

TENNESSEE

(1) Generally infested area.

Carter County. That portion of the county bounded by a line beginning at the intersection of Walnut Mountain Road and the south shoreline of Watauga Lake; thence extending in an easterly direction along the shoreline of Watauga Lake to its intersection with the Carter-Johnson County line and extending southeast along said line to the Tennessee-North Carolina State line; thence southwest along said State line to its intersection with Walnut Mountain Road; thence northwest along Walnut Mountain Road to the point of beginning.

Johnson County. The entire county.

Loudon County. The entire county except the southeast corner lying east of the Little Tennessee River and lying south of Federal Aid Secondary Road 2423.

Roane County. That portion of the county bounded by a line beginning at the intersection of U.S. Highway 70 and Federal Aid Secondary Road 2555; thence easterly along U.S. Highway 70 to the Roane-Loudon County line; thence south along said line to its intersection with the Tennessee River; thence in a westerly direction along the north shoreline of said river to its intersection with Wolf Creek; thence north along said creek to its intersection with Federal Aid Secondary Road 2555; thence north along said road to the point of beginning.

Sullivan County. That portion of the county bounded by a line beginning at the intersection of the Tennessee-Virginia State line and the western city limits of Bristol; thence easterly along said State line to its intersection with the Sullivan-Johnson County line; thence southwesterly along said county line to its intersection with the Right Prong Hatcher Creek; thence northwesterly along said creek to its intersection with Federal Aid Secondary Road 2373; thence westerly and northerly along said road to its intersection with the Bristol City limits; thence westerly and north along said city limits to the point of beginning.

That portion of the county lying within the incorporated city boundary and the unincorporated urban boundary of the city of Kingsport.

Washington County. That portion of the county lying within the incorporated city boundary and the unincorporated urban boundary of the city of Johnson City.

(2) Suppressive area. None.

VERMONT

(1) Generally infested area. The entire State.

(2) Suppressive area. None.

VIRGINIA

(1) Generally infested area. The entire State.

(2) Suppressive area. None.

WEST VIRGINIA

(1) Generally infested area. The entire State.

(2) Suppressive area. None.

(Secs. 8 and 9, 37 Stat. 318, sec. 106, 71 Stat. 33; 7 U.S.C. 161, 162, 150ee; 29 F.R. 16210, as amended; 7 CFR 301.48-2)

This supplemental regulation shall become effective upon publication in the FEDERAL REGISTER when it shall supersede 7 CFR 301.48-2a, effective December 28, 1968.

The Director of the Plant Pest Control Division has determined that infestations of the Japanese beetle exist or are

likely to exist in the civil divisions and parts of civil divisions listed above, or that it is necessary to regulate such localities because of their proximity to infestations or their inseparability for quarantine enforcement purposes from infested localities.

The Director has further determined that each of the quarantined States, wherein only portions of the State have been designated as regulated areas, is enforcing a quarantine or regulation with restrictions on intrastate movement of the regulated articles substantially the same as the restrictions on interstate movement of such articles imposed by the quarantine and regulations in this subpart, and that designation of less than the entire State as a regulated area will otherwise be adequate to prevent the interstate spread of the Japanese beetle. Therefore, such civil divisions and parts of civil divisions listed above, are designated as Japanese beetle regulated areas.

The purpose of this revision is to add to the regulated areas all or parts of the following counties: Barrow, Fayette, Jackson, and Madison in Georgia; Jefferson, Orange, and Switzerland in Indiana; Clay, Gallatin, and Powell in Kentucky; Hancock and Seneca in Ohio; and Loudon, Roane, Sullivan, and Washington in Tennessee. It also extends the regulated areas in some previously regulated counties.

This document imposes restrictions that are necessary in order to prevent the dissemination of Japanese beetles and should be made effective promptly to accomplish its purposes in the public interest. Accordingly, it is found upon good cause under the administrative procedure provisions of 5 U.S.C. 553, that notice and other public procedure with respect to the foregoing regulation are impracticable and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Hyattsville, Md., this 3d day of November 1969.

D. R. SHEPHERD,
Director,

Plant Pest Control Division.

[F.R. Doc. 69-13300; Filed, Nov. 6, 1969; 8:48 a.m.]

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS

Commuted Traveltimes Allowances

Pursuant to the authority conferred upon the Director of the Plant Quarantine Division by § 354.1 of the regulations concerning overtime services relating to imports and exports (7 CFR 354.1), effective July 13, 1969 (34 F.R. 11548), administrative instructions (7 CFR 354.2), effective August 19, 1967, as amended February 9, 1968, April 19, 1968, July 25, 1968, December 14, 1968, February 19, 1969, June 6, 1969, July 12, 1969, August 14, 1969, and October 9,

Morgan County. The entire county.
Muskingum County. The entire county.
Noble County. The entire county.
Perry County. The entire county.
Pike County. The entire county.
Portage County. The entire county.
Preble County. The township of Jefferson.
Richland County. The entire county.
Ross County. The townships of Colerain, Franklin, Green, Harrison, Huntington, Jefferson, Liberty, Paxton, Scioto, Springfield, and Twin; and the city of Chillicothe.
Sandusky County. The city of Bellevue.
Seneca County. The townships of Jackson and Loudon; and the city of Fostoria.
Scioto County. The entire county.
Stark County. The entire county.
Summit County. The entire county.
Trumbull County. The entire county.
Tuscarawas County. The entire county.
Vinton County. The entire county.
Warren County. The townships of Deerfield, Hamilton, Harlan, Salem, and Union; and the city of Loveland.
Washington County. The entire county.
Wayne County. The entire county.
Wood County. The townships of Lake, Perry, Perrysburg, Ross, and Rossford; and the cities of Fostoria and Perrysburg.

(2) Suppressive area. None.

PENNSYLVANIA

(1) Generally infested area. The entire State.

(2) Suppressive area. None.

RHODE ISLAND

(1) Generally infested area. The entire State.

(2) Suppressive area. None.

SOUTH CAROLINA

(1) Generally infested area.

Aiken County. The entire county.
Cherokee County. The entire county.
Dillon County. The entire county.
Florence County. The entire county.
Greenville County. The entire county.
Horry County. That portion of the county bounded by a line beginning at a point where State Secondary Highway 215 junctions with Bryant Road, thence extending northeast along said road to its intersection with 29th Avenue extension, thence southeast along said extension to its junction with the corporate limits of the city of Myrtle Beach, thence in a westerly direction along said corporate limits to its intersection with State Secondary Highway 215, thence north along said highway to the point of beginning.

Lancaster County. That area bounded by a line beginning at a point where State Primary Highway 9 (Business) junctions with U.S. Highway 521 (Business) and State Primary Highway 200, said junction being approximately 1 mile southeast of the intersection of State Primary Highway 9 (Bypass) and U.S. Highway 521, thence extending south and southwest along State Primary Highway 200 to its junction with State Primary Highway 914 and State Secondary Highway 25, thence northwest along State Primary Highway 914 to its junction with State Primary Highway 9 (Business), thence northeast along said highway to the point of beginning.

Lexington County. The entire county.
Marion County. The entire county.
Marlboro County. The entire county.
McCormick County. The entire county.
Oconee County. The entire county.
Pickens County. The entire county.
Richland County. The entire county.
Spartanburg County. The entire county.
(2) Suppressive area. None.

1969 (32 F.R. 11981, 33 F.R. 2757, 5987, 10561, 18580, 34 F.R. 2351, 9025, 11547, 13148, 15636), prescribing the commuted traveltime that shall be included in each period of overtime or holiday duty, are hereby amended by adding to and deleting from the "lists" therein as follows:

§ 354.2 Administrative instructions prescribing commuted traveltime.

OUTSIDE METROPOLITAN AREA

TWO HOURS

Add: Baytown, Tex. (served from Houston, Tex.).

THREE HOURS

Delete: Baytown, Tex. (served from Houston, Tex.).

FOUR HOURS

Add: Arecibo, P.R. (served from San Juan, P.R.).

These commuted traveltime periods have been established as nearly as may be practicable to cover the time necessarily spent in reporting to and returning from the place at which the employee performs such overtime or holiday duty when such travel is performed solely on account of such overtime or holiday duty. Such establishment depends upon facts within the knowledge of the Plant Quarantine Division. It is to the benefit of the public that this amendment be made effective at the earliest practicable date. Accordingly, pursuant to the provisions of 5 U.S.C. 553, it is found upon good cause that notice and public procedure on this amendment are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making this amendment effective less than 30 days after publication in the *FEDERAL REGISTER*.

(64 Stat. 561; 7 U.S.C. 2260)

This amendment shall become effective upon publication in the *FEDERAL REGISTER*.

Done at Hyattsville, Md., this 3d day of November 1969.

[SEAL]

F. A. JOHNSTON,
Director,
Plant Quarantine Division.

[F.R. Doc. 69-13299; Filed, Nov. 6, 1969; 8:48 a.m.]

Chapter IV—Federal Crop Insurance Corporation, Department of Agriculture

PART 401—FEDERAL CROP INSURANCE

Subpart—Regulations for the 1969 and Succeeding Crop Years

APPENDIX; DISCONTINUANCE OF INSURANCE IN COUNTIES PREVIOUSLY DESIGNATED FOR POTATO CROP INSURANCE

The counties listed below are hereby deleted from the list of counties published in the *FEDERAL REGISTER* on August 26, 1969 (34 F.R. 13651), which

were designated for potato crop insurance for the 1970 crop year pursuant to the authority contained in § 401.101 of the above-identified regulations.

CALIFORNIA

Modoc.

IDAHO

Bannock.
Bingham.
Bonneville.
Canyon.
Cassia.

Jefferson.
Minidoka.
Owyhee.
Power.
Twin Falls.

OREGON

Jefferson.
Klamath.

Malheur.

WASHINGTON

Adams.
Franklin.

Grant.

(Secs. 506, 516, 52 Stat. 73, as amended, 77, as amended; 7 U.S.C. 1506, 1516)

[SEAL] RICHARD H. ASLAKSON,
Manager, Federal
Crop Insurance Corporation.

[F.R. Doc. 69-13268; Filed, Nov. 6, 1969; 8:46 a.m.]

Chapter VIII—Agricultural Stabilization and Conservation Service (Sugar), Department of Agriculture

SUBCHAPTER F—DETERMINATION OF NORMAL YIELDS AND ELIGIBILITY FOR ABANDONMENT AND CROP DEFICIENCY PAYMENTS

[Sugar Determination 847.2, Rev., Supp. 15]

PART 847—PUERTO RICO

Approved Local Producing Areas for 1968-69 Crop

Pursuant to the provisions of S.D. 847.2, as revised (27 F.R. 6080), the following determination is hereby issued:

§ 847.17 Approved local producing areas in Puerto Rico.

For purposes of considering eligibility of farms for abandonment and crop deficiency payments on the 1968-69 sugarcane crop in Puerto Rico, the Director of the Caribbean Area Agricultural Stabilization and Conservation Service Office, has determined with respect to the local producing areas listed herein, that, due to flood, the actual yields of commercially recoverable sugar for the 1968-69 crop year from 10 percent or more of the total number of farms or part of farms; or from 10 percent or more of the total planted acreage of sugarcane in each such local producing area were below 80 percent of the applicable farm normal yields:

Single wards. Wards Cidra, Corcovada, Miraflores, and Playa, of the municipality of Anasco; and Ward Quebrada Vuelitas, of the municipality of Fajardo.

STATEMENT OF BASES AND CONSIDERATIONS

One of the conditions of eligibility of a farm in Puerto Rico for an acreage abandonment or crop deficiency payment in connection with the production of sugar from sugarcane is that the farm be located in a local producing area for which the Director of the Caribbean

Area Agricultural Stabilization and Conservation Service Office determines that drought, flood, storm, disease, or insects have damaged a substantial part of the sugarcane crop in such area.

The purpose of this supplement is to set forth that the specified single wards have been determined to comprise local producing areas for the 1968-69 crop which have qualified under the requirements relating to crop damage. Any sugarcane producer on a farm which is located in whole or in part in any one of these local producing areas, and which is otherwise qualified, may apply for payment accordingly, if he has not already done so.

(Secs. 303, 403, 61 Stat. 930, 932; 7 U.S.C. 1153, 1153)

Effective date: Date of publication.

Signed at Washington, D.C., on November 3, 1969.

CHARLES M. COX,
Acting Deputy Administrator,
State and County Operations.

[F.R. Doc. 69-13264; Filed, Nov. 6, 1969; 8:45 a.m.]

Chapter IX—Consumer and Marketing Service (Marketing Agreements and Orders; Fruits, Vegetables, Nuts), Department of Agriculture

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

Expenses and Rate of Assessment and Carryover of Unexpended Funds

On October 2, 1969, notice of rule making was published in the *FEDERAL REGISTER* (34 F.R. 15361) regarding proposed expenses and the related rate of assessment for the period August 1, 1969, through July 31, 1970, and the carryover of unexpended funds, pursuant to the marketing agreement, as amended, and Order No. 906, as amended (7 CFR Part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). After consideration of all relevant matters presented, including the proposals set forth in such notice which were submitted by the Texas Valley Citrus Committee (established pursuant to said amended marketing agreement and order), it is hereby found and determined that:

§ 906.209 Expenses and rate of assessment and carryover of unexpended funds.

(a) *Expenses.* Expenses that are reasonable and likely to be incurred by the Texas Valley Citrus Committee during the period August 1, 1969, through July 31, 1970, will amount to \$660,000.

(b) *Rate of assessment.* The rate of assessment for said period, payable by each handler in accordance with § 906.34, is fixed at \$0.045 per 3/10 bushel carton.

or an equivalent quantity of oranges and grapefruit.

(c) *Reserve.* Unexpended assessment funds, in excess of expenses incurred during the fiscal period ended July 31, 1969, shall be carried over as a reserve in accordance with applicable provisions of § 906.35(a)(2) of the said marketing agreement and order.

It is hereby further found that good cause exists for not postponing the effective date hereof until 30 days after publication in the *FEDERAL REGISTER* (5 U.S.C. 553) in that (1) the relevant provisions of said marketing agreement and this part require that the rate of assessment fixed for a particular fiscal period shall be applicable to all assessable fruit from the beginning of such period, and (2) the current fiscal period began on August 1, 1969, and the rate of assessment being fixed will automatically apply to all assessable oranges and grapefruit beginning with such date.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: November 4, 1969.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Consumer and Marketing Service.

[F.R. Doc. 69-13303; Filed, Nov. 6, 1969; 8:48 a.m.]

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

Expenses of Raisin Administrative Committee and Rate of Assessment for 1969-70 Crop Year

Notice was published in the October 18, 1969, issue of the *FEDERAL REGISTER* (34 F.R. 17032) regarding proposed expenses of the Raisin Administrative Committee for the 1969-70 crop year and rate of assessment for that crop year, pursuant to §§ 989.79 and 989.80 of the marketing agreement, as amended, and Order No. 989, as amended (7 CFR Part 989), regulating the handling of raisins produced from grapes grown in California. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674).

The notice afforded interested persons opportunity to submit written data, views, or arguments with respect to the proposal. None were received during the prescribed time.

After consideration of all relevant matter presented, including that in the notice, the information and recommendations submitted by the Raisin Administrative Committee, and other available information, it is found that the expenses of the Raisin Administrative Committee and the rate of assessment for the crop year beginning September 1, 1969, shall be as follows:

§ 989.320 Expenses of the Raisin Administrative Committee and rate of assessment for the 1969-70 crop year.

(a) *Expenses.* Expenses (other than those specified in § 989.82) in the amount

of \$132,600 are reasonable and likely to be incurred by the Raisin Administrative Committee during the crop year beginning September 1, 1969, for the maintenance and functioning of the Committee and the Raisin Advisory Board and for such purposes as the Secretary may, in accordance with § 989.79, determine to be appropriate.

(b) *Rate of assessment.* The rate of assessment for that crop year which each handler is required, pursuant to § 989.80, to pay to the Raisin Administrative Committee as his pro rata share of the expenses is fixed at 85 cents per ton applicable to each of the following:

(1) Free tonnage raisins acquired by the handler during the crop year, exclusive of such quantity thereof as represents the assessable portions of other handlers' raisins pursuant to subparagraph (3) of this paragraph;

(2) Reserve tonnage raisins released or sold to the handler for use as free tonnage during the crop year; and

(3) Standard raisins (which he does not acquire) recovered by the handler by the reconditioning of off-grade raisins but only to the extent of the aggregate quantity of the free tonnage portions of these standard raisins that are acquired by other handlers during the crop year.

It is further found that good cause exists for not postponing the effective time of this action until 30 days after publication in the *FEDERAL REGISTER* (5 U.S.C. 553) in that: (1) The relevant provisions of said amended marketing agreement and order require that the rate of assessment fixed for a particular crop year which handlers are required to pay shall be applicable to all free tonnage raisins of the crop year and to all reserve tonnage raisins released or sold to handlers for use as free tonnage during the crop year; and (2) the current crop year began on September 1, 1969, and the rate of assessment fixed herein will automatically apply to all such raisins beginning with that date.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: November 3, 1969.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Consumer and Marketing Service.

[F.R. Doc. 69-13265; Filed, Nov. 6, 1969; 8:45 a.m.]

PART 991—HOPS OF DOMESTIC PRODUCTION

Subpart—Administrative Rules and Regulations

ADVANCE PAYMENTS BY EQUITY HOLDERS OF POOLED RESERVE HOPS

Notice was published in the October 18, 1969, issue of the *FEDERAL REGISTER* (34 F.R. 17032) of a proposal based upon the unanimous recommendation of the Hop Administrative Committee, whereby the Committee may require advances by equity holders of pooled re-

serve hops to cover expenses relative to such hops. This subpart is operative pursuant to Marketing Order No. 991, as amended (7 CFR Part 991), regulating the handling of hops of domestic production, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674).

The notice afforded interested persons opportunity to submit written data, views, or arguments with respect to the proposal. None were received within the prescribed time.

After consideration of all relevant matter presented, including that in the notice, the information and recommendations submitted by the Committee and other available information, it is hereby found that amendment of the administrative rules and regulations, as hereinafter set forth, will tend to effectuate the declared policy of the act.

Therefore, § 991.205 of Subpart—Administrative Rules and Regulations is hereby amended to read as follows:

§ 991.205 Advance payments by equity holders of pooled reserve hops.

As a condition of accepting and including the reserve hops of any producer-handler in the reserve pool, the Committee may require advance payments from equity holders of pooled reserve hops. Such advances shall be in an amount, as determined by the Committee, as will be necessary to meet all charges attributable to reserve pooling but shall not exceed \$4 per bale.

It is found that good cause exists for not postponing the effective time of this action until 30 days after publication in the *FEDERAL REGISTER* (5 U.S.C. 553) in that: (1) Producer-handlers are in the process of beginning to deliver reserve hops to the reserve pool; (2) should advances be required, and, if so, in what amount, equity holders should be informed as soon as possible prior to such deliveries; and (3) no useful purpose would be served by delaying the effective time hereof.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674)

Dated: November 3, 1968.

PAUL A. NICHOLSON,
Deputy Director,
Fruit and Vegetable Division.

[F.R. Doc. 69-13266; Filed, Nov. 6, 1969; 8:45 a.m.]

Title 9—ANIMALS AND ANIMAL PRODUCTS

Chapter I—Agricultural Research Service, Department of Agriculture

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

MISCELLANEOUS AMENDMENTS TO SUBCHAPTER

On July 11, 1969, there was published in the *FEDERAL REGISTER* (34 F.R. 11489) and on July 17 republished in the *FEDERAL REGISTER* (34 F.R. 12042) a notice

of proposed rule making with respect to proposed amendments to the regulations relating to viruses, serums, toxins, and analogous products in Parts 112, 113, and 114 of Title 9, Code of the Federal Regulations, issued pursuant to the provisions of the Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151-158). A notice extending the period to submit written data, views, or arguments to October 17, 1969, was published in the September 10, 1969, issue of the *FEDERAL REGISTER* (34 F.R. 14224).

After due consideration of all relevant matters, including the proposals set forth in the aforesaid notice of rule making, 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 proposed amendments of Parts 112, 113, and 114 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 in full herein, subject to the following noted modifications:

The words "Standard Requirements" have been deleted from the section headings as being repetitious and superfluous. The index has been changed accordingly.

Section 113.3(a) (1) has been clarified by deleting the word "inactivation" and inserting "safety" in (i) and rewording (ii) and (iii) to provide for random selection. Subdivision (i) has also been changed to provide for samples of bulk material.

Section 113.3(b) (4) has been clarified by deleting the words "the exclusive of" from the first sentence and rewording the second sentence.

Section 113.4(a) has been redesignated § 113.4(b) and the proviso has been deleted. Section 113.4(b) has been redesignated § 113.4(a).

Section 113.5 has been clarified by deleting the words "of day" from the second sentence of paragraph (b); by rewording the second sentence of paragraph (c) to provide for results of tests instead of test reports; and by rewording paragraph (e) to limit applicability to products not released and restrict release to products found to be satisfactory.

The word "licensed" has been deleted from § 113.6(a).

Section 113.7(b) has been rewritten for clarification. The words "at least" have been inserted in § 113.7(d).

The word "animal" has been substituted for the words "vaccination challenge" in § 113.8 (a) and (b). Section 113.8(c) has been deleted.

PART 112—LABELS

1. Part 112 is amended by deleting §§ 112.26 and 112.27. The heading and index is to read as follows:

LABELS

Sec.	
112.1	Containers.
112.2	Required and permitted information.
112.3	Diluent labels.
112.4	Reference to distributors and permittees.
112.5	Review and approval of labels and other material.

Sec.

112.6	Packaging desiccated products.
112.7	Special additional requirements.

PART 113—STANDARD REQUIREMENTS

2. Chapter I of Title 9 of the Code of Federal Regulations is amended by adding a new Part 113, reading as follows:

APPLICABILITY

Sec.	
113.1	Compliance.
113.2	Ingredients of biological products.
113.3	Sampling of biological products.
113.4	Outline of production.
113.5	General testing.
113.6	Division testing.
113.7	Multiple fractions.
113.8	Virus titrations in lieu of test for antigenicity.

AUTHORITY: The provisions of this Part 113 issued under 37 Stat. 832-833; 21 U.S.C. 151-158.

APPLICABILITY

§ 113.1 Compliance.

The regulations in this part apply to each serial or subserial of a licensed biological product manufactured in a licensed establishment and to each serial or subserial of a biological product in each shipment imported for distribution and sale.

§ 113.2 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.

§ 113.3 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 paragraphs (a) and (b) of this section. Additional samples may be purchased in the open market by a Division representative.

(a) Prerelease test samples for Division use shall be forwarded to the place designated by the Director and in the number and quantity as prescribed. Comparable samples shall be used by the licensee and permittee for similar tests.

(1) Each licensee shall select prerelease samples as follows:

(i) Nonviable liquid products—either bulk or final container samples of completed product shall be used for purity, safety, or potency tests. Biological product in final containers shall be used for sterility tests.

(ii) Viable liquid products; samples shall be in final containers and shall be randomly selected at the end of the filling operation. Samples from bulk containers of completed product may be submitted when authorized by the Director.

(iii) Desiccated 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.

(2) Each permittee shall select prerelease samples so that each serial or subserial in each shipment shall be represented.

(b) 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 the licensee or permittee. 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 35° to 45° F. for 6 months after the expiration date stated on the labels. These samples shall be stored in this manner and shall be delivered to the Division upon request.

§ 113.4 Outline of production.

(a) The test methods and procedures contained in all applicable Standard Requirements shall be complied with unless otherwise exempted by the Director and provided that such exemption is noted in the approved outline.

(b) To comply with the test requirements in § 114.8(b) of this chapter, each outline shall designate the test methods and procedures by which the biological product shall be evaluated for purity, safety, and potency.

§ 113.5 General testing.

(a) No biological product shall be released prior to the completion of required tests necessary to establish the product to be satisfactory for purity, safety, and potency.

(b) Tests of biological products shall be observed by a competent employee of the manufacturer during all critical periods. A critical period shall be the time when certain specified reactions must occur in required tests to properly evaluate the results.

(c) Records of all tests shall be kept in accordance with Part 116 of this chapter. Results of all tests shall be submitted to the Division. Blank forms shall be furnished upon request to the Veterinary Biologics Division.

(d) When a serial or subserial has not been found satisfactory by the test methods and procedures designated in § 113.4, and a repeat test is to be conducted, the same test method shall be used.

(e) When new test methods are developed and approved by the Division, biological products released thereafter shall be evaluated by such methods, and if not found to be satisfactory when so tested shall not be released.

§ 113.6 Division testing.

A biological product shall with reasonable certainty yield the results intended

when used as recommended or suggested in its labeling or proposed labeling prior to the expiration date.

(a) The Director is authorized to cause a biological product, manufactured in the United States or imported into the United States, to be examined and tested for one or more of the following: purity, safety, potency, or effectiveness; in which case, the licensee or permittee shall withhold such product from the market until a determination has been made.

(b) A serial or subserial of a biological product which has not been found satisfactory by applicable test methods or procedures is not in compliance with the regulations in Parts 101 through 121 of this subchapter and shall not be released for market.

§ 113.7 Multiple fractions.

(a) When a biological product contains more than one immunogenic fraction, the completed product shall be evaluated by tests applicable to each fraction.

(b) When similar potency tests are required for more than one fraction of a combination biological product, different animals must be used to evaluate each fraction except when written Standard Requirements or outlines of production make provisions and set forth conditions for use of the same animals for testing different fractions.

(c) When the same safety test is required for more than one fraction, requirements are fulfilled by satisfactory results from one test of the completed product.

(d) Biological products containing one or more chemically inactivated fraction(s) and one or more live virus or modified live virus fraction(s) shall be prepared as recommended for use and held at room temperature for at least 30 minutes before initiating virus titrations or potency tests.

(e) Virus titrations for a multivirus product shall be conducted by methods which will quantitate each virus.

§ 113.8 Virus titrations in lieu of test for antigenicity.

(a) The Director may exempt a live virus vaccine from a required animal test for release if the efficacy can with reasonable certainty be determined by:

(1) Testing the seed virus for potency in a manner approved by the Director; and

(2) Establishing the lowest satisfactory virus titer based on the minimum protective does plus an adequate overage allowance for uncertain conditions; and

(3) Conducting virus titrations on each serial or subserial in an accepted titration test system.

(b) One or more serials or subserials of a biological product which has been exempted from a required animal test according to the conditions in paragraph (a) of this section may be subjected to said test by the Division or the licensee. If found unsatisfactory, the biological product shall be removed from the market.

PART 114—MISCELLANEOUS REQUIREMENTS FOR LICENSED ESTABLISHMENTS

3. Part 114 is amended by deleting §§ 114.5(c), 114.13, 114.14, and 114.18.

NOTE: The reporting and/or recordkeeping requirements contained herein have been approved by the Bureau of the Budget in accordance with the Federal Reports Act of 1942.

Effective date: Thirty days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 3d day of November 1969.

R. J. ANDERSON,
Acting Administrator,
Agricultural Research Service.

[F.R. Doc. 69-13301; Filed, Nov. 6, 1969; 8:48 a.m.]

Title 14—AERONAUTICS AND SPACE

Chapter I—Federal Aviation Administration, Department of Transportation

SUBCHAPTER E—AIRSPACE

[Airspace Docket No. 69-CE-116]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Federal Airway

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to redesignate the segment of VOR Federal airway No. 430 between Havre, Mont., and Williston, N. Dak.

V-430 airway is presently designated from Havre via Glasgow, Mont., to Williston, with a south alternate segment between Glasgow and Williston. The FAA is relocating the Glasgow VOR to a new site on the Glasgow International Airport (lat. 48°12'48" N., long 106°37'07" W.) to provide better instrument approach procedures into the International Airport. The relocation of the VOR must be accomplished before inclement weather prohibits the moving of the VOR. Accordingly, action is taken herein to redesignate V-430 segment from Havre via Glasgow; INT Glasgow 100° T (083° M) and Williston 263° T. (248° M); to Williston.

Since the relocation of the VOR and the redesignation of V-430 segment must be accomplished before the onset of inclement weather and since the deviation of the new alignment from the present designation is minor in nature, notice and public procedure are impracticable and unnecessary.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 g.m.t., December 11, 1969, as hereinafter set forth.

In § 71.123 (34 F.R. 4509) V-430 is amended by deleting all between "Havre, Mont.;" and "Minot, N. Dak.;" and sub-

stituting "14 miles, 100 miles 50 MSL, Glasgow, Mont.; INT Glasgow 100° and Williston, N. Dak., 263° radials, 22 miles, 33 miles 55 MSL, Williston;" therefor.

(Sec. 307(a), Federal Aviation Act of 1958, 49 U.S.C. 1348; sec. 6(c), Department of Transportation Act, 49 U.S.C. 1655(c))

Issued in Washington, D.C., on November 3, 1969.

H. B. HELSTROM,
Chief, Airspace and Air
Traffic Rules Division.

[F.R. Doc. 69-13286; Filed, Nov. 6, 1969; 8:47 a.m.]

[Airspace Docket No. 69-80-128]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to alter the Aiken, S.C., transition area.

The Aiken transition area is described in § 71.181 (34 F.R. 4637). In the description, an extension is predicated on the 048° bearing from the Aiken RBN and has a designated width of 2 miles each side of the bearing and a length of 8 miles.

U.S. Standards for Terminal Instrument Procedures (TERPs), issued after extensive consideration and discussion with Government agencies concerned and affected industry groups, are now being applied to update the criteria for instrument approach procedures. The criteria for the designation of controlled airspace protection for these procedures was revised to conform to TERPs and achieve increased and efficient utilization of airspace.

Because of this revised criteria, it is necessary to alter the description by increasing the width of the transition area extension from 2 to 3 miles each side and the length from 8 to 8.5 miles.

In consideration of the foregoing, notice and public procedure hereon are unnecessary and Part 71 of the Federal Aviation Regulations is amended, effective immediately, as hereinafter set forth.

In § 71.181 (34 F.R. 4637), the Aiken, S.C., transition area is amended as follows: All after " * * longitude 81°41'25" W.); " * * " is deleted and " * * " within 3 miles each side of the 048° bearing from Aiken RBN (lat. 33°39'06" N., long. 81°40'38" W.), extending from the 8-mile radius area to 8.5 miles northeast of the RBN " * * " is substituted therefor.

(Sec. 307(a), Federal Aviation Act of 1958, 49 U.S.C. 1348(a), sec. 6(c), Department of Transportation Act 49 U.S.C. 1655(c))

Issued in East Point, Ga., on October 27, 1969.

JAMES G. ROGERS,
Director, Southern Region.

[F.R. Doc. 69-13282; Filed, Nov. 6, 1969; 8:45 a.m.]