

§§ 1924.123–1924.149 [Reserved]**§ 1924.150 OMB Control Number.**

The reporting requirements contained in this subpart have been approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 0575–0164. Public reporting burden for this collection of information is estimated to vary from 5 minutes to 10 minutes per response, with an average of .13 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Department of Agriculture, Clearance Officer, OIRM, Ag Box 7630, Washington, D.C. 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB #0575–0164), Washington, D.C. 20503.

Exhibit A of Subpart C [Removed and Reserved]

3. Exhibit A of subpart C is removed and reserved.

Dated: April 14, 1995.

Michael V. Dunn,

Acting Under Secretary for Rural Economic and Community Development.

[FR Doc. 95–11309 Filed 5–8–95; 8:45 am]

BILLING CODE 3410–07–U

Animal and Plant Health Inspection Service**9 CFR Part 78**

[Docket No. 94–134–2]

Brucellosis in Cattle; State and Area Classifications; Colorado

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Colorado from Class A to Class Free. We have determined that Colorado meets the standards for Class Free status. The interim rule was necessary to relieve certain restrictions on the interstate movement of cattle from Colorado.

EFFECTIVE DATE: June 8, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Michael J. Gilsdorf, Senior Staff Veterinarian, Cattle Diseases and

Surveillance Staff, VS, APHIS, USDA, Suite 3B08, 4700 River Road Unit 36, Riverdale, MD 20737–1236; (301) 734–4918.

SUPPLEMENTARY INFORMATION:**Background**

In an interim rule effective and published in the **Federal Register** on January 23, 1995 (60 FR 4371–4372, Docket No. 94–134–1), we amended the brucellosis regulations in 9 CFR part 78 by removing Colorado from the list of Class A States in § 78.41(b) and adding it to the list of Class Free States in § 78.1(a).

Comments on the interim rule were required to be received on or before March 24, 1995. We did not receive any comments. The facts presented in the interim rule still provide a basis for the rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12778, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 78—BRUCELLOSIS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR 78.41 and that was published at 60 FR 4371–4372 on January 23, 1995.

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC, this 28th day of April 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–11373 Filed 5–8–95; 8:45 am]

BILLING CODE 3410–34–P

9 CFR Part 113

[Docket No. 93–071–2]

Viruses, Serums, Toxins, and Analogous Products; Detection of Extraneous Agents by the Fluorescent Antibody Technique

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning testing by the fluorescent antibody technique for extraneous agents (viruses) in cells of animal origin that are used in the manufacture of veterinary biologics. The amendment allows the use of alternative fluorochromes that may be conjugated to an antibody, revises the list of extraneous agents to be tested for, and includes extraneous agents for which equine cells are to be tested. In addition, the word “agent” is replaced with the word “virus” since this is the agent being tested for. The amendment is necessary to update the requirements related to the testing for extraneous viruses.

EFFECTIVE DATE: June 8, 1995.

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**

In accordance with the regulations contained in 9 CFR part 113, standard requirements are prescribed for the preparation of veterinary biological products. A standard requirement consists of specifications, procedures, and test methods which define the standards of purity, safety, potency, and efficacy for a given type of veterinary biological product. Microorganisms, animal cells, and ingredients of animal origin used in production are required to be tested for extraneous viruses. In part, this involves testing for the presence of extraneous viruses by the fluorescent antibody technique described in § 113.47. When the current standard requirement was established, fluorescent antibodies were constructed by conjugating antibodies to one of the fluorochromes, fluorescein. Fluorochromes are any of a variety of chemicals used in cytochemistry to produce a secondary fluorescence in the specimen. In the intervening years, additional fluorochromes have been developed for use as cytochemical markers or stains.

Standard requirements included in the regulations specify that cells, master seed virus, and most ingredients of animal origin used in the production of biological products be tested for contaminating bacteria, fungi, mycoplasma, cytopathogenic organisms, viruses, hemadsorbing agents, and extraneous agents (viruses) detectable by the fluorescent antibody technique. The presence of specific fluorescence associated with the use of certain antibodies, in comparison with the

appropriate controls, is an indication of the presence of the contaminating antigen or extraneous virus against which the antibody was made.

Current § 113.47 lists the types of extraneous viruses against which fluorescein-conjugated antibodies are to be used in testing cells from certain species of animals. New viruses have since been identified as animal pathogens. No viruses which are disease agents of horses are included in the current § 113.47. As new knowledge has developed, testing for these agents has become necessary.

On March 21, 1994, we published in the **Federal Register** (59 FR 13257–13259, Docket No. 93–071–1) a proposal to amend the regulations by revising § 113.47 to allow the use of additional fluorescent stains in the testing of extraneous viruses by the fluorescent antibody technique. The current regulations in § 113.47 limit the stain used in the fluorescent antibody test to fluorescein (a fluorochrome). Other fluorochromes, when conjugated to antibodies, may be expected to perform as well as fluorescein in the test for extraneous viruses. The amendment thus allows for the use of alternative fluorochromes in such tests. The term “fluorescein-conjugated antibody” is replaced with “fluorochrome-conjugated antibody” everywhere it appears in §§ 113.47 and 113.52(b)(2) (i) and (ii).

The current regulations in § 113.47 lists the specific extraneous viruses against which antibodies are used in the testing of certain types of cells. We have revised the list of cell types to be tested for extraneous viruses to include equine cells. Those using other cells for the production of biologics may also be required to test for specific viruses before such use is approved.

We solicited comments concerning our proposal for a 60-day comment period ending April 20, 1994. We received one comment by that date from a manufacturer of veterinary biological products. We carefully considered the comment which is discussed below.

The comment was in two parts. The first was that the fluorescent antibody (FA) test was not as sensitive for detecting bluetongue virus as seroconversion in sheep, and the use of the FA test would require firms to introduce this organism into their testing facility. The second was that testing of bovine cells for bovine respiratory syncytial virus was also a new requirement.

In response to the comment, the Animal and Plant Health Inspection Service has found that the FA test is a sensitive, specific, and accurate test for

the detection of extraneous viruses in seeds, cells and ingredients of animal origin. When used with the required controls, the FA test detects the presence of specific antigens indicative of the presence of specific extraneous viruses. The use of positive and negative controls with the FA test eliminates the incidence of false positives and false negatives. The FA test also has the advantage of relieving the firms from the need to locate and maintain seronegative sheep.

APHIS acknowledges that requiring firms to test for the bluetongue virus will result in the introduction of the agent onto their premises. This should, however, pose no greater problem to the firms than introducing other viruses for the purpose of conducting these tests. If no firm's biosecurity is adequate to contain such viruses as those causing bovine virus diarrhea, canine parvovirus diarrhea, or pseudorabies, it should be able to contain bluetongue virus. Further, there is no threat of human disease from the use of bluetongue virus in association with this test as bluetongue virus is not known to affect humans.

With respect to the requirement for testing bovine cells for bovine respiratory syncytial virus, APHIS has determined that this virus may be present as an extraneous agent in cells of bovine origin. One of the major purposes of the rule is to update the list of extraneous viruses for which seeds, cells, and ingredients of animal origin are tested. The new requirements are based on current knowledge of animal diseases. No changes are made to the regulations in response to the commenter.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule with one conforming change in § 113.300(c)(1).

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been reviewed under Executive Order 12866. This 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.

These amendments should not have a significant economic impact on manufacturers since they will broaden the range of fluorochrome stains that may be used in conducting the fluorescent antibody test and will revise the list of extraneous agents for which various cell types are to be tested with the fluorescent antibody technique. The

amendments will thus remove outdated requirements and provide flexibility in the types of antibody that may be used in tests for extraneous agents. On balance, therefore, there should be no net increase in testing requirements over the current requirements.

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

Executive Order 12372

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

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

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

List of Subjects in 9 CFR Part 113

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

Accordingly, 9 CFR part 113 is amended as follows:

PART 113—STANDARD REQUIREMENTS

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

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

2. Section 113.47 is revised to read as follows:

§ 113.47 Detection of extraneous viruses by the fluorescent antibody technique.

The test for detection of extraneous viruses by the fluorescent antibody technique provided in this section shall be conducted when prescribed in an applicable Standard Requirement or in a filed Outline of Production for a product.

(a) Monolayer cultures of cells (monolayers), at least 7 days after the

last subculturing, shall be processed and stained with the appropriate antiviral fluorochrome-conjugated antibody as specified in paragraph (b) of this section.

(1) Three groups of one or more monolayers shall be required for each specific virus prescribed in paragraph (b) of this section.

(i) At the time of the last subculturing, one group of test monolayers shall be inoculated with approximately 100–300 FAID₅₀ of the specific virus being tested for as positive controls.

(ii) One group of monolayers shall be the "material under test."

(iii) One group of monolayers, that are of the same type of cells as the test monolayers and that have been tested as prescribed in §§ 113.51 or 113.52 (whichever is applicable), shall be prepared as negative controls.

(2) Each group of monolayers shall have a total area of at least 6 cm².

(3) Positive control monolayers may be fixed (processed so as to arrest growth and assure attachment of the monolayer to the surface of the vessel in which they are grown) before 7 days after subculturing if fluorescence is enhanced by doing so, *Provided*, That a monolayer of the material under test is also fixed at the same time as the positive control and a monolayer of the material under test is also fixed at least seven days after subculturing.

Monolayers that are fixed before 7 days after subculturing shall be stained at the same time as the test monolayers and negative controls fixed at least 7 days after subculturing.

(b) The antiviral fluorochrome-conjugated antibodies to be used shall depend on the type of cells required to be tested for extraneous viruses as specified in an applicable Standard Requirement or in a filed Outline of Production. Antiviral fluorochrome-conjugated antibodies specific for the extraneous viruses shall be applied to each respective type of cell in accordance with the following list.

Under certain circumstances, additional tests may need to be conducted, as determined by the Administrator. When a specific antiviral fluorochrome-conjugated antibody is used in testing for the listed extraneous viruses specified in more than one cell type, it need only be applied to the most susceptible cell type.

(1) All cells shall be tested for:

- (i) Bovine virus diarrhea virus;
- (ii) Reovirus; and
- (iii) Rabies virus.

(2) Bovine, caprine, and ovine cells shall, in addition, be tested for:

- (i) Bluetongue virus;

- (ii) Bovine adenoviruses;
- (iii) Bovine parvovirus; and
- (iv) Bovine respiratory syncytial virus.

(3) Canine cells shall, in addition, be tested for:

- (i) Canine coronavirus;
- (ii) Canine distemper virus; and
- (iii) Canine parvovirus.

(4) Equine cells shall, in addition, be tested for:

- (i) Equine herpesvirus; and
- (ii) Equine viral arteritis virus.

(5) Feline cells shall, in addition, be tested for:

- (i) Feline infectious peritonitis virus; and
- (ii) Feline panleukopenia virus.

(6) Porcine cells shall, in addition, be tested for:

- (i) Porcine adenovirus;
- (ii) Porcine parvovirus;
- (iii) transmissible gastroenteritis virus; and
- (iv) Porcine hemagglutinating encephalitis virus.

(7) Firms that do not have rabies virus on premises either for research or production purposes are exempt from having to produce positive rabies virus control monolayers. Fixed positive rabies virus control monolayers will be provided by the National Veterinary Services Laboratories.

(c) After staining, each group of monolayers shall be examined for the presence of specific fluorescence attributable to the presence of extraneous viruses.

(1) If the material under test shows any evidence of specific viral fluorescence, it is unsatisfactory and may not be used; *Provided*, That, if specific fluorescence attributable to the virus being tested for is absent in the positive control monolayers, the test is inconclusive and may be repeated.

(2) If the fluorescence of the monolayers inoculated with the specific virus as positive controls is equivocal, or if the negative monolayers show equivocal fluorescence indicating possible viral contamination, or both, the test shall be declared inconclusive, and may be repeated; *Provided*, That, if the test is not repeated, the material under test shall be regarded as unsatisfactory for use in the production of biologics.

3. Section 113.52, paragraph (b)(2)(i) and (ii), is revised to read as follows:

§ 113.52 Requirements for cell lines used for production of biologics.

* * * * *

(b) * * *

(2) * * *

(i) At least two monolayers shall be stained with an antispecies

fluorochrome-conjugated antibody unrelated to the species of origin of the MCS.

(ii) At least two monolayers shall be stained with an antispecies fluorochrome-conjugated antibody specific to the species of origin of the MSC.

* * * * *

§§ 113.51, 113.52 and 113.53 [Amended]

4. In the following places, the word "agents" are removed and the word "viruses" added in its place:

- a. Section 113.51, paragraph (c)(3)(ii).
- b. Section 113.52, paragraph (f)(4)(ii).
- c. Section 113.53, paragraph (c)(6)(ii).

5. In § 113.300, paragraph (c)(1), the term "fluorescein" is removed and the term "fluorochrome" added in its place.

Done in Washington, DC, this 1st day of May 1995.

B. Glen Lee,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–11294 Filed 5–8–95; 8:45 am]

BILLING CODE 3410–34–M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 19, 20, 30, 32, 40, 50, 51, 60, 61, 70, 71, 72, 73, 74, 76, and 150

RIN 3150–AF34

Changes to NRC Addresses and Telephone Numbers

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to indicate the current addresses, telephone numbers, and organizational titles within the NRC. These changes reflect the agency's consolidation of headquarters employees to Rockville, Maryland.

EFFECTIVE DATE: May 9, 1995.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 415–7163.

SUPPLEMENTARY INFORMATION:

Background

The Nuclear Regulatory Commission is revising the regulations in 10 CFR Parts 2, 19, 20, 30, 32, 40, 50, 51, 60, 61, 70, 71, 72, 73, 74, 76, and 150 to provide