The Coalition's campaign features the trench-coated, floppy-eared dog, McGruff, popularized on radio and television and in newspapers and magazines. His message is basic and direct: We can all "Take a Bite Out of Crime" by playing a role in neighborhood block watches, citizen patrols, escort services for the elderly and the vulnerable, and similar activities and by taking a few simple precautions.

The Congress, by Senate Joint Resolution 121, has designated August 11, 1987, as "National Neighborhood Crime Watch Day" and has authorized and requested the President to issue a proclamation in observance of this event.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim August 11, 1987, as National Neighborhood Crime Watch Day. I call upon the people of the United States to spend the period from 8:00 p.m. to 9:00 p.m. on that date with their neighbors in front of their homes to demonstrate support for community crime watch programs and to signal to criminals that neighborhoods are joining together to fight crime.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of August, in the year of our Lord nineteen hundred and eighty-seven, and of the Independence of the United States of America the two hundred and twelfth.

Ronald Reagan

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Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210, 215, and 220

Elimination of the Private School Tuition Limitation

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This rule eliminates the tuition limitation that previously prohibited private schools charging over $2,000 in annual tuition from participation in the school nutrition programs authorized under the National School Lunch Act and the Child Nutrition Act of 1966. The programs affected are the National School Lunch Program, Part 210; the Special Milk Program, Part 215; and the School Breakfast Program, Part 220. This amendment is required by Pub. L. 100–71, which was enacted on July 11, 1987.

EFFECTIVE DATE: July 1, 1987.

FOR FURTHER INFORMATION CONTACT: Mr. Lou Pastura, Chief, Policy and Program Development Branch, Child Nutrition Division, FNS, USDA, Alexandria, Virginia 22302; (703) 756–3620.

SUPPLEMENTARY INFORMATION:

Classification

This rule eliminates the private school tuition limitation as specifically prescribed by statute and therefore is nondiscretionary. For this reason, the Administrator of the Food and Nutrition Service has determined, in accordance with 5 U.S.C. 553(b) and 553(d), that prior notice and comment are unnecessary and contrary to the public interest and that good cause exists for making the rule effective upon publication. Further, the rule relieves a restriction and pursuant to 5 U.S.C. 553(d) may be made effective upon publication.

This final rule has been reviewed under Executive Order 12291 and has been classified as not major because it does not meet any of the three criteria identified under the Executive Order. This action will not have an annual effect on the economy of $100 million or more, nor will it result in major increases in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Furthermore, it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Administrator of the Food and Nutrition Service has certified that this rule will not have a significant economic impact on a substantial number of small entities.

This action imposes no new reporting or recordkeeping requirements that are subject to Office of Management and Budget (OMB) review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520). The programs being amended are approved by OMB under the following control numbers: National School Lunch Program, 0584–0006; Special Milk Program, 0584–0005; and School Breakfast Program, 0584–0012.

The National School Lunch, Special Milk, and School Breakfast Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, 10.556 and 10.553, respectively; and are subject to the provision of Executive Order 12372 which requires intergovernmental consultation with State and local officials. (7 CFR Part 3015, Subpart V and 48 FR 29112, June 24, 1983.)

Background

The Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, excluded private schools with an average yearly tuition exceeding $1,500 per child from participating in the National School Lunch Program, Special Milk Program, and School Breakfast Program. Subsequently, Pub. L. 99–661 increased the private school tuition limit to $2,000 effective October 1, 1986 and provided for future indexing for inflation. The program regulations were amended to reflect the $2,000 limit on March 12, 1987 (52 FR 7559).

Current Legislation

Public Law 100–71 amended section 12(d)(5) of the National School Lunch Act (42 U.S.C. 1760(d)(5)) and section 15(c) of the Child Nutrition Act of 1966 (42 U.S.C. 1784(c)) to remove the tuition limitation previously imposed on private schools as a condition of eligibility for participation in the school nutrition programs. Public Law 100–71 specifies an effective date of July 1, 1987. Therefore, all private schools are now eligible to apply for participation in any of the school nutrition programs authorized under the Nation School Lunch Act and Child Nutrition Act.

List of Subjects

7 CFR Part 210

Food assistance programs, Nation School Lunch Program, Commodity School Program, Grant programs—social programs, Nutrition, Children, Reporting and recordkeeping requirements, Surplus agricultural commodities.

7 CFR Part 215

Food assistance programs, Special Milk Program, Grant program—social programs, Nutrition, Children, Milk, Reporting and recordkeeping requirements.

7 CFR Part 220

Food assistance programs, School Breakfast Program, Grant programs—social programs, Nutrition, Children, Reporting and recordkeeping requirements.

Accordingly, Parts 210, 215, and 220 are amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

1. The authority citation for Part 210 continue to read as follows:

Authority: Sec. 2–12, 60 Stat. 230, as amended; Sec. 10, 80 Stat. 889, as amended; 84 Stat. 270; 42 U.S.C. 1751–1760, 1779.

§ 210.2 [Amended]

2. Section 210.2 is amended as follows:

a. The definition, "High tuition private school" is removed;

b. In the definition of "School", the first sentence in paragraph (a) is amended by removing the semicolon after the word "buildings" and adding a period in its place and removing the remainder of the sentence; and

c. The definition "Tuition" is removed.

PART 215—SPECIAL MILK PROGRAM

1. The authority citation for Part 215 continues to read as follows:

Authority: Sec. 3, 10; 80 Stat. 885, 889, as amended (42 U.S.C. 1772, 1779).

§ 215.2 [Amended]

2. Section 215.2 is amended as follows:

a. Paragraph (k–1) "High tuition private school" is removed;

b. The first sentence in paragraph (v)(1) is amended by removing the semicolon after the word "buildings" and adding a period in its place and removing the remainder of the sentence; and

c. Paragraph (bb) "Tuition" including subparagraphs (1) and (2), and paragraph (cc) "Special needs children" are removed.

PART 220—SCHOOL BREAKFAST PROGRAM

1. The authority citation for Part 220 continues to read as follows:

Authority: Secs. 4 and 10, 80 Stat. 886, 889 (42 U.S.C. 1773, 1779).

§ 220.2 [Amended]

2. Section 220.2 is amended as follows:

a. Paragraph (j–1) "High tuition private school" is removed;

b. The first sentence in paragraph (u)(1) is amended by removing the semicolon after the word "buildings" and adding a period in its place and removing the remainder of the sentence; and

c. Paragraph (bb) "Tuition", including subparagraphs (1) and (2), and paragraph (cc) "Special needs children" are removed.

Date: August 5, 1987.

Anna Kondratas,

Administrator.

[FR Doc. 87–18522 Filed 8–12–87; 8:45 am]

BILLING CODE 3410-30-M

Animal and Plant Health Inspection Service

9 CFR Parts 101, 102, 103, 104, 107, and 114

[Docket No. 87–029]

Viruses, Serums, Toxins, and Analogous Products; Experimental Products and Exempted Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Security Act of 1985 amended the Virus-Serum-Toxin Act of 1913 (VST Act) to give the Secretary of Agriculture jurisdiction over intrastate as well as interstate shipments of animal biologics, subject to certain exemptions. Products which are exported are now also subject to the Act. Under the VST Act, it is unlawful to import or to ship in or from the United States animal biologics that are worthless, contaminated, dangerous, or harmful. It is also unlawful to ship animal biologics which are manufactured within the United States and intended for use in the treatment of animals unless they are prepared in compliance with regulations prescribed by the Secretary in a properly licensed establishment.

This final rule amends the regulations in several respects so that they conform to the 1985 amendments of the Act. It prescribes exemptions relevant to products prepared by a person for administration to that person's own animals, and products prepared by a veterinarian solely for administration to animals under that veterinarian's client-patient relationship. It also prescribes exemptions relevant to those products which are prepared solely for distribution within the State of production pursuant to an approved State licensing program, and makes other conforming changes.

In order to assure that public concern for the environment, and the health and safety of both humans and animals are properly addressed, this amendment also addresses environmental aspects of the use of biological products, especially those containing live organisms.

EFFECTIVE DATE: September 14, 1987.

FOR FURTHER INFORMATION CONTACT: Dr. Peter L. Joseph, Senior Staff Veterinarian, Veterinary Biologics Staff, VS, APHIS, USDA, Room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–6332.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

This rule contains no new or amended recordkeeping, reporting, or application requirements or any type of information collection requirement subject to the Paperwork Reduction Act of 1980.

Executive Order 12291

This rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1512–1, and has been classified as a "Non-major Rule."

This action will not have a significant effect on the economy and will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It will also not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises, in domestic markets.

Certification Under the Regulatory Flexibility Act

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. Its purpose is to prescribe procedures and criteria with respect to exemptions and other provisions mandated by the Virus-Serum-Toxin Act, as amended.

Background

In amending the Virus-Serum-Toxin Act of 1913 (VST Act), the Food Security Act of 1985 expanded the Department's authority over veterinary biologics in several respects. Under the amended statute, it is unlawful to ship or deliver for shipment any worthless, contaminated, dangerous, or harmful veterinary biologic intended for use in the treatment of animals anywhere in or from the United States. The preparation of such products in the District of Columbia, the Territories, or in any place under the jurisdiction of the United States is also prohibited. Previously, intrastate shipments and exports were not subject to the VST Act. It is also unlawful (subject to certain exemptions) to ship veterinary biologics, manufactured within the United States and intended for use in the treatment of animals, in or from the United States, unless they were prepared in compliance with regulations prescribed by the Secretary of Agriculture in an establishment licensed by the Secretary. Products prepared in the District of Columbia, in the Territories, or in any

place under the jurisdiction of the United States must be prepared pursuant to a license. The amendment expands the Secretary's rulemaking authority by authorizing the promulgation of any rules and regulations deemed necessary to carry out the purposes of the Act (the main purpose being to prevent the distribution of worthless, contaminated, dangerous or harmful veterinary biologics for use in the treatment of animals, *i.e.*, diagnosis, prevention, and cure of disease). The Secretary is also authorized to inspect any establishment preparing animal biologics at any hour, day or night. Previously, only licensed establishments were subject to such inspection. Additionally, the amended statute contains provisions for detention, seizure, and condemnation of products. It also provides for injunctive relief and penalties for assaulting or resisting Department officials during their performance of official duties under the Act.

The current regulations in 9 CFR 103.3 contain widely used provisions for the interstate shipment of unlicensed biological products for experimental use in domestic animals for the purpose of evaluating such products. These products have been shipped for a variety of reasons, but mainly for field safety studies prior to licensing and release of the products for use in the general treatment of animals. Because of the expanded jurisdiction under the 1985 amendment to the VST Act, this revision amends § 103.3 of the regulations by deleting the reference to interstate shipments and by adding a provision for exports. This will have the effect of making the provisions of the section applicable to all shipments subject to the Act. The shipment of unlicensed biological products for experimental treatment of animals anywhere in or from the United States is prohibited without prior authorization by the Deputy Administrator. Requests for authorization must be accompanied by information specified in the regulations, including information relevant to the product's effect on the environment. Additional safeguards and tests may be required in the case of products which contain live organisms and which are prepared either through conventional means or through the use of biotechnology. For the purposes of the VST Act, the term "ship" shall be used in its broadest sense. It shall mean transportation by any means from one place to another and shall be synonymous with delivering for shipment.

Part 104 is amended by revising § 104.4 pertaining to biological products imported for research and evaluation. Section 104.4(a) is revised by stating that a permittee may be required to provide any information needed to properly assess an imported product's impact on the environment. Section 104.4(b) is amended by prohibiting any permittee or research investigator from shipping a product, imported under § 104.4, in or from the United States unless authorization to do so is obtained pursuant to the provisions of § 103.3 of the regulations.

The 1985 amendment of the VST Act provides that the Secretary shall exempt by regulation from the requirement of preparation pursuant to a license any animal biologics prepared by a person, firm, or corporation: (1) Solely for administration to animals of such person, firm, or corporation; (2) solely for administration to animals under a veterinarian-client-patient relationship in the course of such person's, firm's, or corporation's practice of veterinary medicine; and (3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet certain specified criteria. Certain provisions of the Act are still applicable to such animal biologics, regardless of whether or not they are exempted from the licensing provisions. Anyone shipping products which are worthless, contaminated, dangerous, or harmful is subject to the sanctions under the Act, including detention, seizure, and condemnation. A new Part 107 provides for the exemptions specified in the amendment to the Act. The regulations include conditions to be met in order to establish a valid veterinarian-client-patient relationship. Such conditions have been established under the Federal Food, Drug, and Cosmetic Act for the purpose of applying the prescription drug restraints and have been accepted by the American Veterinary Medical Association. Veterinarians preparing products subject to the exemption under the Act will be required to maintain and make available for inspection such records as are necessary to establish that a valid veterinarian-client-patient relationship exists. Prior to the shipment of products which contain live organisms and which are prepared either through conventional means or through the use of biotechnology, or at any other time deemed necessary, persons exempt from licensure will be required to provide any information necessary to determine the products' safety and effect on the environment. This final rule has been clarified to properly reflect these requirements.

Section 107.2 of the regulations addresses the criteria to be met by State licensing programs in order that State licensed products may be eligible for the statutory exemption. This provision of the regulations specifies that appropriate State officials are responsible for providing the Agency with information to assure compliance with the provisions of the Act. The State officials will be required to identify each manufacturer and each product to be considered for exemption. Provisions for review of procedures used by State regulatory officials and on-site evaluation of facilities and products to be exempted are also included in the regulations.

The current regulations in 9 CFR 114.2(c) provide that, except for experimental products prepared in compliance with Part 103, no biological products may be prepared in a licensed establishment unless the person holding the establishment license also holds an unexpired, unsuspended, and unrevoked product license for each product. Section 114.2(b) provides that when an establishment license is issued for an interim period not to exceed 4 years, the establishment may continue preparing certain specified unlicensed products provided, that: (a) Such products were prepared in the establishment within the 12-month period prior to issuance of the establishment license; (b) the unlicensed products are not distributed interstate; (c) no new unlicensed products are prepared after issuance of the establishment license; and (d) other specified requirements are satisfied. By the end of the interim licensure period, all products in the establishment must be licensed. The purpose of § 114.2(b) is to give intrastate producers an opportunity to become licensed without being required to immediately remove all intrastate products from their premises.

The VST Act, as amended, requires that all veterinary biologics (with the exception of certain exempt products) shipped in or from the United States must be produced pursuant to a license. However, the Act provides that products prepared for intrastate distribution or exportation during the 12-month period prior to the enactment of the Act (December 23, 1985) may continue to be produced and sold until January 1, 1990, *Provided*, that, an exemption from preparation pursuant to a license was claimed by January 1, 1987. That exemption may then be extended by the Deputy Administrator for up to 12 months. In light of this provision,

establishment licenses issued for an interim period under § 114.2(b) will only be effective until January 1, 1990 (or where an exemption is extended, until the exemption expires). All unlicensed products produced for intrastate distribution or for export are subject to the exemption provision of the Act.

Therefore, § § 114.2(b) and 102.4(h) are amended to provide for interim licensure until January 1, 1990, unless the exemption granted for the unlicensed products produced in the establishment under § 114.2(b) is extended by the Deputy Administrator. In such case, the interim license shall continue until the exemption expires. Other conforming amendments are also made.

The definition of research investigator or research sponsor in § 101.2 of the regulations is amended to conform to the new authority under the Act by deleting reference to "interstate" movement.

Comments Received

On November 20, 1986, a notice of proposed rulemaking was published in the **Federal Register** at 51 FR 41975 discussing these revisions and soliciting comments.

Comments were received from a State Veterinarian, a national trade association which includes among its members the major manufacturers of veterinary biological products, three licensed manufacturers of veterinary biological products, and two consultants to biologics manufacturers.

One commenter expressed concerns regarding the provisions in the Act that veterinary biologics prepared solely for administration to one's own animals would be exempted from preparation pursuant to a license. The commenter was concerned that this exemption would lead to serious abuses of the Act, especially with respect to biological products used in poultry operations, since the question of ownership may be subject to interpretation.

It is common practice in the poultry industry for integrated poultry producers to contract with growers to raise poultry. In these situations, the integrater provides chicks, technical expertise, medications (including vaccines), and other services. The growers provide housing, labor, equipment, water, heat and electricity. The growers are paid through various contractual agreements to raise the birds. The integrater assumes financial responsibility for losses due to expected morbidity and mortality occurring in the flocks. In such contractual agreements, the integrater has "Title of Ownership" and does not transfer ownership of the birds to the farmer. The integrater is said to own the poultry. Therefore, the exemption for veterinary biological products prepared solely for use in one's own animals would apply. These products are exempted from preparation pursuant to a license. However, they are subject to all the Act's prohibitions against shipping products which are worthless, contaminated, dangerous, or harmful. The Act gives to the Agency the authority to seize, detain, and condemn products that are in violation of these requirements.

Three comments were received regarding Part 107, Exemption From Preparation Pursuant to An Unsuspended and Unrevoked License. Section 107.1(a) addresses products prepared by a veterinary practitioner solely for administration to animals in a state-licensed professional practice of veterinary medicine under a veterinarian-client-patient relationship. The conditions to be met in order to establish a valid veterinarian-client-patient relationship are specified in § 107.1(a) of the regulations. These conditions are analogous to those established under the Food, Drug and Cosmetic Act and have been accepted by the American Veterinary Medical Association.

Section 107.2 of the regulation addresses the statutory exemptions relevant to veterinary biological products prepared under a state licensing program. Commenters recommended that this section should make reference to the prohibitions in the Act regarding worthless, contaminated, dangerous or harmful products, and that periodic inspections or on-site evaluations should be provided for. Section 107.2 states that the exemption regarding state licensed products shall be consistent with the intent of the Act to prohibit the sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful products. Also, § 107.2(d) does not limit the number of site evaluations or inspections. Policy and procedures are being developed to assure that state licensing programs subject to section 107 are consistent with requirements of the Act and regulations. The Agency is also developing policies and procedures for monitoring the distribution of exempted products.

Three commenters thought that the special restriction provision and the requirement that applicants submit environmental information in § 103.3 are overly broad. The section as proposed gives the Deputy Administrator the authority to impose special restrictions or tests when deemed necessary. The preamble to the proposed rules states that additional safeguards and tests may be required in the case of products which contain live organisms prepared either through conventional means or through the use of new biotechnology methods. The commenters suggested that § 103.3 be narrowed to a reasonable extent to be consistent with the preamble. It is anticipated that in the majority of cases special restrictions and additional tests would be imposed in the case of products containing live organisms which have been genetically modified. Therefore, this final rule, as modified, contains the statement that such special restrictions and tests may be imposed, especially in the case of products which contain live organisms. However, the Deputy Administrator retains the option of requiring them in other cases when necessary or advisable.

Section 103.3 also requires the submission of any information the Deputy Administrator may need in order to assess the product's impact on the environment. When such assessment is performed, each product is assessed individually on a case by case basis. As scientific knowledge advances, such advancements should be reflected in regulating affected products by requiring more data when necessary and relaxing requirements when possible. Most, if not all, necessary environmental information is routinely submitted by applicants for permits to do field studies under § 103.3 as part of the data which is reviewed for the purposes of the permit. The review process for live viral vaccines has always included considerations such as the purity of ingredients, primary cells, cell lines, and master seed virus. Information regarding genetic stability of cell lines and genetic stability of the vaccine by demonstrating nonpathogenicity and nonreversion to virulence through a significant number of backpassages in host animal has also been included in the review of live viral vaccines. When considered necessary in a particular case, the Agency has requested data for live products to include studies to determine the fate of the organism when injected into the host and its ability to shed, transmit, and maintain itself in a livestock population. Most, if not all, of this information is required to be submitted by applicants for permit under § 103.3. The specific intent of § 103.3(h) is to assure that any additional information not already made available during the application process is submitted for purposes of an environmental assessment.

There was also a question and comments with respect to products that

would be exempted from being prepared pursuant to a license. The commenters expressed uncertainty regarding whether license refers to a product or to an establishment license, and one commenter stated that it would be unnecessary to require an establishment license of a person making only exempted products. It is the Agency's view that the exemption from preparation pursuant to a license encompasses both the establishment and product licenses. Therefore, language is added to § 107.1 and 107.2 to clarify this concept.

List of Subjects in 9 CFR Parts 101, 102, 103, 104, 107, and 114

Animal biologics.

After consideration of all relevant matters, including the comments on the proposed rulemaking, and under the authority of the Virus-Serum-Toxin Act of March 4, 1913, as amended by the Food Security Act of 1985 (21 U.S.C. 151–159), the amendments of Parts 101, 102, 103, 104, 114, and the addition of new Part 107, Subchapter E, Chapter I, Title 9 of the Code of Federal Regulations are adopted as follows:

PART 101—DEFINITIONS

1. The authority citation for Part 101 is revised to read as follows:

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

2. Section 101.2 is amended by revising paragraph (o) to read as follows:

§ 101.2 Administrative terminology.

* * * * *

(o) *Research investigator or research sponsor.* A person who has requested authorization to ship an experimental biological product for the purpose of evaluating such product, or has been granted such authorization.

* * * * *

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

1. The authority citation for Part 102 is revised to read as follows:

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

2. Section 102.4 is amended by revising paragraphs (h)(1) and (h)(2) to read as follows:

§ 102.4 U.S. Veterinary Biologics Establishment License.

* * * * *

(h) * * *

(1) The U.S. Veterinary Biologics Establishment License issued for an interim period shall expire January 1, 1990, unless an extension for exemption from licensing under the Act of products prepared solely for intrastate shipment or export is granted by the Deputy Administrator pursuant to § 114.2(d)(3) of this subchapter. In such case, the licensee may retain the interim license until the exemption period ends.

(2) Prior to the expiration of the interim license, the licensee may request issuance of a license for an indefinite period by application as provided in § 102.3 of this part.

* * * * *

PART 103—EXPERIMENTAL PRODUCTION, DISTRIBUTION, AND EVALUATION OF BIOLOGICAL PRODUCTS PRIOR TO LICENSING

1. The authority citation for Part 103 is revised to read as follows:

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

2. The section heading, introductory text, and paragraph (a) of § 103.3 are revised and a new paragraph (h) is added as follows:

§ 103.3 Shipment of experimental biological products.

Except as provided in this section, no person shall ship or deliver for shipment in or from the United States, the District of Columbia, or any Territory of the United States any unlicensed biological product for experimental use in animals. For the benefit of license applicants and to permit and encourage research, a person may be authorized by the Deputy Administrator to ship unlicensed biological products for the purpose of evaluating such experimental products by treating limited numbers of animals, *Provided*, that, the Deputy Administrator determines that the conditions under which the experiment is to be conducted are adequate to prevent the spread of disease and approves the procedures set forth in the request for such authorization. Special restrictions or tests may be imposed, especially in the case of products containing live organisms, when they are deemed necessary or advisable by the Deputy Administrator. A request for authorization to ship an unlicensed biological product for experimental study and evaluation shall be accompanied by the following:

(a) One copy of a permit or letter of permission from the proper State or foreign animal health authorities of each State or foreign country involved.

* * * * *

(h) Any information the Deputy Administrator may require in order to assess the product's impact on the environment.

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

1. The authority citation for Part 104 is revised to read as follows:

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

2. Section 104.4 is amended by revising paragraphs (a) and (b) to read as follows:

§ 104.4 Products for research and evaluation.

(a) An application for a U.S. Veterinary Biological Product Permit to import a biological product for research and evaluation shall be accompanied by a brief description of such product, methods of propagating antigens including composition of medium, species of animals or cell cultures involved, degree of inactivation or attenuation, recommendations for use, and the proposed plan of evaluation. The applicant shall also provide any information the Deputy Administrator may require in order to assess the product's impact on the environment.

(b)(1) A permit to import a biological product for research and evaluation shall not be issued unless the scientific capabilities of the investigator are determined to be adequate to safeguard domestic animals and protect public health, interest, or safety from any deleterious effects which might result from use of such product. Special restrictions or tests may be specified as part of the permit when they are deemed necessary or advisable by the Deputy Administrator.

(2) No person shall ship a product imported under this section for research and evaluation anywhere in or from the United States unless authorized by the Deputy Administrator in accordance with the provisions of § 103.3 of this subchapter.

* * * * *

1. A new Part 107 is added to Subchapter E to read as follows:

PART 107—EXEMPTIONS FROM PREPARATION PURSUANT TO AN UNSUSPENDED AND UNREVOKED LICENSE

Sec.

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

§ 107.1 Veterinary practitioners and animal owners.

Products prepared as provided in paragraphs (a) and (b) of this section and establishments in which such

products are prepared, shall be exempt from preparation pursuant to unsuspended and unrevoked establishment and product licenses. Persons exempt from licensure under this part shipping products which contain live organisms shall provide any information the Deputy Administrator may require prior to shipment, or at any other time deemed necessary, in order to assess the products' safety and effect on the environment. The shipment or delivery for shipment anywhere in or from the United States of any exempted product which is worthless, contaminated, dangerous, or harmful is prohibited, and any person shipping such product, or delivering such product for shipment, shall be subject to sanctions under the Act.

(a)(1) Products prepared by a veterinary practitioner (veterinarian) solely for administration to animals in the course of a State licensed professional practice of veterinary medicine by such veterinarian under a veterinarian-client-patient relationship and establishments in which such products are prepared shall be exempt from licensing under the Act and regulations. Such a relationship is considered to exist when:

(i) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when

(ii) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when

(iii) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen.

(2) Veterinarians preparing products subject to the exemption for products under this section shall maintain and make available for inspection by Veterinary Services representatives or other Federal employees designated by the Secretary such records as are necessary to establish that a valid veterinarian-client-patient relationship exists and that there is a valid basis for the exemption under this section.

(b) Products prepared by a person solely for administration to animals owned by that person shall be exempt from the requirement that preparation be pursuant to an unsuspended and unrevoked license.

§ 107.2 Products under State license.

(a) The Deputy Administrator shall exempt from the requirement of preparation pursuant to an unsuspended and unrevoked USDA establishment and product license, any biological product prepared solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Deputy Administrator to be consistent with the intent of the Act to prohibit the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful biological products.

(b) A request for exemption under this section must be made by the appropriate State authority and shall include information demonstrating that:

(1) The State has the authority to license viruses, serums, toxins, and analogous products and establishments that produce such products; and

(2) The State has the authority to review the purity, safety, potency, and efficacy of such products prior to relase to the market; and

(3) The State has the authority to review product test results to assure compliance with applicable standards of purity, safety, and potency prior to release to the market; and

(4) The State has the authority to deal effectively with violations of State law regulating viruses, serums, toxins, and analogous products; and

(5) The State effectively exercises the authority specified in paragraphs (b) (1) through (4) of this section consistent with the intent of the Act prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products.

(c) Each product to be exempted and each establishment preparing such product shall be identified by the State and the State shall give written notification to the Deputy Administrator of each such product and establishment. The State shall also give written notice ot the Deputy Administrator of each new license issued and of each license terminated.

(d) In order to determine whether a State exercises its authority with respect to biological products and establishments and whether its laws and regulations are being achieved, the Deputy Administrator, in cooperation with proper State authorities, may conduct an on-site evaluation of the State's program which may include inspection of establishments and/or products to be included under the exemptions in this section.

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

1. The authority citation for Part 114 continues to read as follows:

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

2. In § 114.2, paragraphs (b) introductory text, (b)(1), (b)(9) and (c) are revised to read as follows:

§ 114.2 Products not prepared under license.

* * * * *

(b) An establishment license may be issued for an interim period not to extend beyond January 1, 1990. The establishment holding an interim license may continue preparing certain specified unlicensed biological products with the permission of the Deputy Administrator; *Provided*, that:

(1) Such unlicensed products had been prepared in the establishment within the 12 months prior to December 23, 1985.

* * * * *

(9) An exemption has been claimed for the unlicensed products produced in the establishment pursuant to § 114.2(d) of this subchapter.

(c) Except as provided in Part 103 and paragraph (b) of this section, 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 Deputy Administrator to prepare such biological product, or unless the products prepared are subject to the provisions of § 107.2 of this subchapter.

Done at Washington, DC, this 6th day of August 1987.

J.K. Atwell,

Deputy Administrator, Veterinary Services.

[FR Doc. 87–18406 Filed 8–12–87; 8:45 a.m.]

BILLING CODE 3410-34-M

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9 CFR Parts 115 and 118

[Docket No. 87–028]

Viruses, Serums, Toxins, and Analogous Products; Inspections; Detention, Seizure, and Condemnation

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Virus-Serum-Toxin Act of 1913 (VST Act), as amended by the Food Security Act of 1985, authorizes

any officer, agent, or employee of the Department of Agriculture to enter and inspect any establishment preparing animal biologics at any hour, day or night. Previously, only licensed establishments were subject to this provision. The amendment also provides for detention, seizure, and condemnation of products. This amendment of the regulations adds the expanded inspection authority to Part 115, and establishes a new Part 118 entitled, "Detention, Seizure, and Condemnation."

EFFECTIVE DATE: September 14, 1987.

FOR FURTHER INFORMATION CONTACT: Dr. Peter L. Joseph, Senior Staff Veterinarian, Veterinary Biologics Staff, VS, APHIS, USDA, Room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–6332.

SUPPLEMENTARY INFORMATION:

This rule contains no new or amended recordkeeping, reporting, or application requirements or any type of information collection requirement subject to the Paperwork Reduction Act of 1980.

Executive Order 12291

This final action has been reviewed under USDA procedures established in Departmental Regulation 1512–1 to implement Executive Order 12291 and has been classified as a "Nonmajor Rule."

The action will not have a significant effect on the economy and will not result in a major increase in costs or prices to consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises, in domestic markets.

Certification Under the Regulatory Flexibility Act

The Administrator of the Animal and Plant Health Inspection Service has determined that this action will not result in adverse economic impact on a substantial number of small entities. Its purpose is to implement new enforcement provisions contained in the 1985 amendments to the VST Act.

Background

Part 115 of the regulations is amended to provide for the expanded inspection authority under the VST Act. It is revised to state that any establishment (rather than only a licensed establishment) which prepares biological products is subject to inspection at any time, day or night.

New enforcement authority was also provided by the 1985 amendment to the Act which incorporated the procedures of sections 402, 403, and 404 of the Federal Meat Inspection Act. These procedures, which relate to detentions, seizures, condemnations, and injunctions are applicable to the enforcement of the VST Act with respect to any animal biological prepared, sold, bartered, exchanged, or shipped in violation of the Act or regulations.

This rule establishes a new Part 118 entitled Detention; Seizure; and Condemnation. It is modeled after the regulations under the Federal Meat Inspection Act (9 CFR 329.1 et seq.) The period of detention will not exceed 20 days. The owner of the veterinary biologic or the owner's agent, or other person having custody of the product, will be given written notice of the detention. Movement of the detained product may be allowed in accordance with the regulations. The procedures to be followed in seizing and condemning biological products are those which are specified in section 403 of the Federal Meat Inspection Act.

Comments Received

On November 4, 1986, a notice of proposed rulemaking was published in the **Federal Register** at 51 FR 40030, discussing these revisions and soliciting comments.

Comments were received from a State Veterinarian who vigorously supported the proposed rulemaking. Other comments were from a trade association which includes among its members major manufacturers of veterinary biologicals, a trade association representing intrastate biological laboratories, two licensed manufacturers, and a consultant to biologics manufacturers. These generally supported the proposed rulemaking and raised the following issues.

One licensed manufacturer agreed with the proposal and suggested that the word "licensed" be removed from the title of § 115.1 to agree with the intent of the revisions. The Agency agrees with this comment and the title is modified as suggested.

In commenting on proposed § 115.1(a), three commenters suggested that the authority to inspect any establishment where biological products are prepared at any hour during the day or night is undesirable and too broad. It was suggested this authority be deleted or amended in order to be more reasonable. In order to carry out the

intent of the Act, the Agency is required to conduct initial, routine, and special inspections of establishments and products. Usually initial inspections are scheduled with the establishment in advance. Routine inspections, and in most cases, special inspections are unannounced and conducted during normal duty hours. The Agency has no plans to change this policy in conducting the majority of its inspections. However, there have been instances when it has been necessary to carry out inspections either at night and on week-ends. The language in § 115.1(a) regarding inspections authority is based on the language of the Act and will remain as proposed.

There were two comments with regard to § 115.2-Inspection of Biological Products. They both questioned why the language "Any biological product, the container of which bears a United States Veterinary License Number of a United States Permit Number or other mark required by the regulations, may be inspected at any time or place" was no changed to state that any product may be inspected at any time or place. The Virus-Serum-Toxin Act does not grant authorty to inspect any product at any time or place. The amendment of § 115.2 removes unnecessary language and revises the language referring to shipments at the end of the section to properly reflect the new authority under the Act.

One commenter pointed out that Parts 105, 115, and new Part 118, are in many instances similar in their practical effect, and asked that there be some cross-referencing. It is true that the specified regulations are similar insofar as they are intended to prevent the preparation, sale, or shipment of biological products in violation of the Act or regulations. Part 105 deals specifically with license suspensions and revocations; Part 115 deals with inspections; and the new Part 118 deals with detention, seizure, and condemnation. The parts are related but independent of each other. However, there can be some interplay between them. Therefore, § 115.2 is further revised by the addition of a reference to new Part 118.

List of Subjects in 9 CFR Parts 115 and 118

Animal biologics.

After consideration of all relevant matters, including the comments on the proposed rulemaking, and under the authority of the Virus-Serum-Toxin Act of March 4, 1913, as amended by the Food Security Act of 1985 (21 U.S.C. 151–159) the amendment of Part 115 and the addition of new Part 118, Subchapter E, Chapter I, Title 9, Code of Federal Regulations, are adopted as follows:

PART 115—INSPECTIONS

1. The authority citation for Part 115 continues to read as follows:

Authority: 21 U.S.C. 151–159; 37 Stat. 832–833.

2. Part 115 is amended by revising §§ 115.1 and 115.2 to read as follows:

§ 115.1 Inspections of establishments.

(a) Any inspector shall be permitted to enter any establishment where any biological product is prepared, at any hour during the day or night, and shall be permitted to inspect, without previous notification, the entire premises of the establishment, including all buildings, compartments, and other places, all biological products, and organisms and vectors in the establishment, and all materials and equipment, such as chemicals, instruments, apparatus, and the like, and the methods used in the manufacture of, and all records maintained relative to, biological products produced at such establishment.

(b) Each inspector will have in his or her possession a numbered USDA badge or identification card. Either shall be sufficient identification to entitle him/her to admittance at all regular entrances and to all parts of such establishment and premises and to any place at any time for the purpose of making an inspection pursuant to paragraph (a) of this section.

§ 115.2 Inspections of biological products.

Any biological product, the container of which bears a United States veterinary license number or a United States veterinary permit number or other mark required by these regulations may be inspected at any time or place. If, as a result of such inspection, it appears that any such product is worthless, contaminated, dangerous or harmful, the Secretary shall give notice thereof to the manufacturer or importer and to any jobbers, wholesalers, dealers or other persons known to have any of such product in their possession, and may proceed against such product pursuant to the provisions of Part 118 of this subchapter. Unless and until the Secretary shall otherwise direct, no persons so notified shall thereafter sell, barter, or exchange any such product in any place under the jurisdiction of the United States or ship or deliver for shipment any such product in or from any State, Territory, or the District of Columbia. However, failure to receive such notice shall not excuse any person

from compliance with the Virus-Serum-Toxin Act.

3. A new Part 118 is added to Subchapter E to read as follows:

PART 118—DETENTION; SEIZURE AND CONDEMNATION

Sec.

Authority: 21 U.S.C. 151–159; 99 Stat 1654–1656.

§ 118.1 Administrative detention.

Whenever any biological product which is prepared, sold, bartered, exchanged, or shipped in violation of the Act or regulations is found by any authorized representative of the Deputy Administrator upon any premises, it may be detained by such representative for a period not to exceed 20 days, pending action under § 118.4, and shall not be moved by any person from the place at which it is located when so detained, until released by such representative.

§ 118.2 Method of detention; Notifications.

An authorized representative of the Deputy Administrator shall detain any biological product subject to detention under this part by:

(a) Giving oral notification to the owner of the biological product if such owner can be ascertained, and, if not, to the agent representing the owner or to the immediate custodian of the biological product; and

(b) Promptly furnishing the person so notified with a preliminary notice of detention which shall include identity and quantity of the product detained, the location where detained, the reason for the detention, and the name of the authorized representative of the Deputy Administrator.

(c) Within 48 hours after the detention of any biological product, an authorized representative of the Deputy Administrator shall, if the detention is to continue, give written notification to the owner of the biological product detained by furnishing a written statement which shall include the identity and quantity of the product detained, the location where detained, specific description of the alleged noncompliance including reference to the provisions in the Act or the regulations which have resulted in the detention, and the identity of the authorized representative of the Deputy Administrator; or, if such owner cannot be ascertained and notified within such period of time, furnish such notice to the agent representing such owner, or the carrier or other person having custody of the biological product detained. The notification, with a copy of the preliminary notice of detention shall be served by either delivering the notification to the owner or to the agent or to such other person, or by certifying and mailing the notification, addressed to such owner, agent, or other person, at the last known residence or principal office or place of business.

§ 118.3 Movement of detained biological products; Termination of detention.

Except as provided in paragraphs (a) and (b) of this section, no biological product detained in accordance with the provisions in this part shall be moved by any person from the place at which such product is located when it is detained.

(a) A detained biological product may be moved from the place at which it is located when so detained for the purpose of providing proper storage conditions if such movement has been approved by an authorized representative of the Deputy Administrator; *Provided,* that, the biological product so moved shall be detained by an authorized representative of the Deputy Administrator after such movement.

(b) A detained biological product may be moved from the place at which it is detained on written notification by an authorized representative of the Deputy Administrator that the detention is terminated; *Provided,* that, the conditions under which the detained biological product may be moved will be specified in the written notification of the termination. The notification of termination shall be served by either personally delivering the notification, or by certifying and mailing the notification addressed to such person at the last known residence or principal office or place of business of the owner, agent, or other person having custody of the biological product.

§ 118.4 Seizure and condemnation.

Any biological product which is prepared, sold, bartered, exchanged, or shipped in violation of the Act or regulations shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court within the jurisdiction of which the product is found. If the product is condemned, it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct, and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United

States, but the product shall not be sold contrary to the provisions of the Act or the laws of the jurisdiction in which it is sold: *Provided*, that, upon the execution and delivery of a good and sufficient bond conditioned that the product shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws or jurisdiction in which disposal is made, the court may direct that such product be delivered to the owner thereof subject to such supervision by authorized representatives of the Deputy Administrator as is necessary to ensure compliance with the applicable laws. When a decree of condemnation is entered against the product and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the product. The proceedings in such libel cases shall conform, as nearly as may be practicable, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

Done at Washington, DC, this 6th day of August, 1987.

J. K. Atwell,

Deputy Administrator, Veterinary Services.

[FR Doc. 87-18405 Filed 8-12-87; 8:45 am]

BILLING CODE 3410-34-M

Food Safety and Inspection Service

9 CFR Part 318

[Docket No. 85-031F]

BHA and BHT in Pizza Toppings and Meatballs

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) has been petitioned to amend the Federal meat inspection regulations to permit the use of Butylated Hydroxyanisole and Butylated Hydroxytoluene as antioxidants in cooked or raw pizza toppings and cooked or raw meatballs. The Food and Drug Administration (FDA) has listed these substances as generally recognized as safe (GRAS) for use in foods under certain conditions. The petitioners have supplied FSIS with sufficient information to satisfy the requirements of the Federal meat inspection regulations to permit the requested use (9 CFR 318.7(a)(2)). The Administrator has determined that it is appropriate to add pizza toppings and meatballs to the list of products permitted to contain BHA and BHT as added antioxidants.

EFFECTIVE DATE: September 14, 1987.

ADDRESS: Written comments to United States Department of Agriculture, Food Safety and Inspection Service, Attn: FSIS Hearing Clerk, Room 3168, South Agriculture Building, Washington, DC 20250. (See also "Comments" under "Supplementary Information.")

FOR FURTHER INFORMATION CONTACT: Ms. Margaret O'K Glavin, Director, Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, United States Department of Agriculture, Washington, DC 20250, (202) 447-6042.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined in accordance with Executive Order 12291 that this rule is not a "major rule." It will not result in an annual increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions. It will not have a significant effect on competition, employment, investment, productivity, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This rule provides for the use of Butylated Hydroxyanisole (BHA) and Butylated Hydroxytoluene (BHT) as antioxidants in cooked or raw pizza toppings and meatballs. The Federal meat inspection regulations currently provide for their use in beef patties which are similar in composition to pizza toppings and meatballs. The regulated industry will benefit from this action through ability to use these antioxidants in a wider variety of products to increase their shelf life.

Effect on Small Entities

The Administrator has determined that his action will not have a significant economic impact upon a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This rule will impose no new requirements on industry; it allows meat processors to use BHA and BHT in pizza toppings and meatballs to increase their shelf life.

Comments

This is a final rule consistent with the provisions of § 318.7(a) (2) and (3) of the Federal meat inspection regulations. As such, no prior request for public