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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 98

[Docket No. 02–046–2]

RIN 0579–AB79

Importation of Swine and Swine Products From the European Union

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of animals and animal products into the United States to apply a uniform set of importation requirements related to classical swine fever (CSF) to a region consisting of all of the 15 Member States of the European Union (EU) that comprised the EU as of April 30, 2004 (the EU–15) and prohibit for a specified period of time the importation of live swine and swine products from any area in the EU–15 that is identified by the veterinary authorities of the region as a restricted zone. We have determined these changes are necessary to help prevent the introduction of CSF into the United States while increasing our responsiveness to changes in the CSF situation in the EU.

DATES: *Effective Date:* June 19, 2006.

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SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) 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 in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including classical swine fever (CSF), rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, swine vesicular disease, and African swine fever.

Sections 94.9 and 94.10 of the regulations state that CSF is known to exist in all regions of the world, except for those regions listed in §§ 94.9(a) and 94.10(a). The importation of live swine and swine products from regions not recognized as free of CSF is restricted or prohibited. In addition, with regard to CSF, the regulations restrict the importation of live swine and swine products from a region consisting of certain European Union (EU) Member States and portions of Member States, even though that region is listed as being free of the disease. The restrictions on imports from that EU region were established in a final rule published in the **Federal Register** on April 7, 2003 (68 FR 16922–16941, Docket No. 98–090–5).

In that final rule, we established certain mitigation measures for the importation of live swine, pork and pork products, and swine semen from the region. Although there were no CSF outbreaks in EU domestic swine within the defined region at the time, the risk analyses that we conducted in conjunction with that rulemaking assumed that, because CSF was endemic in wild boar in several parts of the EU, it was likely CSF would continue to occur in domestic swine in the region. Further, the risk analyses considered the open borders among EU Member States. To address these situations, the final rule required that commodities from the region of the EU that was considered to be unaffected with CSF be segregated from those from CSF-affected regions of the EU and other CSF-affected regions, and that measures be taken to ensure that donor boars providing semen for export to the United States are truly free of CSF.

On April 8, 2005, we published in the **Federal Register** (70 FR 17928–17940, Docket No. 02–046–1) a proposal to amend the regulations governing the importation of animals and animal products into the United States to recognize a region consisting of the 15 Member States of the EU that comprised the EU as of April 30, 2004 (the EU–15) as a single region of low risk for CSF. The EU–15 consists of those Member States that we had recognized as a single region regarding CSF in our 2003 final rule, plus additional Member States. We proposed to apply a uniform set of importation requirements related to CSF to the EU–15 and to prohibit for a specified period of time the importation of live swine and swine products from any area in the EU–15 that is identified by the veterinary authorities of the region as a restricted zone.

We solicited comments concerning our proposal for 60 days ending June 7, 2005. We received 10 comments by that date. They were from an importer of swine semen, a swine producer and pork processor, a representative of the National Pork Producers Council, a representative of the National Pork Board, representatives of State governments, a representative of the European Commission (EC), and other members of the public.

Two commenters opposed the proposal in general. One commenter expressed general support for the importation of swine and swine products, as long as appropriate testing, quarantine, and certification are carried out. Several commenters agreed with the concept of allowing movement of live swine from a restricted zone, or products derived from such swine, after an appropriate period of time, but either expressed concerns regarding certain provisions of the proposal or recommended specific changes. One commenter expressed general support for regulating the importation or exportation of animals. Another commenter opposed the importation of all swine and swine products from the EU. The specific issues raised by the commenters are discussed below by topic.

Forty-Day Holding Period Before the Shipment of Swine Semen to the United States

In § 98.38 of the proposed rule, we set out conditions for exporting swine

semen to the United States from the EU–15. One of those conditions (set out in § 98.30(f) of the proposal) was that, before swine semen may be exported to the United States from the EU–15, the donor boar must be held at the semen collection center and observed by the center veterinarian for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF. This requirement, which we proposed to apply to importations of swine semen from anywhere in the EU–15, is already in place in the current regulations in § 98.38(h), but only with regard to the importation of swine semen from those Member States of the EU–15 that we recognized as a single region for CSF in our April 2003 final rule. The import restrictions established in that final rule, including the restrictions on swine semen, did not apply to those five Member States that APHIS had recognized as free of CSF before the April 2003 final rule (Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom).

Our April 2005 proposal extended those restrictions on the importation of swine semen to the entire EU–15, including Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom. We explained that we believed such an extension of the restrictions was necessary because, as part of the EU, those five Member States trade with the rest of the EU under what is essentially an open-border trading policy and, therefore, the CSF risk from those five Member States must be considered the same as from the region we recognized in our April 2003 final rule.

Several commenters addressed the provisions in the proposed rule regarding the importation of swine semen. Of these, one commenter supported the proposed restrictions. The other commenters objected to those restrictions.

The commenter who supported the proposed provisions stated that it was his understanding that the requirement for a 40-day holding period in § 98.38(h) was established because swine do not develop a rapid or predictable antibody response to the CSF virus, at least with currently available diagnostic tests. According to the commenter, the 40-day holding period provides a reasonable buffer that facilitates the detection of CSF exposure, even in poor-responding animals.

Three commenters expressed concern with the proposed 40-day holding period for semen, stating that the 40-day holding period would render fresh boar semen worthless, because there are no extenders available that will preserve sperm cells for more than 7 to 10 days. The commenters stated that freezing of the semen is not a feasible alternative because the fertility of frozen boar semen is vastly inferior to that of fresh semen.

One commenter stated that the 40-day holding period is unnecessary because, according to the commenter, donor boars must already be held in a separate facility for 6 months before the semen is collected for export and no swine may be added to the donor boar population for 60 days before the semen is collected. The commenter did not specify the source of the requirements described. The commenter stated that, because of these requirements, it would be more logical to require that the donor boar be tested with negative results for CSF in the mini-stud (an area where a group of boars from the larger group of boars at the semen collection center are held for semen collection) than to require the 40-day post-collection holding period.

The same commenter stated that another option would be to exclude the importation of swine semen from Denmark from the 40-day holding requirement. The commenter stated that the proposed rule did not take into account the safeguards already in place for the importation of Danish fresh boar semen. Additionally, said the commenter, the proposed rule did not recognize the ''extraordinary measures'' that Denmark employs to keep the country free of CSF and other diseases of economic importance, such as government-operated truck disinfection facilities at the border with Germany.

One commenter stated that a requirement for a 40-day holding period following collection of swine semen is disproportionate to the risk of the transmission of CSF through semen, and that the routine use of a combination of antibiotics, as required under the EC Directive 90/429/EEC, should be sufficient to deal with any risk that might be present.

APHIS response. As we stated above, the current requirement for a 40-day, post-collection holding period for swine semen, set forth in § 98.38, was established by a final rule APHIS published in April 2003, and currently applies to the importation of swine semen from some Member States of the EU–15, but not all. The 40-day hold on semen was based on risk analyses we conducted in support of the April 2003 final rule.[1] These risk analyses indicated that, without mitigation, the importation of swine semen from the EU region recognized by the final rule would present a relatively high risk of introducing CSF into the United States. The 40-day hold was determined to be an effective mitigation measure and is consistent with the internationally recognized recommendations of the World Organization for Animal Health (OIE) for semen exported from countries that are free of CSF in domestic swine but that have CSF infection in wild boar populations (Article 2.6.7.13, 2004 OIE International Animal Health Code). With regard to the commenter who stated that donor boars must already be held in a separate facility for 6 months before the semen is collected for export, APHIS regulations do not include that requirement.

We continue to consider it necessary to mitigate the CSF risk from the importation of swine semen from the EU. However, in light of the comments we received on our proposed rule suggesting the possibility of alternative methods of risk mitigation that would be less economically disruptive than a 40-day hold, we are not, at this time, making final the requirement for a 40-day hold with regard to those five EU Member States that we had previously individually recognized as free of CSF (Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom). Instead, we will give the issue of a 40-day hold further consideration based on the information available to us, including the information received in comments in response to our April 2005 proposed rule. After we consider all the information available to us, we will publish a document in the **Federal Register** discussing our conclusions. If we consider it warranted to formally assess the effectiveness of alternative mitigation measures, we will make such an assessment available to the public for comment.

Request That the Final Rule Apply to More Than the EU–15

Two commenters stated that the provisions of the proposed rule should not be limited to the EU–15, but should also be applied to the 10 Member States that became part of the EU after April 30, 2004 (the EU–10). Both commenters stated that every EU Member State is required to adhere to the same EC regulations, directives, and decisions, including a comprehensive monitoring

[1] Biological Risk Analysis: Risk assessment and management options for imports of swine and swine products from the European Union—June 2, 1999; and Risk Analysis for Importation of Classifical Swine Fever Virus in Swine and Swine Products from the European Union—December 2000.

and control system for the containment and eradication of CSF outbreaks wherever they may occur across the EU. Therefore, stated the commenters, the same APHIS rationale that supports application of the proposed rule to the EU–15 equally supports its application to the EU–10. One of the commenters stated that this conclusion is further supported by the fact that, with limited exceptions, animals and animal products can move freely within the EU–25. One of the commenters stated that the rule should also apply to all future EU Member States. Another commenter asked how the proposed rule will be extended to address the inclusion of additional countries with varying degrees of veterinary equivalency as they join the EU.

One commenter stated that, at a minimum, Poland should be added to the Member States covered by the proposed rule. The commenter also requested that APHIS identify (1) any statutory requirement that a risk assessment of Poland's (or any other country's) animal disease status be completed before determining its animal health status and (2) any statutory or regulatory impediment to using the EU accession process, and the materials used for that, as a basis for modifying Poland's animal disease status, without conducting a separate risk assessment.

APHIS response. It would not be appropriate to include EU Member States other than the EU–15 in this final rule without first providing the public with full notice and opportunity to comment under the Administrative Procedure Act. In addition, APHIS regulations at 9 CFR 92.2 specify that the public have access to the information upon which a risk analysis is based and the methodology used in the risk analysis during the comment period of a proposed rule. In developing our April 2005 proposal to recognize the EU–15 as a single region with regard to CSF, we considered three analyses of risk and provided for notice and comment regarding those analyses.[2] Because this criterion has not yet been met for Member States beyond the EU–15, we cannot, at this time, include such Member States in the region recognized by this final rule.

APHIS intends to evaluate each of the EU–10 Member States regarding CSF. As part of these evaluations, APHIS conducted site visits to Hungary, Lithuania, Poland, and Slovakia in 2004 and to the Czech Republic, Latvia, Estonia, and Slovenia in 2005. The risk analysis for each new Member State will progress independently as the necessary information becomes available to APHIS. We will use these risk analyses as tools to identify what risk mitigation measures, if any, would be necessary to protect U.S. livestock if swine and swine products were to be imported from the countries evaluated.

If, in the future, there appear to be acceptable alternatives to the procedures currently specified under § 92.2 of the regulations, we will consider such alternatives. We will provide the public with an opportunity to comment on such alternatives—and will take such comments into consideration—before making any changes to the regulations.

With regard to the comment that specifically addressed imports from Poland, we are currently in the process of preparing a proposed rule that would make our analysis regarding such imports available to the public. Although there is no statutory requirement that APHIS complete a separate risk assessment before determining a country's animal health status, we consider such an assessment to be an integral component of the Agency's decision-making process.

Concerns That the Proposed Rule Would Severely Restrict Exports From the EU–15

In our proposed rule, § 94.24(b) contained requirements governing the importation of live swine from the EU–15. (Please note: The provisions we are making final that were included in § 94.24 of the proposed rule appear in this final rule in § 94.25. An APHIS final rule regarding bovine spongiform encephalopathy published on January 4, 2005 (70 FR 460–553, Docket No. 03–080–3) redesignated § 94.24 as § 94.25.) Among the conditions in proposed § 94.24(b) was the requirement that the swine have not lived in:

- A restricted zone in the EU–15, established because of a CSF outbreak in domestic swine, during the 6 months following depopulation of the swine in the restricted zone and the cleaning and disinfection of the last infected premises in the zone;
- A restricted zone established because of the detection of CSF in wild boar, until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State; or
- Any other region classified in §§ 94.9(a) and 94.10(a) as a region in which CSF is known to exist.

Additionally, § 94.24(b)(2) of the proposed rule required that the swine must not have transited any of the areas described above unless they were moved through the zone or region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination. Further, the swine must never have been commingled with swine that were in such a zone or region.

The provisions of proposed § 94.24(a) applied the same restrictions described above to swine from which pork or products intended for export to the United States were derived.

One commenter stated that, because the Member States of the EU–10 are considered by APHIS to comprise a region in which CSF is known to exist, the proposed rule would prohibit the exportation to the United States of swine or swine products from the EU–15 if the swine have lived in or transited (except for direct transit under the conditions described below under the heading ''Request for Clarification of Extent of Restrictions on Swine and Swine Products'') any part of the EU–10 or have been commingled with swine from any part of the EU–10. The commenter stated that, considering the nature of the internal EU market, which encompasses all 25 EU Member States, such a provision would severely restrict export from the EU–15 to the United States and is a further reason why the rule should be expanded, in line with Article 15 of the Veterinary [Equivalence] Agreement, to include all Member States of the EU–25. (The stated objective of the Veterinary Equivalence Agreement is to facilitate trade in live animals and animal products between the EU and the United States by establishing a mechanism for the recognition of equivalence of sanitary measures, consistent with the protection of public and animal health, and improve communication and cooperation on sanitary issues.)

APHIS response. We recognize that, under this rule, swine and swine products from the EU–15 will be prohibited importation into the United States if the swine involved have been in other EU Member States or have been commingled with swine from other Member States. However, as discussed above, it would not be in accordance with the regulations in § 92.2 and with the Administrative Procedure Act to include EU Member States other than the EU–15 in this final rule without first providing the public with full notice of

[2] Biological Risk Analysis: Risk assessment and management options for imports of swine and swine products from the European Union—June 2, 1999; Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union—December 2000; and APHIS Supplememntal Risk Analysis for Importation of the Classical Swine Fever Virus in Swine and Swine Products from France and Spain—November 2003.

and opportunity to comment on such inclusion.

Request for Clarification of Extent of Restrictions on Swine and Swine Products

One commenter requested clarification of whether a pig that was in a restricted zone while it was a restricted zone would be permanently banned from importation into the United States, or be banned only during the time that the area is considered a restricted zone. The commenter stated that the latter should be the case. The commenter said the same question applies to pork and pork products from swine that were in a restricted zone at the time it was a restricted zone.

It was not our intention to permanently prohibit the importation of swine, or swine products or semen derived from swine, that have been in an area during the time it was a restricted zone, and we explain below, under the heading, ''Scope of Restrictions on the Importation of Swine and Swine Products from the EU–15,'' the wording we are using in this final rule to make that clear.

Before we explain that, however, we wish to (1) explain a wording change we are making in this final rule to be more precise about the nature of CSF contamination, and (2) clarify a statement we made in the proposed rule regarding the depopulation of swine following an outbreak of CSF.

1. *''Infected'' and ''affected.''* In §§ 94.24(a)(1)(ii)(A) and 98.38(b)(2)(i) of our proposal we referred to cleaning and disinfection of infected premises in a restricted region or zone. Properly speaking, the description ''infected'' should be used to apply to the animals contaminated with the disease agent, and the premises where the animals are located should be referred to as being ''affected.'' We are using that terminology in this final rule.

2. *Depopulation of swine after a CSF outbreak.* As noted above, we proposed to require that live swine not have been in a restricted zone in the EU–15, established because of a CSF outbreak in domestic swine, during the 6 months following depopulation of the swine in the restricted zone and the cleaning and disinfection of the last infected premises in the zone. This same condition was included in the proposed rule with regard to swine from which pork and pork products intended for export to the United States from the EU–15 were derived, and with regard to donor boars from which semen intended for export to the United States from the EU–15 was collected.

We did not intend to imply that all swine in a restricted zone would need to be depopulated before we would accept swine and swine products from that area. Consistent with international standards and with standard practice in the United States when a limited outbreak of a disease of concern occurs, only those swine on the affected premises would need to be depopulated. The boundaries of a restricted area are drawn to encompass more than just the affected premises, in order to temporarily restrict the movement of animals from other than the affected premises that may pose an increased risk of being infected with the disease due to proximity to the infected animals or other factors. Therefore, in this final rule, we are making it clear that we intend that only the swine on the affected premises in the restricted zone must have been depopulated.

Scope of Restrictions on the Importation of Swine and Swine Products From the EU–15

As noted above, it was not our intention to permanently prohibit the importation of swine, or swine products or semen derived from swine, that have been in an area during the time it was a restricted zone. Once sufficient time has elapsed to ensure that swine from the formerly restricted zone are not infected with CSF, they, and products and semen derived from such swine, may be imported into the United States. This is consistent with the intention stated in our December 2000 risk analysis to accept exports of swine, swine products, and semen only from regions that have not experienced a CSF outbreak within the previous 6 months.[3]

In this final rule, we are being more specific in §§ 94.25(a), 94.25(b), and 98.38(b) to make clearer the conditions under which swine and swine products are eligible for importation into the United States from the EU–15 with regard to CSF. In this final rule, we are setting forth the following:

1. *Pork and pork products.* Among the provisions included in § 94.25(a) of this final rule, we are providing that the pork and pork products must not have been derived from swine that were in any of the following regions or zones at any time during the following periods, unless the swine were slaughtered after the periods described:

- Any region when the region was classified in §§ 94.9(a) and 94.10(a) as one in which CSF is known to exist, except for the EU–15;
- A restricted zone in the EU–15 established because of detection of CSF in domestic swine, from the time of the detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or
- A restricted zone in the EU–15 established because of the detection of CSF in wild boar, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State.

For the period described above following the detection of CSF in domestic swine, we provide that the period during which exports to the United States are prohibited could be longer than 6 months if the EU–15 has not yet removed its designation of the area as a restricted zone by that time. We expect that this situation, if it arises at all, will occur infrequently. However, we consider it prudent to provide for any such situations where the EU has reason to believe the designation of an area as a restricted zone should be extended.

Additionally, we are providing in § 94.25(a)(2) that the pork and pork products must not have been commingled with pork or pork products derived from other swine that were in any of the regions or zones described above, unless the other swine were slaughtered after the periods described. Additionally, the pork and pork products must not have been derived from swine that were commingled with other swine that were in any of the regions or zones described above, unless the swine from which the pork and pork products were derived were slaughtered after the periods described.

In § 94.25(a)(3), we are providing that the swine from which the pork and pork products were derived must not have transited any region or zone described above, unless the swine were moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the swine were slaughtered after the periods described.

2. *Live swine.* Among the provisions included in § 94.25(b) of this final rule, we are providing that live swine imported from the EU–15 must not have been in any regions or zones described above, unless the swine are exported after the periods described.

[3] Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union—December 2000.

Additionally, we are providing in § 94.25(b)(3) that the swine must not have been commingled with other swine that have at any time been in any of the regions or zones described above, unless the swine are exported after the periods described. We are also providing that the swine must not have transited any region or zone described above, unless the swine were moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the swine are exported after the periods described.

3. *Swine semen.* Among the provisions included in § 98.38 of this final rule, we are providing that swine semen imported from the EU–15 must not have been collected from a donor boar that was in any of the regions or zones described above, unless the semen was collected after the periods described.

We are providing in § 98.38(c) that the semen must not have been collected from a donor boar that was commingled with swine that at any time were in any of the regions or zones described above, unless the semen was collected after the periods described.

Additionally, we are providing in § 98.38(d) that the semen must not have been collected from a donor boar that transited any region or zone described above, unless the donor boar was moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the semen was collected after the periods described.

Concerns With EU Removal of Movement Restrictions in Less Than 6 Months

Several commenters expressed concern that, even though the proposed rule would not allow the importation into the United States of swine and swine products from a restricted zone until 6 months after the depopulation of swine in the zone and the cleaning and disinfection of the last infected premises in the zone, the EU allows free movement of animals and products from such a zone after only 20 or 30 days. One commenter stated that the shorter EU ''release period'' would require the United States to track any swine or swine products moving from a restricted zone to some other area of the EU before the 6 months are up, in order to ensure that the swine or swine products are not exported to the United States.

APHIS Response. We are making no changes based on these comments. The commenter is correct that EC regulations would allow movement of animals and products from CSF restricted zones before a 6-month period expired. However, the proposed rule anticipated the potential for this ''shorter EU 'release period.' '' As we stated in the proposed rule, swine and swine products would not be allowed importation from the EU–15 unless they are accompanied by certification by an official of the competent veterinary authority of the EU–15 Member State that the conditions of this rule have been met. In considering the CSF risk in the EU–15, we evaluated the ability of officials in that region to ensure that prohibitions on the importation into the United States of swine and swine products from the restricted zones would be effectively enforced.

The commenters are correct that, because of the potential difference between the restrictions of the EC and those of this rule with regard to when restrictions are removed, it will be necessary to track the movement of any swine that are moved from a restricted area before 6 months have elapsed. However, such tracking will be the responsibility of EU veterinary officials.

How APHIS' Proposed Restrictions Compare to International Standards

One commenter stated that the provision that would prohibit the importation of live swine and pork and pork products from restricted zones for 6 months after depopulation of swine in the restricted zone and the cleaning and disinfection of the last infected premises in the zone is more stringent than the standards contained in Article 2.6.7.6 of the Terrestrial Animal Health Code of the World Organization for Animal Health (OIE Code). The commenter stated that Article 2.6.7.6 of the OIE Code provides that if a CSF outbreak occurs in an establishment in a country or zone free of CSF in domestic and wild swine or free of CSF in domestic pigs only, the status of the country or zone may, under certain measures, be restored 30 days after completion of a policy for ''stamping out'' the disease.

APHIS response. We are making no changes based on this comment. Current EU regulations allow CSF restrictions in protection zones to be removed no earlier than 30 days after completion of preliminary cleaning and disinfection measures on the infected holding (no earlier than 20 days in surveillance zones). Measures are lifted only after clinical examinations and serology indicate that the pigs remaining in the zones are free of CSF. Presumably, after restrictions are released, swine from the area could be moved throughout the EU.

Based on observations and assumptions that we discussed in two risk analyses used to support our April 2005 proposed rule, we proposed to recognize the EU–15 as a region of low risk for CSF rather than as a CSF-free region.[4] As discussed in our proposed rule, we are concerned that a 30-day period following a CSF outbreak in the EU–15 is insufficient to ensure that the area where an outbreak occurred is no longer affected by the disease.

We consider a 6-month waiting period to be appropriate for several reasons. First, as described in our risk analyses, we are concerned by the recurrence of CSF in several areas of the EU shortly after EC restrictions were removed from those areas and the movement of swine commenced. For example, in December 2001 a CSF outbreak was confirmed in Osoma, Spain, 22 days after release of EC movement restrictions (83 days after depopulation of the last previous outbreak in Spain). A CSF outbreak in August 2002 in Luxembourg was epidemiologically linked to an outbreak that occurred in June 2002. The August 2002 outbreak occurred 27 days after release of EC movement restrictions (56 days after depopulation of the affected pigs involved in the June outbreak). During the 1997–1998 CSF epidemic, the EC usually maintained movement restrictions for more than 30 days, but disease spread was nonetheless extensive. These observations and the EC actions suggest that 30 days may be an insufficient duration for restrictions.

Our proposed 6-month period for restrictions was based on the relevant OIE standard (OIE Code, 2004) at the time our risk documentation was developed. The 6-month waiting period was the OIE standard for a country or zone free of CSF in domestic pigs but with infection in the wild pig population. In that standard, OIE recommended that, where a stamping out policy without vaccination has been implemented for CSF control, recognition of freedom from CSF may be acquired 6 months after the last outbreak in domestic pigs. The commenter is correct that the OIE standard has been recently revised (OIE Code 2005) and currently recommends release of restrictions 30 days after completion of the appropriate stamping out activities. However, that change was made after development of our proposed rule, which did not invite public comment regarding the change in the OIE recommendations.

Despite the change in the OIE recommendations, we continue to be concerned that restrictions for only 30 days may not be sufficient, for the reasons discussed above. However, we

[4] See footnote 1 above.

welcome any relevant scientific information regarding this issue and, if we consider it warranted after review of the information, could consider alternatives to a 6-month restriction period in future rulemaking.

Concerns That the Rule as Proposed Would Eliminate APHIS Site Visits to the EU–15

Several commenters expressed concern that implementation of the proposed rule would eliminate APHIS site visits to the EU–15 for the purpose of evaluating compliance with procedures deemed critical for the protection of the U.S. swine industry. One commenter recommended that USDA officials be required to make onsite evaluations in the EU–15 before importations of swine and swine products are allowed to resume from a restricted zone. Another commenter stated that the rule should not prohibit such onsite evaluations. A third commenter requested further clarification of the reasons for eliminating site visits to the EU, and stated that site visits are an important component of the risk assessment process. That commenter stated that a site visit that APHIS conducted in response to a regionalization request from Mexico allowed U.S. officials to become aware of the occurrence of porcine ''blue eye disease'' that may have gone unnoticed had such a visit not been conducted.

APHIS response. We are making no changes based on these comments. We agree that site visits are valuable tools in evaluating and verifying animal disease conditions, especially in countries where there has been limited history of animal and animal product trade with the United States. As we stated in our proposed rule, APHIS reserves the right to make site visits and review documentation related to the outbreak and eradication activities. Additionally, § 92.2(g) of the current regulations, regarding application for recognition of the animal health status of a region, provides that, if a region is granted animal health status in accordance with the regulations, that region may be required to submit additional information pertaining to animal health status or allow APHIS to conduct additional information collection activities in order for that region to maintain its status. Such additional information collection activities could include a site visit if deemed necessary by APHIS.

APHIS considers its knowledge of the CSF conditions and the effectiveness of CSF control measures in the EU–15 to be extensive. Although our risk analyses assumed there will be future CSF outbreaks in domestic swine within the EU–15, they concluded that the EU is capable of detecting, controlling, and eradicating CSF in its domestic swine if an outbreak occurs. Because we expect future CSF outbreaks to occur in what we are considering a low-risk region for CSF, and expect that such outbreaks will be quickly and effectively controlled, we do not anticipate a need to make routine site visits to the region. However, this rule does not prohibit APHIS from taking such action if conditions warrant.

Concern That Assessment of Disease Status Will Become Less Transparent

One commenter stated that, although the current process for assessing and changing the CSF-status of countries or other regions in the EU is laborious, it is also highly transparent.

APHIS response. We do not consider that a significant level of transparency will be lost by the new approach, whereas the amount of labor and time required to re-initiate trade will be significantly reduced. With respect to transparency, OIE reports of CSF outbreaks in the region will continue to be available to interested parties. Procedurally, this rulemaking explains clearly how APHIS will respond to those reports. As discussed above, APHIS has gained confidence in control of CSF by the EC through extensive evaluations of the EU–15 region and the history of trade of swine and swine products between the EU–15 and the United States. We consider the process established in this rule to be warranted and advantageous, allowing APHIS to respond more quickly to changes in CSF conditions within a recognized low-risk region while maintaining the Agency's sanitary standards.

Concerns Regarding Efficacy of EU CSF Control Measures and Risk Levels

One commenter stated that, to date, control measures in EU Member States have not been effective in preventing the introduction of CSF into domestic swine herds in the EU.

APHIS response. As previously stated, the risk analyses we conducted with regard to the imports of swine and swine products from the EU–15 demonstrate that the risk of exporting CSF from the EU–15 and having it enter and become established in the United States is low, even assuming continuing outbreaks in the region. Among the factors we consider in conducting a risk analysis is whether a region seeking to export commodities to the United States has a veterinary infrastructure capable of detecting, controlling, and eradicating the disease efficiently in the case of an outbreak. We have determined that the EC veterinary infrastructure possesses such capabilities.

Request for Additional Surveillance

One commenter expressed concern that, although the proposed rule would result in all of the EU–15 Member States being considered as having the same level of risk for CSF exposure because of freedom of trade within the EU, it would appear that different levels of risk exist throughout the EU and that certain areas should be required to undergo significant additional surveillance to ensure detection of CSF exposure.

APHIS response. We are making no changes to the final rule based on this comment. The final rule anticipates that additional surveillance is necessary for areas within the EU–15 where the CSF virus has been detected either in domestic swine or wild boar. The APHIS evaluation has shown that surveillance plans are implemented at a Member State or regional level. The EC reviews and approves individual surveillance plans. The continuing appropriateness of the plans to a given situation or local risk spectrum is assessed during inspections by the EC's Food and Veterinary Office. In addition, APHIS reviews surveillance programs during its initial onsite evaluations and also reviews the adequacy of detection methods by laboratories throughout the region. Finally, APHIS considers the surveillance approaches described in individual contingency plans, detection capabilities, and movement restrictions and control measures implemented at the EU level under EC regulation [Council Directive 2001/89/EC] to be adequate for detection, control, and eradication of CSF in domestic swine.

Request That the Rule Apply to Diseases in Addition to CSF

One commenter requested that the proposed rule be extended to apply to all animal diseases and not be confined to CSF. The commenter stated that if APHIS will accept the decisions of the EU with regard to CSF, then APHIS should also accept the decisions of the EU with regard to other animal diseases. Another commenter stated that the proposed rule would not fulfill U.S. obligations under the Veterinary [Equivalence] Agreement, which the commenter stated would entail regionalization of the EU not just for CSF, but for all major animal diseases.

APHIS response. We are making no changes based on these comments. The regionalization approach and import conditions established by this final rule

are based on the CSF-specific conditions that exist in the EU–15 and the CSF control measures applied in that region. These conditions and measures are discussed in the document ''APHIS Risk Considerations on Importation of Classical Swine Fever (CSF) Virus in Breeding Swine, Swine Semen, and Fresh Pork from a European Union Region of Fifteen Member States,'' which was released for public review and comment when our proposed rule was published in April 2005. The conditions and control measures for other major animal diseases were not addressed in that document. However, we are considering establishing the same or similar regionalization approaches with regard to other major animal diseases. We would make any such proposed expanded application of this approach available for public comment, along with any supporting evaluations.

Smallest Administrative Unit To Be Considered for Regionalization in Italy

One commenter stated that, although the proposal identified the ''Region'' as the smallest administrative unit in Italy that APHIS will consider for regionalization, in its ''Notice of Availability of Draft Document Concerning the Identification of the EU Administrative Units,'' APHIS announced that the *Aziende Sanitarie Locali* will be the smallest administrative unit in Italy considered for regionalization.

APHIS response. At the time the proposed rule was published in April 2005, the ''Region'' was recognized by APHIS as the smallest administrative unit for the purpose of regionalizing Italy in the event of future animal disease outbreaks. However, after the proposed rule was published, we reevaluated the issue of the appropriate smallest administrative unit for regionalization in Italy and identified the *Aziende Sanitarie Locali* as that administrative unit. On April 21, 2005, we gave notice in the **Federal Register** (70 FR 20733–20734, Docket No. 04–081–1) of the availability of a draft document listing what APHIS considered the smallest appropriate administrative units for regionalization in Italy and in other EU Member States. On July 29, 2005, we published a notice in the **Federal Register** (70 FR 43838–43839, Docket No. 04–081–2) advising the public that we were making the draft document final with minor changes. Therefore, APHIS considers the *Aziende Sanitarie Locali* to be the smallest appropriate administrative unit in Italy for purposes of regionalization.

Request for Clarification of the Likely Source of CSF Diagnosed in France

One commenter noted that the proposed rule stated that infected wild boar are the suspected source of virus linked to an April 2002 CSF outbreak in France. The commenter expressed concern that this statement erroneously suggests that the outbreak was linked to infection in wild boars in France. The commenter stated that epidemiological investigations in fact suggested that the introduction of CSF occurred when a farmer from Germany visited the holding in France where the CSF was detected.

APHIS response. We agree that the language in the proposed rule may have erroneously given the impression that the 2002 outbreak in Chemery-les-Deux in France was linked to CSF-infected wild boar populations in that country. The commenter correctly points out that the epidemiology investigation for that outbreak, as described in the ''APHIS Risk Analysis for Importation of the Classical Swine Fever Virus in Swine and Swine Products from France and Spain—November 2003,'' reported that French authorities hypothesized that the outbreak was the result of secondary spread of infection from a CSF outbreak in a domestic swine herd in Germany. It should be noted that this clarification does not alter APHIS' conclusion that EU control measures for CSF in wild boar are a critical component of the overall EU controls for CSF. The risk analyses conducted by APHIS' assessment demonstrated that infected wild boar continue to be a potential source of infection in domestic swine. However, the risk of the spread of CSF infection originating in wild boar is mitigated by the EC regulations that place movement restrictions on domestic swine from infected wild boar areas.

Certification Clarifications

In § 94.25(b)(6) of this rule, we provide that live swine exported from the EU–15 must be accompanied to the United States by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the EU–15 Member State. This requirement was included in our proposed rule. For pork and pork products, § 94.25(a)(5) provides that pork and pork products imported from the EU–15 must be accompanied by a certificate issued by an official of the competent veterinary authority of the EU–15 Member State who is authorized to issue the foreign meat certificate required by 9 CFR 327.4 This requirement was likewise included in our proposed rule. However, in § 98.38(g) of the proposed rule with regard to the importation of swine semen from the EU–15, we stated only that the semen must be accompanied to the United States by a certificate issued by a salaried veterinary officer of the EU–15 Member State, and did not indicate that the veterinary officer must be employed by the competent veterinary authority of that State. To clarify our intent and to be consistent with the other provisions in this final rule, we are providing in § 98.38(i) that the individual issuing the certificate with regard to swine semen must be a salaried veterinary officer of the competent veterinary authority of the EU–15 Member State.

Section 93.505 of the current regulations requires that, except for swine from Canada, all swine intended for importation into the United States be accompanied by official certification regarding the health status of the swine and the disease status of the region of origin. Paragraph (a) of § 93.505 requires that the certificate accompanying the swine show that the entire region of origin of the swine is free of CSF and other specified diseases of swine. In accordance with our proposed action to allow the importation of breeding swine from the EU–15, we proposed to change the language in § 93.505 to clarify that certification that the entire region is free of CSF does not apply to the EU–15. The wording we used in proposed § 93.505 was as follows: ''* * * except for the region consisting of the EU–15 for the purposes of classical swine fever, for which alternative certification is required under § 94.24(b)(4), for domestic swine the certificate shall show that the entire region of origin is free of classical swine fever.''

Our use of the term ''alternative certification'' was intended to apply only to the certification requirement in § 93.505(a) regarding CSF. We did not intend to imply that there were alternative certification requirements regarding diseases other than CSF for swine imported from the EU–15. For diseases other than CSF, the certification requirements in § 93.505 will continue to apply to imports from the individual EU Member States. To make clear our intention, in this final rule we are replacing the term ''alternative certification'' with the term ''additional certification.'' Additionally, we are adding a note to § 93.505(a) to make clear that we consider the EU–15 to be a single region of origin only with regard to CSF and not with regard to any other diseases of swine.

Equipment and Materials Used To Transport Swine

The conditions in § 94.25 regarding the importation of live swine from the EU–15 include the requirement that no equipment or materials used to transport the swine may have been used previously for transporting swine that do not meet the requirements of the final rule, unless such equipment and material have first been cleaned and disinfected. A similar requirement is included in § 98.38 regarding donor boars from which swine semen intended for export is collected. These requirements are necessary to guard against contamination of the animals with the CSF disease agent.

Although the same risk mitigation measure is necessary for swine from which pork and pork products intended for importation from the EU–15 are derived, our proposed rule did not explicitly include that requirement for such swine. To make clear our intent, we are providing in § 94.25(a)(4) that no equipment or materials used in transporting the swine from which the pork and pork products were derived from the farm of origin to the slaughtering establishment may have been used previously for transporting swine that do not meet the requirements of this final rule, unless such equipment and materials have first been cleaned and disinfected.

Other Nonsubstantive Changes

In this final rule, we have made certain nonsubstantive changes, such as redesignations of paragraphs and corresponding changes to paragraph references, to accommodate the changes discussed above.

Conclusion

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.

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.

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock. APHIS decides whether animals and animal products may be exported from foreign regions to the United States based on disease risk assessments.

In this rule we are amending the regulations in 9 CFR part 94 to (1) apply a uniform set of importation requirements related to CSF to a region consisting of the EU–15, and (2) prohibit for a specified period of time the importation of live swine and swine products from any area in the EU–15 that is identified by the veterinary authorities of the region as a restricted zone.

The purpose of this rule is to enable APHIS to respond more readily to changes in CSF status within the EU, while maintaining the Agency's sanitary safeguards. The rule will change the requirements by which imports of swine, swine meat, and swine genetics are allowed to resume following restoration of CSF-free status for areas within the EU–15 that have been quarantined because of this disease.

Separate rulemaking each time an area within the EU–15 experiences a CSF outbreak and each time CSF-free status is restored will no longer be required. Rather, APHIS will recognize EU quarantine decisions and require the EU to certify that the conditions set forth in this rule are met. As an additional safeguard, imports of swine, swine meat, and swine genetics by the United States from areas in which CSF had been detected in domestic swine will be restricted from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later.

This action is being taken based on APHIS' analysis of the risks of CSF introduction from the EU. CSF is a highly contagious and fatal disease of swine. It was eradicated from the United States in 1976 after a 16-year effort, at a cost to USDA and individual States of about $140 million ($479 million in 2005 dollars). The potential for reintroduction of CSF into the United States remains a major concern, not only because of production losses and eradication costs, but also because of the adverse effects reintroduction would have on U.S. swine and pork exports.

In this analysis, expected benefits and costs of the rule are examined in accordance with Executive Order 12866. Impacts for small entities are also considered, as required by the Regulatory Flexibility Act.

An alternative to the rule would be to not change the regulations, that is, to continue to initiate rulemaking whenever the CSF status of an area within the EU–15 changes. Continuing with the current procedures would not achieve the objective of improving the Agency's responsiveness to CSF status changes. A second alternative would be to not include in the rule the 6-month period of import restriction following restoration of an area's CSF-free status when CSF had been detected in domestic swine. This alternative would forfeit the additional sanitary assurance that the 6-month period will provide to the U.S. swine and swine product industries that the reestablished imports are CSF-free. The rule is preferable to these alternatives in allowing timelier resumption of imports from areas restored to CSF-free status, while ensuring that sanitary safeguards are adequate.

Effects of the Rule

Simplification of the process by which an area in the EU–15 region that has been quarantined for CSF reacquires CSF-free status will allow for timelier resumption of U.S. imports of swine, swine meat, and swine genetics from the area. In addition, the rule will result in more efficient use of APHIS resources. These areas of impact are discussed below.

More Timely Reestablishment of CSF-Free Status. With this rule, reestablishment of CSF-free status for an area that has been under quarantine is expected to require less time than currently, notwithstanding the 6-month restriction on importation of swine and swine products from the area following depopulation of the swine on affected premises in the quarantined zone and completion of cleaning and disinfection measures, if domestic swine were infected. More timely recognition of an area's CSF-free status will allow imports of swine, swine meat, and swine genetics from the area to resume sooner than at present.

The economic effect will depend on the time saved, and the additional swine, swine meat, and swine genetics that will be imported because of more timely reinstatement of an area's CSF–free status. We cannot predict the number of swine or quantity of swine products imported that the rule will affect, but they are unlikely to be significant. Less than 6 percent of domestically available swine (U.S. production plus imports minus exports) and less than 3 percent of domestically available pork are imported. Most swine imports come from one country, Canada, and most swine product imports come from two, Canada and Denmark.

Impacts of the rule for the U.S. swine and swine product industries will be minor. However, we expect the rule to lead more generally to improved trade relations between the United States and the EU. One or more of the areas within the EU–15 region not yet recognized by the United States as free of CSF—i.e., Luxembourg and parts of Germany and Italy—may be among the first to benefit from this rule.

More Efficient Use of APHIS Resources. A second area of impact will be the effect of the rule on APHIS operations. The rule will result in fewer site visits, risk assessments, **Federal Register** publications, and other rulemaking tasks currently required for reinstating an area's CSF-free status. Resources that are devoted to these tasks will become available for other uses.

Gains to the Agency from the reallocation of resources are not readily quantified. They will be realized in terms of the additional time APHIS staff have for other tasks, and will depend on the frequency with which CSF quarantines and CSF-free status reinstatements take place within the EU–15 region.

Swine Semen Import Requirements. In April 2003, APHIS published a final rule that recognized—with the exception of specified regions in Germany and Italy—the countries of Austria, Belgium, Germany, Greece, Italy, the Netherlands, and Portugal as a single region in which CSF is not known to exist, but from which the importation of live swine and swine products into the United States is restricted because of CSF infection in wild boar populations. Among the restrictions applied to importations from that region are certain requirements regarding swine semen. One requirement is that, before swine semen is exported to the United States, the donor boar be held at the semen collection center and observed by the center veterinarian for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF. The 40-day hold is considered an effective mitigation measure and is consistent with OIE recommendations for semen exported from countries that are free of CSF in domestic swine but that have CSF infection in wild boar populations.

Before publication of the April 2003 final rule, five EU Member States—Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom—were considered CSF–free. In our April 8, 2005 proposed rule, we proposed to begin applying the 40–day hold requirement to these five EU countries.

Some of the comments we received in response to our proposed rule addressed the issue of the 40–day hold on semen. We discussed these comments, above, under the heading ''Forty-Day Holding Period Before the Shipment of Swine Semen to the United States.'' As we stated, above, we continue to consider it necessary to mitigate the CSF risk from the importation of swine semen from the EU. However, in light of the comments received on the proposed rule suggesting the possibility of alternative methods of risk mitigation that would be less economically disruptive than a 40-day hold, we are not, at this time, making final the requirement for a 40-day hold with regard to those five EU Member States that we had previously individually recognized as free of CSF (Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom). Instead, we will give the issue of a 40–day hold further consideration based on the information available to us. After we consider all the information available to us, we will publish a document in the **Federal Register** discussing our conclusions.

In the economic analysis we conducted for the proposed rule, we raised the question of possible effects of the 40-day hold on the five EU Member States that APHIS had recognized as free of CSF before the April 2003 final rule. However, because this final rule will not change swine semen import requirements for those five Member States, we are not addressing in this analysis potential effects on those five Member States of a 40–day hold requirement.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to evaluate the potential effects of their proposed and final rules on small businesses, small organizations, and small governmental jurisdictions.

U.S. entities that could be affected by the rule are swine producers and swine product wholesalers. The size of entities that may be affected by the rule is unknown. However, it is reasonable to assume that most fall below the U.S. Small Business Administration's (SBA) small-entity thresholds.

The SBA defines small hog and pig farms as those earning not more than $750,000 in annual receipts. National Agricultural Statistics Service (NASS) data show that the average value of hogs and pigs sold in 2002 was about $67 per animal. Based on this average price, the number of hogs and pigs sold annually would need to be fewer than about 11,200 animals for annual receipts to be not more than $750,000. NASS data are structured to show how many hog and pig farms sold 7,500 or more animals. NASS data indicate that only about 6 percent of hog and pig farms sold 7,500 or more animals in 2002. Clearly, most swine producers are small entities.

Swine product wholesalers are also likely to be mainly small entities. The SBA small-entity standard for these businesses is not more than 100 employees. We do not know the size distribution of meat wholesalers, but the 2002 Economic Census indicates that the average number of employees per establishment that year was 15.

U.S. imports of swine, swine meat, and swine genetics from the EU–15 are expected to be timelier because of the rule. To the extent that the rule results in less delay in imports, any import-related impacts for U.S. producers and wholesalers will occur more quickly as well. We cannot predict the number of swine or quantity of swine products that the rule will affect, but they are unlikely to be significant. Rather, the major benefit of the rule will be improved trade relations between the United States and the European Union.

APHIS has not taken steps to minimize significant economic impacts of the rule on small entities because we do not expect any significant impacts. An alternative to the proposed rule would be to not change the regulations, that is, to continue to initiate rulemaking whenever the CSF-status of an area within the EU–15 changes. Continuing with the current procedures would not achieve the objective of improving the Agency's responsiveness to CSF–status changes. A second alternative would be to not include in the rule the 6-month period of import restriction following restoration of an area's CSF–free status when CSF had been detected in domestic swine. This alternative would forfeit the additional sanitary assurance that the 6-month period will provide to the U.S. swine and swine products industries. The rule is preferable to these alternatives in allowing resumption of imports from areas restored to CSF–free status in a timelier manner, while ensuring that sanitary safeguards are sufficient.

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 0579–0265.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

9 CFR Part 93

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

9 CFR Part 94

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

9 CFR Part 98

Animal diseases, Imports.

■ Accordingly, we are amending 9 CFR parts 93, 94, and 98 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 § 93.500, a new definition of *European Union–15 (EU–15)* is added, in alphabetical order, to read as follows:

§ 93.500 Definitions.

* * * * *

European Union–15 (EU–15). The organization of Member States consisting of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

■ 3. In § 93.505, paragraph (a), the last sentence is removed and three sentences are added in its place to read as follows:

§ 93.505 Certificate for swine.

(a) * * * For domestic swine, the certificate shall also show that the entire region of origin is free of African swine fever and swine vesicular disease and that, for 60 days immediately preceding the time of movement from the premises of origin, no swine erysipelas or swine plague has existed on such premises or on adjoining premises. Additionally, except for the region consisting of the EU–15 for the purposes of classical swine fever, for which additional certification is required under § 94.25(b)(6), for domestic swine the certificate shall show that the entire region of origin is free of classical swine fever.

Note: The EU–15 is considered a single region only for the purposes of classical swine fever and not for the purposes of any other swine disease.

* * * * *

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

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

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 5. In § 94.0, definitions of *European Union–15 (EU–15)* and *restricted zone for classical swine fever* are added, in alphabetical order, to read as follows:

§ 94.0 Definitions.

* * * * *

European Union–15 (EU–15). The organization of Member States consisting of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

Restricted zone for classical swine fever. An area, delineated by the relevant competent veterinary authorities of the region in which the area is located, that surrounds and includes the location of an outbreak of classical swine fever in domestic swine or detection of the disease in wild boar, and from which the movement of domestic swine is prohibited.

* * * * *

■ 6. Section 94.9 is amended as follows:
■ a. Paragraph (a) and footnote 10 are revised to read as set forth below.
■ b. Paragraphs (b) and (c) are redesignated as paragraphs (c) and (d), respectively.
■ c. A new paragraph (b) is added to read as set forth below.
■ d. The introductory text of newly designated paragraph (c) is revised to read as set forth below.
■ e. In newly redesignated paragraph (c)(1)(iii)(C)(*2*), the words ''paragraph (b)'' are removed each time they occur and the words ''paragraph (c)'' are added in their place.
■ f. In newly redesignated paragraph (c)(2), the words ''paragraph (b)'' are removed and the words ''paragraph (c)'' are added in their place.
■ g. In newly redesignated paragraph (c)(3), the words ''paragraph (b)'' are removed each time they occur and the words ''paragraphs (c)'' are added in their place.
■ h. In newly redesignated paragraph (d), the words ''paragraph (b)'' are removed and the words ''paragraph (c)'' are added in their place.

§ 94.9 Pork and pork products from regions where classical swine fever exists.

(a) Classical swine fever is known to exist in all regions of the world except Australia; Canada; Chile; Fiji; Iceland; the Mexican States of Baja California, Baja California Sur, Chihuahua, and Sinaloa; New Zealand; Norway; and Trust Territory of the Pacific Islands.[10]

(b) The EU–15 is a single region of low-risk for CSF.

(c) Except as provided in § 94.25 for the EU–15, no fresh pork or pork product may be imported into the United States from any region where classical swine fever is known to exist unless it complies with the following requirements:

* * * * *

■ 7. Section 94.10 is revised to read as follows:

§ 94.10 Swine from regions where classical swine fever exists.

(a) Classical swine fever is known to exist in all regions of the world, except Australia; Canada; Chile; Fiji; Iceland; the Mexican States of Baja California, Baja California Sur, Chihuahua, and Sinaloa; New Zealand; Norway; and Trust Territory of the Pacific Islands.

(b) The EU–15 is a single region of low-risk for CSF.

(c) Except as provided in § 94.25 for the EU–15, no swine that are moved

[10] See also other provisions of this part and parts 93, 95, and 96 of this chapter, and part 327 of this title, for other prohibitions and restrictions upon the importation of swine and swine products.

from or transit any region where classical swine fever is known to exist may be imported into the United States, except for wild swine imported into the United States in accordance with paragraph (d) of this section.

(d) Wild swine may be allowed importation into the United States by the Administrator upon request in specific cases under § 93.501 or § 93.504(c) of this chapter.

■ 8. Section 94.25 is revised to read as follows:

§ 94.25 Restrictions on the importation of pork, pork products, and swine from the EU–15.

(a) *Pork and pork products.* In addition to meeting all other applicable provisions of this part, fresh pork and pork products imported from the EU–15 must meet the following conditions:

(1) The pork or pork products must not have been derived from swine that were in any of the following regions or zones, unless the swine were slaughtered after the periods described:

(i) Any region when the region was classified in §§ 94.9(a) and 94.10(a) as one in which classical swine fever is known to exist, except for the EU–15;

(ii) A restricted zone in the EU–15 established because of detection of classical swine fever in domestic swine, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(iii) A restricted zone in the EU–15 established because of the detection of classical swine fever in wild boar, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State.

(2) The pork and pork products must not have been commingled with pork or pork products derived from other swine that were in any of the regions or zones described in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, unless the other swine were slaughtered after the periods described. Additionally, the pork and pork products must not have been derived from swine that were commingled with other swine that were in any of the regions or zones described in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, unless the swine from which the pork or pork products were derived were slaughtered after the periods described.

(3) The swine from which the pork or pork products were derived must not have transited any region or zone described in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, unless the swine were moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the swine were slaughtered after the periods described.

(4) No equipment or materials used in transporting the swine from which the pork or pork products were derived from the farm of origin to the slaughtering establishment may have been used previously for transporting swine that do not meet the requirements of this section, unless the equipment and materials have first been cleaned and disinfected.

(5) The pork and pork products must be accompanied by a certificate issued by an official of the competent veterinary authority of the EU–15 Member State who is authorized to issue the foreign meat inspection certificate required by § 327.4 of this title, stating that the applicable provisions of paragraphs (a)(1) through (a)(4) of this section have been met.[20]

(b) *Live swine.* In addition to meeting all other applicable provisions of this title, live swine imported from the EU–15 must meet the following conditions:

(1) The swine must be breeding swine.

(2) The swine must not have been in any of the following regions or zones, unless the swine are exported to the United States after the periods described:

(i) Any region when the region was classified in §§ 94.9(a) and 94.10(a) as one in which classical swine fever is known to exist, except for the EU–15;

(ii) A restricted zone in the EU–15 established because of the detection of classical swine fever in domestic swine, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(iii) A restricted zone in the EU–15 established because of the detection of classical swine fever in wild boar, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State.

(3) The swine must not have been commingled with other swine that have at any time been in any of the regions or zones described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, unless the swine are exported after the periods described.

(4) The swine must not have transited any region or zone described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section, unless the swine were moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the swine are exported after the periods described;

(5) No equipment or materials used in transporting the swine may have been used previously for transporting swine that do not meet the requirements of this section, unless the equipment and materials have first been cleaned and disinfected.

(6) The swine must be accompanied by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the EU–15 Member State, stating that the conditions of paragraphs (b)(1) through (b)(5) of this section have been met.[21]

(c) The certificates required by paragraphs (a)(5) and (b)(6) of this section must be presented by the importer to an authorized inspector at the port of arrival, upon arrival of the swine, pork, or pork products at the port.

(Approved by the Office of Management and Budget under control numbers 0579–0218 and 0579–0265).

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND SEMEN

■ 9. The authority citation for part 98 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.

■ 10. In § 98.30, definitions of *European Union–15 (EU–15)* and *restricted zone for classical swine fever* are added, in alphabetical order, to read as follows:

§ 98.30 Definitions.

* * * * *

European Union–15 (EU–15). The organization of Member States consisting of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the

[20] The certification required may be placed on the foreign meat inspection certificate required by § 327.4 of this title or may be contained in a separate document.

[21] The certification required may be placed on the certificate required by § 93.505(a) of this chapter or may be contained in a separate document

Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

Restricted zone for classical swine fever. An area, delineated by the relevant competent veterinary authorities of the region in which the area is located, that surrounds and includes the location of an outbreak of classical swine fever in domestic swine or detection of the disease in wild boar, and from which the movement of domestic swine is prohibited.

* * * * *

■ 11. Section 98.38 is revised to read as follows:

§ 98.38 Restrictions on the importation of swine semen from the EU–15.

In addition to meeting all other applicable provisions of this part, swine semen imported from the EU–15 must meet the following conditions, except as noted in paragraph (h) of this section with regard to swine semen imported from Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom:

(a) The semen must come from a semen collection center approved for export by the competent veterinary authority of the EU–15 Member State.

(b) The semen must not have been collected from a donor boar that was in any of the following regions or zones, unless the semen was collected after the periods described:

(1) Any region when the region was classified in §§ 94.9(a) and 94.10(a) of this chapter as one in which classical swine fever is known to exist, except for the EU–15;

(2) A restricted zone in the EU–15 established because of the detection of classical swine fever in domestic swine, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State or until 6 months following depopulation of the swine on affected premises in the restricted zone and the cleaning and disinfection of the last affected premises in the zone, whichever is later; or

(3) A restricted zone in the EU–15 established because of the detection of classical swine fever in wild boar, from the time of detection until the designation of the zone as a restricted zone is removed by the competent veterinary authority of the EU–15 Member State.

(c) The semen must not have been collected from a donor boar that was commingled with swine that at any time were in any of the regions or zones described in paragraphs (b)(1) through (b)(3) of this section, unless the semen was collected after the periods described.

(d) The semen must not have been collected from a donor boar that transited any region or zone described in paragraphs (b)(1) through (b)(3) of this section during the periods described, unless the donor boar was moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, or unless the semen was collected after the periods described;

(e) The donor boar must be held in isolation for at least 30 days prior to entering the semen collection center.

(f) No more than 30 days prior to being held in isolation as required by paragraph (e) of this section, the donor boar must be tested with negative results with a classical swine fever test approved by the Office International des Epizooties (World Organization for Animal Health).

(g) No equipment or materials used in transporting the donor boar from the farm of origin to the semen collection center may have been used previously for transporting swine that do not meet the requirements of this section, unless such equipment or materials have first been cleaned and disinfected.

(h) Except for semen collected from swine in Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom, before the semen is exported to the United States, the donor boar must be held at the semen collection center and observed by the center veterinarian for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of classical swine fever.

(i) The semen must be accompanied by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the EU–15 Member State, stating that the provisions of paragraphs (a) through (h) of this section have been met.[3]

(Approved by the Office of Management and Budget under control numbers 0579–0218 and 0579–0265).

Done in Washington, DC, this 16th day of May 2006.

Jeremy Stump,

Acting Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 06–4681 Filed 5–18–06; 8:45 am]

BILLING CODE 3410–34–P

[3] The certification required may be placed on the certificate required under § 98.35(c) or may be contained in a separate document.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–24517; Directorate Identifier 2006–NE–18–AD; Amendment 39–14591; AD 2006–10–07]

RIN 2120–AA64

Airworthiness Directives; Hamilton Sundstrand Model 14RF–9 Propellers; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2006–10–07. That AD applies to Hamilton Sundstrand Model 14RF–9 propellers. We published AD 2006–10–07 in the **Federal Register** on May 12, 2006 (71 FR 27600). An incorrect phrase was used in the compliance section, which impacts the intent of the compliance. This document corrects that phrase. In all other respects, the original document remains the same.

DATES: *Effective Date:* Effective May 19, 2006.

FOR FURTHER INFORMATION CONTACT: Frank Walsh, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7158; fax (781) 238–7170.

SUPPLEMENTARY INFORMATION: A final rule AD, FR Doc. 06–4390, that applies to Hamilton Sundstrand Model 14RF–9 propellers was published in the **Federal Register** on May 12, 2006 (71 FR 27600). The following correction is needed:

§ 39.13 [Corrected]

■ On page 27601, in the third column, in compliance paragraph (i)(1), in the second line, ''after accumulating an additional 500 flight cycles'' is corrected to read ''within an additional 500 flight cycles''.

Issued in Burlington, MA, on May 15, 2006.

Robert J. Ganley,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 06–4679 Filed 5–18–06; 8:45 am]

BILLING CODE 4910–13–P