

establishments, including permittees. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

We do not expect that this rule will impose any additional testing or economic burden on these manufacturers because manufacturers currently test their products for moisture content by methods specified in their filed Outline of Production and the reagents and equipment necessary to perform the gravimetric test for moisture content that will be required under this rule are expected to be comparable in cost.

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

Executive Order 12372

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

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

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

List of Subjects in 9 CFR Part 113

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

■ Accordingly, we are amending 9 CFR part 113 as follows:

PART 113—[AMENDED]

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

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 113.29 is revised to read as follows:

§ 113.29 Determination of moisture content in desiccated biological products.

Methods provided in this section must 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. Firms currently using methods other than those provided in this section for determining the moisture content in desiccated biological products have until November 5, 2004 to update their Outlines of Production to be in compliance with this requirement.

(a) Final container samples of completed product shall be tested. The weight loss of the sample due to drying in a vacuum oven shall be determined. All procedures should be performed in an environment with a relative humidity less than 45 percent. The equipment necessary to perform the test is as follows:

(1) Cylindrical weighing bottles with airtight glass stoppers.

(2) Vacuum oven equipped with validated thermometer and thermostat. A suitable air-drying device should be attached to the inlet valve.

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

(4) Desiccator jar equipped with phosphorous pentoxide, silica gel, or equivalent.

(5) Desiccated vaccine in original sealed vial. Sample and control should be kept at room temperature in their original airtight containers until use.

(b) Test procedure:

(1) Thoroughly cleaned and labeled sample-weighing bottles with stoppers should be allowed to dry at 60 ± 3 °C under vacuum at less than 2.5 kPa.

(i) Transfer hot bottles and stoppers into the desiccator and allow to cool to room temperature.

(ii) After bottles have cooled, insert stoppers and weigh and record the weights of the bottles as "A."

(iii) Return weighing bottles to the desiccator.

(2) Remove the sample container seal.

(i) Using a spatula, break up the sample plug and transfer the required amount of sample to the previously tared weighing bottle.

(ii) Insert the stopper and weigh and record the weights of the weighing bottles as "B."

(3) Place the weighing bottle with the stopper at an angle in the vacuum oven. Set the vacuum to < 2.5 kPa and the temperature to 60 ± 3 °C.

(4) After a minimum of 3 hours of drying time, turn off the vacuum pump and allow dry air to bleed into the oven until the pressure inside the oven is equalized with the prevailing atmospheric pressure.

(5) While the bottle is still warm, replace the stopper in its normal position and transfer the weighing bottle to the desiccator.

(i) Allow a minimum of 2 hours for the weighing bottle to cool to room temperature or for its weight to reach equilibrium.

(ii) Weigh, and record the weight as "C."

(6) Calculate the percentage of moisture in the original sample as follows:

$(B - C)/(B - A) \times (100)$ = Percentage of residual moisture, where:

A = tare weight of weighing bottle

B - A = weight of sample before drying

B - C = weight of sample after drying

(7) The results are considered satisfactory if the percentage of residual moisture is less than or equal to the manufacturer's specification.

■ 3. In § 113.64, paragraph (e) is amended by adding a new paragraph (e)(3) to read as follows:

§ 113.64 General requirements for live bacterial vaccines.

* * * * *

(e) * * *

(3) Final container samples of completed product from each serial and subserial must be tested for moisture content in accordance with the test provided in § 113.29.

■ 4. Section 113.300 is amended by revising paragraph (e) to read as follows:

§ 113.300 General requirements for live virus vaccines.

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(e) *Moisture content.* (1) The maximum moisture content in desiccated vaccines must be stated in the filed Outline of Production.

(2) Final container samples of completed product from each serial or subserial must be tested for moisture content in accordance with the test prescribed in § 113.29.

Done in Washington, DC, this 30th day of September 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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