§ 58.2532 Test methods.

All required tests shall be performed in accordance with DA Instruction No. 918–RL, ''Instruction for Resident Grading Quality Control Service Programs and Laboratory Analysis,'' Dairy Grading Branch, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20090–6456; the latest revision of ''Official Methods of Analysis of the Association of Official Analytical Chemists''; or the latest edition of ''Standard Methods for the Examination of Dairy Products'', available from the American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

Explanation of Terms

§ 58.2537 Explanation of terms.

(a) *With respect to flavor:*

(1) *Slight.* Detected only upon critical examination.

(2) *Definite.* Not intense but detectable.

(3) *Bitter.* Distasteful, similar to the taste of quinine.

(4) *Chalky.* A tactual type of flavor lacking in characteristic milk flavor.

(5) *Cooked.* Similar to a custard flavor and imparts a smooth aftertaste.

(6) *Feed.* Feed flavors (such as alfalfa, sweetclover, silage, or similar feed) in milk carried through into the nonfat dry milk.

(7) *Flat.* Insipid, practically devoid of any characteristic reconstituted nonfat dry milk flavor.

(8) *Oxidized.* A flavor resembling cardboard and sometimes referred to as ''cappy'' or ''tallowy''.

(9) *Scorched.* A more intensified flavor than ''cooked'' and imparts a burnt aftertaste.

(10) *Storage.* Lacking in freshness and imparting a ''stale'' aftertaste.

(11) *Utensil.* A flavor that is suggestive of improper or inadequate washing and sanitation of milking machines, utensils, or manufacturing equipment.

(b) *With respect to physical appearance:*

(1) *Practically free.* Present only upon very critical examination.

(2) *Reasonably free.* Present only upon critical examination.

(3) *Slight pressure.* Only sufficient pressure to disintegrate the lumps readily.

(4) *Moderate pressure.* Only sufficient pressure to disintegrate the lumps easily.

(5) *Grainy.* Minute particles of undissolved powder appearing in a thin film on the surface of a glass or tumbler.

(6) *Lumpy.* Loss of powdery consistency but not caked into hard chunks.

(7) *Natural color.* A color that is white to light cream.

(8) *Unnatural color.* A color that is more intense than light cream and is brownish, dull, or grey-like.

(9) *Visible dark particles.* The presence of scorched or discolored specks.

Supplement to U.S. Standards for Grades of Nonfat Dry Milk (Spray Process): U.S. Heat Treatment Classification

§ 58.2538 Basis for obtaining heat treatment classification.

Heat treatment classification is not a U.S. grade requirement except in cases when the higher solubility index specified for U.S. High-heat product is permitted. In all other instances, product submitted for USDA grading may be analyzed for heat treatment classification upon request and the results shown on the grading certificate. Heat treatment classification will be made available only upon a product graded by USDA.

§ 58.2339 Nomenclature of U.S. Heat Treatment Classification.

The nomenclature of U.S. Heat Treatment Classification is as follows:

(a) U.S. High-heat.

(b) U.S. Medium-heat.

(c) U.S. Low-heat.

§ 58.2540 Basis for determination of U.S. Heat Treatment Classification.

The whey protein nitrogen test shall be used in determining the heat treatment classification as follows:

(a) *U.S. High-heat.* The finished product shall not exceed 1.50 mg. undenatured whey protein nitrogen per gram of nonfat dry milk.

(b) *U.S. Medium-heat.* The finished product shall exceed 1.50 mg. undenatured whey protein nitrogen per gram of nonfat dry milk and shall be less than 6.00 mg. undenatured whey protein nitrogen per gram of nonfat dry milk.

(c) *U.S. Low-heat.* The finished product shall be not less than 6.00 mg. undenatured whey protein nitrogen per gram of nonfat dry milk.

§ 58.2541 Test method; whey protein nitrogen.

The whey protein nitrogen test shall be performed in accordance with DA Instruction 918–RL, ''Instruction for Resident Grading Quality Control Service Programs and Laboratory Analysis,'' Dairy Grading Branch, Dairy Division, Agricultural Marketing Service, U. S. Department of Agriculture, Washington, DC 20090–6456, or the latest edition of ''Standard Methods for the Examination of Dairy Products'', available from the American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005.

Dated: February 24, 1995.

Kenneth C. Clayton,

Acting Administrator.

[FR Doc. 95–5293 Filed 3–3–95; 8:45 am]

BILLING CODE 3410–02–P

Animal and Plant Health Inspection Service

9 CFR Parts 102, 104, 105, and 116

[Docket No. 93–072–1]

Viruses, Serums, Toxins, and Analogous Products; Licenses, Inspections, Records, and Reports

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations under the Virus-Serum-Toxin Act to clarify certain provisions concerning licenses, inspections, records, and reports. The effect of the rule is to ensure that licensees are aware of the fact that licenses are issued on the condition that the licensee permit inspection of establishments, products, and records, and that a licensee must have at least one product license in order to maintain a valid establishment license. Failure to permit inspection would make the license subject to suspension or revocation. We are also proposing amendments concerning the content of records and reports and their availability for inspection. The proposed rule is necessary to clarify and simplify certain provisions of the regulations.

DATES: Consideration will be given only to comments received on or before May 5, 1995.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 93–072–1, Animal and Plant Health Inspection Service, Regulatory Analysis and Development, Program and Policy Development, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 93–072–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to

inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Anne Goodman, Chief Staff Microbiologist, Veterinary Biologics, BBEP, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737–1237. 301–734–8245.

SUPPLEMENTARY INFORMATION: The Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151–159), as amended, is intended to ensure that veterinary biological products shipped in or from the United States are not worthless, contaminated, dangerous, or harmful. To achieve that purpose, the Act requires that such products be prepared in compliance with USDA regulations at an establishment holding an unsuspended and unrevoked USDA establishment license. No such products may be imported into the United States without a permit issued by the Administrator. Provisions regarding veterinary biological product licenses, license suspensions, and inspections appear in the regulations. See for example, 9 CFR Parts 102, 105, and 116.

The regulations currently provide in § 102.4(f) that when a licensee holding an establishment license no longer holds an unexpired, unsuspended, or unrevoked product license authorizing preparation of a product in the licensed establishment, the establishment license shall be submitted to the Administrator for termination.

Pursuant to § 102.2 of the regulations, licensees producing biological products in the United States are required to hold at least one unexpired, unsuspended, and unrevoked product license in addition to an establishment license. Therefore, and establishment license without a product license would not be valid. Section 102.2 would be amended to make this clear.

Section 102.4 would also be amended by revising paragraph (f) and by adding new paragraph (g). Paragraph (f) would be revised to provide that an establishment license is not valid unless the licensee also holds a product license, or is in the process of obtaining one. This would include activities such as requesting or filing a product license application or being involved in the development of a product. Paragraph (g) would provide that licenses for establishments where biological products are prepared shall be issued on condition that the licensee shall permit the inspection by USDA inspectors of such establishments and of products prepared in these establishments. Failure to permit such inspection could result in license suspension or revocation. This proposed change simply reflects the language in § 157 of the Virus-Serum-Toxin Act.

In § 104.6(b), editorial changes would be made to reflect organizational changes within the Animal and Plant Health Inspection Service. The words ''Veterinary Services'' would be removed and the words ''Animal and Plant Health Inspection Service'' would be added in their place.

Amendments would also be made to two sections of part 105 of the regulations which deal with suspension, revocation, or termination of biological product licenses or permits. In § 105.1, current paragraphs (a)(4) and (5) would be redesignated paragraphs (a)(5) and (6). New § 105.1(a)(4) would be added to assure that licensees, permittees, or foreign manufacturers of products that are imported under permit, maintain and make available for inspection all records relevant to the development and preparation of a product. Records and reports would be required to be complete and accurate.

Otherwise a license or permit could be subject to suspension or revocation under § 105.1. This proposed amendment to clarify the regulations is necessary because of recent incidence of noncompliance and refusal by licensees or permittees to produce requested records and reports. Since recordkeeping is already required under current § 116.8, no new paperwork burden would be imposed.

The second amendment which would be made in Part 105 is to § 105.4 concerning termination of licenses for inactivity. Proposed § 105.4(a) would specify that a product license or a permit would be terminated for inactivity unless intent to resume activity is demonstrated. Proposed § 105.4(b) would also specify that certain records be completed and retained in accordance with provisions in § 116.8. The proposed amendment would help to make the section clearer and easier to administer.

The proposed rule would also amend several sections of Part 116 which deal with records and reports. First § 116.1 would be amended to provide that detailed records and reports concerning biological products must be maintained at the establishment in which the products are produced, unless otherwise authorized (See proposed § 116.1(c)). This proposed change is necessary because of problems which have arisen during inspections involving records which were not available at the producing establishment. Since such records and reports are already required under current §§ 116.5 and 116.8, no new reporting or recordkeeping burden would be imposed.

Proposed § 116.1(b) would also be added to provide for appropriate records at the permittee's place of business. Proposed § 116.1(c) would be added to provide for maintenance of records at an alternate location. Such an alternate location would have to be confirmed by filing an addendum to the plot plan legend. The proposed amendment would provide for archiving of records, maintenance of distribution records, and compilation of consumer reports in off-premise facilities and other locations. Such archiving of records and reports should not result in paperwork burden that is greater than that already required under current §§ 116.5 and 116.8.

Section 116.5 would be amended to clarify that producers and importers of biological products may be required to submit reports containing information related to production activities or the purity, safety, potency, and efficacy of a product. The proposed amendment would clarify that APHIS be notified when a consumer report raises a question regarding purity, safety, potency, and efficacy of a product or a product is found to be unsatisfactory, or prepared, tested, or distributed in violation of the act or regulations. Again, the amendment is necessary to clarify for licensees, permittees, and foreign manufacturers the type of information that must be provided to APHIS. Since product purity, safety, potency, and efficacy remain the responsibility of licensees and permittees, no new paperwork burden would be imposed by these amendments over what is required in current part 116.

Section 116.7 would be amended to state that test summaries prepared from reports must be submitted to APHIS on Form 2008 or its equivalent prior to serial or subserial release.

Finally § 116.8, which deals with records and their retention, would be amended by including permittees in the requirement that records concerning biological products (other than disposition records) be completed prior to product marketing or export. In addition, permittees would be required to retain all records at a designated establishment or place of business for a specified period of time after the expiration date of the product. Since the permittee is normally a licensee or a representative of a foreign manufacturer, who already has recordkeeping requirements under current § 116.8, no new recordkeeping requirements would be imposed by this amendment.

Executive Order 12866 and Regulatory Flexibility Act

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

The proposed rule would amend the regulations in 9 CFR parts 102, 104, 105, and 116 to clarify existing provisions concerning licenses, inspections, records, and reports. Licenses are issued on condition that the licensee permit inspection of establishments, products, and records. The proposed rule would provide that the failure to permit such inspection would make the license subject to suspension or revocation. In order to hold a valid establishment license, licenses are required to have at least one unexpired, unsuspended, and unrevoked product license. Otherwise, the establishment license would be invalid. We are also proposing amendments concerning the content of records and reports and the availability of their inspection.

The proposed rule would make clear and unambiguous certain regulatory provisions. No new requirements are added in the proposed rule. Therefore, no adverse economic impact would result from the rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0013.

List of Subjects

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 104

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

9 CFR Part 105

Animal biologics.

9 CFR Part 116

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 102, 104, 105, and 116 would be revised as follows:

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

1. The authority citation for part 102 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 102.2, the introductory paragraph would be designated as paragraph (a) and a new paragraph (b) would be added to read as follows:

§ 102.2 Licenses required.

* * * * *

(b) An applicant who applies for an establishment license must also apply for at least one product license. An establishment license will not be issued without a license authorizing the production of a biological product in the establishment.

3. In § 102.4, paragraph (f) would be revised, paragraphs (g) and (h) would be redesignated as paragraphs (h) and (i), respectively, and new paragraph (g) would be added to read as follows:

§ 102.4 U.S. Veterinary Biologics Establishment License.

* * * * *

(f) When a licensee no longer holds at least one unexpired, unsuspended, or unrevoked product license authorizing the preparation of a biological product, or is in the process of obtaining a product license, the establishment license shall no longer be valid and shall be returned to the Administrator. In the case where an establishment license expires or is suspended or revoked, any product license authorizing preparation of a product at such establishment shall be invalid indefinitely or for as long as the suspension is in effect.

(g) Any license issued under this Part to establishments in which biological products are prepared shall be issued on condition that the licensee permit the inspection of such establishments, products, product preparation, and all relevant records as provided in Part 115. Failure to permit inspection may result in the license being suspended or revoked.

* * * * *

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

4. The authority citation for part 104 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

§ 104.6 [Amended]

5. In § 104.6, paragraph (b), the words ''Veterinary Services'' would be removed and the words ''Animal and Plant Health Inspection Service'' would be added in their place.

6. In 9 CFR part 105, the heading for the part would be revised to read as follows:

PART 105—SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS

7. The authority citation for part 105 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

8. In § 105.1, paragraphs (a)(4) and (a)(5) would be redesignated paragraphs (a)(5) and (a)(6), new paragraph (a)(4) would be added, and redesignated paragraph (a)(5) would be revised to read as follows:

§ 105.1 Suspension or revocation.

* * * * *

(a) * * *

(4) The licensee, permittee, or the foreign manufacturer has failed to maintain and make available for inspection records in connection with the development and preparation of product, has failed to provide complete and accurate information when requested, or has failed to provide complete and accurate information in the Outline of Production or in reports and records;

(5) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations in this subchapter;

* * * * *

9. Section 105.4 would be revised to read as follows:

§ 105.4 Termination of licenses and permits for inactivity.

(a) If a biological product has not been prepared by a licensee, or imported by a permittee for a period of five years or more, the Administrator may require the licensee to show intent to resume production, or the permittee to show intent to resume importation, within six months of notification. If the licensee does not resume preparation, or the permittee does not resume importation, within six months of notification, or within a mutually agreeable period, the product license, or permit, may be terminated by the Administrator.

(b) When a license or permit is terminated, the licensee or permittee shall continue to be subject to applicable records provisions of § 116.8.

10. In 9 CFR part 116, the heading for the part would be revised to read as follows:

PART 116—RECORDS AND REPORTS

11. The authority citation for part 116 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

12. In § 116.1, paragraphs (a), (b) and (c) would be redesignated as paragraphs (a)(1), (a)(2), and (a)(3), respectively; redesignated paragraph (a)(1) would be revised; the introductory paragraph would be designated as paragraph (a) and would be revised; and new paragraphs (b) and (c) would be added to read as follows:

§ 116.1 Applicability and general considerations.

(a) Each licensee, permittee, and foreign manufacturer of biological products imported into the United States shall maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within such establishment. Such records shall include, but shall not be limited to, the items enumerated in this part.

(1) Records shall be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any gain or loss of product from the beginning to the end of product preparation.

* * * * *

(b) In the case of imported products, each permittee shall maintain at the permittee's place of business detailed and accurate records that are relevant to each imported product and that include, but are not limited to, importation documents, sampling records, tests summaries, shipping records, and inventory and disposition records as required in § 116.2.

(c) When authorized by the Administrator, the licensee, permittee, or foreign manufacturer may maintain and retain records required under part 116 at an alternative location. Such authorization shall be confirmed by the filing of an addendum to the plot plan legend. The addendum shall list the location of the records and the condition of their storage and shall permit the inspection of the records by APHIS inspectors, or foreign inspectors acting on behalf of APHIS.

(Approved by the Office of Management and Budget under control number 0579–0013)

§§ 116.2, 116.3, 116.4, and 116.6 [Amended]

13. At the end of §§ 116.2, 116.3, 116.4, and 116.6, the reference to OMB control number ''0579–0059'' would be removed and the number ''0579–0013'' would be added in its place.

14. Section 116.5 would be revised to read as follows:

§ 116.5 Reports.

(a) When required by the Administrator, reports containing accurate and complete information concerning biological products, including but not limited to, product development and preparation, consumer reports, and market suspensions and recalls, shall be prepared and submitted to the Animal and Plant Health Inspection Service by the licensee, permittee, or foreign manufacturer whose products are being imported or offered for importation. Unless otherwise authorized by the Administrator, records necessary to make such reports shall be maintained in each establishment.

(b) If, at any time, consumer reports concerning the use of products raise questions regarding purity, safety, potency, or efficacy of the products; or a biological product appears to be unsatisfactory or is found to have been prepared, tested, or distributed in violation of the Virus-Serum-Toxin Act or the regulations; the licensee, permittee, or foreign manufacturer shall immediately report the circumstances and the action taken, if any, to the Animal and Plant Health Inspection Service.

(Approved by the Office of Management and Budget under control number 0579–0013)

15. In § 116.7, the second sentence would be revised to read as follows:

§ 116.7 Test records.

* * * Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. * * *

* * * * *

16. Section 116.8 would be revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

Done in Washington, DC, this 28th day of February 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–5406 Filed 3–3–95; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Parts 102 and 114

[Docket No. 93–136–1]

Viruses, Serums, Toxins, and Analogous Products; State-Federal Licensure of Veterinary Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning State-Federal licensing of veterinary biological products. The effect of the amendment would be that a Federally licensed establishment would not be allowed to produce the same veterinary biological product under both a State and Federal product license. Autogenous biologics would not be subject to the same requirement, in that a Federally licensed establishment could hold both State and Federal product licenses for autogenous biologics, but must choose to produce each specific serial of such biologic