of Salmonella is noted, the plates shall be incubated an additional 18–24 hours and again examined.

(e) If suspicious colonies are observed, further subculture on suitable media shall be made for positive identification. If Salmonella is found, the bulk suspension is unsatisfactory.

§ 113.31 Detection of avian lymphoid leukosis.

The complement-fixation test for detection of avian lymphoid leukosis provided in this section shall be conducted on all biological products containing virus which has been propagated in substrates of chicken origin: *Provided*, An inactivated viral product shall be exempt from this requirement if the licensee can demonstrate to Veterinary Services that the agent used to inactivate the vaccine virus would also inactivate lymphoid leukosis virus.

(a) Propagation of contaminating lymphoid leukosis viruses, if present, shall be done in chick embryo cell cultures.

(1) Each vaccine virus, cytopathic to chick embryo fibroblast cells, shall be effectively neutralized, inactivated, or separated so that minimal amounts of lymphoid leukosis virus can be propagated on cell culture during the 21-day growth period. If a vaccine virus cannot be effectively neutralized, inactivated, or separated, a sample of another vaccine prepared the same week from material harvested from each source flock (or other sampling procedure acceptable to Veterinary Services) used for the preparation of the questionable vaccine virus that cannot be neutralized, inactivated, or separated shall be tested each week during the preparation of such questionable vaccine.

(2) When cell cultures are tested, 5 ml of the final cell suspension as prepared for seeding of production cell cultures shall be used as inoculum. When desiccated vaccines are tested, 200 doses of Newcastle disease vaccine, or 500 doses of other vaccines for use in poultry, or the equivalent of one dose of vaccine for use in animals other than poultry shall be rehydrated with 5 ml of cell culture media and used as inoculum. Control cultures shall be prepared from the same cell suspension as the cultures for testing the vaccine.

(3) Uninoculated chick embryo fibroblast cell cultures shall act as negative controls. One set of chick fibroblast cultures inoculated with subgroup A virus and another set inoculated with subgroup B virus shall act as positive controls, A and B respectively.

(4) The cell cultures shall be propagated at 35–37° C for at least 21 days. They shall be passed when necessary to maintain viability and samples harvested from each passage shall be tested for group specific antigen.

(b) The microtiter complement-fixation test shall be performed using either the 50 percent or the 100 percent hemolytic end point technique to determine complement unitage. Five 50 percent hemolytic units or two 100 percent hemolytic units of complement shall be used for each test.

(1) All test materials, including positive and negative controls, shall be stored at −60° C or colder until used in the test. Before use, each sample shall be thawed and frozen three times to disrupt intact cells and release the group specific antigen.

(2) The antiserum used in the microtiter complement-fixation test shall be a standard reagent supplied or approved by the Veterinary Services. Four units of antiserum shall be used for each test.

(3) Presence of complement-fixing activity in the harvested samples (from passages) at the 1:4 or higher dilution, in the absence of antieomplementary activity, shall be considered a positive test unless the activity can definitely be established to be caused by something other than lymphoid leukosis virus, subgroups A and/or B. Activity at the 1:2 dilution shall be considered suspicious and the sample further subcultured to determine presence or absence of the group specific antigen.

(4) Biological products or primary cells which are found contaminated with lymphoid leukosis viruses are unsatisfactory. Source flocks from which contaminated material was obtained are also unsatisfactory.

§ 113.32 Detection of Brucella contamination.

The test for detection of Brucella contamination provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in a filed Outline of Production for the product.

(a) One ml of the minced tissue used as the source of cells or 1 ml of the extract of the tissue prior to the addition of antibiotics, diluent and stabilizer, shall be inoculated onto each of three tryptose agar plates and incubated in a 10 percent CO_2 atmosphere at a temperature of 35–37° C for at least 7 days.

(b) If colonies are identified as Brucella, the biological product is unsatisfactory.

(c) If colonies suspicious of Brucella are observed but cannot be identified as a Brucella species, either

(1) The biological product shall be regarded as unsatisfactory and destroyed; or

(2) Further subculture or other procedures shall be carried out until a positive identification can be made.

§ 113.33 [Reserved]

§ 113.34 Detection of hemagglutinating viruses.

The test for detection of hemagglutinating viruses provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Final container samples of completed product rehydrated as recommended on the label shall be used as inoculum: *Provided*, That poultry vaccines distributed without diluent shall be rehydrated with 30 ml of sterile distilled water per 1,000 doses and used as inoculum. When one or more fractions are to be used in combination with Newcastle Disease Vaccine, test samples shall be collected from bulk suspensions of each prior to mixing with the Newcastle Disease Vaccine.

(b) Each of ten 9- to 10-day-old embryonating eggs from Newcastle disease susceptible flocks shall be inoculated into the allantoic cavity with 0.2 ml of the undiluted inoculum.

(1) Test five uninoculated embryos of the same age and from the same flock as those used for the test as negative controls.

(2) Test an allantoic fluid sample of Newcastle disease virus as a positive control.

(c) Three to five days post-inoculation, a sample of allantoic fluid from each egg shall be tested separately by a rapid plate test for hemagglutinating activity using a 0.5 percent suspension of fresh chicken red blood cells.

(d) If the results are inconclusive, one or two blind passages shall be made using fluids from each of the original test eggs. Fluids from dead and live embryos may be pooled separately for inoculum in these passages.

(e) If hemagglutinating activity attributable to the product is observed, the serial is unsatisfactory.

§ 113.35 Detection of viricidal activity.

The test for detection of viricidal activity provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product for a liquid fraction used as a diluent for a desiccated live virus fraction in a combination package.

(a) Rehydrate two vials of vaccine with the liquid fraction under test according to the labeled dosage and pool contents.

(b) Rehydrate two vials of vaccine with sterile distilled water according to the label dosage and pool contents.

(c) Hold the two pools of vaccine at room temperature for 2 hours. This is 0 hour; *Provided*, That, in the case of biological products containing more than one virus component and one or more has to be neutralized for determination of the virus titer, 0 hour begins after the period of neutralization.

(d) Titrate the virus(es) in each pool. Titrations shall be conducted using 0.5 $\log_{10}$ dilution steps and a minimum of 10 substrate units per dilution. Compare titers.

(e) The diluent under test is satisfactory if the titer of virus rehydrated with that diluent is no more than 0.7 $\log_{10}$ below the titer of virus rehydrated with sterile distilled water and both titers are sufficient to satisfy minimum release titers specified in the appropriate Standard Requirement or in the filed Outline of Production for the product, or both.

(f) A retest may be conducted if the difference in titers is not greater than 1.0 $\log_{10}$.

§ 113.36 Detection of extraneous pathogens by the chicken inoculation test.

The test for detection of extraneous pathogens provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) The biological product to be tested shall be prepared for use as recommended on the label, or in the case of desiccated vaccine to be used in poultry, rehydrated with sterile distilled water at the rate of 30 ml per 1,000 doses.

(b) At least 25 healthy susceptible young chickens, properly identified and obtained from the same source and hatch, shall be immunized at least 14 days prior to being put on test. The immunizing agent shall be the same as the product to be tested but from a serial previously tested and found satisfactory.

(c) At least 20 of the previously immunized birds shall be inoculated with 10 label doses of the vaccine being tested by each of the following routes: Subcutaneous, intratracheal, eye-drop, and comb scarification (1 cm^2). Twenty birds may be used for each route or combination of routes.

(d) At least five birds shall be isolated as control birds.

(e) All birds shall be observed for 21 days for signs of septicemic diseases, respiratory diseases, or other pathologic conditions.

(f) If the controls sicken or die, the test is inconclusive. If the controls remain healthy and sickness or deaths occur in the vaccinates, the serial is unsatisfactory.

§ 113.37 Detection of extraneous pathogens by the chick embryo inoculation test.

The test for detection of extraneous pathogens provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) The biological product to be tested shall be prepared for use as recommended on the label, or in the case of desiccated vaccine to be used in poultry, rehydrated with sterile distilled water at the rate of 30 ml per 1,000 doses.

(b) One volume of the prepared vaccine shall be mixed with up to nine volumes of sterile heat-inactivated specific antiserum to neutralize the vaccine virus in the product. Each lot of antiserum shall be demonstrated by virus neutralization tests not to inhibit other viruses known to be possible contaminants.

(c) After neutralization, 0.2 ml of the vaccine-serum mixture shall be inoculated into each of at least 20 fully susceptible chicken embryos.

(1) Twenty embryos, 9 to 11 days old, shall be inoculated on the chorio-allantoic membrane (CAM) with 0.1 ml, and in the allantoic sac with 0.1 ml.

(2) Eggs shall be candled daily for 7 days. Deaths occurring during the first 24 hours shall be disregarded but at least 18 viable embryos shall survive 24 hours post-inoculation for a valid test. Examine all embryos and CAM's from embryos which die after the first day. When necessary, embryo subcultures shall be made to determine the cause of a death. The test shall be concluded on the seventh day post-inoculation and the surviving embryos (including CAM's) examined.

(d) If death and/or abnormality attributable to the inoculum occur, the serial is unsatisfactory: *Provided*, That, if there is a vaccine virus override, the test may be repeated, using a higher titered antiserum.

3. Part 113 is further amended by redesignating the current provisions of § 113.2 as § 113.50, and reserving § 113.2 and 12 new sections designated as § 113.38–§ 113.49, and adding three new sections 113.51–113.53, to read as follows:

§ 113.2 [Reserved]

§ 113.38–§ 113.49 [Reserved]

INGREDIENT REQUIREMENTS

§ 113.50 Ingredients of biological products.

All ingredients used in a licensed biological product shall meet accepted standards of purity and quality; shall be sufficiently nontoxic so that the amount present in the recommended dose of the product shall not be toxic to the recipient; and in the combinations used shall not denature the specific substances in the product below the minimum acceptable potency within the dating period when stored at the recommended temperature.

§ 113.51 Requirements for primary cells used in biological product production.

Prior to release of any serial of biological product prepared from primary cells, samples from each batch of primary cells or samples from one subculture used in the preparation of such product shall be tested for contaminating microorganisms as provided in this section.

(a) Final container samples of completed product or samples of the final pool of harvested material or samples of each subculture of cells used to prepare the biological product shall be shown free of mycoplasma by the method provided in § 113.28. The sample for testing cells shall consist of at least 75 cm^2 of actively-growing cells or the equivalent in harvest fluids: *Provided*, That all sources of cells in the batch of primary cells are represented.

(b) Final container samples of completed product or samples of the final pool of harvested material or samples of each subculture of cells used to prepare the biological product shall be shown free of bacteria and fungi by methods provided in §§ 113.25 and 113.26.

(c) Each batch of primary cells or each subculture of such cells used to prepare a biological product shall be shown free of adventitious agents as provided in this paragraph. The samples for testing shall consist of at least two separate monolayers of cells, each at least 75 cm^2 in area. The monolayers shall be maintained for at least 28 days using the media (with additives) intended for growth and maintenance and under conditions similar to those used to prepare biological products. Subculturing of the cells is permitted, if necessary, to maintain the cells throughout the required period.

(1) The monolayers shall be examined regularly throughout the required period for evidences of cytopathology attributable to adventitious agents.

(2) At least one monolayer, at the conclusion of the required observation period, 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 45° C for an appropriate incubation period and the monolayer examined for evidences of hemadsorption in the cell culture.

(3) At least one monolayer, at the conclusion of the required observation period, shall be alternately frozen and thawed three times. A 1.0 ml aliquot of disrupted cells with fluids shall be dispensed onto at least one monolayer of Vero (African green monkey) or other appropriate cell monolayer with a total area of at least 75 cm^2. The monolayer of Vero (or other appropriate) cells shall then be examined regularly throughout an additional observation period of at least 14 days for evidences of cytopathology attributable to adventitious agents.

(4) If specific cytopathology or hemadsorption attributable to adventitious agents are found, the subculture or batch of primary cells is unsatisfactory and shall not be used to prepare biological products. If adventitious agents are suspected because of cytopathology or hemadsorption and cannot be eliminated as a possibility by additional testing, the batch of primary cells is unsatisfactory.

(d) Each batch of primary cells of bovine origin of each subculture of such cells used to prepare a biological product shall be shown free of Bovine Virus Diarrhea (BVD) virus. The samples for testing shall consist of at least 10 monolayers of cells, each with an area at least as large as a 10.5 x 22 mm coverslip. The samples for testing shall be obtained from at least the second subpassage from intact tissue. The monolayers shall be grown to at least 80 percent confluency using the media (with additives) intended for growth and maintenance and under conditions similar to those used to prepare the product. At least five of the monolayers shall be inoculated with BVD virus as positive controls. All monolayers shall be further incubated at 35–37° C for an additional 4 to 6 days. All monolayers shall then be removed from their media, processed, and stained with anti-BVD fluorescein-tagged antibody conjugate, and examined for presence of specific fluorescence attributable to BVD virus.

(1) If the uninoculated monolayers show evidences of specific BVD fluorescence, the batch of primary cells is unsatisfactory: *Provided*, That if specific fluorescence attributable to BVD virus is absent in more than one of the monolayers deliberately inoculated as positive controls, the test is inconclusive.

(2) If the fluorescence of the monolayers inoculated with BVD virus as positive controls is equivocal or if the uninoculated monolayers show equivocal fluorescence suspicious of BVD contamination or both, the test shall be declared inconclusive and may be repeated; *Provided*, That, if the test is not repeated, the cells shall be regarded as unsatisfactory and not used for production. When a test is repeated, use:

(i) At least 10 additional monolayers prepared from at least one subpassage from that used as a test sample, or

(ii) Fluids from the uninoculated monolayers which shall be added to 10 monolayers or cells known to be free of BVD virus and essentially equivalent in BVD sensitivity to primary bovine kidney cells.

(e) Each batch of primary cells or each subculture of cells used to prepare a biological product shall be shown free of other specific viruses using applicable fluorescent antibody tests.

(f) Each batch of primary cells of chicken origin or each subculture of such cells used to prepare a biological product shall be tested for lymphoid leukosis virus as provided in § 113.31. Cells found to contain lymphoid leukosis virus are unsatisfactory.

§ 113.52 Requirements for selection of cell lines.

All cell lines used to prepare biological products shall be tested as provided in this section. Cell lines which are unsatisfactory by any of the tests provided shall not be used.

(a) General requirements.

(1) Cell lines shall be derived from normal tissues of healthy animals. A complete record shall be kept, such as, but not limited to the source, passage history, and media used.

(2) Not more than 20 passages from the Master Cell Stock (MCS) shall be permitted.

(3) Each lot of cells shall be monitored for the characteristics determined to be normal for the cell line, such as, but not limited to microscopic appearance, growth rate, acid production, or other observable features.

(4) A minimum of 50 mitotic cells shall be examined at both the MCS level and the highest passage permitted. The modal number in the highest passage shall not exceed plus or minus 15 percent of the MCS. Marker chromosomes, if any, shall persist over the useful passage level. If the modal number exceeds the limits and/or the marker chromosomes do not persist over the useful passage level, the cell line shall not be used for vaccine production.

(5) Sufficient 1.0 ml or larger aliquots of MCS and the highest passage of cells permitted shall be prepared, kept in a frozen state, and made available to Veterinary Services upon request for performing the tests prescribed in this section.

(b) The MCS and either each subculture of cells used to prepare a biological product or the final pool of harvested material (with or without the stabilizer) for each serial of such product shall be shown to be free of mycoplasma by methods prescribed in § 113.28. The sample for testing shall consist of at least 75 cm^2 of actively growing cells or the equivalent in harvest fluids. The cells shall represent all sources of cells in the batch.

(c) The MCS and each subculture used to prepare a biological product or the final pool of harvested material for each serial of such product shall be tested for bacteria and fungi as provided in § 113.26. If bacteria or fungi are found in the MCS, the MCS shall not be used. If bacteria or fungi are found in a subculture, the subculture shall not be used.

(d) The MCS shall be shown to be free of adventitious agents by methods prescribed in subparagraphs (1), (2), (3), (4), (5), and (6) of this paragraph. The samples for testing shall be at least 75 cm^2 in area. The monolayers shall be maintained for at least 28 days using the media (with additions) intended for growth and maintenance and under conditions similar to those used in the preparation of biological products. Subculturing the cells is permitted, if necessary, to maintain the cells throughout the required period.

(1) The monolayers shall be examined regularly throughout the required period for evidence of cytopathology attributable to adventitious agents.

(2) At least one monolayer, at the conclusion of the required observation period, shall be shown to be free of hemadsorbing agents by methods provided in § 113.51(c)(2).

(3) At least one monolayer, at the conclusion of the required observation period, shall be stained with a suitable cytological stain and the entire monolayer examined for evidences of inclusion bodies, abnormal number of giant

cells, or other cytopathology indicative of cell abnormalities attributable to adventitious agents.

(4) At least one monolayer, at the conclusion of the required observation period, shall be alternately frozen and thawed three times. A 1.0 ml aliquot of disrupted cells shall be dispensed onto at least one monolayer (at least 75 cm^2 in area) of each of the following cells:

(i) Vero African green monkey kidney cells,

(ii) BHK_{21} baby hamster kidney cells,

(iii) Embryonic or neonatal bovine kidney cells,

(iv) Embryonic or neonatal kidney cells, of the species for which the biological product is intended (if not bovine or hamster), and

(v) Embryonic or neonatal kidney cells of the species of origin of the cell line (if not bovine or hamster).

(iv) Neonatal canine kidney cells, of the species for which the biological product is intended (if not bovine or canine), and

(vi) Embryonic or neonatal kidney cells of the species of origin of the cell line (if not bovine or canine).

(5) The monolayers of cells specified in subparagraph (4) of this paragraph shall be examined regularly throughout an additional period of at least 14 days for evidences of cytopathology attributable to adventitious agents. At the conclusion of the observation period, each monolayer of the specified cells shall be shown to be free of hemadsorbing agents by methods provided in § 113.51(c)(2).

(6) If specific cytopathology or hemadsorption attributable to adventitious agents are found, the MCS is unsatisfactory. If adventitious agents are suspected because of cytopathology or hemadsorption and cannot be eliminated as a possibility by additional testing, the MCS shall be regarded as unsatisfactory.

(e) Each MCS either derived from or intended for use in bovine species shall be shown to be free of BVD virus using the procedure provided in § 113.51(d).

(f) Each MCS shall be shown to be free of other specified viruses using the procedure provided in § 113.51(d), but substituting the antiviral fluorescein-tagged antibody conjugate specific for each of the other specified viruses. The viruses specified and the tests conducted will depend upon the species from which the MCS tissues and additives of animal origin were obtained. When available, reagents for the tests may be furnished by Veterinary Services. Test conditions or periods, or both, may be varied from those in § 113.51(d) if positive control monolayers grown in known clean cells indicate fluorescence is enhanced in the positive controls by so doing.

(g) Tumorigenicity and oncogenicity requirements. The MCS shall be shown to be free of tumorigenicity and oncogenicity by methods provided in this paragraph. The samples for testing shall consist of cells from a 50 percent mixture of the MCS and the highest passage used to prepare a biological product.

(1) Cell lines found to be tumorigenic in conditioned laboratory animals or by hamster cheek pouch inoculation shall be considered satisfactory if no oncogenicity occurs using disrupted cells in laboratory animals and if intact cells do not produce tumors when inoculated into the species for which the product is recommended. Also, a cell line which produces only benign, nonproliferating or regressing tumors in laboratory animals limited to the site of inoculation shall be considered satisfactory.

(2) Cell lines shall be considered unsatisfactory to prepare a biological product if evidence of oncogenicity or malignant tumorigenicity is demonstrated. A cell line which produces a malignant or progressively proliferating tumor shall be unsatisfactory.

(3) One of the test procedures provided in this paragraph shall be used to test the tumorigenicity of the cell line. No cell line shall be used which does not pass one of these tests: *Provided*, That if the cell line is tested according to the test procedure in subdivision (iii) of this subparagraph and meets the requirements, the cell line may be used regardless of results obtained from other tests, but if it fails to meet these requirements, the cell line shall not be used.

(i) To condition laboratory animals, treat them with cortisone, or X-ray, or lymphocyte antiserum, or thymocyte antiserum, or a combination of these agents. Inoculate each animal by a suitable route with 10^7 viable cells suspended into 0.1 ml of medium so that at least 20 animals shall survive a post-inoculation period of 60 days. At least 10 positive control animals shall be inoculated with a cell line known to be tumorigenic. At least 10 negative control animals shall be inoculated with new medium of the same formulation used to grow the cells. The test is valid if progressively proliferating tumors are found in approximately 50 percent of the positive controls and no tumors are found in the negative controls. In a valid test, if progressive tumors are found in test animals inoculated with the cell line to be used for vaccine, the cell line is unsatisfactory. Microscopic examination shall be required to establish any suspected tumor as benign.

(ii) When cheek pouch inoculation of unconditioned hamsters is used, 10^4 viable cells suspended in 0.1 ml of medium shall be inoculated into the cheek pouch of each test animal. At least 20 animals shall be used for the unknown cell line and at least 20 positive controls shall be inoculated with a cell line known to be tumorigenic. After 60 days post-inoculation, all test animals shall be necropsied and examined. The test shall be valid if progressive tumors are found in 50 percent or more of the positive controls. In a valid test, if progressive tumors are found in test animals inoculated with the cell line to be used to prepare a biological product, the cell line is unsatisfactory. Microscopic examination shall be required to establish that any suspected tumor is benign.

(iii) When unconditioned domestic animals of each species for which the final biological product shall be recommended are used, 10^7 viable cells suspended in 0.5 to 1.0 ml of medium shall be inoculated subcutaneously into the inguinal region of each of not less than 20 animals. Twenty negative control animals shall each be inoculated with 0.5 to 1.0 of the suspending medium. Sixty days post-inoculation, the test animals shall be necropsied. The inoculation site shall be examined microscopically. If there is no evidence of proliferating cells at site of inoculation in the controls, the test is valid. If proliferating cells are detected at the inoculation site of any of the 20 cell-inoculated test animals in a valid test, the cell line is unsatisfactory.

(4) One of the test procedures provided in this paragraph shall be used to test the oncogenicity of the cell line. No cell line shall be used to prepare a biological product if a 50 percent mixture of the MCS and the highest passage to be used fails to meet the requirements in the test procedure used.

(i) When conditioned laboratory animals are used, the test shall be conducted simultaneously with the tumorigenicity test prescribed in subparagraph (3)(i) of this paragraph. Common positive and negative control animals shall be used for both tests. At least 10^6 cells, disrupted by freeze-thaw cycles or minimal sonication, in 0.1 ml of medium shall be inoculated into each of at least 20 animals. Sixty days post-inoculation, all test animals shall be necropsied and the inoculation site examined microscopically. The test shall be valid if progressively proliferating tumors are found in approximately 50 percent of the positive controls and no tumors or proliferating tumor cells are found at the site of inoculation in the negative controls. In a valid test, if proliferating tumor cells are found at the inoculation site in the test animals receiving the cell line, the cell line is unsatisfactory.

(ii) When unconditioned laboratory animals are used, each of at least 20 newborn hamsters and each of at least 20 newborn mice shall be inoculated subcutaneously in the scapular region with 0.1 ml of a suspension containing 10^7 cells per ml which have been disrupted completely by alternate freeze-thaw cycles or sonication. At least 20 negative controls for each species shall be inoculated in the same manner as the test animals with cell suspension medium that has been treated in the same manner as the cell suspension. For a test to be valid, a minimum of 20 hamsters and 20 mice shall survive a post-inoculation period of 6 months. All survivors shall be necropsied. In a valid test, if any of the survivors or any inoculated animals which died earlier show a malignancy related to the inoculum, the cell line is unsatisfactory.

(5) The MCS shall be shown to be of the same species of origin as that reported in § 113.52(a)(1) by the following method. The samples for testing shall consist of at least four monolayers of

cells, each with an area at least as large as a 10.5 x 22 mm coverslip. The monolayers shall be grown to at least 80 percent confluency using media that does not contain any additives whose species of origin match the species of origin of the MCS. The monolayers shall then be removed from their media, processed, and stained in the following fashion. At least two monolayers shall be stained with an antispecies fluorescein-tagged antibody conjugate unrelated to the species of origin of the MCS and with an antispecies fluorescence tagged antibody conjugate specific to the species of origin of the MCS. All monolayers shall then be examined for evidences of specific fluorescence.

(i) If specific fluorescence is not found in the monolayers stained with the conjugate specific to the species of origin of the MCS, the cell line is unsatisfactory and shall not be used for vaccine production.

(ii) If nonspecific fluorescence is found in the monolayers stained with conjugate from an unrelated species of origin, or other results make the test results equivocal, the procedure shall be repeated until either specific fluorescence is found only in the monolayers stained with conjugate specific to the species of origin of the MCS and not in the control monolayers, or, alternately, specific fluorescence cannot be identified and the MCS is declared unsatisfactory.

(iii) Alternate tests to determine the species of origin of the MCS may be used if approved by Veterinary Services.

§ 113.53 Requirements for ingredients of animal origin.

Each lot of ingredient of animal origin, which is not subjected to heat sterilization, such as, but not limited to serum and albumin, used in the preparation of biological products shall be tested as prescribed in this section. Each lot found unsatisfactory shall not be used.

(a) General requirements.

(1) *Mycoplasma contamination.*—Samples shall be tested for mycoplasma in accordance with the test provided in § 113.28.

(2) *Bacteria and fungi.*—Samples shall be tested for bacteria and fungi in accordance with the test provided in § 113.26.

(b) Nutrient serums shall be tested according to the tests provided in this paragraph.

(1) Serum of equine origin shall be negative to the Coggins test for equine infectious anemia antibodies.

(2) Samples of the serum shall be tested in cells of the same animal origin as the serum sample using cells found satisfactory by appropriate tests in either § 113.51 or § 113.52. The growth medium shall contain 15 percent of the serum being tested. When subculturing, the serum under test shall also be used as the nutrient serum and the same medium and additives of animal origin shall be used. Monolayer cultures of test cells equal to four 75 cm^2 flasks (total area 300 cm^2) shall be used for testing, and the growth medium for the 300 cm^2 shall be 100 ml.

(3) One flask prepared as provided in subparagraph (2) of this paragraph shall be maintained for 28 days to observe for virus effects, such as cytopathogenic effect (CPE), vacuolization or giant cell formation. Between subculturings, the growth medium may be changed to maintenance medium with a lower percentage of test serum. If no evidence of viruses is observed, the flask shall be stained with a suitable stain and observed for virus induced abnormalities, such as inclusion bodies.

(4) One flask prepared as provided in subparagraph (2) of this paragraph shall be maintained for 28 days to observe for hemadsorbing and hemagglutinating viruses. Subculturing the cells may be done to maintain such cells throughout the required period. After 28 days incubation, the maintenance medium shall be decanted aseptically into a sterile container and saved for the hemagglutination test in subparagraph (5) of this paragraph. The cells shall be tested for hemadsorption as prescribed in § 113.51(c)(2).

(5) The hemagglutination test on the medium saved, as provided in subparagraph (4) of this paragraph, shall be conducted against human "O," guinea pig, and chicken erythrocytes respectively over at least 1:2 through 1:64 dilutions. Negative controls consisting of uninoculated growth medium without test serum shall be run in parallel with this test.

(6) One flask prepared as provided in subparagraph (2) of this paragraph shall be maintained for 28 days. If the cells have remained normal, they shall be disrupted by freezing and thawing. A 1.0 ml sample of disrupted cells and fluids shall be dispensed onto a monolayer of Vero cells (green monkey) or other appropriate cells and observed for an additional 14 days for virus effect.

(7) One flask prepared as provided in subparagraph (2) of this paragraph shall be maintained for 21 days and if the cells remain normal, they shall be subcultured into Leighton tubes containing coverslips. Applicable fluorescent antibody tests shall be conducted on these cells when confluent. The specific conjugates used shall include potential viral contaminants from the species from which the serum was obtained.

(8) Each lot of serum of bovine origin shall be additionally tested for the presence of adventitious BVD virus using subcultures from the flask used in subparagraph (7) of this paragraph.

(i) After two subcultures of not less than 5 days growth for each subculture, a third subculture is seeded into at least 10 Leighton tubes containing coverslips. When the cell layers are at least 80 percent confluent, five tubes of cell cultures shall be inoculated with a known strain of BVD virus as a positive control.

(ii) Five to seven days post-inoculation, all the coverslips shall be removed from the tubes, identified, processed, and stained with anti-BVD conjugate and examined for specific BVD fluorescence.

(iii) The bovine serum is satisfactory if at least four of the five inoculated cell cultures show fluorescence and none of the five uninoculated cell cultures show evidence of BVD specific fluorescence.

(iv) Specific fluorescence in cells from tubes of cell cultures not inoculated with BVD virus indicates adventitious BVD virus contamination and the lot of bovine serum tested is unsatisfactory for vaccine production.

(9) If test results disclose the presence of an adventitious agent, the material being tested shall not be used as an ingredient for biological products.

Effective date. This amendment takes effect November 29, 1973.

Done at Washington, D.C., this 24th day of October 1973.

J. M. HEJL,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.73-22965 Filed 10-29-73;8:45 am]

Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rulemaking prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 987]

DOMESTIC DATES PRODUCED OR PACKED IN RIVERSIDE COUNTY, CALIF.

Proposed Free and Restricted Percentages and Withholding Factors for 1973–74 Crop Year

Notice is hereby given of a proposal to establish, for the 1973–74 crop year, free and restricted percentages and withholding factors of 100 percent, 0 percent, and 0 percent, respectively, applicable to marketable Deglet Noor, Zahidi, Halawy, and Khadrawy dates. That crop year began October 1, 1973. The proposed percentages and withholding factors would be established in accordance with the provisions of the marketing agreement, as amended, and Order No. 987, as amended (7 CFR Part 987). The amended marketing agreement and order regulate the handling of domestic dates produced or packed in Riverside County, California, and are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674).

The free percentages, restricted percentages, and withholding factors, for the 1973–74 crop year, applicable to marketable dates, are pursuant to §§ 987.44 and 987.45. These percentages and factors are based on the California Date Administrative Committee's estimates of supply and trade demand adjusted for handler carryover. Trade demand means the aggregate quantity of whole or pitted dates which the trade will acquire from all handlers during the crop year for distribution in the continental United States, Canada, and such other countries as the Committee finds will acquire dates at prices reasonably comparable with prices received from the continental United States.

In determining the percentages, for each of the four varieties, the Committee considered the following data and estimates for the crop year beginning October 1, 1973:

	Deglet Noor	Zahidi	Halawy	Khadrawy
		(1,000 pounds)		
1. Production of marketable dates (1973–74 crop)	31,960	1,656	153	522
2. Plus: Noncertified handler carryover as of September 30, 1973, of marketable dates	347	66	16	69
3. Total marketable supply	32,307	1,722	169	591
4. Trade demand for free whole and pitted dates (continental United States and Canada)	17,500	1,600	150	450
5. Plus: Desirable handler carryover as of September 30, 1974, to assure date supplies for early demand	8,500	500	75	225
6. Less: Certified handler carryover as of September 30, 1973, of free dates	585	4	4	34
7. Need for free dates	25,415	2,096	221	641

With respect to dates of the Deglet Noor variety, it is expected that a strong overseas demand, and grade and size regulations effective during the 1973–74 crop year, will cause a portion of the total marketable supply to be exported or sold in the form of products. This quantity is expected to exceed the apparent excess of 6.9 million pounds.

All persons who desire to file written data, views, or arguments in connection with the aforesaid proposal should file the same in quadruplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, to be received not later than November 10, 1973. All written submissions made pursuant to this notice will be available for public inspection at the office of the Hearing Clerk during regular hours of business (7 CFR 1.27(b)).

The proposal is as follows:

§ 987.221 Free and restricted percentages and withholding factors.

The various free percentages, restricted percentages, and withholding factors applicable to marketable dates of each variety shall be, for the crop year beginning October 1, 1973, and ending September 30, 1974, as follows: (a) Deglet Noor variety dates: Free percentage, 100 percent; restricted percentage, 0 percent; and withholding factor, 0 percent; (b) Zahidi variety dates: Free percentage, 100 percent; restricted percentage, 0 percent; and withholding factor, 0 percent; (c) Halawy variety dates: Free percentage, 100 percent; restricted percentage, 0 percent; and withholding factor, 0 percent; (d) Khadrawy variety dates: Free percentage, 100 percent; restricted percentage, 0 percent; and withholding factor, 0 percent.

Dated October 24, 1973.

CHARLES R. BRADER,
Acting Director,
Fruit and Vegetable Division.

[FR Doc.73-23093 Filed 10-29-73;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

APPROVAL AND PROMULGATION OF STATE IMPLEMENTATION PLANS

Review of Indirect Sources

On June 18, 1973 (38 FR 15834), the Administrator of the Environmental Protection Agency (EPA) promulgated amendments to 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of State Implementation Plans, under section 110 of the Clean Air Act, as amended. Those amendments were designed primarily to provide for long-term maintenance of the national ambient air quality standards. Among other requirements, States were directed to expand their present procedures for review of buildings or other facilities prior to construction or modification in order to include consideration of the air quality impact not only of pollutants emitted directly from stationary sources, but also of pollution arising from mobile source activity associated with such buildings or facilities (termed indirect sources).

Pursuant to an order of the U.S. Court of Appeals for the District of Columbia Circuit in the case of Natural Resources Defense Council, Inc. et al v. EPA, 475 F. 2d 968 (D.C. Cir. 1973) entered on January 31, 1973, and modified March 12 and July 27, 1973, States were required to submit plan revisions to comply with the new requirements involving indirect source review by August 15, 1973 (38 FR 12920). Thus far, EPA has received plan revisions from Alabama, Florida, Puerto Rico, Guam, Maine, New York, and Oregon; they will be made available for public comment before EPA acts to approve or disapprove them. Since EPA will not take action on these revisions until the 30-day public comment period has expired, and since the Court order requires the Administrator to approve or disapprove such plan revisions by October 15, 1973, the disapproval of all State implementation plans with respect to maintenance of the national standards, as published March 8, 1973 (38 FR 6279), and amended May 17, 1973 (38 FR 12920), remains in effect.

The Court further requires the Administrator to promulgate regulations by December 15, 1973, where a State fails to submit indirect source review regulations or the regulations submitted are unapprovable. The Administrator is now proposing such regulations. Based on a preliminary review of the plan revisions submitted to date, the Administrator has