United States unless their importation is authorized by a permit, the provisions of § 93.404(a)(3) have been sufficient to prevent the entry of live ruminants from regions affected with BSE. However, the regulations in part 93 provide exemptions from the permit requirement for ruminants from several regions, including Canada, under certain circumstances. Given that the denial of a permit application may not serve in all cases to provide a regulatory basis for preventing the importation of ruminants from regions affected with BSE, we have amended the regulations in § 93.401, ''General prohibitions; exceptions,'' to include an explicit prohibition on the importation of ruminants that have been in any region listed in § 94.18(a)(1) or (a)(2).

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the introduction of BSE into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This emergency situation makes timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility analysis.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has retroactive effective to May 20, 2003; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR parts 93 and 94 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 93.401, paragraph (a) is revised to read as follows:

§ 93.401 General prohibitions; exceptions.

(a) No ruminant or product subject to the provisions of this part shall be brought into the United States except in accordance with the regulations in this part and part 94 of this subchapter;[3] nor shall any such ruminant or product be handled or moved after physical entry into the United States before final release from quarantine or any other form of governmental detention except in compliance with such regulations. Notwithstanding any other provision of this subpart, the importation of any ruminant that has been in a region listed in § 94.18(a)(1) or (a)(2) of this subchapter is prohibited. *Provided, however,* the Administrator may upon request in specific cases permit ruminants or products to be brought into or through the United States under such conditions as he or she may prescribe, when he or she determines in the specific case that such action will not endanger the livestock or poultry of the United States.

* * * * *

PART 94—RINDERPEST, FOOT–AND–MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 3. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.18 [Amended]

■ 4. In § 94.18, paragraph (a)(1) is amended by adding, in alphabetical order, the word ''Canada,''.

Done in Washington, DC, this 23rd day of May, 2003 .

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13440 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 02–109–3]

Importation of Beef From Uruguay

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence presented in a recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action will provide for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of foot-and-mouth disease.

EFFECTIVE DATE: May 29, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Hatim Gubara, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, VS, APHIS, 4700 River Road Unit

[3] Importations of certain animals from various regions are absolutely prohibited under part 94 because of specified diseases.

38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including rinderpest, foot-and-mouth disease (FMD), African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Section 94.1 of the regulations lists regions of the world that are considered free of rinderpest or free of both rinderpest and FMD. The Animal and Plant Health Inspection Service (APHIS) considers rinderpest or FMD to exist in all regions of the world not listed.

On February 10, 2003, we published in the **Federal Register** a proposed rule (68 FR 6673–6677, Docket No. 02–109–1) to amend the regulations by allowing the importation of fresh (chilled or frozen) beef from Uruguay provided certain conditions were met. In that proposed rule, we notified the public of the availability of a risk assessment entitled, ''Risk Assessment—Importation of Fresh (chilled or frozen) Beef from Uruguay'' (November 2002).

We solicited comments concerning the proposed rule and the risk assessment for 60 days ending April 11, 2003. On April 14, 2003, we published in the **Federal Register** a notice (68 FR 17886, Docket No. 02–109–2) in which we reopened and extended the comment period for a period of 2 weeks ending April 25, 2003. We received a total of 28 comments by that date. The comments were submitted by domestic cattle producers, domestic cattle and livestock associations, a food company, a trade association, a State department of agriculture, a State public lands council, State veterinarians, foreign livestock associations, a representative of a foreign government, and other members of the public. Five commenters were supportive of the proposed rule, and three additional commenters generally supported the proposed rule provided APHIS continues to evaluate the validity and efficacy of the mitigation measures. The other commenters expressed concern about the effects of the proposed rule and about some of the specific provisions of the proposal. These comments are discussed by subject below.

Trade Issues

Several commenters expressed concern that there would be negative economic effects on the domestic cattle industry if fresh beef is allowed to be imported from Uruguay. Under its statutory authority, APHIS may prohibit or restrict the importation or entry of any animal or article in order to prevent the introduction or dissemination of a pest or disease of livestock. APHIS does not, however, have authority to restrict trade based on its potential economic effects. It should be noted, however, that past importations of fresh beef from Uruguay have comprised 0.2 percent or less of the total U.S. beef supply.

Equivalency and Verification Issues

Several commenters expressed concerns that Uruguay's health environment, level of management of disease control, and epidemiology are not equivalent to those of the United States. Based on our evaluation of information obtained from Uruguay, from APHIS site visits to that country, and from periodic visits conducted by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), we have concluded that Uruguay's health standards, demonstrated ability to implement effective disease control methods in the event of an outbreak, and familiarity with modern epidemiology are effective.

One commenter stated that APHIS ''needs to verify that the Uruguay FMD surveillance program is valid and that Uruguay is indeed free of the virus'' and that ''if APHIS confirms that FMD has been eliminated it must verify that the mitigating measures of de-boning, no blood clots, lymphatic tissue, and a pH of 5.8 or less is achieved in Uruguay.'' The commenter also stated that ''[i]f these steps are verified, a wealth of scientific data indicates beef from Uruguay will not pose an FMD threat to the United States.'' Three commenters asked if APHIS had evaluated Uruguay's FMD surveillance program, processing system, and mitigation measures. One commenter stated that ''APHIS must also verify that these mitigating measures are being conducted in an adequate manner in Uruguay.* * *'' Three commenters suggested that evaluation teams include State laboratory officials, representatives of APHIS, the U.S. Food and Drug Administration (FDA), State animal health officials, and industry representatives. One commenter stated that more stringent inspections by non-Uruguayan officials are needed. Some of these commenters asked whether we would develop a verification plan.

We evaluate each request for initiation or resumption of trade in animals or animal products with foreign countries individually. The complete review process involves a thorough evaluation of the relevant infrastructure of the individual country by technical experts with experience in country disease evaluation and risk assessment. The risk assessment process, which is detailed below, is implemented specifically to evaluate and verify the efficacy of the surveillance programs, border controls, processing systems, and other disease control measures of the country in question.

The information is evaluated by personnel from APHIS's National Center for Import and Export (NCIE); Centers for Epidemiology and Animal Health (CEAH), which is an Office International des Epizooties (OIE) collaborating center for risk assessment and surveillance;[1] other Veterinary Services (VS) personnel, as appropriate; personnel from the National Veterinary Services Laboratories (NVSL); and personnel from APHIS's International Services who have first-hand knowledge of the animal health conditions in the region under evaluation. APHIS reviews the information provided by foreign government officials for completeness and acceptability with regard to all of the factors for evaluation listed in 9 CFR 92.2, ''Application for recognition of the animal health status of a region.'' Topics covered in this review include, but are not limited to, border controls, surveillance, slaughter/processing plant controls, and security of sample integrity. In addition, the evaluation addresses effectiveness of veterinary infrastructure, disease status of the region, status of adjacent regions, disease control programs, vaccination status, separation of the region from adjacent higher risk regions, animal movement controls, livestock demographics and marketing practices, laboratory capabilities, and emergency response capabilities. APHIS requests additional information, if necessary, and seeks relevant information from other sources such as published literature.

Once the information provided by foreign officials is considered sufficient to conclude that the risks are low enough that the evaluation may proceed, a site visit to the region is

[1] In 1998, the OIE designated CEAH as a Collaborating Center for Risk Analysis and Animal Disease Surveillance Systems. The OIE is the international animal health standard-setting organization recognized by the World Trade Organization. The role of the collaborating center is to provide member countries of the OIE with scientific and technical assistance and expert advice on topics linked to animal health risk analysis and disease surveillance and control.

scheduled. In addition to representation by VS personnel, the site review team also includes field personnel from APHIS's International Services, a State veterinarian, and, if a quantitative model is used to assess risk, individuals with expertise in quantitative risk analysis techniques.

We believe that the disease evaluation expertise of personnel from NCIE and CEAH, with input as appropriate from other APHIS units for additional expertise in quantitative risk analysis techniques and in-country conditions, and the foreign animal disease (FAD) laboratory expertise of NVSL are adequate for these evaluations. We do not include FDA personnel, as FAD evaluations are not within the FDA's authority or expertise. We do not include State laboratory personnel since FAD laboratory expertise is provided by NVSL.

Industry representatives have not historically participated in APHIS evaluations. APHIS believes that it is not appropriate to include industry commodity groups on country evaluation teams for several reasons, but primarily because industry participation might make it appear that the review is not impartial. Inclusion of industry representatives might generate the appearance of, and potential for, conflicts of interest between the U.S. and foreign industry interests. In addition, APHIS questions whether information would be provided freely by foreign governments and commercial interests if U.S. industry representatives were present. In this regard, the site visit teams typically include visits to commercial facilities that might be unwilling to openly exchange commercial or proprietary information, which is critical to the verification and evaluation process. Also from a practical standpoint, industry representation would be necessarily limited to a very few individuals representing a very limited spectrum of the industry, thereby possibly providing a competitive advantage for participants. Further, inclusion of industry representation on a team that will provide recommendations to the agency could raise concerns under the Federal Advisory Committee Act unless the team was formally chartered as a Federal advisory committee. This would not be feasible for site visit teams.

The information obtained from these reviews is used to conduct an assessment of the risk of importation of the requested commodity. The risk assessments APHIS prepares are made available for public review prior to any final rulemaking. All comments from the public are considered in the final decisionmaking process.

Uruguay's surveillance program, border controls, and processing and slaughter controls, as well as its implementation of various mitigation measures, have all been evaluated during our site visits in preparation for the risk assessment. Evidence of the effectiveness of the measures being taken is presented in the risk assessment. Periodic visits to the slaughtering establishments are also conducted by FSIS. Although we do not conduct scheduled, annual visits to the processing plants, we note that we have an APHIS representative who is permanently located in Uruguay, and that all processing plants approved for export must allow periodic on-site evaluation and subsequent inspection of their facilities, records, and operations by an APHIS representative at our request. We will continue to monitor the situation in Uruguay and will conduct reinspections if we feel they are necessary.

We do not consider it necessary to establish a specific verification plan for Uruguay. In fact, on March 6, 2003, we published in the **Federal Register** (68 FR 10667, Docket No. 01–036–1) a proposed rule that, if made final, will reinforce our current authority to reevaluate regions when there is a reason for concern.

Several commenters asked whether we will provide for reinspection of fresh beef from Uruguay at the U.S. port of first arrival to verify that all mitigation measures, including measurement of pH levels, have been effectively and adequately carried out. Based on the evidence in the risk assessment and the site visit report regarding Uruguay's effective implementation of the required mitigation measures, reinspection would be unlikely to provide additional risk mitigation. Reinspection at the port of first arrival would be a valid safeguard only if it could provide verification of the pH level of the beef at the time of maturation. Variations in pH levels during cold storage, freezing, and transport, however, would make it very difficult to obtain data that can be correlated with pH levels at the time of maturation. Therefore, the type of reinspection upon arrival suggested by the commenters would offer no additional protection. Inspectors at the port of first arrival will, however, monitor all shipments that come into the United States and verify that the beef is accompanied by the foreign meat inspection certificates required under this rule to ensure that all requirements have been met.

One commenter stated that we should enforce documentation measures to protect against the possibility of transshipment (*i.e.,* beef from Uruguay being shipped through another FMD-affected country while en route to the United States). The regulations in § 94.1(d) provide conditions that must be met in order for fresh (chilled or frozen) meat that enters a port or otherwise transits a region where rinderpest or FMD exists to be eligible for importation into the United States. Those conditions include certification requirements and safeguarding measures, including the use of official seals, to prevent the meat from coming into contact with any other cargo or being handled during transit. However, the provisions of § 94.1(d) apply specifically to the transshipment of fresh (chilled or frozen) meat of ruminants or swine raised and slaughtered in a region free of FMD and rinderpest. Therefore, in response to this comment, we are amending § 94.1(d) in this final rule to provide that the conditions in that paragraph also apply to fresh (chilled or frozen) beef from Uruguay. We are also amending paragraph (b) of § 94.1, which refers to the provisions of paragraph (d), to reflect this change.

Technical Questions

Two commenters expressed concern about the risk posed by formerly exposed cattle who can carry the FMD virus in the oropharynx, where it can persist for between 30 and 36 months and be preserved by refrigeration or freezing. According to Thomson (1994) [2], recovered cattle or vaccinated cattle that had been exposed to diseased animals, the FMD virus was found only in the pharyngeal area of carriers, and in only minute quantities. This virus usually is bound to antibodies and virus inhibitors. In general, carriers have high levels of circulating antibodies. Carrier animals do not have the virus in the blood (viremia), bone marrow, lymph nodes, or muscle tissue. In addition, the head, in which the oropharynx is located, is one of the bovine parts that is prohibited importation.

We proposed that beef imported from Uruguay must come from bovine carcasses that were allowed to maturate for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. We also proposed that any carcass in which the

[2] Thomson, G., ''Foot-and-Mouth Disease,'' Infectious Diseases of Livestock (ed. Coetzer, Thomson and Tustin). Chapter 2, pp 825–852, Oxford University Press. Capt Town, South Africa, 1994.

pH did not reach 5.8 after 36 hours could maturate an additional 24 hours and be retested. If the carcass had not reached a pH of 5.8 or less after 60 hours, the meat from the carcass could not be exported to the United States. Several commenters stated that, based on OIE standards, standards of specific international markets, and cited studies, the minimum maturation time for beef from countries where vaccination is practiced should be 24 hours rather than the 36 hours that we proposed, with an additional 12 hours allowed for beef that had not reached 5.8 or less after 24 hours. The commenters stated that a minimum maturation time of 36 hours is cost prohibitive and logistically difficult to maintain. One of the commenters stated that the pH level in beef tends to rise when maturation time exceeds 24 hours.

We are making no changes based on these comments. The scientific literature available to us does not support the statement that the pH level in beef tends to rise when maturation time exceeds 24 hours. Available literature showed that there is a gradual trend towards lower pH with time and that the pH averages 5.6 to 5.8 after 48 hours of aging, although the pH does tend to rise slightly after 72 to 96 hours of maturation.[3] Other research indicated that, although the FMD virus survived for 24 hours in beef stored at 4 °C, the virus was inactivated by the third day after the pH had declined.[4]

The data used in our risk assessment for the proposed rule change comes from our site visits and from data provided by Uruguay. Because all plants in Uruguay currently operate according to the European Union's (EU) requirement of a minimum of 24 hours of maturation and a pH level of less than 6.0, the only data available to us were for the number of carcasses in Uruguay that failed to meet that level. That rejection rate was used in assessing the proportion of viremic carcasses that could pass undetected through the processing system. However, because the current rejection rate is based on a pH threshold of less than 6.0, APHIS' requirement of pH 5.8 could increase the rejection rate by an unknown amount. Since we are requiring a minimum maturation time of 36 hours, and the literature indicates a gradual trend towards lower pH over time, we considered it unlikely that the rejection rate will increase significantly. Using that information, we concluded that fresh beef could be imported from Uruguay in accordance with the conditions described in the proposed rule without an unacceptable risk of FMD being present in the beef. Because no data are available to us regarding the rejection rate at pH 5.8 or less after a minimum of 24 hours of maturation, we are retaining the requirement that fresh beef from Uruguay undergo maturation for a minimum of 36 hours and reach a pH of 5.8 or less.

One commenter stated that pH measurements should be taken at the middle of both *longissimus dorsi* muscles. Although we did not specify this requirement in the proposed rule because it is common practice, for clarity's sake we are including it in the final rule.

Because of the importance of proper pH measurements, one commenter asked (1) how we will verify that Uruguayan processing plants use the best available pH testing technology, (2) if we will initiate an approved pH meter standard, (3) if we will require the processing plants to have standard operating procedures for the use of pH meters on file, and (4) if we will require them to record pH meter serial numbers and document their meter standardization. Another commenter requested that a certified U.S. veterinary official oversee all pH testing and verify that conditions at slaughter facilities are equivalent to U.S. standards. One commenter requested that APHIS require the presence of a full-time APHIS or FSIS inspector to ensure that all processing is done in compliance with U.S. standards.

The pH control in Uruguay is regulated under the Government of Uruguay's Procedure 2001/2, ''Generic procedure for maturation and pH control in bovine and ovine meat and offal'' and Circular 2002/4, ''Procedure for official verification of the calibration of pH measuring devices for meat.'' The former procedure specifies time and temperature for the maturation process and requires that all meat processed for export be pH-tested. The latter procedure requires calibration of pH measuring devices at the beginning of each workday and after every 200 measurements. Other Uruguayan requirements include official control of the preparation and storage of buffer solutions.

As noted in our site visit report, we evaluated pH control procedures at the San Jacinto plant, which exports to the EU and to other countries, during the July 2002 site visit to Uruguay. We verified that the instrument used to measure pH is calibrated according to the manufacturer's specifications. There is a laboratory in the plant where pH calibration takes place on a daily basis. Calibration and rejection records were examined and verified. All records were found to be adequate. In addition, we verified that pH testing is done by plant personnel under strict supervision by official inspectors. We concluded that adequate pH measuring technologies are available at export plants and that calibration of devices and control of pH inspection is carried out under the control of official authorities. Based on this evidence, we do not believe it is necessary for this rule to require an additional approved pH meter standard or to specifically require every plant keep its standard operating procedures for the use of pH meters on file, to record pH meter serial numbers, and to document their meter standardization, since these measures are already required by the Uruguayan government and all of the necessary documentation and procedures are already on file in each plant. Nor do we consider continuous APHIS supervision of the process necessary. However, this rule provides that APHIS reserves the right to conduct reinspections at any time that we feel it is necessary.

One commenter noted that, according to two studies,[5] pH can change slightly during cold storage. As a result, although beef may have achieved a pH of 5.8 or less in Uruguay, upon arrival in the United States the pH level may have increased slightly. The commenter requested that APHIS develop a project to collect pH data from specific lots of beef destined for export to the United States and then to verify the pH upon departure and arrival in order to establish a baseline of pH changes during transport. This baseline could then be used to verify that the beef had reached a pH of 5.8 during the maturation process in Uruguay.

The variations in pH level fluctuations would make it difficult, if not impossible, to correlate the pH levels of beef arriving in the United States with the pH levels that had been achieved at maturation in Uruguay. We do not believe that a project of this type would offer meaningful data or provide additional protection. Additionally, for the reason discussed previously, we consider the pH readings reported by Uruguayan officials to be sufficient.

One commenter noted that although the risk assessment states that

[3] Cottral *et al.,* ''The Survival of Foot-and-Mouth Disease Virus in Cured and Uncured Meat,'' American Journal of Veterinary Research, 1960, pp 288–297.

[4] Henderson, W. and Brooksby, J., ''The Survival of Food-and-Mouth Disease in Meat and Offal,'' Journal Hyg. Camb., 1948, 46(4):394–402.

[5] Sair, L. and Cook, W.H., Canadian Journal of Research, 16 (section D, No. 9: 255–267), 1938.

Wierbicki, E., *et al.,* Food Technology, (8): 506–511, 1954.

vaccinating twice with an oil adjuvant vaccine offers 99 percent protection, the proposed rule does not require any specific vaccine or number of vaccinations. The commenter questioned whether changes in Uruguay's choice of vaccine or the number of doses would affect the efficacy of the mitigation measure and affect the outcome of the risk assessment. The commenter also asked if we would change the import requirements and mitigation measures if Uruguay decides to stop vaccinating in the future.

Because Uruguay responded so quickly to the outbreak of FMD in April 2001, officials there did not have the opportunity to test different FMD vaccines to determine which was most effective. Uruguay used trivalent vaccines from Brazil and Paraguay and bivalent vaccines from Colombia and Argentina that had been approved and certified in their respective country of origin by the competent sanitary authority. In all cases, safety and efficacy tests used were those established by the regional reference agency, the Pan American FMD Center (PANAFTOSA). Once the outbreak was under control, however, Uruguay's Ministry of Livestock, Agriculture, and Fisheries, together with PANAFTOSA, conducted tests on a variety of vaccines in order to determine which would be most effective for use in the ongoing vaccination program. We have reviewed the results of these tests and have found Uruguay's choice of vaccine, which offered a protection level of 99.7 percent after revaccination, to be adequate and effective. We do not believe it is necessary to require the use of a particular vaccine in this rule, as it is unlikely that Uruguay will choose a less efficacious vaccine in the future. However, we will continue to monitor the situation and make any necessary adjustments to the mitigation measure requirements if any changes occur.

As stated in the site visit report, under Uruguayan law, cattle are not allowed to be moved until they have been vaccinated against FMD twice. All cattle that are moved within Uruguay are required to be accompanied by a certificate that contains information about the date, brand, and series of vaccine that was used. Because this dosage requirement is already in place, we do not believe it is necessary to add this requirement to the rule. We will continue to monitor the situation and will reassess the situation and the risk level if any changes in Uruguay's vaccination requirements occur.

One commenter, referring to the scenarios presented in the risk assessment, asked about the expected incursions of FMD using a scenario of over 100 undetected herds.

We believe the commenter has misinterpreted the scenarios presented in the risk assessment. First, we note that the risk assessment never states that the data refer to potential ''incursions'' of FMD. The results from the scenarios described in the risk assessment were derived from the negative binomial distribution, which calculates the number of years before the first importation of FMD-infected beef, not the first outbreak or case of FMD, from such imports. Second, the commenter appears to assume that we are comparing scenarios with a maximum of 35 undetected, infected herds versus a maximum of 62 undetected, infected herds. In our risk assessment, we developed two scenarios. The first scenario, which we believe is the most realistic, offers data for a situation involving between 1 and 35 undetected, infected herds. This scenario was run using a uniform distribution of values rather than point values, which means that every value within the range of 1 to 35 has an equal likelihood of occurrence. The second scenario, which we believe is less realistic but necessary in order to capture the full range of possible uncertainty, offers data for a situation involving between 1 and 62 undetected, infected herds, with a most likely value of 35 undetected, infected herds.

In order to reasonably evaluate a scenario for over 100 undetected, infected herds, we also had to present point value results at 35 and at 62 undetected herds. The results are presented in table 1, below. These results represent the number of years until the first importation of FMD-infected beef from Uruguay, not the first expected incursion of FMD.

TABLE 1.—RISK SCENARIO FOR OVER 100 UNDETECTED HERDS

	Point estimate of the number of infected and undetected herds		
	35	62	100
Mean number of years until the first importation of FMD-infected beef from Uruguay	10,500	5,900	3,700
Most likely number of years until the first importation of FMD-infected beef from Uruguay	6,200	550	510

The results show that for an average of 100 undetected, infected herds per year in Uruguay, the most likely number of years until the first importation of FMD-infected beef is 510. However, based on past history, we believe that it is likely that FMD would be detected before the number of undetected infected herds reached 100. Therefore, we do not believe that this risk scenario offers any realistic information about the risk of importing fresh (chilled or frozen) beef from Uruguay.

Serological Surveillance

One commenter noted that APHIS did not discuss FMD infection in feral species in Uruguay. The commenter asked if surveillance has been done in feral populations. Although the information available to us indicates that there is no surveillance of wildlife populations in Uruguay, we have no evidence that indicates that feral animal populations in Uruguay are infected with FMD. To our knowledge, infections of FMD in wildlife were not a factor in the spread of FMD, nor were wildlife populations reservoirs of infection in past outbreaks. We have concluded that authorities in Uruguay are conducting adequate surveillance for FMD to detect the disease if it were to be reintroduced into the country. While there was no specific information presented to show that susceptible feral animals in Uruguay are free of FMD, the active surveillance program includes domestic animals that may be exposed to feral animal populations.

One commenter inquired whether there were any results available from surveillance in susceptible species other than bovine. Uruguay has conducted surveillance of sheep, as discussed below. There has been no active surveillance of swine in Uruguay, partly because there are only approximately 300,000 pigs in the entire country. During the past outbreak, only 112 pigs were affected by FMD. Based on the small population of swine, combined with the fact that the FMD virus that was present in Uruguay affects

primarily cattle, and that swine react differently to FMD in general, we do not consider swine to be critical as the primary focus of serological surveillance.

One commenter asked whether the results of the sampling of sheep that was scheduled to be completed by May 2002 were available. A serological survey of the sheep population of Uruguay was conducted between May and August 2002. The survey was designed to detect virus activity in 1 percent of the sheep population and to identify sheep flocks with 5 percent or more infected sheep. Three groups were defined for sampling by geographical strata based on distance from the nearest FMD focus in previous outbreaks: Stratum I-less than 5 km, stratum II–5–10 km, and stratum III-greater than 10 km. Within each group, sheep operations were randomly selected in proportion to flock size.

The survey sampled 18,296 sheep from 340 flocks. Using the Virus Infection Associated Antigen (VIAA) test, the estimated seroprevalence for antibodies to the FMD virus was 0.16 percent. The results show a decline from a previous survey. By geographic area, the seroprevalence was 0.23 percent in stratum I, 0.08 percent in stratum II, and 0.04 percent in stratum III. A subsequent epidemiological investigation of the 20 seropositive animals concluded that the positive results were due to residual antibodies from exposure during the previous epidemic.

Because unvaccinated sheep were not involved in large numbers during the most recent outbreak of FMD, one commenter questioned the utility of using unvaccinated sheep as sentinels for the virus. We agree that sheep were not a major factor in the establishment and spread of FMD during the 2001 outbreak in Uruguay. In addition, the available evidence suggests that sheep may not be good sentinels for detecting the presence of clinical disease. However, the serological evidence provided by Uruguay indicates that sheep may serve as serological sentinels based on the data on seroconversion that were received during surveys conducted in 2001. Monitoring the fluctuations in the levels of antibodies that the sheep develop will give scientists and veterinarians a warning about the presence of FMD.

One commenter asked if serosampling since February 2002 has continued to show a decline in prevalence. Serological sampling of the cattle population in November 2002 indicated a decline in FMD prevalence compared to previous surveys. As stated in the risk assessment, Uruguay conducted two serological surveys in 2001 and 2002 in the cattle population, using the 3ABC enzyme-linked immunosorbent assay (ELISA) to detect antibodies against FMD non-structural protein. The seroprevalence of FMD was estimated to be 9.26 percent in 2001 and 2.3 percent in February 2002.

Using the 3B ELISA test for non-structural antibodies to the FMD virus, the estimated seroprevalence in November 2002 was 1.98 percent. Sera positive on the 3B ELISA were retested using the 3A ELISA in order to increase specificity, resulting in an adjusted seroprevalence estimate of 0.65 percent. This indicates that there is a declining trend of non-structural antibodies.

One commenter asked whether the USDA had looked at the test kit variation for the 3ABC ELISA test. We have evaluated test results obtained by Uruguay in their serological survey conducted in February 2002 in cattle. The data were obtained using two different 3ABC ELISA kits (United Biomedical Incorporated (UBI) and Pirbright 3ABC ELISA kits) and the Virus Infection Associated Antigen (VIAA) test. The types of tests and the results obtained during that survey are provided in table 2. The FMD prevalence estimates provided by Uruguay were based on results obtained using the UBI kit. After retesting of serum samples using the Pirbright 3ABC ELISA kit and the VIAA test, the data showed a three-fold reduction in the number of positive samples. However, the number of positive samples in the two additional tests were quite comparable. In order to maximize the risk estimates, APHIS used the prevalence estimates that were obtained using the UBI kit in the quantitative risk assessment.

TABLE 2.—SEROLOGICAL SAMPLING IN CATTLE IN URUGUAY 2002

Regions*	Holdings sampled	Holdings with positive sera—		
		UBI	Pirbright 3ABC	VIAA
Stratum I (< 5 km)	59	18	7	10
Stratum II (5–10 km)	65	16	6	5
Stratum III (>10 km)	75	15	5	2

*Regions for sampling were established based on their distance from the nearest FMD focus in the previous outbreaks.

One commenter noted that the site visit report states that ''[a]lthough the team felt that positive 3ABC ELISA tests may not be a result of field virus, that possibility cannot be totally excluded,'' and asked if more serological surveys will be done to exclude the possibility of circulating FMD virus.

We will continue to monitor the situation in Uruguay and will evaluate the results of serological surveys being conducted by Uruguay. We evaluated data from the two previous serological surveys conducted in 2001 and 2002 and concluded that serological surveillance and sampling schemes were adequate. In addition, APHIS concluded that the official national laboratory in Montevideo, which is the only laboratory approved to carry out FMD serological testing in Uruguay, has the capacity to run valid serological tests for FMD.

Based on the serological data provided by Uruguay, APHIS could not exclude the possibility that positive 3ABC ELISA tests are due to field virus. APHIS believes that this possibility cannot be excluded under any circumstances. In the July 2002 site visit report, APHIS mentioned that the positive results were likely due to the use of partially purified or unpurified vaccines, or to false-positive tests for the following reasons: (1) There was a declining pattern of FMD prevalence in the two surveys, which indicates that the positive response may not be due to infection; (2) the distribution of the positive holdings was quite comparable among the three different geographical regions (strata I, II, and III), which suggested false-positive tests since both strata II and III did not include any farms with registered FMD cases at any time during the outbreaks; and (3) when the sera were further processed by the central laboratory using 3ABC ELISA kits from a different source, in addition to the VIAA test, the number of positives was markedly reduced (see

table 2). The 101 total positive sera from the UBI kit were distributed among 49 different holdings that were scattered all over the country with no geographical or epidemiological relationship. We used the higher prevalence estimates based on 101 positive animals in our quantitative risk assessment in order to maximize the risk estimate.

One commenter asked what the future follow-up procedures for serosamples found to be positive using the 3ABC ELISA test will be and how we will ensure that 3ABC positive serology cases trigger follow-up testing for virus isolation by OIE approved methods.

In bovine sampling, Uruguay has been using the UBI ELISA test kit to identify 3B FMD non-structural antibodies. According to the manufacturer's recommendation, the ELISA test for the detection of 3A FMD non-structural antibodies is used as a confirmatory test. As stated in the site visit report, this testing and retesting strategy has been followed in Uruguay. In cases in which positive animals persist after the two rounds of tests, Uruguayan officials proceed with clinical investigation of the susceptible species in order to confirm or reject any suspected presence of the disease.

One commenter asked what the scientific basis was for the statement in the risk assessment that fully protected animals are unlikely to become viremic. According to the commenter, a 2002 Pirbright Laboratory study showed that vaccinated swine will become viremic and shed virus despite their lack of clinical signs.

First, we note that our risk assessment was conducted specifically to determine the risk level associated with beef from Uruguay. The word ''animal'' throughout the risk assessment refers exclusively to the bovine species from which beef is derived.

Second, based on several different transmission studies,[6] a case can be made for the lack of significant viremia in vaccinated cattle. The findings of these studies suggest that higher immunity levels due to multiple applications of FMD vaccine or increased duration between vaccination and virus challenge result in reduced virus production or none at all.

We also note that swine respond differently than cattle do to the FMD virus. The study cited by the commenter relates to vaccinated swine, which were not largely affected by the strain of the virus that was present in Uruguay, and is not pertinent to this rule. However, we welcome any additional information or data that the commenter can provide, and we will review all such information as appropriate.

One commenter asked whether we had reviewed Uruguay's surveillance data to determine if Uruguay satisfies the OIE's ''FMD-free with vaccination'' status requirements. Although we do take international standards into consideration, we conduct independent risk assessments using our own stringent criteria as detailed previously. This rule relates to determining what mitigation measures would be effective in protecting the United States from the introduction of FMD in light of the fact that Uruguay does vaccinate, and this rule does not address whether Uruguay can be considered FMD-free with vaccination according to OIE standards.

One commenter expressed concern that FMD is often carried in animals that show no signs of disease until they are under stress. The commenter wanted to know how we would protect against this. We note that animals that show signs of FMD when under stress will do so as a consequence of viremia. All of our mitigation measures specifically target viremic animals.

General Questions

Several commenters expressed concern that the last outbreak of FMD was too recent for Uruguay to be considered a safe source of imported beef. Two of these commenters stated that we should require a longer disease-free waiting period, ranging from 3 to 5 years, and one commenter suggested that we conduct periodic, independent verification of the disease-free status of Uruguay during that waiting period. One commenter stated that we need to evaluate and take into consideration both the FMD status of Uruguay and the longevity of its disease-free status.

Our risk assessment process is thorough and rigorous. All of the evidence in our risk assessment and site visit report indicates that Uruguay is effectively controlling FMD and has established adequate precautions, including border and movement controls and surveillance and vaccination programs, to ensure the safety of the commodity it wishes to export. Further, the mitigation measures that we require offer additional protection against the introduction of FMD into the United States from the importation of fresh (chilled or frozen) beef from Uruguay. We do not consider a 3 to 5 year disease-free waiting period to be either necessary or required by international requirements or standards.

One commenter noted that vampire bats are common in South America and asked if we had taken into account the fact that they could spread disease among cattle and how we planned to protect against this possibility. The commenter did not provide data to support the hypothesis that vampire bats are a transmission issue for FMD in Uruguay, and we are unaware of any such evidence.

One commenter noted that some of the supporting documents that accompanied the proposed rule were made available only in Spanish. The commenter stated that expenses to the reader are incurred when countries do not supply us with translated documents.

Although we were unable to identify the supporting documentation to which the commenter referred, the regulations in 9 CFR 92.2, which relate to applications by regions for recognition of the animal health status of that region, require that countries supply supporting documents in English. While we occasionally post supporting documents in a foreign language, these are usually documents obtained and discussed during site visits. In these instances, oral translation was provided to the site visit team, but no English language version of the document was made available. We have not always required written translations of such documents since the information in them, which was presented orally during the site visit, is included in the site visit report.

Two commenters stated that Uruguay should establish agreements with its neighboring countries and trading partners to ensure that they receive timely information about the presence of FMD in those countries. We agree that FMD in South America presents a regional challenge and that an effective regional approach is necessary to reduce the risk of disease spread from the region. Such a regional approach does exist. As noted in our site visit report, Uruguay, Argentina, and Brazil participate in the Cuenca del Plata FMD program under the auspices of PANAFTOSA. The main objective of the Cuenca del Plata program is to eradicate FMD with a regional, harmonized approach. Shortly after FMD outbreaks in 2001 in Argentina, Uruguay, and

[6] Barnett, P.V. and Carabin, H., A review of emergency foot-and-mouth disease (FMD) vaccines. Vaccine, (2002), 20:1505–1514.

Doel, T.R., Natural and vaccine-induced immunity to foot-and-mouth disease: the prospect for improved vaccines. Revue Scientifique et Technique, OIE, (1996), 15(3):883–911.

Donaldson, A.I. and Kitching, R.P., Transmission of foot-and-mouth disease by vaccinated cattle following natural challenge. Research in Veterinary Science, (1989), 46:9–14.

Sellers, R.F., Herniman, K.A.J., and Gumm, I.D., The airborne dispersal of foot-and-mouth virus from vaccinated and recovered pigs, cattle and sheep after exposure to infection. Research in Veterinary Science, (1977), 23:70–75.

Brazil, PANAFTOSA conducted inspection visits in the three countries and issued recommendations to strengthen and improve the existing FMD programs.

In addition, Uruguay has reviewed its own FMD strategy and has increased the authority of local offices in border areas, improved communication between local offices, developed a communication and education program for producers, and established a National Honorary Animal Health Commission with the participation of producers and both private and official veterinarians. The regional situation has greatly improved since 2001.

It is evident that Uruguay's government is committed to strengthening and improving its information systems for FMD surveillance and eradication in the region. Uruguay is continually reviewing and improving its regional coordination agreements. As a matter of national policy, Uruguay is coordinating with neighboring countries to establish common strategies for combating FMD and for direct information exchange between both official and private sectors.

We carefully considered the regional situation as an integral part of assessing Uruguay's FMD status, and we are continually monitoring the FMD situation in South America. We believe that Uruguay, Argentina, and Brazil have an effective cooperative, regional approach to FMD surveillance and control programs, and that each of these countries is committed to transparency and to collaboration in controlling and eradicating FMD.

A few commenters asked what guarantee we have that FMD has been eradicated in Uruguay. As noted in our site visit report, we have no evidence of the presence of the FMD virus in Uruguay, and have concluded that Uruguay has the ability to detect, control, and respond to FMD outbreaks in an effective way. The mitigation measures that we have put in place protect against the introduction of FMD into the United States.

A few commenters expressed concern that Uruguay is not able to determine where every beef animal is located or to confirm whether wild cattle are pastured on the same ranches with domestic cattle or that every herd is FMD-free. All cattle in Uruguay are identified with tags for movement that indicate the farm and herd of origin. All shipments of cattle must be accompanied by certificates that indicate that each animal has been vaccinated twice, and information about the date, brand, and series of vaccine that was used must also be on the certificate. In addition, Uruguay's ongoing surveillance program, combined with all of the movement control measures, provide adequate levels of surveillance for FMD in herds in Uruguay. Also, international trade agreements entered into by the United States provide that we should not require more of our trading partners than we carry out ourselves. The United States does not have a system that allows us to determine where every beef animal is located.

One commenter asked what guarantee we have that the mitigating measures are effective. The scientific literature supporting the efficacy of the mitigation measures such as the requirement that carcasses reach a pH level of 5.8 or below and the requirement that all bones, major lymph nodes, and blood clots be removed, is cited in the risk assessment. In addition, these measures comply with or exceed international standards for importing fresh (chilled or frozen) beef from countries that vaccinate against FMD. The OIE prescribes that the meat reach a pH level below 6.0 during the first 24 hours of maturation. Our requirement of a pH level of 5.8 or below provides a margin of safety and ensures the complete inactivation of the FMD virus.

One commenter requested that we provide details about the FSIS export plant approval process, Hazard Analysis and Critical Control Point (HACCP) related equivalency, and resampling procedures used to verify microbiological and residue requirements monitored upon arrival in the United States.

The FSIS regulations related to imported products are found in 9 CFR part 327. In those regulations, § 327.2(a)(2)(i) requires foreign countries to have a system of meat inspection that provides standards equivalent to those of the Federal system of meat inspection in the United States in areas that include, but are not limited to, ultimate control and supervision by the national government; the assignment of competent, qualified inspectors; and inspection, sanitation, quality, species verification, and residue standards.

The requirement listed in § 327.2(a)(2)(ii)(H) states that the foreign country must have an HACCP system as described in 9 CFR part 417. The regulations in § 327.2(a)(3) require a responsible official of the foreign meat inspection system to certify processing plants as eligible to participate in an export program according to all FSIS regulations contained within 9 CFR part 327. Sections 327.5 and 327.6 list the regulations and instructions related to importer applications for inspection of products for entry and related to reinspection of imported products. The actual procedures that FSIS uses for sampling and reinspection are detailed in that agency's Import Manual of Procedures. Information about FSIS requirements, procedures, and regulations can also be obtained on the Internet at *http://www.fsis.usda.gov.*

One commenter asked whether Uruguay's bovine spongiform encephalopathy (BSE) safeguarding system is equivalent to that of the United States. Although the intent of the proposal was to address the risk of importing fresh beef from Uruguay in the absence of other diseases, not to assess the risk of BSE in Uruguay, it should be noted that there is no evidence of which we are aware that BSE is a concern in Uruguay. Canada has evaluated Uruguay and found it to be low risk for BSE. Through our tricountry agreement with Canada and Mexico, we accept Canada's evaluation for our purposes. Furthermore, Uruguay has had minimal, if any, imports from Europe, and therefore minimal potential exposure to BSE. Additionally, regulations are set forth in § 94.18 of the regulations to guard against the introduction of BSE into the United States. We will continue to monitor the health status of Uruguay, and will reassess the situation if we determine that BSE has become a cause for concern with respect to Uruguay.

A few commenters asked how we will ensure that all biologicals, chemotherapeutics, extra-label usage, and pesticides in raw feed production are used under an approval system equivalent to ours. The issues raised by the commenters are beyond the scope of this rulemaking and deal primarily with products and practices that are under the purview of the FSIS and FDA and outside of our regulatory authority.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is warranted to relieve certain restrictions on the importation of fresh (chilled or frozen) beef from Uruguay that are no longer necessary. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be

effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

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

This rule amends the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from Uruguay. Based on the evidence documented in our recent risk assessment, we believe that fresh (chilled or frozen) beef can be safely imported from Uruguay provided certain conditions are met. This action provides for the importation of beef from Uruguay into the United States while continuing to protect the United States against the introduction of FMD.

This rule reopens the U.S. market to Uruguayan beef producers. Beef producers and importers in the United States should not experience any notable economic effects as a result of these changes because the United States has imported only a small amount of beef from Uruguay in the past (table 3).

TABLE 3.—VALUE OF U.S. SUPPLY AND IMPORTS OF FRESH (CHILLED OR FROZEN) BEEF AND URUGUAY'S SHARE

Year	U.S. imports from Uruguay	Total U.S. imports		U.S. supply (domestic production + imports − exports)	
	(In millions)	(In millions)	Uruguay's share	(In millions)	Uruguay's share
1997	$37.5	$1,407.9	2.7%	$22,941	0.2%
1998	29.2	1,609.8	1.8%	23,184	0.1%
1999	43.5	1,907.7	2.3%	23,846	0.2%
2000	40.9	2,221.0	1.8%	24,000	0.2%

Sources: Imports and Exports: U.S. Department of Commerce, Bureau of the Census, as reported by the World Trade Atlas. Domestic production: Calculated from quantities reported in Table 7–72 of Agricultural Statistics 2000, with a wholesale price for the 3 years conservatively approximated at $90 per hundredweight.

Uruguay's share in the value of U.S. imports of fresh (chilled or frozen) beef has been very small. From 1997 to 2000, Uruguayan exports accounted for only 1.8 to 2.7 percent of total U.S. imports of fresh (chilled or frozen) beef. During the same period, imports from Uruguay accounted for 0.2 percent or less of the value of the U.S. supply (domestic production plus imports minus exports) of fresh (chilled or frozen) beef.

Impact on Small Entities

According to the Small Business Administration's (SBA) size standards, beef cattle ranches and farms having $750,000 or less in annual revenue, and cattle feedlots having $1,500,000 or less in annual revenue, are considered small entities. The number of farms and ranches with beef herds in the United States in 1997 was reported to be 766,991, and 99.8 percent of these beef farms could be categorized as small according to the SBA's criteria.[7] It is impossible to determine from published data how many U.S. cattle feedlots could be categorized as small according to the SBA's criteria. Industry analysts suggest that feedlots with a capacity of roughly 1,000 head of cattle would have annual revenues of approximately $1,500,000. In 2000, roughly 18 percent (2,508) of cattle feedlots in the United States would have been considered small by SBA standards.[8]

Although this rule could potentially affect a large number of small beef farms and a relatively small number of small feedlots because it allows Uruguayan beef into the U.S. market, it is not expected to have a significant economic effect on these entities because the import volumes involved are low.

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 12988

This final rule has been reviewed under Executive Order 12988, 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 final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

[7] USDA, National Agricultural Statistics Service, 1997, Census of Agriculture-United States Data table 28, page 32.

[8] Unpublished National Agricultural Statistics Service data, from *Changes in the U.S. Feedlot Industry 1994–1999,* USDA/APHIS/NAHMS, August 2000.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 94.1, paragraph (b)(2) and the introductory text of paragraph (d) are revised and a new paragraph (b)(4) is added to read as follows:

§ 94.1 Regions where rinderpest or foot-and-mouth disease exists; importations prohibited.

* * * * *

(b) * * *

(2) Except as provided in paragraph (d) of this section for fresh (chilled or frozen) meat of ruminants or swine that is otherwise eligible for importation under this part but that enters a port or otherwise transits a region where

rinderpest or foot-and-mouth disease exists; and

* * * * *

(4) Except as provided in § 94.21 for fresh (chilled or frozen) beef from Uruguay.

* * * * *

(d) Except as otherwise provided in this part, fresh (chilled or frozen) meat of ruminants or swine raised and slaughtered in a region free of foot-and-mouth disease and rinderpest, as designated in paragraph (a)(2) of this section, and fresh (chilled or frozen) beef exported from Uruguay in accordance with § 94.21, which during shipment to the United States enters a port or otherwise transits a region where rinderpest or foot-and-mouth disease exists may be imported provided that all of the following conditions are met:

* * * * *

■ 3. A new § 94.21 is added to read as follows:

§ 94.21 Restrictions on importation of beef from Uruguay.

Notwithstanding any other provisions of this part, fresh (chilled or frozen) beef from Uruguay may be exported to the United States under the following conditions:

(a) The meat is beef from bovines that have been born, raised, and slaughtered in Uruguay.

(b) Foot-and-mouth disease has not been diagnosed in Uruguay within the previous 12 months.

(c) The beef came from bovines that originated from premises where foot-and-mouth disease has not been present during the lifetime of any bovines slaughtered for the export of beef to the United States.

(d) The beef came from bovines that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.

(e) The beef came from bovines that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.

(f) The beef consists only of bovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter. Bovine parts that may not be imported include all parts of bovine heads, feet, hump, hooves, and internal organs.

(g) All bone and visually identifiable blood clots and lymphoid tissue have been removed from the beef.

(h) The beef has not been in contact with meat from regions other than those listed in § 94.1(a)(2).

(i) The beef came from bovine carcasses that were allowed to maturate at 40 to 50° F (4 to 10° C) for a minimum of 36 hours after slaughter and that reached a pH of 5.8 or less in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both *longissimus dorsi* muscles. Any carcass in which the pH does not reach 5.8 or less may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still has not reached a pH of 5.8 or less after 60 hours, the meat from the carcass may not be exported to the United States.

(j) An authorized veterinary official of the Government of Uruguay certifies on the foreign meat inspection certificate that the above conditions have been met.

(k) The establishment in which the bovines are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

Done in Washington, DC, this 21st day of May 2003.

Bobby R. Acord,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–13248 Filed 5–28–03; 8:45 am]

BILLING CODE 3410–34–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 791

Rules of NCUA Board Procedure; Promulgation of NCUA Rules and Regulations; Public Observance of NCUA Board Meetings

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: This final rule, Interpretive Ruling and Policy Statement (IRPS) 03–2, amends the Regulatory Flexibility Act provisions of NCUA's IRPS 87–2, Developing and Reviewing Government Regulations. The Regulatory Flexibility Act generally requires federal agencies to prepare analyses to describe the impact of proposed and final rules on small entities. Since 1981, the NCUA has defined small entity in this context to mean those credit unions with less than one million dollars in assets. This final rule redefines small entity to mean those credit unions with less than ten million dollars in assets. In addition, the rule amplifies a provision regarding NCUA's policy of reviewing all existing regulations every three years by stating that one-third of existing regulations will be reviewed each year and the public will receive notice of those regulations under review. The rule also updates IRPS 87–2 with a reference to the U.S. Small Business Administration guidance on implementation of the Regulatory Flexibility Act and to a Small Business Regulatory Enforcement Fairness Act requirement for publication of the factual basis supporting any certification that a particular rule will not have a significant economic impact on a substantial number of small entities.

DATES: This rule is effective June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Paul M. Peterson, Staff Attorney, Office of General Counsel, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428 or telephone: (703) 518–6555.

SUPPLEMENTARY INFORMATION:

A. Background

In 1981, the NCUA defined small credit union for purposes of the Regulatory Flexibility Act (RFA), Pub. L. 96–354, as any credit union having less than one million dollars in assets. NCUA IRPS 81–4, 46 FR 29248, June 1, 1981. IRPS 87–2 superseded IRPS 81–4 but continued the definition of small credit unions for purposes of the RFA as those with less than one million dollars in assets. 52 FR 35231, 35232, September 8, 1987. IRPS 87–2 is incorporated by reference into NCUA's current rule governing the promulgation of regulations. 12 CFR 791.8(a).

The Board believes that NCUA's current definition of small credit union as one with less than one million dollars in assets, adopted in 1981, is now outdated. On November 21, 2002, the Board issued a Notice of Proposed Rulemaking (NPRM) to amend the definition of small credit union in IRPS 87–2. 67 FR 72113, December 4, 2002. The Board proposed to change the qualifying asset size for a small credit union from less than one million dollars in assets to less than ten million dollars in assets. This final rule adopts the proposed rule's definition of small credit union.

As discussed in the NPRM, the RFA is intended in part to encourage federal agencies to give special attention when making rules to the inability of smaller entities to handle incremental compliance burdens created by new rules. Credit unions with ten or more million dollars in assets have staff that may devote some of their time to compliance issues and incremental compliance burdens, but credit unions with significantly less than ten million