Proposed Rules

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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 rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 101

[Docket No. 99–040–1]

Viruses, Serums, Toxins, and Analogous Products; Definitions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations by adding a definition of the term *dog* to include all members of the species *Canis familiaris, Canis lupus,* or any dog-wolf cross. APHIS believes that dogs, wolves, and any dog-wolf cross can be safely and effectively vaccinated with canine vaccines. This action would allow canine vaccines that are recommended for use in dogs to be recommended for use in wolves and any dog-wolf cross.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by November 29, 1999.

ADDRESSES: Please send your comment and three copies to: Docket No. 99–040–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 99–040–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Operational Support Section, Center for Veterinary Biologics, Licensing and Policy Development, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 112 set forth packaging and labeling requirements for veterinary biological products. The Animal and Plant Health Inspection Service (APHIS) requires a product's label to identify the animals for which the product has been demonstrated to be effective and safe. Paragraph (b) of § 113.209 requires a rabies vaccine to be tested for immunogenicity in each species for which it will be recommended. Therefore, rabies vaccines recommended for use in dogs may be tested in any member of the species historically named *Canis familiaris* and recommended for use in breeds of dog of the species *Canis familiaris.*

In 1993, the second edition of ''Mammal Species of the World, A Taxonomic and Geographic Reference,'' stated that domestic dogs, formerly identified as *Canis familiaris,* were a member of the species *Canis lupus,* which is the grey wolf. This publication is widely accepted as the standard for mammalian taxonomy. However, there is disagreement within the expert community.

In 1995, as a result of reclassifying dogs into the species *Canis lupus,* owners of wolves and dog-wolf crosses petitioned APHIS to recognize rabies vaccines approved for use in dogs as effective in wolves and dog-wolf crosses. The petitioners pointed out that many jurisdictions do not recognize the vaccination of wolves and dog-wolf crosses against rabies. Therefore, if these animals are involved in an incident in which rabies vaccination is an issue, they may be subject to euthanasia.

In April 1996, after consulting with taxonomists regarding the petition, APHIS hosted a meeting in Riverdale, MD, to review the issues of whether dogs and wolves were members of the same species *Canis lupus* and whether rabies vaccines recommended for use in dogs should be considered effective in wolves and any dog-wolf cross. Experts from the disciplines of animal taxonomy, molecular genetics, veterinary immunology, wildlife biology, and veterinary public health attended the meeting. During the meeting, there was disagreement as to whether dogs and wolves belonged to the same species, but there was consensus that inactivated rabies vaccines should be safe and effective in wolves and any dog-wolf cross. It was proposed that if rabies vaccines could be assumed to be safe and effective in wolves and dog-wolf crosses, then modified live vaccines against other dog diseases should also be safe and effective in wolves and dog-wolf crosses. However, the experts could not agree to this proposal without data demonstrating the safety of modified live canine vaccines in wolves and dog-wolf crosses. Without a clear consensus that the immune systems of wolves and dogs were equivalent, APHIS took no action at that time to allow canine vaccines that were recommended for use in dogs to be recommended for use in wolves and any dog-wolf cross.

As a follow up to the meeting, wolf and dog-wolf cross fanciers submitted supplemental data to support the use of modified live canine vaccines in wolves and dog-wolf crosses. The data indicated that 216 wolves and 460 dog-wolf crosses were vaccinated with various modified live canine vaccines without any reported adverse reactions attributable to the vaccines. Many of these animals received multiple vaccinations over several years. These data provide only limited statistical inference; however, the fact that wolves and dog-wolf crosses share the same environment with dogs and have similar exposure to disease agents with ample evidence of protection against those diseases for which the animals were vaccinated provide strong evidence that wolves and dog-wolf crosses respond to canine vaccines in a manner similar to dogs. Further, the lack of reported adverse reactions after vaccination provides strong epidemiological evidence that wolves and dog-wolf crosses respond to canine vaccines in a manner similar to dogs. In addition, manufacturers of canine vaccines acknowledge that their products have

been used extensively in wolves and dog-wolf crosses with no reported adverse reactions.

Based upon the above, APHIS believes that dogs, wolves, and any dog-wolf cross can be safely and effectively vaccinated with canine vaccines. Therefore, we are proposing to add a definition of *dog* to 9 CFR part 101 to include all members of the species *Canis familiaris, Canis lupus,* or any dog-wolf cross. This would allow canine vaccines recommended for use in dogs to be recommended for use in wolves and any dog-wolf cross. Manufacturers who wish to include wolves and dog-wolf crosses on the labels for their canine vaccines could add these animals to the labels. APHIS believes that, even without this change, all canine vaccines labeled for use in dogs would be accepted as being safe and effective in wolves and any dog-wolf cross. If manufacturers wish to include wolves and any dog-wolf cross on their labels, the labels would first need to be approved by and filed with APHIS.

We would not require additional efficacy and safety studies to be performed; however, manufacturers could perform additional efficacy and safety studies, at their discretion, prior to recommending the use of their canine vaccines in wolves and any dog-wolf cross.

Executive Order 12866 and Regulatory Flexibility Act

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

This proposed rule would amend the Virus-Serum-Toxin Act regulations by adding a definition of the term *dog* to include all members of the species *Canis familiaris, Canis lupus,* or any dog-wolf cross. As a consequence, canine vaccines that are recommended for use in dogs could also be recommended for use in wolves and any dog-wolf cross. Manufacturers could include wolves and any dog-wolf cross on the labels for their canine vaccines. The labels would need to be approved by and filed with APHIS.

This proposed rule would affect all licensed veterinary biologics establishments that produce vaccines for use in dogs. Currently, there are approximately 150 veterinary biologics establishments. According to the standards of the Small Business Administration, most of these establishments would be classified as small entities, and approximately 10 percent of these establishments currently produce vaccines for use in dogs. Because the efficacy and safety of licensed canine vaccines have already been demonstrated in accordance with the regulations, and because this proposed rule does not require manufacturers to replace labels for their products for use in wolves and any dog-wolf cross, any additional costs manufacturers would incur if this proposed rule is adopted should be minimal.

Currently, manufacturers of veterinary biological products do not recommend canine vaccines for use in wolves and any dog-wolf cross. Under this proposed rule, if manufacturers recommend their canine vaccines for use in wolves and dog-wolf crosses, additional efficacy and safety data would not be required. Therefore, manufacturers would not incur any additional costs as a result of the rule. This proposed rule would not restrict manufacturers from using their discretion to elect to perform additional efficacy and safety studies prior to recommending the use of their canine vaccines in wolves and dog-wolf crosses. However, if a canine vaccine is used on wolves or dog-wolf crosses in accordance with the label recommendations, this proposed rule would not relieve the manufacturer of responsibility for the performance of the product (e.g., adverse reactions).

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The 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 proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects in 9 CFR Part 101

Animal biologics.

Accordingly, we propose to amend 9 CFR part 101 as follows:

PART 101—DEFINITIONS

1. The authority citation for part 101 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 101.2, a definition of ''dog'' would be added in alphabetical order to read as follows:

§ 101.2 Administrative terminology.

* * * * *

Dog. All members of the species *Canis familiaris, Canis lupus,* or any dog-wolf cross.

* * * * *

Done in Washington, DC, this 22nd day of September 1999.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–25177 Filed 9–27–99; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket No. EE–RM/TP–99–500]

RIN 1904–AA52

Energy Conservation Program for Consumer Products: Test Procedure for Dishwashers

AGENCY: Office of Energy Efficiency and Renewable Energy.

ACTION: Notice of proposed rulemaking and public workshop.

SUMMARY: The Department of Energy (We, DOE, or the Department) is proposing to amend its test procedure for dishwashers. The proposal adds test procedures for dishwashers with soil-sensing technology. It also revises some of the inputs for calculating the estimated annual operating cost, adds new specifications to improve testing