a value was computed or such handler pursuant to § 1124.60(k).

* * * * *

11. In § 1124.73, paragraphs (c)(2) and (d)(2) are amended by removing the phrase ''paragraph (a)(2)(i) through (iii) of this section'' and adding in its place the phrase ''paragraph (a)(2)(i) through (iv) of this section''; paragraphs (a)(2)(ii) through (vi), (c) introductory text, (c)(1), and (f)(2) are revised; and a new paragraph (a)(2)(vii) is added to read as follows:

§ 1124.73 Payments to producers and to cooperative associations.

(a) * * *

(2) * * *

(ii) Add the amount that results from multiplying the protein price for the month by the total pounds of protein in the milk received from the producer;

(iii) Add the amount that results from multiplying the other solids price for the month by the total pounds of other solids in the milk received from the producer;

(iv) Add the amount that results from multiplying the total hundredweight of milk received from the producer by the producer price differential for the month as adjusted pursuant to § 1124.74(a);

(v) Subtract payments made to the producer pursuant to paragraph (a)(1) of this section;

(vi) Subtract proper deductions authorized in writing by the producer; and

(vii) Subtract any deduction required pursuant to § 1124.86 or by statute; and

* * * * *

(c) Each handler shall pay to each cooperative association which operates a pool plant, or to the cooperative's duly authorized agent, for butterfat, protein and other solids received from such plant in the form of fluid milk products as follows:

(1) On or before the second day prior to the date specified in paragraph (a)(1) of this section, for butterfat, protein, and other milk solids received during the first 15 days of the month at not less than the butterfat, protein, and other milk solids prices, respectively, for the preceding month; and

* * * * *

(f) * * *

(2) The total pounds of milk delivered by the producer, the pounds of butterfat, protein and other solids contained therein, and, unless previously provided, the pounds of milk in each delivery;

* * * * *

§ 1124.74 [Amended]

12. In § 1124.74 paragraph (c), the phrase ''weighted average differential price'' is removed and the phrase ''producer price differential'' is added in its place everywhere it appears.

§ 1124.75 [Amended]

13. In § 1124.75, the second sentence of paragraph (a)(1)(i) is amended by adding the phrase ''or statistical uniform price'' after the words ''estimated uniform price'' and the phrase ''estimated uniform price'' in the first sentence of paragraph (b)(4) is removed and the phrase ''statistical uniform price'' is added in its place.

§ 1124.85 [Amended]

14. In § 1124.85 paragraph (b), the phrase ''§ 1124.60 (h) and (j)'' is removed and the phrase ''§ 1124.60 (i) and (k)'' is added in its place.

Dated: August 19, 1996.

Lon Hatamiya,

Administrator.

[FR Doc. 96–21491 Filed 8–22–96; 8:45 am]

BILLING CODE 3410–02–P

Animal and Plant Health Inspection Service

9 CFR Part 101

[Docket No. 93–152–1]

RIN 0579–AA65

Viruses, Serums, Toxins, and Analogous Products; Definition of Biological Products and Guidelines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations by revising the definition of ''biological products.'' The amendment is necessary in order to reflect current usage and advances in scientific knowledge, and to clarify certain parts of the definition.

We are also proposing to add a definition of ''guidelines'' to the regulations. Guidelines are used to assist manufacturers of veterinary biologics and other interested persons regarding test procedures, methods, and other considerations that would be acceptable to the agency in support of licensure of a veterinary biological product. This action would clarify in the regulations the purpose and intent of guidelines.

DATES: Consideration will be given only to comments received on or before October 22, 1996.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 93–152–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 93–152–1. 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. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1237, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

Veterinary biological products are licensed under the Virus-Serum-Toxin Act (hereinafter referred to as the VSTA) on the basis of their purity, safety, potency, and efficacy. Any ''virus, serum, toxin, or analogous product'' intended for use in the treatment of animals is subject to regulation under the VSTA. Such substances are commonly referred to as biologics or biological products. The definitions of terms related to veterinary biological products appear in 9 CFR 101.

The Food and Drug Administration (FDA) regulates drugs for use in animals. The Federal Food, Drug, and Cosmetic Act (FFDCA) defines ''drugs'' to include, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals. Articles that are used to improve animal performance, such as increased rate of gain and enhanced feed efficiency, are ''drugs'' under the FFDCA. Section 902(c) of the FFDCA states that nothing in the FFDCA shall affect, modify, repeal, or supersede the provisions of the VSTA. FDA regulations under 21 U.S.C. 510.4 provide that an animal drug produced in full conformance with the VSTA will not be subject to the new animal drug approval requirements of the FFDCA.

Definition of Biological Product

The definition of ''biological products'' in 9 CFR 101.2 was last amended on April 2, 1973 (See 38 FR 8426–8428). Since that time, the VSTA

has been amended by the 1985 Food Security Act (Pub. L. 99–198) and scientific advances have improved our understanding of how veterinary biologics work.

The 1985 Food Security Act provided for additional enforcement authorities under the VSTA. These authorities include detention, seizure, and condemnation and injunctive procedures. In addition, unless otherwise exempted, all veterinary biological products shipped in or from the United States must meet Federal standards for licensure related to purity, safety, potency, and efficacy. Products manufactured in foreign countries may not be imported without a permit issued under the Act and regulations. The main purpose of the VSTA is to protect those who use veterinary biologics from products which are worthless, contaminated, dangerous, or harmful. In this regard, products which are represented to be biological products also fall under the jurisdiction of the VSTA.

Since 1973, our understanding of how veterinary biologics work has advanced substantially. It is now recognized in the scientific literature that the generation or stimulation of an immune response involves both antigens and certain protein regulatory factors referred to as cytokines. Some cytokines (e.g. interleukins) serve as essential components in the generation and expression of an immune response, without which the vaccine would be worthless. These cytokines may be elicited through stimulation with antigens or certain ''immunomodulators''.

Cytokines are also produced in many body tissues and act on cell types other than those of the immune system. Cytokines of natural or synthetic origin can be prepared as products for administration to animals. Because of the diverse biological activity of the cytokines, not all products consisting of these substances would be regulated under the VSTA. Many of these cytokines intended to be used as drugs would fall under the jurisdiction of the Food and Drug Administration. In such instances, the VSTA would not apply.

Both cytokines and immunomodulators are analogous to biological products when they are used to stimulate, supplement, enhance, or modulate the immunity of animals in the treatment of disease. Products consisting of these substances that work through these immune mechanisms in the treatment of specific disease appropriately fall within the definition of ''biological products''. Certain immunomodulators (e.g., cell wall extracts and products derived from the aloe vera plant) that are used in the treatment of specific diseases of animals have been regulated by the Animal and Plant Health Inspection Service (APHIS) since 1980.

APHIS received a citizen's petition dated September 14, 1993, from the Animal Health Institute, a national trade association, requesting that the definition of ''biological products'' be amended as set forth below:

The term ''animal biological product'' means any virus, serum, toxin, or analogous product represented as an animal biological product intended for use in the diagnosis, prevention, treatment and cure of disease in animals, including any vaccine, bacterin, toxoid, whole blood, plasma, serum, antiserum, antitoxin, other blood components involved in passive and active immunization, allergen, diagnostic component, or analogous product, whether any of these products is of natural or synthetic origin, or results from synthesizing or altering antigen or antibody components or similar technologies.

1. A virus is interpreted to be not only a product containing the infective agent known as a virus, but also a product containing any live or killed microorganism and the antigenic or immunizing components of microorganisms.

2. A serum product is whole blood or any product derived therefrom.

3. A toxin product is a component or product of an organism (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics) which is poisonous to other living organisms and which stimulates antibodies to itself when administered at sublethal doses.

4. A product is analogous to a vaccine, bacterin, toxoid, whole blood, plasma, serum, antiserum, antitoxin, other blood components involved in passive and active immunization, allergen, or diagnostic components, and includes, but is not limited to filterable viruses, bacteria, rickettsia, fungi, mycoplasma and parasites, if it is intended to have a similar effect in the stimulation, enhancement, supplementation, or modulation of immunity of animals or in the detection or measurement of antigens, antibodies, nucleic acids or immunity of animals.

In drafting the proposed definition, APHIS has considered the citizen's petition. APHIS has also reviewed its own definition of ''biological products'' in 9 CFR 101.2. Such review has been ongoing because it has become apparent that some clarification and updating of the definition is necessary. In response to the citizen's petition and to reflect its own efforts to update the definition, APHIS is proposing this rule to amend the definition of ''biological products'' in § 101.2.

The proposed APHIS definition of ''biological products'' in § 101.2 would refer to all viruses, serums, toxins (excluding antibiotics), or analogous products at any stage of production, shipment, distribution, or sale.

Under the VSTA, a ''virus'' is not only a product containing the infective agent known as a virus, but also a product containing any live or killed microorganism and the antigenic or immunizing components of microorganisms.

In addition, the proposed APHIS definition would:

1. *Recognize multiple components that interact in the functioning of the immune system.*

Such biological products would be used in the treatment of specific diseases of animals through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response.

The use of a biological product would be determined, among other things, by the approved label claim in the filed Outline of Production. The approved label claim would define the purpose and condition for use of the biological product.

For purposes of this rule, the terms ''stimulation,'' ''supplementation,'' ''enhancement,'' and ''modulation'' of the immune system would have the following meanings. ''Stimulation'' would refer to ''active immunization'' and ''supplementation'' of the immune system would refer to ''passive immunization'' (by blood or other components). ''Enhancement'' or ''modulation'' of the immune system would refer to the ''up regulation'' or ''fine tuning,'' respectively, of the immune system in the generation of an effective immune response.

2. *Recognize as biological products certain immunomodulators used in the treatment of specific diseases of animals.*

Biological products would include, but not be limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, whether they are of natural or synthetic origin, or products which result from synthesizing or altering various substances.

3. *Recognize genetically engineered products.*

These substances would include microorganisms and their antigenic or immunizing components, genes or genetic sequences, carbohydrates, proteins, allergens, and antibodies.

4. *Define analogous products.*

The term ''analogous products'' in the proposed definition of ''biological products'' would include substances, at any stage of production, shipment,

distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, by stimulating, supplementing, enhancing, or modulating the immune system or immune response. This term would also apply to substances, at any stage of production, shipment, distribution, or sale, which do not act or are not intended to act by stimulating, supplementing, enhancing, or modulating the immune system or immune response, but which resemble or are represented as biological products through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means. For example, a substance consisting of water and coloring which appears to be a biological product or which is packaged or labeled or represented as a biological product would be considered an analogous product intended for use in the treatment of animals. The intended use would be determined using an objective standard and not a subjective one, and would be based on factors such as representations, claims, packaging, labeling, or appearance.

5. *Clarify coverage of diagnostic products and components.*

The proposed term ''analogous products'' would also include products intended for use in the treatment of diseases of animals by detecting or measuring antigens, antibodies, nucleic acids, or immunity of animals.

6. *Recognize blood or other components involved in passive or active immunization.*

Terms such as whole blood and plasma are not specifically included since whole blood intended for replacement of blood volume only would not be deemed a biological product. Whole blood, plasma, and other substances which meet the definition of analogous product would be covered under the definition.

The proposed APHIS definition of ''biological products'' is somewhat similar to that proposed by the citizen's petition, but differs in some respects. For example, in the first paragraph of the definition in the citizen's petition, the term ''represented'' has been moved to paragraph (1)(a) in the APHIS definition. Other concepts and terms proposed in the petition have been adopted, but may be included in the definition in a different manner.

7. *Define the term ''treatment''.*

The term ''treatment'' in the definition of ''biological products'' would mean the prevention, diagnosis, management, or cure of diseases of animals.

For the reasons discussed, APHIS proposes to amend the regulations by revising the definition of the term ''biological products'' to address advances in scientific knowledge, the recommendations in the citizen's petition submitted by the Animal Health Institute, and to clarify certain questions which have arisen.

Definition of Guidelines

We are also proposing to add a definition of ''guidelines'' to the administrative terminology section of § 101.2. ''Guidelines'' establish principles or practices related to test procedures, manufacturing practices, product standards, scientific protocols, labeling, or other technical or policy considerations. ''Guidelines'' that are issued by the agency include Veterinary Biologics Licensing Considerations, Memoranda, Notices, and Supplemental Assay Methods.

The purpose of ''guidelines'' is to assist licensees and applicants in matters related to procedures, methods, and other considerations that would be acceptable to the agency. ''Guidelines'' also clarify and explain agency practice and requirements.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for purposes of Executive Order 12866, and, therefore, has been reviewed by the Office of Management and Budget.

APHIS is proposing to amend the definition of the term ''biological products'' in its regulations under the Virus-Serum-Toxin Act, based on a petition that APHIS received from the Animal Health Institute, a national trade association, requesting that the definition be updated to reflect current scientific usage. The agency is also proposing to amend the definition based on its own efforts to update the definition.

Regulatory actions that are likely to result in a rule that may create a serious inconsistency or otherwise interfere with the actions taken or planned by another agency are considered ''significant'' under the Executive Order. Because of potential overlap between the definition of ''animal drugs'', that are regulated by the Food and Drug Administration (FDA), and the definition of ''veterinary biological products'', that are regulated by APHIS, the proposed rule was designated as ''significant'' under Executive Order 12866.

In efforts to reduce inconsistency and to coordinate regulatory efforts between the two agencies, APHIS requested on July 1, 1994, specific comment from the Food and Drug Administration (FDA) regarding the proposed definition prior to its publication. In addition, meetings were held between representatives of the two agencies on October 25, November 8, November 22, 1994, and January 20, 1995, to clarify specific points in the proposed definition. In December 1994 and January 1995, APHIS revised its proposed definition in response to the comments received and the discussions at the meetings held with the FDA.

Based on progress made during several meetings between APHIS and the FDA to discuss the proposed definition, and the specific changes made to the proposed definition in response to FDA comments, APHIS believes that the proposed rule on the definition of ''biological products'' should not lead to serious inconsistency or otherwise interfere with actions taken or planned by another agency.

The primary effect of the proposed rule would be to update the definition of ''biological products'' and add a definition of the term ''guidelines.'' This amendment to the regulations should have no adverse economic impact on firms and may even provide a benefit since the issuance of ''guidance'' documents may help to reduce the amount of time or resources required to complete licensure or testing of a biological product. It is anticipated that the amendment would benefit manufacturers of veterinary biologics by providing definitions that reflect current usage and accommodate advances in scientific knowledge.

The proposed rule is also anticipated to provide guidance to manufacturers of veterinary biologics as to the scope of the term ''biological products.'' Biologics manufacturers should thus be aided in their decisionmaking related to the choice of submissions to APHIS for licensure of veterinary biological products or to the Food and Drug Administration for the approval of veterinary drugs.

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 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. There are no administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This document 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, 9 CFR part 101 would be amended as follows:

PART 101—DEFINITIONS

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

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

2. Section 101.2 would be amended by revising the term ''biological products'' to read as follows:

§ 101.2 Administrative terminology.

* * * * *

Biological products. The term ''biological products,'' also referred to in this subchapter as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, *e.g.*, antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term ''biological products'' includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

(1) The term analogous products shall include:

(a) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplemention, enhancement, or modulation of the immune system or immune response, or

(b) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity, or

(c) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(2) The term ''treatment'' shall mean the prevention, diagnosis, management, or cure of diseases of animals.

* * * * *

§ 101.2 [Amended]

3. In § 101.2, the term ''Guidelines'' would be added in alphabetical order to read as follows:

* * * * *

Guidelines. Guidelines establish principles or practices related to test procedures, manufacturing practices, product standards, scientific protocols, labeling, and other technical or policy considerations. Guidelines contain procedures or standards of general applicability that are usually not regulatory in nature, but that are related to matters that fall under the Virus-Serum-Toxin Act. Guidelines issued by the agency include Veterinary Biologics Licensing Considerations, Memoranda, Notices, and Supplemental Assay Methods.

* * * * *

Done in Washington, DC, this 20th day of August 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–21556 Filed 8–22–96; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 362

RIN 3064–AA29

Activities and Investments of Insured State Banks

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Proposed rule.

SUMMARY: The FDIC is proposing to amend its regulations governing the activities and investments of insured state banks. In general, subject to certain exceptions, insured state banks are prohibited from making equity investments of a type and in an amount that are not permissible for national banks or engaging as principal in activities of a type not permissible for national banks. The regulation requires banks to file with the FDIC their plan for the divestiture of any prohibited equity investments, establishes procedures regarding notices to the FDIC pertaining to excepted equity investments, delegates authority to act on notices, applications and divestiture plans, requires that banks provide certain information to the FDIC regarding existing insurance underwriting activities that the law allowed banks to continue, provides for application procedures to obtain consent to engage in otherwise impermissible activities, and establishes a number of exceptions to required consent. The proposed amendment substitutes a notice for an application when banks meet specified requirements for particular real estate, life insurance and annuity investment activities. If the FDIC does not object to the notice during the notice period, the bank may proceed with the planned investment activities.

DATES: Comments must be received by October 22, 1996.

ADDRESSES: Send comments to Jerry L. Langley, Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street N.W., Washington, D.C. 20429. Comments may be hand delivered to room F–402, 1776 F Street N.W., Washington, D.C. on business days between 8:30 a.m. and 5 p.m. Comments may be sent through facsimile to: (202) 898–3838 or by the Internet to: comments@fdic.gov. Comments will be available for inspection at the FDIC Public Information Center, room 100, 801 17th Street, N.W., Washington, D.C. on business days between 9:00 a.m. and 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Shirley K. Basse, Review Examiner,