The proposed amendments under § 114.2(c) would require that autogenous biological products produced in a USDA-licensed establishment be identified as produced under the provisions of the State license or the Federal license at the time that a culture of microorganisms (the isolate) is received at the establishment. If, after producing the product pursuant to one license, the licensee elects to produce an autogenous biologic from the same isolate under the other license, approval of the other licensing authority would have to be obtained.

In addition, the proposed amendment would require that a State-licensed autogenous biologic prepared in a Federally licensed establishment bear a "true name" indicating the State of licensure, such as "(name of State) Autogenous Bacterin" or "(name of State) Autogenous Vaccine."

# 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The effect of the proposed rule would be to remove outdated sections from the regulations in §§ 102.1 and 102.4(h) and § 114.2 (b) and (d). These sections refer to outdated provisions related to the implementation of the 1985 amendments to the Virus-Serum-Toxin Act. These provisions expired on June 30, 1991.

The proposed rule would also establish conditions applicable to some 100 producers to prepare a biological product under either a State or USDA product license in a USDA licensed establishment. An exception would be provided for autogenous biologics. The proposed amendment would not have an adverse economic impact on these producers of biologics since it would still allow the production of both State and Federally licensed products in Federally licensed establishments. Therefore, it is not anticipated that the amendment would impose economic burdens on producers or small businesses.

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**

This document contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

## **List of Subjects**

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 114

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 102 and 114 would be amended 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).

### §102.1 [Revised]

2. Section 102.1 would be revised to read as follows:

Each establishment qualified to prepare biological products under the Virus-Serum-Toxin Act shall hold an unexpired and unrevoked U.S. Veterinary Biologics Establishment License issued by the Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment unless the product is subject to the provisions of 9 CFR parts 103 or 106 of this subchapter.

## §102.4 [Amended]

- 3. In § 102.4, paragraph (b)(3), the words "Veterinary Services" are removed and the words "Animal and Plant Health Inspection Service" are added in their place.
- 4. In § 102.4, paragraph (h) would be removed.

#### §102.6 [Amended]

5. In § 102.6, in the introductory paragraph and paragraph (a), the term "Deputy" is removed.

### PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

6. The authority citation for part 114 would be revised to read as follows:

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

7. Section 114.2, paragraphs (b) and (d) would be removed; paragraph (c) would be redesignated paragraph (b) and revised; and a new paragraph (c) would be added to read as follows:

## § 114.2 Products not prepared under license.

\* \* \* \* \*

- (b) Except as provided in 9 CFR part 103, a biological product shall not be prepared in a licensed establishment unless the person to whom the establishment license is issued holds an unexpired, unsuspended, and unrevoked product license issued by the Administrator to prepare such biological product, or unless the products prepared are subject to the provisions of § 107.2 of this subchapter.
- (c) A biological product produced in a USDA-licensed establishment shall be produced under a U.S. Veterinary Biological Product License or a License granted by a State under § 107.2 (referred to as a State biological product license and the products prepared pursuant thereto as State-licensed biological products, including autogenous biologics), but not under both a U.S. Veterinary Biological Product License and a State biological product license. Before a U.S. Veterinary Biological Product License (including a conditional license) is issued, the licensee shall relinquish its State license for that product: Provided, That autogenous biologics shall not be subject to this provision when they are prepared in accordance with the provisions of paragraph (c)(5) of this
- (1) State-licensed biological products (including autogenous biologics) shall only be distributed or shipped intrastate, must not bear a U.S. Veterinary Biologics Establishment License Number, and must not otherwise be represented in any manner as having met the requirements for a U.S. Veterinary Biological Product license. Labeling of State- and USDA-licensed biological products produced in the same establishment must be distinctly different in color and design.