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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 97-079-2]

RIN 0579-AA91

Importation of Pork and Pork Products From Yucatan and Sonora, Mexico

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning the importation of animal products to relieve certain restrictions on the importation of pork and pork products from the Mexican State of Yucatan. Because of the existence of hog cholera in Mexico, we have required pork and pork products from Yucatan to be heated or cured and dried to certain specifications to be eligible for entry into the United States. This rule establishes new conditions for the importation of fresh and processed pork and pork products from Yucatan into the United States and also provides for the movement of pork and pork products from Yucatan through areas where hog cholera may exist in transit to the United States. We are also amending the regulations that provide for the importation of fresh pork from the Mexican State of Sonora to also allow the importation of pork products from Sonora and to modify the import conditions for Sonoran pork and pork products so that those conditions parallel the import conditions for pork and pork products from Yucatan. These amendments provide for the importation of pork products from Sonora and for the in-transit movement of Sonoran pork and pork products through areas where hog cholera may exist and make it clear that pork and pork products from Sonora must be

derived from swine slaughtered at federally inspected slaughter plants.

EFFECTIVE DATE: February 10, 2000.

FOR FURTHER INFORMATION CONTACT: Dr. John Cougill, Senior Staff Veterinarian, Products Program, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; (301) 734-3399; or e-mail: john.w.cougill@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country. The regulations pertaining to the importation of animals and animal products are set forth in the Code of Federal Regulations (CFR), title 9, chapter I, subchapter D (9 CFR parts 91 through 99).

The regulations in 9 CFR part 94 pertain to, among other things, the importation of meat and other animal products into the United States. Until the effective date of this rule, § 94.20 allows fresh (chilled or frozen) pork from Sonora, Mexico, to be imported if: The pork is meat from swine that were born, raised, and slaughtered in Sonora; the pork has not been in contact with pork from regions other than those listed in § 94.9(a) as regions where hog cholera is not known to exist; and an authorized official of Mexico has certified on the foreign meat inspection certificate (required by 9 CFR 327.4) that the above conditions have been met.

On February 23, 1999, we published in the **Federal Register** (64 FR 8755-8761, Docket No. 97-079-1) a proposal to amend § 94.20 to (1) expand the importation of fresh pork to include any type of pork or pork products from Sonora; (2) allow the importation, under certain conditions, of pork and pork products from Yucatan, Mexico; and (3) amend some of the provisions pertaining to pork from Sonora so that the same import requirements apply to pork and pork products from both Sonora and Yucatan, Mexico. We based our proposed rule on information presented to APHIS by the Mexican Government in 1995 in a request to recognize the Mexican State of Yucatan

as free of hog cholera and on a site visit that APHIS officials made to Yucatan in 1996 to verify that Yucatan had the veterinary infrastructure, disease control programs, diagnostic capabilities, and surveillance programs necessary to diagnose and prevent an introduction of hog cholera. Following the site visit, we performed a qualitative risk assessment on the importation of pork and pork products from federally inspected slaughtering plants in Yucatan. The qualitative risk assessment indicated that such importations would present a negligible risk of introducing hog cholera into the United States.

Based on the finding of negligible risk, we proposed to allow the importation of pork and pork products from Yucatan, Mexico. However, we proposed to allow these importations to occur only under certain conditions (set forth below) to help prevent the possibility that pork or pork products from swine raised in regions of Mexico other than Yucatan or Sonora could be exported to the United States via Yucatan. As stated above, we proposed to amend the import conditions for pork from Sonora at § 94.20 to provide the same import conditions for pork and pork products from both Sonora and Yucatan. We wanted to prevent the following possibilities: That swine from regions of Mexico other than Sonora or Yucatan could be moved to Yucatan or Sonora for slaughter, processing, and export to the United States; that pork or pork products from other regions could be moved to Yucatan or Sonora for export to the United States; or that, once leaving Yucatan or Sonora, pork and pork products from Yucatan or Sonora could be commingled with pork or pork products from other regions of Mexico in transit to the United States. We stated our belief that the proposed import conditions would provide a higher degree of safety against the occurrence of any of these scenarios than the requirements then listed in § 94.20.

In the proposed rule, we set forth (1) our reasons for believing that the importation, under certain conditions, of pork and pork products from Yucatan can be accomplished safely; (2) our reasons for proposing to amend the import conditions for pork from Sonora and to allow the importation of pork products from Sonora; (3) the proposed import conditions for pork and pork products from Yucatan and Sonora; and

(4) our basis for the proposed import conditions. The proposed import conditions follow:

1. The pork or pork product must be from swine that were born and raised in Sonora or Yucatan and slaughtered in Sonora or Yucatan at a federally inspected slaughter plant under the direct supervision of a full-time salaried veterinarian of the Government of Mexico, and the slaughter plant must be approved to export pork and pork products to the United States in accordance with 9 CFR 327.2.

2. If processed in any manner, the pork or pork product must be processed at a federally inspected processing plant located in either Sonora or Yucatan under the direct supervision of a full-time salaried veterinarian of the Government of Mexico.

3. The pork or pork product must not have been in contact with pork or pork products from any State in Mexico other than Sonora or Yucatan or from any other region not listed in § 94.9(a) as a region where hog cholera is not known to exist.

4. The foreign meat inspection certificate for the pork or pork product (required by 9 CFR 327.4) must be signed by a full-time salaried veterinarian of the Government of Mexico. The certificate must include statements that certify the above conditions have been met. The certificate must also show the seal number on the shipping container if a seal is required (see below).

5. In addition, if the pork or pork product is going to transit any State in Mexico other than Sonora or Yucatan or any other region not listed in § 94.9(a) as a region where hog cholera is not known to exist, a full-time salaried veterinarian of the Government of Mexico must apply serially numbered seals to the containers carrying the pork or pork products at the federally inspected slaughter or processing plant located in Sonora or Yucatan, and the seal numbers must be recorded on the foreign meat inspection certificate.

6. Prior to its arrival in the United States, the shipment of pork or pork products must not have been in any State in Mexico other than Sonora or Yucatan or in any other region not listed in § 94.9(a) unless the pork or pork products have remained under seal until arrival at the U.S. port and either (1) the numbers on the seals match the numbers on the foreign meat inspection certificate or (2) if the numbers on the seals do not match the numbers on the foreign meat inspection certificate, an APHIS representative at the port of arrival is satisfied that the pork or pork

products were not contaminated during movement to the United States.

We solicited comments concerning our proposal for 60 days ending April 26, 1999. We received four comments by that date. They were from a State government, an association representing veterinarians, and associations representing the U.S. swine industry and the Yucatan swine industry. Two commenters supported the proposed rule; one commenter asked numerous questions about many aspects of the proposed rule but expressed support for the proposed import conditions; and one commenter expressed many concerns about the information in the background section of the proposed rule without specifically expressing support or opposition to the proposed rulemaking action. Some of the comments were outside the scope of this rulemaking action. Our responses to the comments pertinent to the proposed rule are discussed below by topic.

Veterinary Infrastructure

Two commenters asked general questions about the veterinary infrastructure in Yucatan, including whether Mexican and Yucatan laws, regulations, and policies support the maintenance of surveillance for hog cholera and whether Mexican animal health officials have the necessary resources to restrict movements of swine and swine products from Mexican States where hog cholera may exist. One commenter asked about Yucatan producer awareness of hog cholera, producer and practitioner reporting responsibilities with regard to suspect cases, and the continued level of suspect hog cholera investigations in Yucatan. The commenter further asked about the testing requirements administered by Yucatan animal health officials for new breeding stock introduced from other Mexican States. Finally, the commenter asked whether a feral swine population exists in Yucatan and, if so, whether it has been tested for hog cholera.

We believe that the Mexican veterinary infrastructure has the ability and resources to restrict movements into Yucatan of swine and swine products from areas of greater risk for hog cholera. When we conducted the 1996 site visit, we thoroughly studied Yucatan's veterinary infrastructure. In addition to learning about the individual responsibilities of and relationship between the various levels of government overseeing animal health activities in Mexico, we reviewed activities to prevent the introduction of hog cholera into Yucatan. Mexican animal health officials exercise tight

movement controls on all land, air, and maritime traffic in Yucatan. Detailed descriptions of the veterinary infrastructure in Mexico, particularly in Yucatan, and these movement controls may be found in the site visit report as well as in the qualitative risk assessment. For copies of these documents, contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Through APHIS employees stationed in Mexico and at our headquarters in Riverdale, MD, we remain in constant contact with Mexican animal health officials. We continue to have confidence in their abilities to prevent the introduction of hog cholera into the Yucatan swine population and, in the unlikely event an outbreak would occur, to identify and contain it appropriately. In regard to producer awareness of hog cholera, Yucatan swine producers could have greater awareness of hog cholera than some U.S. swine producers because of more recent experience with the disease. While the last case of hog cholera in Yucatan occurred in 1982, hog cholera was eradicated from the United States in the 1970's. In addition, Mexican animal health officials have erected signs on major roadways in Yucatan proclaiming the State as free of hog cholera and stating restrictions on the movement into Yucatan of commodities that could reintroduce hog cholera into the State. Suspect cases of hog cholera infection are reported and investigated in Yucatan in a similar manner as in the United States.

The Yucatan swine industry imports breeding stock from the United States, Canada, and Sonora. Swine movements into Yucatan are not allowed from any other area in Mexico. We are unaware of the existence of any feral swine population in Yucatan.

Laboratory Capabilities

A commenter asked whether positive controls or periodic check tests are used in Mexican animal health laboratories to confirm the quality of their testing. Two commenters asked whether Mexican laboratory officials had acted upon recommendations from the site visit report regarding check-testing by the APHIS National Veterinary Services Laboratories (NVSL) in Ames, IA, of the diagnostic results obtained for blood samples tested for hog cholera at Mexican animal health laboratories.

We have confidence in the diagnostic capabilities of Mexican animal health laboratories. As stated in the proposed rule, these laboratories meet the standards of the Office International des Epizooties. In addition, in 1997 we sent "blind" samples twice to the regional

laboratory in Merida, Yucatan, and the central laboratory in Mexico City. These laboratories administered the diagnostic tests with the proper controls, and the results reported agreed with the findings reached by NVSL.

Traceback Capabilities

A commenter asked about procedures in place by APHIS and the Mexican Government to trace shipments of pork or pork products that might be contaminated as a result of the identification of an animal or herd in Yucatan as suspect or positive for hog cholera.

If Mexican animal health officials were to find an animal that was positive for hog cholera, they would report the case immediately to APHIS officials. We would immediately prohibit the importation of pork and pork products from Yucatan. As in any other similar situation in which a foreign region reports an outbreak of an animal disease of concern to us, we would work with USDA's Food Safety and Inspection Service to try to trace any potentially contaminated products that had been imported from that region.

Commercial Production

A commenter expressed concern regarding the biosecurity measures practiced by communal production facilities in Yucatan (small, shared herds of 15 to 40 sows). The commenter was concerned that these facilities are considered part of the commercial production system in Yucatan. (As such, according to the proposed rule, pork and pork products from swine from these facilities could be eligible for export to the United States if the swine were slaughtered in a federally inspected slaughter plant.) The commenter further asked how Yucatan producers know if their herds are "export-eligible" and how the federally inspected plants know upon the arrival of hogs whether they are from export-eligible herds.

The commenter supported the proposed change to the import conditions for pork from Sonora that would require pork and pork products from Sonora to be derived from swine slaughtered at federally inspected slaughter plants. The commenter asked whether there has been any cause for concern about the exportation to the United States of Sonoran pork from Sonoran slaughter plants that are not federally inspected.

The commercial swine industry in both Sonora and Yucatan is concentrated among relatively few producers. In Yucatan, as of 1996, 3 producers owned 65 percent of the

65,000 sows in the commercial production facilities. As a good business practice, the federally inspected slaughtering facilities in Yucatan and Sonora accept swine only from the large, commercial production facilities in those States. By doing so, the slaughtering facilities have assurance regarding the health status of the swine they accept for slaughter. The biosecurity measures practiced at communal swine production facilities in Yucatan do not meet the level of biosecurity measures practiced in the large, integrated commercial production facilities in Yucatan. Mexican animal health officials have confirmed that the federally inspected slaughtering establishments in Yucatan do not accept swine from communal production facilities; swine from these facilities are processed in municipal plants for local use only. Moreover, under Mexican federal regulations, only commercially raised swine may be slaughtered for export to the United States. For that reason, we do not believe that pork has been exported to the United States from other than federally inspected slaughtering plants in Sonora.

Surveillance Procedures

We received numerous comments regarding activities by Mexican animal health officials to determine whether hog cholera exists in the Yucatan swine population. We have divided these comments into three groups, which are discussed in separate sections below as follows: Comments pertaining to procedures for determining the extent of the Yucatan swine population are under the heading Census Results; comments pertaining to blood sampling of the Yucatan swine population for hog cholera are under the heading Serologic Surveys; and comments pertaining to the methodology used to determine the number of blood samples that must be taken from the Yucatan swine population to obtain a reasonable degree of confidence that, if hog cholera existed in the population, it would be detected are under the heading Sampling Methodology. Following a description of all of these comments is our discussion of them.

Census Results

A commenter asked how the 1993 census of Yucatan swine herds was taken, especially in regard to "backyard" farms. The commenter further asked how many backyard farms were in existence when serologic surveys of commercial and backyard farms were performed in 1995. Another commenter asked about the results of the 1996 census of backyard swine and

whether the serologic surveillance of the backyard swine population was modified as a result of that census.

Serologic Surveys

A commenter expressed the opinion that a surveillance survey conducted for a period of 3 months might not truly reflect the disease status of any region. (The commenter was referring to a serologic survey of Yucatan swine herds conducted from January through March 1995.) The commenter asked about the results of an APHIS evaluation of the methodology used by Mexican animal health officials to collect serologic samples in Yucatan and whether APHIS made recommendations regarding the methodology used.

Two commenters asked whether a serologic survey was conducted in 1996 and, if so, about the results. One commenter asked upon what census the 1996 serologic survey was based. The commenter further asked about the level of monitoring of the backyard herds that APHIS or Mexican animal health officials consider necessary for ensuring the hog cholera status of these herds.

Sampling Methodology

A commenter asked how the prevalence figure of 0.2 percent was arrived at for use in the sampling methodology and stated that, if a lower prevalence were used, the number of samples required for the survey would increase drastically. The commenter further stated that the site visit report made a recommendation regarding sampling methodology but that no indication has been given that the recommendation was implemented and what the results were. Another commenter asked about the conclusions of the review of the sampling methodology in backyard pigs and whether this review resulted in modifications to the current sampling to increase the likelihood of detecting disease. The commenter further asked whether experience with hog cholera in backyard herds provided any indication of the expected ranges of seroprevalence in positive herds.

In taking a census of the Yucatan swine population in 1993 and again in 1996, Mexican animal health officials used standard methods to gather data, including visiting townships in Yucatan to interview swine producers. The data from the 1993 census was used in conducting the serologic survey in 1995. While we do not know the total number of backyard swine farms that existed in Yucatan in 1995, the 1993 census reported the number of swine in Yucatan backyard farms as 114,254. We do not expect Mexican animal health

officials to conduct a yearly census of Yucatan swine, nor do we believe that such a census is necessary. Mexican officials have collected swine census data for Yucatan, and, as a result of ongoing serologic sampling by animal health technicians, that data has been updated from year to year.

In the serologic survey conducted in 1995, samples were taken from every commercial farm, with a total of 2,459 samples taken from such farms. Samples were also taken from backyard farms in proportion to each municipality's swine population based on the 1993 census. Mexican animal health officials used the sampling methodology just described

again in 1996 and 1997 to sample commercial and backyard farms. In every year's survey, all samples have been negative for hog cholera. The following table presents the number of serum samples collected and evaluated with negative results at Yucatan swine facilities from 1995 to 1997:

Type of operation	1995	1996	1997	Total
Commercial Farms	2,459	2,526	2,502	7,487
Backyard Farms	429	1,185	1,743	3,357
Community Slaughterhouses	641	660	1,301
Federally Inspected Slaughterhouses	1,378	1,360	2,738
Total	2,888	5,730	6,265	14,883

The seroprevalence figure of 0.2 percent was established by Mexican animal health officials to determine the sampling strategy. It is true that a lower prevalence figure would increase the number of samples to be taken. However, if hog cholera were endemic in Yucatan, the prevalence figure would far exceed 0.2 percent. Based on our own judgment and experience with hog cholera eradication in the United States, if hog cholera existed in Yucatan, the seroprevalence would be higher than 0.2 percent because Yucatan's swine population is immunologically naive as a result of being unvaccinated for several years. Moreover, we do not believe that hog cholera could survive in the backyard herds in Yucatan without passing into the commercial herds and quickly being detected.

Currently, serologic surveys are being conducted as follows: Every year, samples are taken from all commercial herds and from 300 randomly selected backyard herds. For the backyard swine population in Yucatan, 300 herds is the sample size needed to detect hog cholera with a 95 percent confidence level if the disease exists at a herd prevalence of 1 percent or higher. The census results do not change this number. The census serves to give a complete listing of all of the farms that have an equal chance of being sampled. At the backyard farms in Yucatan, up to five samples are taken per herd.

The same sampling procedures are being conducted in Campeche and Quintana Roo (the two Mexican States that border Yucatan) as in Yucatan. Every year, Mexican animal health officials take blood samples from 300 randomly selected backyard herds (up to 5 samples per herd) in each of those 2 States. In addition, Mexican animal health officials are sampling an additional 600 backyard herds in Campeche along the State border with

Tabasco. Most of the herds being sampled have fewer than five animals.

In the site visit report, we stated, "Pending further analysis of the data, recommendations may be made to modify their current sampling methodology to increase the likelihood of detecting disease." We have recommended increased sampling of backyard farms in high-risk areas, such as along the borders with other States, and this recommendation has been followed. Based on available data, we do not believe that a precise level of monitoring of backyard herds in Yucatan on a periodic basis can be determined. Such a determination would require such additional information as an evaluation of the veterinary infrastructure and disease status of Yucatan's neighboring States. However, we have confidence that the current annual sampling of 300 backyard herds as described previously would reveal any hog cholera virus present in those herds.

We would like to emphasize that serologic surveillance of the Yucatan swine population was only one component of our proposal to allow the importation under certain conditions of pork and pork products from Yucatan. Many other factors, which are listed in the proposed rule and the qualitative risk assessment, were considered and continue to be important. As examples, hog cholera has not been diagnosed within Yucatan for more than 15 years and is not known to exist in any adjacent State, and Yucatan has prohibited vaccination of swine for hog cholera for more than 5 years. As a result, the Yucatan swine population has become immunologically naive, so any introduction of hog cholera virus would spread quickly, easing detection. In considering many factors altogether, including the fact that serologic surveillance has been maintained for

several years now with no findings of animals positive for hog cholera, we believe that pork and pork products from Yucatan can be imported into the United States without putting the health of the U.S. swine population at risk.

Risk Assessment

A commenter questioned the statement in the risk assessment that the importation of pork and pork products from Yucatan would present a negligible risk of introducing hog cholera. The commenter asked how the risk of introducing hog cholera from pork and pork products is negligible if the risk of hog cholera introduction from live swine is low.

The site visit report characterizes Yucatan as an area of low risk for hog cholera based on a high-medium-low paradigm. However, APHIS policy on the importation of animals and animal products states that import decisions on animals and animal products will not be based solely on the characterization or status of the exporting region but rather on a risk assessment addressing the risks presented by a specific commodity from a specific region. The risk assessment must consider information about the animal health situation existing in the region and the probability that the commodity would transmit and establish disease in the United States.

Based on the observations of the site visit team and analysis of information submitted by Mexico, we performed a qualitative risk assessment of the importation of pork and pork products from Yucatan into the United States. Taking into account all of the available evidence concerning hog cholera virus and Yucatan, APHIS found that the probability that Yucatan swine are infected with undetected hog cholera virus is small. The pathway for hog cholera introduction into the U.S. swine

population via contaminated imported pork or pork products would be via feeding uncooked or improperly cooked pork or pork products to pigs in this country. Pork is known to be capable of transmitting hog cholera. However, pork is a high-value commodity intended for human consumption, and U.S. consumers routinely cook pork at a temperature sufficient to kill hog cholera virus. Furthermore, before human food waste such as pork can legally be fed to swine, the waste must be cooked again. Therefore, even if a small quantity of pork contaminated with hog cholera virus were to be imported into the United States, the probability that it would be fed uncooked to pigs is extremely small. For these reasons and the many others discussed in this document, the proposed rule, and the qualitative risk assessment, we find the combined evidence sufficient to conclude that imported pork and pork products from Yucatan, even if containing a low level of hog cholera virus, are unlikely to cause an outbreak of hog cholera in the United States.

Request for New Site Visit

A commenter requested that APHIS conduct another site visit to the Yucatan and include veterinary practitioners and representatives of the U.S. swine industry.

We believe that the data gathered from our 1996 site visit is still valid and supports our proposal to allow the importation of pork and pork products from Yucatan under certain conditions, and we do not believe that an additional site visit is necessary to gather additional data. We believe that, if the data has changed in any way, it has likely changed to provide stronger support for the proposed rule. Since our site visit in 1996, more time has passed since the last outbreak of hog cholera in Yucatan and since vaccination for hog cholera was discontinued there. In addition, since our site visit, the States bordering Yucatan have been declared free of hog cholera by the Mexican Government, so the threat of possible introduction of hog cholera into Yucatan from adjacent regions has been further reduced. Moreover, as stated previously, APHIS employees permanently stationed in Mexico maintain constant contact with Mexican agricultural officials. We have confidence in their abilities and efforts to eradicate hog cholera and prevent reintroduction into areas that have been declared free of the disease.

Other Diseases

A commenter asked whether APHIS has conducted a review of diseases that might be present in Mexico and are not considered to be present in the United States other than "List A" diseases. The commenter was particularly concerned about blue eye disease, which the commenter states has been reported in many States in Central Mexico and has been identified in hogs in Yucatan slaughterhouses. The commenter wanted to know whether APHIS has considered the potential for transmission of blue eye virus in pork products from Yucatan and Sonora and what type of surveillance program is in place for this disease.

This rule pertains exclusively to the importation of pork and pork products—not live swine—from Yucatan and Sonora. Other than hog cholera, which is known to be transmitted by fresh pork, no other swine diseases that can be transmitted by pork exist in Mexico. Therefore, our risk assessment pertained exclusively to hog cholera. Mexican animal health officials report that blue eye disease has never been confirmed in Yucatan. In addition, no evidence exists to indicate that the agent that causes blue eye disease is transmitted by fresh pork.

Proposed Conditions

A commenter asked how APHIS or Mexican animal health officials would determine that pork and pork products from Yucatan or Sonora, Mexico, have not been in contact with pork or pork products from any State in Mexico other than Yucatan or Sonora or from any other region not listed in § 94.9(a) as a region where hog cholera is not known to exist.

The commenter asked another question about the proposed regulation regarding seals on the containers of pork and pork products from Yucatan and Sonora. The commenter asked how, in situations where, upon arrival of the pork or pork product in the United States, the numbers on the seals do not match the numbers on the foreign meat inspection certificate, would the APHIS representative at the port of arrival be certain that the shipment contains the original product and has not been subject to contamination.

The commenter also asked about what procedures are in place to ensure that only products from swine born and raised in Sonora or Yucatan will be exported to the United States since Yucatan animal health officials allow the movement into Yucatan of pork products from other Mexican States. Another commenter stated that,

although the intent of allowing only pork or pork products to be imported from federally inspected plants in Yucatan is to eliminate the risk of importing products derived from swine raised in backyard herds, nothing in the rule prohibits a federally inspected plant in Yucatan from accepting such swine.

The Mexican Government is ultimately responsible for ensuring that our import conditions are followed. Mexican animal health officials are responsible for certifying that pork or pork products from Yucatan and Sonora have not been in contact with pork or pork products from regions where hog cholera could possibly exist and that only pork or pork products from swine born and raised in Yucatan or Sonora are exported to the United States. When importations of pork and pork products from Yucatan commence, our Mexican counterparts will have to certify that these conditions have been met.

Regulating the activities of Mexican slaughtering facilities would not be within our purview, so we would not attempt to prohibit federally inspected slaughtering facilities in Yucatan or Sonora from accepting swine from backyard farms. However, we also believe that such a prohibition is unnecessary. As stated previously, Mexican animal health officials have confirmed that the federally inspected slaughtering facilities in Yucatan and Sonora do not accept swine from backyard farms. To ensure that they are receiving high-quality hogs, the federally inspected slaughtering facilities in Yucatan and Sonora accept swine only from the large, commercial production facilities. The owners of the slaughtering facilities know that, to be able to ship pork and pork products to the United States, the facilities must not ship any pork or products derived from pigs with an unknown veterinary health status. In the unlikely event federally inspected slaughtering facilities in Yucatan and Sonora start accepting swine from backyard farms, we could take any necessary action to prevent the importation of pork or pork products derived from such swine. Through publication of an interim rule, we could immediately prohibit such shipments.

Our requirements regarding the seals are the same as our requirements for seals on animal products from many foreign regions. Any manipulation of the seals applied to containers of pork or pork products imported from Yucatan or Sonora and application of new seals must be performed under the direct supervision of a Mexican Government official, and an explanation must accompany the product to the U.S. port

of arrival. If containers of pork or pork products from Yucatan or Sonora arrive at a U.S. port with broken seals and insufficient documentation, we would require that the importer provide the proper documentation within 48 hours or the shipment would be denied entry. In accordance with § 94.7, animal products denied entry into the United States must be disposed of or exported within a prescribed period of time.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget. A summary of the analyses required by Executive Order 12866 and the Regulatory Flexibility Act are set forth below. Copies of the entire analyses may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

In accordance with 21 U.S.C. 111, the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction or dissemination of any contagious, infectious, or communicable disease of animals from a foreign country into the United States. This rule amends the regulations pertaining to the importation of animal products by establishing new, less restrictive, conditions for the importation of fresh and processed pork and pork products from Yucatan, Mexico, into the United States. The rule also provides for the movement of pork and pork products from Yucatan through areas where hog cholera may exist while in transit to the United States. The rule also amends the regulations regarding the importation of fresh pork from Sonora, Mexico, to allow the importation of pork products from Sonora and to modify the import conditions for Sonoran pork and pork products so that those conditions parallel the import conditions for pork and pork products from Yucatan. These amendments provide for the importation of pork products from Sonora and for the in-transit movement of Sonoran pork and pork products through areas where hog cholera may exist and make it clear that pork and pork products from Sonora must be derived from swine slaughtered at federally inspected slaughter plants.

The disease of concern regarding the importation of pork and pork products from Yucatan is hog cholera. The

segment of the U.S. swine industry most likely to be first exposed to hog cholera from imported pork products is the segment that uses human food waste as a feed source. Because the hog cholera virus remains infective in pork products for a long time unless the products are cooked properly, the disease can be transmitted to swine fed discarded, uncooked or insufficiently cooked pork. The Swine Health Protection Act requires that waste-feeding swine operations heat the waste according to prescribed procedures that kill such organisms before feeding the waste to the swine.

A qualitative risk assessment prepared by APHIS indicates that the expected costs of disease introduction are likely to be zero, as the proposed imports pose a low probability of causing a hog cholera outbreak in the United States. APHIS also conducted a quantitative risk assessment based only on serologic survey data of commercial swine operations in Yucatan. Due to modeling constraints, the quantitative risk assessment did not include some of the information most pertinent to risk evaluation, such as the fact that an outbreak of hog cholera has not occurred in Yucatan since 1982. However, the quantitative model is useful in that it provides an upper limit on the estimated probability of a hog cholera outbreak and acknowledges that the actual risk is likely to be lower. Expected costs associated with the anticipated trade in pork and pork products from Yucatan are calculated by multiplying the estimates from the quantitative model of the likelihood of an outbreak and the estimated economic consequences of an outbreak.

In accordance with Executive Order 12866, APHIS has compared the benefits of the increased trade to the expected costs resulting from a disease outbreak. The benefits are calculated as the net change in consumer and producer surplus that results from the estimated volume of trade.

Yucatan generates 7–8 percent of Mexico's pork production and is a net exporter of pork, with 65 percent of the pork produced in the State going to the tourist centers in the neighboring State of Quintana Roo, population centers in and around Mexico City, and Japan. Pork intended for export is produced at the State's only federally inspected slaughter facility, which accepts swine only from commercial producers. Commercial swine production in Yucatan is concentrated among approximately 200 producers, who collectively own about 65,000 sows (1996 data). Three producers alone own 65 percent of these sows, all of which

are housed in highly integrated operations similar to those found in the United States. At full capacity, the federally inspected slaughtering facility in Yucatan can slaughter up to 1,000 head per day, with a maximum annual production of 10,000 metric tons of pork.

Based on existing Yucatan hog production and slaughter capacity, we believe that Yucatan producers could export between 200 and 10,000 metric tons of fresh and frozen pork to the United States per year. The high-volume scenario is based on the maximum output of the federally inspected slaughter facility and assumes that all 10,000 metric tons produced there would be shipped to the United States. Because this scenario is highly unlikely, we also evaluated more realistic scenarios of 1,000 and 200 metric tons. The most likely amount of pork imported into the United States from Yucatan would probably be between these two amounts. Therefore, the regulatory impact analysis summarized here examines the potential economic impact of such imports under low – (200 metric tons per year), medium – (1,000 metric tons per year), and high – (10,000 metric tons per year) volume scenarios.

Results of computer simulation iterations for the low-volume simulations indicate positive net benefits in 90 percent of the iterations run. Results of the medium-volume simulations indicate positive net benefits in 85 percent of the iterations run. Results from the high-volume scenario indicate positive net benefits in 75 percent of the iterations run. In the absence of disease (when likelihood estimates are zero), the annual net benefits of trade for the low-, medium-, and high-volume scenarios are estimated, in 1997 dollars, at \$6,478, \$32,429, and \$329,011, respectively. Therefore, based on these calculations, positive net benefits would result from any of the scenarios. The details are contained in the economic impact analysis, as indicated previously.

In conclusion, we believe that the likelihood of hog cholera introduction and its associated biological and economic consequences is sufficiently low as to warrant allowing the importation of pork and pork products from Yucatan. Assuming that, among other things, Yucatan pork is a perfect substitute for domestic pork, we estimate that the net benefits of Yucatan pork imports will be positive. Importations of Yucatan pork will cause U.S. farm gate prices to decrease marginally, benefitting U.S. consumers.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Federal agencies to analyze possible effects of their regulations on small businesses and to use flexibility to provide relief when regulations could create economic disparities between entities of different sizes. According to the Small Business Administration (SBA), regulations create economic disparities based on size when the regulations have a "significant economic impact on a substantial number of small entities."

Over the past several decades, the U.S. pork industry has experienced enormous structural change, which mirrors the overall trend toward "concentration" in U.S. agriculture. The shift toward fewer but larger farms has been dramatic in the hog sector. According to the 1997 Census of Agriculture, from 1992 to 1997, the number of farms selling hogs decreased by almost 46 percent (from 188,000 to 102,000), while the value of hogs and pigs sold increased by 37 percent (from \$10 billion to \$13.8 billion). The pork processing industry is also characterized by a decreasing number of companies operating increasingly large, capital-intensive processing and packing plants that are dependent on high volumes of raw product and that begin to realize economies of size at about 4 million hogs per year.

In 1994, about 2,000 swine producers were licensed as waste-feeding establishments in the continental United States, and this number has not changed greatly since then. The majority of these premises were located in Texas (871), Florida (309), Arkansas (248), and North Carolina (178). Waste-feeding operations are predominantly small. Based on a 1994 APHIS survey, the median number of swine per waste-feeding premises in the 48 conterminous States was 34 (average of 97). Only 10 of the premises had more than 1,000 swine.

The potential economic effects of the importation of pork and pork products from Yucatan, Mexico, are dependent on a number of factors, such as where the products would be consumed in the United States. While it is currently unknown exactly how Yucatan pork would enter U.S. marketing and distribution channels and where it would ultimately be consumed, we believe that the pork would likely be shipped by ocean vessel from Progreso, Yucatan, to a U.S. Gulf Coast port, most likely in Texas or Florida, perhaps in Louisiana. If Yucatan pork is purchased by a local retail chain or wholesaler in those States, the pork would likely be

consumed locally. If purchased by a national wholesaler, Yucatan pork could be consumed anywhere in the United States. For the purposes of this analysis, we examined both the possibility that Yucatan pork would be consumed locally in selected Gulf Coast States and also the possibility that it would enter national distribution channels.

The SBA defines small hog farms (Standard Industrial Code 0213) as those earning less than \$500,000 in annual receipts. Industry experts suggest that only those hog operations with inventories in excess of 2,000 animals would earn \$500,000 or more in sales annually. According to Census of Agriculture data, 6.5 percent of U.S. hog and pig operations held inventories in excess of 2,000 animals in 1997, so by SBA standards, 93.5 percent of all U.S. hog farms are small entities. By these same criteria, more than 99 percent of hog farms in Texas, Louisiana, and Florida are small entities. The average U.S. small hog farm sold 560 head of stock and reported sales of \$58,531 in 1997. In Texas, Florida, and Louisiana, small hog farmers sold substantially fewer animals (77 head per farm) and earned substantially less in sales (\$7,413 annually).

In 1997, according to the Census of Agriculture, 87,820 small hog farms were in operation nationwide; 4,700 of these were located in the Gulf Coast States of Texas, Florida, and Louisiana. Whether we consider the United States as a whole or just selected Gulf Coast States, the overwhelming majority of hog farms are small entities, so it is reasonable to conclude that a substantial number of small entities could be affected by this rule.

Economic Effect on Small Entities

While no general rule sets threshold or trigger levels for "significant economic impact," it has been suggested that an economic effect that equals a small business' profit margin—5 to 10 percent of annual sales—could be considered significant.

We used estimated changes in producer surplus together with the 1997 Census of Agriculture data on hog inventories and hog sales to develop very rough estimates of the potential economic effects of the rule on small hog farmers across the United States and in selected Gulf Coast States. To do this, we assumed that losses in producer surplus would be shared equally among all hog farms in the geographic area under consideration (either the entire United States or selected Gulf Coast States). We then compared per-farm changes in producer surplus with small farms' annual sales to determine

whether the economic effects approach the 5–10 percent threshold.

If Yucatan pork enters national distribution channels and, therefore, economic effects are shared by all U.S. producers, no significant economic effect on small entities would occur regardless of the volume (low, medium, or high) of imports assumed. Producer surplus losses per U.S. hog farm would range from \$0.63 to \$31.61 per year, and these amounts are substantially less than 1 percent of the typical small hog farmer's annual sales (\$58,531) in every scenario.

If, under the high-volume scenario, the maximum 10,000 metric tons are imported annually from the Yucatan and consumed locally in Louisiana, Texas, and Florida, the imports could result in significant economic effects on small pork producers in those States. In this case, a subset of small hog farmers with considerably fewer head per farm and considerably less in annual revenues than the average U.S. small hog farm would face the most significant economic effects of an increase in imports. The producer surplus losses per small hog farm in those States would range from \$12.02 to \$600.58. The larger amount is equivalent to 8.1 percent of the annual sales of the typical Gulf Coast small hog farmer and, therefore, could be considered a significant economic effect.

In conclusion, the rule could affect a substantial number of small hog farms because almost all hog farms meet the SBA size criteria for small entity. However, it is unclear whether the rule will have a significant economic effect on small hog farms. The latter issue depends on how much Yucatan pork is imported and where it is consumed. Under the most extreme assumptions (highest volume imports and limited geographic area affected), small hog producers in selected Gulf Coast States could experience losses in producer surplus equaling approximately 8 percent of annual sales. Such losses would meet "significant economic impact" criteria. Under the most likely import volume scenario (1,000 metric tons per year), the rule will not have a significant economic effect on small hog farmers either nationwide or in selected Gulf Coast States.

Alternatives Considered

In developing this rule, we considered either (1) making no changes to the existing requirements for the importation of fresh and processed pork and pork products from Yucatan and Sonora, Mexico, (2) allowing the importation of pork and pork products

from Yucatan and Sonora under conditions different from those set forth in this document, or (3) allowing the importation of pork and pork products from Yucatan and Sonora under the conditions set forth in this document.

We rejected the first alternative because it would continue to restrict the importation of pork and pork products from Yucatan under the same conditions that apply to the remainder of Mexico. Because we have determined that pork and pork products can be imported under specified conditions from Yucatan and Sonora with negligible hog cholera risk, taking no action would not be scientifically defensible and would be contrary to trade agreements entered into by the United States. We also rejected the second alternative, which would allow the importation of pork and pork products from Yucatan and Sonora under conditions other than those established by this rule. In developing the criteria for the importation of such pork and pork products, we determined that conditions less stringent than those set forth would present a risk of the introduction of hog cholera into the United States via pork or pork products from regions of Mexico other than Sonora or Yucatan. We further concluded that more stringent conditions would be unnecessarily restrictive. We consider the conditions set forth by this rule to be both effective and necessary in ensuring that the risk of hog cholera introduction via pork and pork product imports from Yucatan and Sonora remains at a negligible level.

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.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for the conclusion that the importation of pork and pork products from Sonora and Yucatan, Mexico, under the conditions specified in this rule will not present a risk of introducing or disseminating hog cholera disease agents into the United States and will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection

Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0138.

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, HOG CHOLERA, 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. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section 94.20 is revised to read as follows:

§ 94.20 Importation of pork and pork products from Sonora and Yucatan, Mexico.

Notwithstanding any other provisions of this part, pork and pork products from the States of Sonora and Yucatan, Mexico, may be imported into the United States under the following conditions:

(a) The pork or pork product is from swine that were born and raised in Sonora or Yucatan and slaughtered in Sonora or Yucatan at a federally inspected slaughter plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico and that is approved to export pork products to the United States in accordance with § 327.2 of this title.

(b) If processed, the pork or pork product was processed in either Sonora or Yucatan in a federally inspected processing plant that is under the direct supervision of a full-time salaried veterinarian of the Government of Mexico.

(c) The pork or pork product has not been in contact with pork or pork products from any State in Mexico other than Sonora or Yucatan or from any other region not listed in § 94.9(a) as a region where hog cholera is not known to exist.

(d) The foreign meat inspection certificate accompanying the pork or pork product (required by § 327.4 of this title) includes a statement certifying that the requirements in paragraphs (a), (b) (if applicable), and (c) of this section have been met and, if applicable, a list of the numbers of the seals required by paragraph (e)(1) of this section.

(e) The shipment of pork or pork products has not been in any State in Mexico other than Sonora or Yucatan or in any other region not listed in § 94.9(a) as a region where hog cholera is not known to exist en route to the United States, unless:

(1) The pork or pork product arrives at the U.S. port of entry in shipping containers bearing intact, serially numbered seals that were applied at the federally inspected slaughter or processing plant in either Sonora or Yucatan by a full-time salaried veterinarian of the Government of Mexico, and the seal numbers correspond with the seal numbers listed on the foreign meat inspection certificate; or

(2) The pork or pork product arrives at the U.S. port of entry in shipping containers bearing seals that have different numbers than the seal numbers on the foreign meat inspection certificate, but, upon inspection of the hold, compartment, or container and all accompanying documentation, an APHIS representative is satisfied that

the pork or pork product containers were opened and resealed en route by an appropriate official of the Government of Mexico and the pork or pork product was not contaminated or exposed to contamination during movement from Sonora or Yucatan to the United States.

(Approved by the Office of Management and Budget under control number 0579-0138)

Done in Washington, DC, this 6th day of January 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00-589 Filed 1-10-00; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NM-24-AD; Amendment 39-11498; AD 2000-01-01]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A300 B2-1A, B2-1C, B2-203, B2K-3C, B4-103, B4-2C, and B4-203 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Airbus Model A300 B2-1A, B2-1C, B2-203, B2K-3C, B4-103, B4-2C, and B4-203 series airplanes, that requires modification of the wire harness routing next to the pitch artificial feel unit, and removal of the green and yellow colors from various connectors. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent the electrical connections of the actuators of the green and yellow hydraulic systems for the pitch artificial feel unit from being cross connected due to the design of the wire harness routing, which could result in a stiff elevator control at takeoff, and consequent reduced controllability of the airplane.

DATES: Effective February 15, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 15, 2000.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Airbus Model A300 B2-1A, B2-1C, B2-203, B2K-3C, B4-103, B4-2C, and B4-203 series airplanes was published in the **Federal Register** on November 16, 1999 (64 FR 62131). That action proposed to require modification of the wire harness routing next to the pitch artificial feel unit, and removal of the green and yellow colors from various connectors.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 1 airplane of U.S. registry will be affected by this AD, that it will take approximately 3 work hours per airplane to accomplish the required replacement, and that the average labor rate is \$60 per work hour. Required parts will cost approximately \$3,079 per airplane. Based on these figures, the cost impact of the AD on the single U.S. operator is estimated to be \$3,259.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2000-01-01 Airbus Industrie: Amendment 39-11498. Docket 99-NM-24-AD.

Applicability: Model A300 B2-1A, B2-1C, B2-203, B2K-3C, B4-103, B4-2C, and B4-203 series airplanes; except those airplanes on which Airbus Modification 10702S20752 (reference Airbus Service Bulletin A300-27-0184, dated August 19, 1996, or Revision 01, dated December 4, 1998) has been accomplished, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance