serial is not retested or the other provisions of this section are not satisfied, the serial shall be deemed unsatisfactory.

(i) If two consecutive retests (tests 2 and 3) show that potency of the serial equals or exceeds the required minimum potency, the serial is satisfactory. If one of the two retests (test 2 or 3) shows that the potency is less than the required minimum potency, the serial is unsatisfactory.

(ii) If one of the retests (tests 2 or 3) shows that the potency equals or exceeds the required minimum potency and the other retest (test 2 or 3) is an equivocal test, a third retest (test 4) may be performed. If the third retest (test 4) shows that the potency of the serial equals or exceeds the required minimum potency, the serial is deemed satisfactory. If both retests (tests 2 and 3) or if the third retest (test 4) is an equivocal test, the accumulated test results shall be considered indicative of a lack of potency and release of the serial withheld, in which case the licensee may submit data confirming the continued validity of the test system to APHIS for review and approval. If the data are acceptable to APHIS, the potency test may be repeated by the firm, subject to the provisions specified in paragraphs (c)(4) (i) and (ii) and (c)(5) (i) and (ii) of this section, and confirmatory testing by APHIS.

(d) *Repeat immunogenicity tests.* (1) The accuracy of the protective dose established for live products in the Master Seed immunogenicity test and defined as live virus titer or live bacterial count shall be confirmed in 3 years in a manner acceptable to APHIS, unless use of the lot of Master Seed previously tested is discontinued.

(2) All determinations of relative antigen content using parallel line immunoassays or equivalent methods shall be conducted with an unexpired reference. The lot of reference used to determine antigenic content shall have an initial dating period equal to the dating of the product or as supported by data acceptable to APHIS, except that frozen references may have an initial dating of up to 5 years, *Provided,* That the request for dating of the frozen references beyond the dating of the product is supported by preliminary data acceptable to APHIS and includes provisions for monitoring the stability of the reference to determine when the potency starts to decline and for taking the appropriate steps to requalify a reference with declining potency either by testing a Qualifying Serial in host animals or by providing other evidence of immunogenicity, e.g., antibody titers or laboratory animal test data previously correlated to host animal protection in a manner acceptable to APHIS. Prior to the expiration date, such reference may be granted an extension of dating, *Provided,* That its immunogenicity has been confirmed using a Qualifying Serial of product in a manner acceptable to APHIS. The dating period of the Master Reference and Working Reference may be extended by data acceptable to APHIS if the minimum potency of the Master Reference is determined to be adequately above the minimum level needed to provide protection in the host animal. If a new Master Reference is established, it shall be allowed an initial dating period equal to the dating of the product or as supported by data acceptable to APHIS, except that frozen references may have an initial dating period of 5 years, or as supported by data acceptable to APHIS. Prior to the expiration date, such reference may be granted an extension of dating by confirming its immunogenicity using a Qualifying Serial of product.

* * * * *

Done in Washington, DC, this 15th day of April 1997.

Donald W. Luchsinger,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–10100 Filed 4–17–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 156

[Docket No. 93–168–2]

Export Certification of Animal Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning inspection and certification of animal byproducts by removing references to ''inedible animal byproducts'' and replacing them with references to ''animal products,'' and by providing for the issuance of export certificates for animal products which do not require inspection. These amendments will facilitate trade in U.S. animal products.

EFFECTIVE DATE: May 19, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. Marolo Garcia, Senior Staff Veterinarian, Products Staff, National Center for Import and Export, VS, APHIS, Suite 3B05, 4700 River Road, Unit 40, Riverdale, MD 20737–1231. Telephone: (301) 734–4401; or E-mail: mgarcia@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 156 (referred to as the regulations) govern the inspection and certification of animal byproducts. These regulations were promulgated under authority contained in sections 203 and 205 of The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1622 and 1624) (the Act). The Act authorizes the Secretary of Agriculture, among other things, to ''inspect, certify, and identify the class, quality, quantity, and condition of agricultural products when shipped or received in interstate commerce, under such rules and regulations as the Secretary of Agriculture may prescribe* * *.'' The Act further states that the intended effect of this authority is that agricultural products may be ''marketed to the best advantage'' and ''that trading may be facilitated.'' The Act also authorizes the Secretary ''to perform such other activities as will facilitate the marketing [and] distribution of agricultural products through commercial channels.'' In addition, the Act states that no person shall be required to use the service.

Animal Byproducts/Animal Products

Until recently, the Animal and Plant Health Inspection Service (APHIS) under the Act was granted authority with respect to voluntary inspection and certification of only inedible animal byproducts. Our regulations have therefore only provided for APHIS to issue export certificates for inedible animal byproducts.

However, effective November 8, 1995, APHIS was granted broader authority under revised delegations of authority from the Secretary of Agriculture and general officers of the Department (see 60 FR 56392, *et seq.*). Among other changes, the Administrator, APHIS, was granted authority to administer the Act ''with respect to voluntary inspection and certification of animal products'' (see 60 FR 56457, 7 CFR 2.80(a)(28)). The effect of this amendment was to give APHIS authority to issue export certificates for all animal products, edible and inedible.

To reflect this change, we published a proposed rule in the **Federal Register** on September 19, 1996, (61 FR 49278–49279, Docket 93–168–2), to amend the regulations to remove the term ''animal byproduct'' wherever it appears, and replace it with the term ''animal

product.'' We also proposed to remove the definition of ''animal byproduct'' and add a definition of ''animal product.''

Export Certificates Without Inspection

Most countries require imported animal products to be accompanied by an official export certificate issued by the country of origin. Without such a certificate, the products cannot be brought into the country. Depending upon the product involved, many importing countries require the export certificate to state only that the exporting country is free of certain diseases. Often there is no requirement that the product itself have been inspected. As part of our proposal of September 19, 1996, we proposed to amend the regulations to provide that APHIS may issue export certificates for animal products or byproducts without conducting an inspection.

We solicited comments concerning our proposal for 60 days ending November 18, 1996. We received 1 comment by that date.

The commenter questioned whether APHIS should issue export certificates for milk, stating that State and other Federal authorities should certify milk for export.

We have carefully considered this comment and determined that no changes in our proposed rule are necessary.

We are not proposing to establish APHIS as the sole certifying authority for milk, or for any other animal products intended for export. Under our proposal, APHIS export certificates for all animal products, including milk, would be available to exporters who request them. APHIS export certificates would be available in addition to, not instead of, acceptable export certificates issued by other Federal and State agencies. We anticipate that exporters are most likely to request export certificates for milk and other dairy products from APHIS when the importing country requires that we provide certified information about the status of certain diseases in this country that could affect dairy cattle. Because APHIS has the authority and the expertise necessary to issue such certificates, we believe exporters should be able to obtain them from APHIS.

We want to make it clear that APHIS does not require export certificates; export certificates are required by the country importing the product. Additionally, APHIS does not specify what information or certifications must appear on an export certificate; that is specified by the country importing the product. APHIS's role is simply to make export certificates available. In fact, an importing country may accept any documentation it chooses, including export certificates issued by other Federal and State agencies.

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 without change.

Executive Order 12866 and Regulatory Flexibility Act

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

This change in the regulations will enable APHIS to issue export certificates for certain animal products without inspecting the products. This is a service many prospective exporters have asked the Agency to provide. Under the amended regulations, exporters will not be required to use this service. However, exporters who choose to obtain export certificates from APHIS will be required to pay a user fee of $21.50 for each certificate.

According to Foreign Agriculture Trade of the United States, FY 1995 Supplement, which contains the most recent data available, approximately $3.5 billion worth of animal products of all types were exported from the United States during FY 94. During FY 1996, APHIS issued approximately 70,000 export certificates for animal products of all types.

In our proposal of September 19, 1996, we invited comments on the impact of this rule. We specifically requested data indicating the number of entities that export animal products, how many entities might export edible animal products under our proposed rule, and how many of these entities might be small entities. Although we received no response to our request, we have no reason to believe that making export certificates available under this voluntary service would have a significant economic impact on small entities.

Executive Order 12988

This rule has been reviewed under Executive Order 12998, 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 new 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 156

Exports, Livestock, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 156, is amended as follows:

PART 156—VOLUNTARY INSPECTION AND CERTIFICATION SERVICE

1. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 1622 and 1624; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.2(d).

2. The heading of part 156 is revised as set forth above.

3. Section 156.2 is amended as follows:

a. Paragraph (g) is removed;

b. All paragraph designations are removed;

c. All definitions are placed in alphabetical order; and

d. A definition of *Animal product* is added, in alphabetical order, to read as follows:

§ 156.2 Definitions.

* * * * *

Animal product. Anything made of, derived from, or containing any material of animal origin.

* * * * *

§§ 156.3, 156.5, and 156.8 [Amended]

4. In the following sections, the word ''byproducts'' is removed and the word ''products'' added in its place:

a. § 156.3, each time it appears;

b. § 156.5; and

c. § 156.8(b), each time it appears.

5. In § 156.6, the first sentence is revised to read as follows:

§ 156.6 Certificates.

The inspector shall sign and issue certificates in forms approved by the Administrator for animal products, if the inspector finds that the requirements as stated in the certification have been met. * * *

Done in Washington, DC, this 15th day of April 1997.

Donald W. Luchsinger,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–10099 Filed 4–17–97; 8:45 am]

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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 280

[Doc. No. 960726209–7088–02]

RIN 0693–AA90

Implementation of the Fastener Quality Act

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Extension of implementation date.

SUMMARY: The Director of NIST, under authority delegated by the Secretary of Commerce, and pursuant to Section 15 of the Fastener Quality Act (Act), (Pub. L. 101–592 as amended by Pub. L. 104–113), has determined that by May 27, 1997, the current implementation date of the Act, there will not be a sufficient number of laboratories accredited to conduct the level of required testing. Accordingly, the Director is extending the implementation date of the Act by one year, to May 26, 1998. NIST will amend 15 CFR 280.12 to reflect this new implementation date in a future document. By May 26, 1998, NIST believes it will have completed the approval/accreditation of a sufficient number of accreditation bodies/laboratories to implement the Act. The total number of laboratories to accredit by the new date of implementation is estimated to be four hundred twenty-five. To accomplish the task of getting these laboratories accredited prior to May 26, 1998, NIST requests all accreditation bodies seeking approval under the NIST Accreditation Body Evaluation Program (ABEP), all laboratories seeking accreditation under the NIST National Voluntary Laboratory Accreditation Program (NVLAP), and all laboratories seeking accreditation from accreditation bodies approved or pending approval by ABEP submit their completed applications to the respective programs by August 1, 1997, in order to be given full and fair consideration for approval/accreditation by the new implementation date.

DATES: The date of implementation of the Act is May 26, 1998.

FOR FURTHER INFORMATION CONTACT: Subhas G. Malghan, NIST, Building 820, Room 306, Gaithersburg, MD 20899; Tel. No. 301–975–6101; Telefax 301–975–2183; E-mail malghan@nist.gov.

SUPPLEMENTARY INFORMATION: The Fastener Quality Act (Act), (Pub. L. 101–592 as amended by Pub. L. 104–113), requires that certain fasteners sold in commerce conform to the standards and specifications to which they are represented to be manufactured and have been inspected, tested, and certified. Inspection and testing mean that the manufacturer of a lot of fasteners shall cause to be inspected and tested a representative sample of the fasteners in such a lot to determine whether the lot of fasteners conform to the standards and specifications to which the manufacturer represents it has been manufactured. Such inspection and testing shall be performed by a laboratory accredited in accordance with the procedures and conditions specified by the Secretary under Section 6 of the Act.

In accordance with Section 15, the requirements of the Act shall be applicable only to fasteners fabricated one hundred eighty days or more after the effective date of final regulations implementing the Act (November 25, 1996). The Secretary may delay the implementation date upon a determination that an insufficient number of laboratories have been accredited to perform the volume of inspection and testing required.

In 1991 NIST requested the Fastener Advisory Committee to address the issue of determining how many laboratories are needed to be accredited to implement the Act without adversely affecting commerce. A task force of members studied the issue and prepared a report to the full Committee which was accepted by the Committee and by NIST. The report concluded that between three hundred twenty-eight and four hundred fifty-seven accredited laboratories would be required to implement the Act.

Both NVLAP and ABEP began their review of applications for accreditation on November 25, 1996, the effective date of the regulations. There has not been a great volume of applications to date. NIST believes there are several reasons for the initial slow response:

(1) Laboratories wanted to wait and see which laboratory accreditation bodies would receive approval under ABEP before determining whether to apply to NYLAP for accreditation or to another accreditation body. The cost of becoming accredited and the fact that some laboratories already have been accredited by a body applying to ABEP for approval were factors in their decision process.

(2) With the amendment to the Act that allows raw material suppliers to certify the chemistry of the metal used to manufacture fasteners, fastener manufacturers are now urging their metal suppliers to become accredited even though the Act and regulations do not require the raw material suppliers to do so. The reason is that a large number of fastener manufacturers rely on a ladle analysis of the metal and this can only be obtained while the metal is being manufactured at the mill. The metal suppliers have been slow in applying for accreditation because their customers, the fastener manufacturers, did not initially request them to do so.

At present forty-two laboratories have applied to NVLAP to be accredited and four laboratory accreditation bodies have applied to ABEP to be approved. NVLAP expects to complete accreditation of the forty-two by September 1997. Approximately another fifteen laboratories have indicated they will apply to NVLAP, and these applications will be processed by January 1998. ABEP intends to complete approval of the four laboratory accreditation bodies by September 1997. Once approved these bodies will be working on accreditation of their populations of laboratories. These four bodies, plus NVLAP, already have approximately three hundred twenty-five laboratories that have either been accredited for fastener testing or indicated that they will seek accreditation. NIST estimates that the accreditation bodies will finish their work on this population of three hundred twenty-five laboratories by April 1998. Based upon expressed interest to ABEP, three additional accreditation bodies are expected to apply for approval soon and will bring an additional seventy-five laboratories whose recognition and accreditation will proceed simultaneously and be completed by May 26, 1998. In addition, the four accreditation bodies undergoing approval process now are expected to add at least twenty-five more laboratories. If these estimates are correct, the total number of accredited laboratories by May 26, 1998, would be four hundred twenty-five. This number is sufficient to implement the Act, based upon estimates provided by the Fastener Advisory Committee and accepted by NIST.

The Act requires that NIST indicate steps being taken to ensure the accreditation of a sufficient number of laboratories. Accordingly, the following