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Recognition of Animal Disease Status of Regions in the European Union; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 71, 92, 93, 94, 98, and 130

[Docket No. 98–090–5]

RIN 0579–AB03

Recognition of Animal Disease Status of Regions in the European Union

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning the importation of animals and animal products to recognize a region in the European Union as a region in which hog cholera (classical swine fever) is not known to exist, and from which breeding swine, swine semen, and pork and pork products may be imported into the United States under certain conditions, in the absence of restrictions associated with other foreign animal diseases of swine. Additionally, we are recognizing Greece and four Regions in Italy as free of swine vesicular disease. These actions are based on a request from the European Commission's (EC's) Directorate General for Agriculture and on our analysis of the supporting documentation supplied by the EC and individual Member States. These actions will relieve some restrictions on the importation into the United States of certain animals and animal products from those regions. However, because of the status of those regions with respect to other diseases, and, in some cases, because of other factors that could otherwise result in a risk of introducing animal diseases into the United States, the importation of animals and animal products into the United States from those regions will continue to be subject to certain restrictions.

EFFECTIVE DATE: April 7, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Colgrove, Director, Sanitary Trade Issues Team, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356. The full risk analysis and economic analysis associated with this rule may be obtained electronically at *http://www.aphis.usda.gov/vs/ncie/reg-request.html,* or by contacting the person listed under this heading.

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 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).

On June 25, 1999, we published in the **Federal Register** (64 FR 34155–34168, Docket No. 98–090–1) a proposal to amend the regulations by recognizing—with the exception of specified regions in Germany and Italy—the countries of Austria, Belgium, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, and Spain as a region in which hog cholera (classical swine fever (CSF)) is not known to exist, and from which breeding swine, swine semen, and pork and pork products may be imported into the United States under certain conditions. The regions in Germany and Italy that were not included in that region are the following: In Germany, the Kreis Vechta in the Land of Lower Saxony, the Kreis Warendorf in the Land of Northrhine Westfalia, and the Kreis Altmarkkreis Salzwedel in the Land of Saxony-Anhalt; and in Italy, the Island of Sardinia (referred to in this document as the Region of Sardegna), and the Regions of Emilia-Romagna and Piemonte.

Additionally, we proposed to add Greece to the list of regions recognized as free of foot-and-mouth disease (FMD). We also proposed to add Greece to the list of FMD-free regions whose exports of ruminant and swine meat and products to the United States are subject to certain restrictions to guard against introducing FMD into this country. These restrictions were proposed because Greece imports fresh meat of ruminants or swine from regions where FMD exists; has a common border with regions where FMD exists; and imports ruminants or swine from regions where FMD exists under conditions less restrictive than would be acceptable for importation into the United States.

Finally, we proposed to add Greece and eight Regions in northern Italy (listed below) to the list of regions recognized as free of swine vesicular disease (SVD). Additionally, we proposed to add Greece and the eight Regions in Italy to the list of SVD-free regions whose exports of pork and pork products to the United States are subject to certain restrictions to guard against introducing SVD into this country. These restrictions were proposed because of the same situations with regard to SVD that were described in the preceding paragraph regarding FMD and Greece. We proposed to add the following Regions in northern Italy to these lists: Abruzzi, Emilia-Romagna, Friuli-Venezia Giulia (referred to in the proposed rule as Friuli), Liguria, Marche, Molise, Piemonte, and Valle d'Aosta.

Before developing our proposed rule, we conducted an analysis to determine the likelihood of introducing CSF from the European Union (EU) and to determine what, if any, mitigation measures we considered necessary. We assessed the likelihood of introducing CSF through the importation of live breeding swine, swine semen, and pork and pork products, and submitted the risk analysis for peer review.

We solicited comments concerning our proposal, including the risk analysis, for 60 days ending August 24, 1999. We received five comments by that date. They were from a domestic industry organization, a veterinary association, the EC, and other members of the public.

One of the comments expressed concerns with several aspects of our risk analysis. Based on that comment, and as recommended by the Department's Office of Risk Assessment and Cost Benefit Analysis based in part on peer review comments, we revised the initial risk analysis and included a supplement that presented in more detail specific information about CSF outbreaks in the EU.

On May 3, 2002, we published in the **Federal Register** a notice (67 FR 22388–22389, Docket No. 98–090–2) that the revised risk analysis was available for public review and we requested comments on the revised document. The comment period was initially scheduled to end July 2, 2002, but on July 5, 2002, in response to a request by a commenter, we published a notice in the **Federal Register** (67 FR 44798–44799, Docket No. 98–090–3) that reopened and extended the comment period until July 17, 2002. We received 21 comments by that date. They were from domestic and foreign industry organizations, individual businesses, a U.S. State Port Authority, the EC, a member State of the EU, and other members of the public.

We carefully considered all comments we received on our June 1999 proposal and our May 2002 notice of availability of the revised risk analysis. For the reasons given in the proposed rule and in this document, we are adopting our June 1999 proposed rule as a final rule, with the changes discussed below. (It should be noted that even though this

final rule removes some importation restrictions on animals and products from certain foreign regions with regard to CSF and SVD, the importation of swine and swine products from the EU may continue to be prohibited or restricted due to the presence in the EU of other diseases affecting swine, such as brucellosis, pseudorabies, and tuberculosis.)

We will first discuss the issues raised by commenters in response to our June 1999 proposed rule, then we will discuss the issues raised in response to our revised risk analysis.

Comments on the June 1999 Proposed Rule

Of the five comments we received in response to our June 1999 proposed rule, three supported the proposal as written. Of the other two comments, one generally supported the proposal, but recommended certain changes. The other expressed concerns with a number of provisions of the proposal and its supporting documentation. We discuss below the issues raised by the commenters.

SVD in Italy

As discussed above, in our June 1999 proposed rule, we proposed to list eight Regions in Italy as those in which SVD is not known to exist. (In Italy, a ''Region'' is a type of political jurisdiction.) Those eight Regions were Abruzzi, Emilia-Romagna, Friuli-Venezia Giulia, Liguria, Marche, Molise, Piemonte, and Valle d'Aosta. One commenter requested that we also recognize the following nine Regions as those in which SVD does not exist: Lombardia, Trentino-Alto Adige, Veneto, Toscana, Umbria, Lazio, Basilicata, Puglia, and Sardegna. We have carefully evaluated the information contained in the comment, and believe that it would be appropriate to allow members of the public to comment on the change requested by the commenter. Therefore, we are not making any changes in this final rule in response to this comment, but we intend to initiate a separate notice and comment rulemaking regarding those additional Regions.

Further, because SVD was diagnosed in the Regions of Abruzzi, Emilia Romagna, Molise, and Piemonte in 2002, we are not including those Regions in this final rule as regions in which SVD does not exist. However, we are developing an updated evaluation of the SVD situation in those Regions. We will publish a notice in the **Federal Register** when the updated evaluation is ready for public review and will accept comment on the evaluation for a specified period of time. Following review of any comments we receive, we will determine whether it is appropriate to consider those Regions as regions in which SVD does not exist. If such a determination is made, we will publish a final rule to that effect in the **Federal Register**.

FMD in Greece

We proposed in our June 1999 proposal to recognize Greece as a region in which FMD does not exist. Following publication of that proposal, FMD was diagnosed in the summer of 2000 in cattle in several prefectures in Greece. However, since September 2000, there have been no incidences of FMD in that country. Therefore, on March 21, 2002, we published a proposal in the **Federal Register** (67 FR 13105–13108, Docket No. 01–059–1) to recognize Greece free of FMD. We solicited comments concerning our proposal for 60 days ending March 20, 2002, and received no comments. Following the comment period, we published a final rule in the **Federal Register** (67 FR 44524–44526, Docket No. 01–059–2) in which we adopted the proposed rule as a final rule without change.

Change in Terminology

Our regulations in 9 CFR chapter I use the term ''hog cholera.'' When we published our June 1999 proposed rule, consistent with the existing regulations, we used the term ''hog cholera.'' However, it is standard practice among veterinary practitioners in the international community to refer to hog cholera as ''classical swine fever'' or ''CSF.'' Therefore, in the remainder of this final rule, including the regulatory text at the end of this document, we use the term ''classical swine fever'' (or ''CSF'') rather than ''hog cholera.'' Additionally, for the sake of consistency throughout our regulations in 9 CFR chapter I, we are removing the term ''hog cholera'' wherever it appears in the existing regulations (*i.e.*, parts 71, 93, 94, 98, and 130) and adding in its place the term ''classical swine fever.''

Administrative Units Considered

As noted above, in Italy, the smallest administrative jurisdiction we considered for purposes of regionalization was the ''Region.'' In Germany, we used the ''kreis.'' One commenter said that it was not clear from the proposal why APHIS concluded that the Italian Region and the German kreis should be considered for regionalization purposes. The commenter stated that the proposal did not include information relating to unique characteristics of the regions and physical boundaries that may or may not be present. Another commenter agreed with our use of the kreis in Germany for CSF regionalization purposes but recommended that, in Italy, we use instead the ''Unita Sanitarie Locali.''

As discussed in our proposed rule, we chose to use the Italian ''Region'' and German ''kreis'' for purposes of regionalization because we considered them to be the smallest administrative jurisdictions in those countries that have effective oversight of normal animal movements into, out of, and within those jurisdictions, and that, in association with national authorities if necessary, have the responsibility for controlling animal disease locally. The commenter who suggested we use the Unita Sanitarie Locali as the smallest administrative jurisdiction in Italy did not offer any information as to how the Unita Sanitarie Locali meets those criteria. Therefore, we are not making any changes based on the comments received, but we welcome further information on this issue.

Information on Outbreaks

One commenter stated that the proposed rule did not include information relating to specific outbreaks in the regions addressed by the proposed rule, and that it would have been instructive for APHIS to have included in the proposed rule a map indicating where the CSF outbreaks occurred in relation to the proposed regionalization, along with a list of reasons for the outbreaks (*e.g.*, wild boar exposure, feeding of uncooked garbage, transport into the area, or unknown origin).

We agree that the type of information referred to by the commenter is important in assessing the CSF risk presented by imports from particular regions, and we considered those factors in our risk analysis. At the time we published the proposed rule, some of the information was available on the APHIS Internet website, which was referenced in the proposed rule. The supplement to our initial risk analysis illustrates in more detail the type of information referred to by the commenter.

Concern With Regionalization

One commenter on our June 1999 proposal expressed concern that, following publication of the proposed rule, an outbreak of CSF occurred in the Kreis Uckermark in the Land of Brandenburg in Germany, which was included in the proposal as an area in which CSF is not known to exist. The commenter stated further that, even

though the prevalence of CSF in wild boars in Brandenburg had been determined to be under 1 percent, that apparently was enough to lead to infection of the domestic population. The commenter concluded that there is insufficient control of the potential sources of the introduction of CSF into herds in Germany to allow that country to be regionalized.

When we developed the risk analysis on which we based our proposed rule, we included among our assumptions the probability that CSF outbreaks would continue to occur in the EU, just as we must assume there is some chance of an outbreak of a particular disease in any country we currently consider free of that disease. Starting from the assumption that future outbreaks of CSF would occur, we evaluated the risk of disease spread based on the length of time between the occurrence of CSF infections and the time that control efforts, such as implementation of new restriction zones, took effect. We concluded that breeding swine, swine semen, and pork and pork products could be imported with extremely low risk from the region we were proposing to establish in the EU, under the conditions set forth in the proposal. It should be noted that the information and data we used for our risk analysis were from outbreaks that occurred in 1997–1998, which constituted one of the worst CSF epidemics in the EU in recent history.

CSF in Germany

One commenter stated that no scientific justification was provided in the proposed rule for identifying the Kreis Vechta, the Kreis Warendorf, and the Kreis Altmarkkreis Salzwedel as those regions in which CSF is considered to exist, or for how the risk from other areas in Germany was assessed.

As we explained in our proposed rule, in establishing geographic boundaries for the regions, we used the boundaries of the smallest administrative jurisdiction that has effective oversight of normal animal movements into, out of, and within that jurisdiction, and that, in association with national authorities if necessary, has the responsibility for controlling animal disease locally. In Germany, this administrative unit is a *kreis.*

We proposed to continue to consider the kreis listed above as regions in which CSF is known to exist because each had an outbreak of CSF during the 6 months prior to the time we developed our proposed rule. In assessing the risk from the remaining areas of Germany, we assumed, as described above, that CSF outbreaks would continue in the EU, and we evaluated risk based on the length of time between the occurrence of infection in a region previously considered free of CSF by the EC and the time that control efforts took effect.

Delay in Disease Detection

In our proposed rule, we stated that, in 1997, an estimated 103 of 611 CSF outbreaks in the EU occurred outside any zones that were under restrictions because of CSF, and that, of those 103, only 1 was a swine semen collection center approved for export, and only 1 was a breeding operation that engaged in export sales. We stated further that epidemiological evidence suggests that the disease was present in various regions for 7 days to nearly 8 weeks before it was detected and the region was placed under restrictions. One commenter expressed concern that this demonstrated that several importations into the United States of semen and breeding stock could occur before a CSF outbreak is detected.

The commenter is correct in concluding that, with unmitigated importation, there is a significant risk of introducing CSF into the United States. Our risk analysis calculated that risk as a probability, and also calculated the probability if mitigation measures were applied. We evaluated the likely volume of imported products and the prevalence of infected versus noninfected products in the estimate of the probability that infected products would be imported. The risk of importing CSF-infected products is not zero but, as discussed in the risk analysis, is quite low. Of the products evaluated, the risk analysis identified swine semen as presenting the greatest risk. Therefore, we proposed that, in addition to the EU's routine biosecurity measures, before swine semen can be exported to the United States from the region in question, the donor boar must be held at the semen collection center for at least 40 days following collection of semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF.

Compliance With Office International des Epizooties (OIE) Guidelines

In discussing the quantitative risk analysis that we used as a basis for our proposed rule, we stated that one of the starting point assumptions we made was that OIE export guidelines are applied to the movement of animals and animal products within the EU. One commenter stated that, elsewhere in our proposal, we indicated we had to take into account that the EC released certain areas from restrictions prior to completion of a 6-month waiting period. The commenter expressed concern that our risk analysis appeared to be using an assumption that is not supported by current practice in the EU, and requested further documentation of adherence to the OIE standard before the proposed rule was made final.

Although we stated that we expected that OIE export guidelines would be applied to movement of animals and animal products within the EU, we did not build that assumption into our quantitative risk assessment. The quantitative assessment was based on the waiting periods actually used by the EU during the 1997–1998 epidemic. With regard to guidelines for export to the United States, whether a region is certified as being free of CSF must be based on U.S. criteria (*i.e.*, at least 6 months must have passed since eradication of the last outbreak of the disease).

One commenter stated it was not possible to determine from the site visit reports done prior to the proposed rule whether movement and import controls complied with EU directives. Additionally, said the commenter, information was not presented regarding compliance with directives regarding truck washing.

When conducting its site visit, the review team observed compliance with EC directives, truck washing, and tracking of swine movements through the ''SANITEL–V'' and ''ANIMO'' databases. (The SANITEL–V database is a computerized database in Belgium that contains information on animal identification, farm registration, and animal movements. The ANIMO database is an EU-wide database that contains origin, destination, and movement information regarding animal movements within the EU.)

Notification of Change in Disease Status

One commenter stated that the proposed rule did not describe the process by which the EU would notify APHIS of a change in regionalization status and how timely we expected that notification to be. The commenter stated additionally that the proposed rule included no discussion of the process by which APHIS would accept or reject a regionalization decision and the impact of that process on EU exports of animals and animal products to the United States.

The U.S.-EU Equivalency Agreement (an agreement covering sanitary measures affecting U.S.-EU trade in all animals and animal products) requires written notification, within 24 hours, of a change in disease status. If the EU

recognizes a region in a previously disease-affected area to be free of a disease, any APHIS acceptance of the EU regionalization will be carried out through the rulemaking process, with an opportunity for the public to comment on and submit information regarding the regionalization.

Values Used in Our Risk Analysis

As noted above, before developing our proposed rule, we conducted an analysis to determine the likelihood of the introduction of CSF from the EU region in question, and to determine what, if any, measures we considered necessary to mitigate risk. We assessed the likelihood of the introduction of CSF through live breeding swine, swine semen, and pork and pork products.

In assessing the risk of CSF introduction, we incorporated certain numerical information into our mathematical model. For breeding swine, for example, we used input values for the following: The number of undetected, CSF-affected breeding farms eligible to supply animals for export, assuming that undetected CSF exists in the EU; the number of breeding herds eligible for export in the EU; the number of weeks that CSF remains undetected in EU breeding herds per year, assuming that undetected CSF exists in the EU; the number of breeding swine shipments per year; the number of breeding herds per shipment; the number of animals selected for export from any given breeding herd; and the probability that an individual animal is infected with CSF, assuming that there is infection in the herd.

One commenter questioned some of the input values we used. The input values in question, the commenter's concerns, and our responses are as follows:

1a. *Input value:* The number of undetected CSF-infected herds in the EU, assuming that undetected CSF exists in the EU within regions eligible to export breeding swine.

1b. *Comment:* It is unclear whether established restriction zones in the EU were based on information available before 1997. If this is not so, the number of herds may be underestimated due to the lack of complete information to identify those restriction zones. In other words, a *post hoc* evaluation of regions is invalid and underestimates the number of infected herds. It may also be useful to give this a triangular distribution, because it is based on the occurrence of one case. If there were not this one case, the model would interpret that there is no risk from breeding stock.

1c. *Response:* The information and data we used in the risk analysis for determining whether infected herds were inside established restriction zones were from outbreaks that occurred in 1997 and 1998. We obtained the information from epidemiological reports provided by the EU and from extensive discussions with EU representatives. The dates that the restriction zones were established were carefully compared to the dates that herds were believed to have become infected. Only one export-oriented swine semen center and one export-oriented breeding operation were identified as having become affected outside of established restriction zones.

We do not agree that the data we used underestimated the potential disease risk. The analysis is based on data from the most severe CSF outbreak documented in EU history and assumes that this event is typical of a severe situation in the EU that might occur in the future. This approach likely overestimates the actual risk. We believe that if the EU made epidemiological data available for the several years prior to the 1997 to 1998 outbreaks, and if these data were incorporated into the risk analysis, the estimated risk levels would be lower than those we reported.

With regard to the recommendation that we use a triangular distribution (*i.e,* a calculation of the minimum, most likely, and maximum estimate), we did sensitivity analyses (*i.e.*, the determination of how variations in input data affect probability outcomes) using a variety of scenarios. Although the results of these multiple analyses were not included in the original risk analysis document, we included them in the revised risk analysis. The results of the multiple analyses did not affect the conclusions of the analysis.

2a. *Input value.* The number of weeks that CSF remains undetected in EU breeding herds per year, assuming that undetected CSF exists in the EU (based on varying lengths of time in different areas of the EU).

2b. *Comment.* The differentiation of detection periods among areas appears to be based on very limited information. It is not clear why the areas need to be differentiated or what the mechanical logic is for the wide range of detection periods.

2c. *Response.* The information regarding the time that infection remained undetected in various locations in the EU was drawn from the actual outbreaks that occurred from 1997 to 1998. The rather substantial differences in duration among various locations (7 to 21 days in several areas to 53 days in one area) were due in part to the fact that some detections occurred in areas with ongoing CSF eradication efforts, which included active surveillance, while other detections occurred in areas where only passive surveillance was being used. In some instances, the initial detection within a country took a great deal longer than subsequent detections in other parts of the country because the initial detection caused heightened awareness and surveillance.

3a. *Input value.* Number of breeding herds per shipment. (The risk analysis used 1 for this value.)

3b. *Comment.* Is it policy that only one herd will be used in a shipment? If not, perhaps it should be.

3c. *Response.* This assumption was incorporated into some of the simulations we performed for the purposes of our risk analysis, because, historically, most shipments have involved one herd. However, the commenter did not provide, and we are not aware of, a disease risk reason to limit shipments to one herd. If all animals to be imported are moved in accordance with the regulations, including more than one herd in a shipment would not present an unacceptable increase in disease risk.

4a. *Input value.* Number of animals selected for export from any given breeding herd. (The geometric mean of the distribution for the number of swine per shipment was 6.125. For the purposes of our risk analysis, we used a value of 6.)

4b. *Comment.* It could be argued that using the geometric mean of 6 probably underestimates the size of future imports. It is more likely that substantial portions of the line will be imported to allow rapid transfer of genetics.

4c. *Response.* We agree that using the geometric mean could result in an underestimate of possible future imports. For this reason, we ran a simulation using an arithmetic mean (38 animals) as well, which is included in our revised risk analysis. We found that increasing the number of breeding swine in a shipment more than six-fold does not change our conclusion that the risk is still very low.

5a. *Input value.* Probability that an individual animal is infected with CSF, assuming that CSF exists in the herd; or proportion of infected animals in a semen center in which CSF exists. The risk analysis used a triangular distribution of 0.05, 0.15, and 0.40 for each of these probabilities. We noted in our risk analysis that indirect reports suggest the value may be extremely variable (*i.e.*, 25 percent to 100 percent, depending on circumstances).

5b. *Comment.* This is a subjective estimate with a value that is extremely variable. It is not clear why the upper

limit is 40 percent in this estimate. The need for the triangular estimate is understood, but the biological possibility of 100 percent is not accounted for.

5c. *Response.* Despite a 40 percent upper limit suggested by EC officials, we performed a sensitivity analysis on this upper limit, and also ran simulations with an upper limit of 100 percent, although that analysis was not reported in the original risk analysis. Using a 40 percent upper limit, the expected frequency of incursion was one or more in every 33,670 years. Using a 100 percent upper limit, the expected frequency of incursion was one or more in every 26,000 years, a 1.3-fold change. We included the results of these additional sensitivity analyses in our revised risk analysis.

Swine Semen Collection Centers

In § 98.38 of our proposed rule, we set forth conditions for the importation of swine semen from the multicountry area of the EU we were proposing to consider as one region. These conditions included origin requirements for the donor boar, requirements for isolation and testing prior to the boar's entry into the semen collection center, transportation requirements, and requirements for holding and observing the boar at the semen collection center for at least 40 days following collection of the semen. One commenter requested that an additional condition be included, *i.e.*, to require that the donor boar be serologically tested while at the semen collection center. The commenter stated that observation alone might not detect very subtle clinical signs of CSF infection.

We are making no changes based on this comment. All boars must be tested for CSF with negative results before entering the semen collection center. We do not consider it necessary to require additional testing at the center to ensure that the donor boar is not infected with CSF. Additionally, if an infected animal were held for at least 40 days at a collection center, it is very likely that the other animals being held at the center would provide a ''sentinel effect''-that is, other animals exposed to the infected animal would likely show clinical signs of the disease while the infected animal was being held at the center. In developing our risk analysis, we created a scenario of maximum risk by not taking into account any sentinel effect. In actuality, it is likely that such an effect would provide a safeguard that an infected animal would be detected.

EU Trading Partners

One commenter said it was not clear from the proposal if importation from the EU region would be dependent on the United States considering countries that export animals and animal products into the EU region as free of CSF, or if the United States would accept the EU designation of its trading partners' CSF status.

Our consideration of whether to allow the importation of animals and animal products from a region in the EU was based on a number of factors. One of the factors we considered was that the exportation of swine into the EU from countries outside the EU is allowed under certain conditions if the animals are accompanied by a declaration that the countries are free of CSF, or if the animals were tested with negative results for CSF. Such movement controls are based on the status of countries outside the EU as recognized by the EU. Additionally, we considered the EU's ability to rapidly detect and eliminate any outbreaks of CSF that might occur within the EU. In our proposal, we discussed the surveillance for CSF that is carried out in the EU and the measures that would be taken to control and eradicate the disease in the event of an outbreak. After assessing these and other factors (as discussed in our proposed rule), we concluded that the conditions we proposed for importing breeding swine, swine semen, and pork and pork products into the United States from the EU would mitigate the risk of introducing CSF into this country.

CSF Outbreaks in France, Spain, Luxembourg, and Germany After June 1999

Following publication of our June 1999 proposed rule, there were CSF outbreaks in domestic swine in parts of the EU, including France, Luxembourg, Spain, and Germany. Following those outbreaks, each of the affected countries took action to eradicate CSF. At this time, we are developing an updated evaluation of the CSF situation in France, Luxembourg, and Spain, and defining the jurisdictional level we could recognize as a region within those countries. We will publish a notice in the **Federal Register** when the updated evaluation is ready for public review and will accept comment on the evaluation for a specified period of time. Following review of any comments we receive, we will determine whether it is appropriate to consider: (1) France, Luxembourg, and Spain (or an appropriate combination of the three) as countries in which CSF does not exist or (2) appropriate jurisdictional units of France and/or Spain as regions in which CSF does not exist. If such a determination is made, we will publish a final rule to that effect in the **Federal Register**.

Additionally, we anticipate developing a similar updated evaluation for those kreis in Germany that had CSF outbreaks after being included in the June 1999 proposed rule, for discussion in a separate notice in the **Federal Register**. Those areas of Germany are as follows: Kreis Heinsberg in the Land of Northrhine-Westphalia; Kreis Oldenberg in the Land of Lower Saxony; Kreis Uckermark in the Land of Brandenburg; Kreis Bernkastel-Wittlich in the Land of Rhineland Palatinate; Kreis Soltau-Fallingbostel in the Land of Lower Saxony; Kreis Rhein-Hunsruche in the Land of Rhineland-Palatinate; Kreis Bitburg-Prüm in the Land of Rhineland Palatinate; Kreis Trier-Saarburg and Kreis Südliche Weinstrasse in the Land of Rhineland Palatinate; and Kreis Donnersbergkreis in the Land of Rhineland Palatinate.

CSF Outbreak in Spain

One commenter expressed concern regarding the site visit report that APHIS completed prior to development of the proposed rule. The commenter noted that the site visit report indicated that no information was available at the time of its drafting regarding the source of an outbreak of CSF in the Province of Segovia in Spain. The commenter requested that any information that was subsequently obtained be made available to the public.

All information that has been made available to us by Spain is posted to the APHIS Internet website.[1] At this time, the source of the outbreak in Segovia has not been determined. However, the current epidemiological situation is being actively monitored in view of the recent outbreaks, and we are not relieving restrictions on imports from Spain at this time.

Movement of Swine Within Germany

One commenter stated that the site visit report noted that if CSF occurs in a district (kreis) in Germany, under EU standards, swine may not be exported to another country from anywhere in the State (Land) in which the district is located. However, districts in the State

[1] The Internet address for accessing the information is *http://www.aphis.usda.gov/vs/ncie/reg-request.html.* At the bottom of that website page, click on ''Information previously submitted by Regions requesting export approval and their supporting documentation.'' At the next screen, click on the triangle beside ''European Union/Not Specified/Classical Swine Fever,'' then on the triangle beside ''Information Supporting Request.''

other than the affected district may move swine within Germany. The commenter stated that there is some question whether this practice continues at present and, if so, questioned whether this practice should affect how the United States views the disease status of Germany.

The type of movement within Germany that is referred to by the commenter is governed by a number of restrictions that reduce any disease risk that might otherwise be present. Swine that are moved from districts in a State other than an affected district must be clinically examined and serologically tested for CSF before being moved within Germany. After being moved, the swine must be held in isolation and clinically examined for 30 days.

Disease Surveillance in the EU

One commenter stated that the site visit report did not provide information on the level of active surveillance in areas next to the regions in the EU in which CSF is considered to exist.

As we stated in our proposed rule, if an outbreak of CSF occurs, eradication measures are conducted on the affected premises, and movement restrictions and active surveillance measures are implemented in surrounding areas. A protection zone with a radius of at least 3 kilometers and a surveillance zone with a radius of at least 10 kilometers are placed around the affected premises. Among the measures taken within the surveillance zone are the serological testing and clinical examination of all swine herds in the zone.

CSF Outbreaks in Previously Free Countries

At the time we published our proposed rule, there were certain countries in Europe that the existing regulations listed as free of CSF. Because these countries were already considered free of the disease, we did not propose to include them in the multicountry EU region we identified in our proposal. One commenter questioned whether, in the event of a CSF outbreak in those ''free'' countries, the United States would accept the EU regionalization strategy in those countries, or would instead address the situation on an ''entire country'' basis. The same commenter stated that the final rule should specify when and how APHIS would choose to invoke safeguarding mechanisms to restrict or prohibit imports from the EU, rather than accept and approve EU regionalization strategies and requests.

We would treat a CSF outbreak in a country we had considered free of the disease in the same way that we would treat an outbreak of any disease of concern in a ''free'' country. According to Article 12 of the U.S.-EU Equivalency Agreement: ''Either Party may take provisional measures necessary for the protection of public or animal health. These measures shall be notified within 24 hours to the other Party and, on request, consultations regarding the situation shall be held within 14 days. The Parties shall take due account of any information provided through such consultations, and shall endeavor to avoid unnecessary disruption to trade. * * *''

In this final rule, we are adding a new § 92.3 that provides that whenever the EC establishes a quarantine in the EU in a region APHIS recognizes as one in which a disease is not known to exist, and the EC imposes restrictions on the movement of animals or animal products from the quarantined area, such animals and animal products are prohibited importation into the United States. If the outbreak appeared likely to continue in a limited part of the country, we would impose a ban on products from the area in question and, through rulemaking, would change the disease status listing of that part of the country. If the outbreak appeared to be spreading to other areas of the country, we would initiate rulemaking to change the disease status listing of the entire country.

FMD in Greece; SVD in Greece and Italy

As noted above, in our proposed rule, we proposed to add Greece to the list of regions recognized as free of FMD. Additionally, we proposed to add Greece and eight Regions in northern Italy to the list of regions recognized as free of SVD. One commenter stated that the information regarding Greece upon which the proposal was based was collected in 1997, and expressed concern that the information did not address political unrest in Yugoslavia and an FMD outbreak in Turkey. The commenter also questioned why APHIS did not consider it necessary to conduct a site visit in Italy.

As noted above, following publication of our June 1999 proposed rule, several outbreaks of FMD occurred in Greece in the summer of 2000. No additional outbreaks have occurred since September 2000. In January 2001, APHIS representatives conducted a site visit to Greece to obtain evidence regarding the FMD status of that country and determined that a proposal to consider Greece free of FMD was warranted. In March 2001, APHIS published in the **Federal Register** a proposal to consider Greece free of the disease, received no comments on the proposal, and made the proposal final in July 2002.

With regard to SVD, we are making no changes based on the comment. The last outbreak of the disease in Greece was diagnosed in 1979. Yugoslavia is recognized as a region in which SVD does not exist. However, we are adding Greece to the list in § 94.13 of SVD-free regions whose exports of pork and pork products to the United States are subject to certain restrictions. We are applying these restrictions because Greece supplements its national pork supply by importing fresh (chilled or frozen) pork from regions where SVD exists; has a common land border with certain regions where SVD exists; and imports swine from regions where SVD exists under conditions less restrictive than would be acceptable for importation into the United States.

We did not conduct a site visit to Italy because we had conducted a site visit to that country 2 years previously (in March 1997) in connection with the Italian request to be recognized as free of African swine fever. That site visit gave us a clear understanding of, and confidence in, Italy's veterinary infrastructure, surveillance, diagnostic capabilities, and detection capabilities.

Noncommingling of Products

One commenter stated that the proposed rule did not describe how APHIS would validate that products destined for export from Greece or Italy are not commingled with or exposed to products originating in regions where SVD exists.

Such validation will be carried out in the same way as in other countries that export animals and animal products to the United States. We require certification by veterinary officials in those countries that our regulatory requirements have been met. Additionally, initial inspections of slaughtering and processing establishments are conducted by the Department's Food Safety and Inspection Service (FSIS) and APHIS, and periodic inspections are subsequently conducted by FSIS.

Comments Received on Revised Risk Analysis

Of the 21 comments we received in response to our May 2002 notice of availability, one requested an extension of the comment period, and all but two of the rest of the commenters either supported the results of the revised risk analysis or recommended that the June 1999 proposed rule be made final.

Of the remaining two commenters, one expressed the opinion that the risk of introducing CSF virus into the United

States via the import of semen is much less than the one estimated in the risk analysis, based on the following reasons:

• Although the swine semen simulation model used in the risk analysis assumes that an outbreak of CSF occurs each 2 years in a semen collection center in the region being analyzed, between 1991 and 2002 only one CSF outbreak occurred in a semen collection center in the region in question.

• Although the risk analysis assumed that the ''risky period'' in the case of an outbreak in a semen collection center would last as long as in any other pig holding—*i.e.*, 3–4 weeks on average—this does not correspond to what actually happened in the Netherlands in 1997, when CSF was introduced into a swine semen center and was recognized in other swine holdings in the vicinity of the center well before confirmation of the disease in the center itself.

• Improvements have been made through EC legislation to reduce the risk of spreading CSF through swine semen. This legislation took into account the experiences of the 1997–1998 outbreak.

The commenter requested that APHIS eliminate the requirement that semen collected in the EU region in question be held for 40 days before being exported to the United States. The commenter further requested that, if APHIS believes that some mitigating measures on the importation of semen are necessary, it consider alternative measures such as the testing of semen before exportation by virological tests.

We are making no changes based on this comment. The application of a 40-day hold on semen was based on the results of the risk assessment we conducted for the proposed rule, which indicated that, without mitigation, the importation of swine semen from the EU region in question would present a disproportionate risk of introducing CSF into the United States. The 40-day hold was determined to be an effective mitigation measure. If we receive a request from a member of the public to consider an alternative means of mitigation, along with supporting information with which to evaluate such a request, or if we receive information that indicates that no mitigation measures may be necessary, we will conduct an assessment of the risk of importing swine semen into the United States under the conditions suggested. If such an assessment indicates that the change would be appropriate, we will publish, in accordance with the Administrative Procedure Act (APA), a proposal in the **Federal Register** to change the regulations accordingly, and provide an opportunity for other members of the public to comment on the proposed action.

The commenter also stated that the provisions of the final rule should reflect the current CSF situation in the EU, not the situation in 1999.

We published our June 1999 proposal in response to a request from the EC that we consider a multi-country area in the EU as one region, and we conducted an analysis of the risk of the introduction of CSF from that region at that time. In accordance with the APA, we invited comments on the proposed rule and are addressing in this final rule the comments we received. We are receptive to requests for further changes to the regulations and will address such changes through notice and comment rulemaking in accordance with the APA. If the existing situation appears to warrant a new analysis, we will conduct one.

One commenter raised a number of issues regarding our proposed rule and specific provisions of the risk analysis. We address below the issues raised by that commenter in a comment/response format.

Comment: APHIS' scientific approach toward the regionalization of the EU and its member States and sublevels seems to differ from APHIS' approach to other countries or regions. Continuing outbreaks of CSF in the EU call into question the ability of the EU to apply appropriate disease control measures and how APHIS can evaluate risk in a dynamic situation.

Response: We agree that the approach we proposed to regionalizing the EU is somewhat different from the way we have historically approached other regionalization actions. This is due to the nature of the request from the EU, which asked that multiple countries be considered as one region, and the infrastructure and regulatory factors specific to the region in question. In recognition of what the commenter refers to as a ''dynamic situation,'' the risk analysis we developed recognized the possibility of continuing sporadic CSF outbreaks in the EU region in question, and the risks associated with these outbreaks, rather than looking at a specific geographic area as free of the disease. Risk was defined as a quantitative probability based on the disease history of the region and was approached on a commodity basis, rather than as an evaluation of disease status. The approach in our risk analysis and proposed rulemaking is consistent with APHIS' obligation under the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (WTO–SPS Agreement) to recognize not only disease-free areas, but also areas of low disease prevalence for which mitigations can be established to reduce risk.

Comment: CSF has been diagnosed in numerous locations in the EU since the data for the revised risk analysis was collected, and these new data should be incorporated into a risk analysis to allow for an accurate conclusion. We believe an outbreak in domestic swine in France in 2002 due to exposure to wild boar contradicted an assumption in the risk analysis that CSF outbreaks in domestic swine in France do not occur due to exposure to wild boar. The descriptive observations in the risk analysis do not predict clearly where outbreaks may occur and, although APHIS stated in its risk analysis that an historical reduction in the spread of CSF from wild boar could be attributed to EU surveillance and control activities, those activities were considered inadequate by the EU to counter outbreaks that occurred after publication of the June 1999 proposed rule, as evidenced by the EC's decision in May 2002 to take further measures for the control of CSF.

Response: Much of the data used in the risk analysis were generated during an extremely severe CSF epidemic that occurred in the EU in 1997 and 1998. As discussed in the risk analysis, this CSF epidemic is considered the most severe the EU has ever experienced. The risk estimates generated in the analysis took into account the effectiveness of EU control measures, and where these measures failed, under these severe conditions. The risk analysis, therefore, anticipates future CSF epidemics of the same magnitude and the same level of detection and control failures as occurred during the 1997–98 epidemic. Given that recent CSF epidemics have been of a lesser magnitude and reflect fewer failures in detection and control, they fall within the expectations of the current risk analysis. Incorporating the data from these recent epidemics into the analysis would likely reduce the estimated risk.

We do not agree that our risk analysis assumed that CSF outbreaks in domestic swine in France do not occur due to exposure to wild boar. The statement that, at the time of the risk analysis, there had not been a CSF outbreak in France was not meant to imply that outbreaks in domestic swine do not occur due to exposure to wild boar, but was simply an observation of what had or had not occurred. The risk analysis recognized the possibility of continuing sporadic outbreaks anywhere in the EU. As discussed above, given that recent CSF epidemics are of a lower magnitude

and reflect fewer failures in detection and control, they fall within the expectations of the risk analysis. The risk analysis was not intended to predict where outbreaks might occur in the EU, but simply to assess the risk to the United States from future situations in the EU where CSF epidemics reach the same magnitude and the same level of detection and control failures as occurred during the 1997–98 epidemic. Again, the 1997–98 CSF epidemic is considered the most severe the EU has ever experienced.

Comment: Unless APHIS establishes what level of risk of a CSF incursion—as measured by ''the expected frequency of one CSF incursion every 'x' years''—it considers acceptable, it is difficult to assess the different levels of risk that are calculated in the risk analysis.

Response: Through the Animal Health Protection Act (AHPA) (7 U.S.C. 8301–8317), Congress declared that ''the Secretary may prohibit or restrict the importation or entry of any animal, article, or means of conveyance * * * if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock'' (7 U.S.C. 8303(a)). Neither the AHPA nor the Secretary through regulations has delineated all the specific conditions that might be considered necessary to protect against the introduction of animal diseases or pests. This allows APHIS to evaluate the specific animal diseases or pests of concern and impose the specific importation conditions necessary to reduce sufficiently the risk of the introduction of such diseases and pests.

APHIS has a long history of evaluating countries or other regions qualitatively for animal disease risk, including the risk of introducing CSF. A qualitative evaluation for this rulemaking was conducted in accordance with the standard approach described in 9 CFR 92.2. The results of this evaluation are presented throughout the final report of the risk analysis.

For this rulemaking, APHIS also conducted a quantitative assessment of the risks. APHIS estimated data parameters for input into the quantitative model that describe risks associated with the most severe outbreak of CSF that has ever occurred in the EU. APHIS reported the results of the assessment as the likelihood of one or more incursions per year or the mean time between incursions. Reporting results using quantitative frequency values of this type was not meant to provide, or imply that APHIS has identified, a precise frequency of incursion as an Appropriate Level of Protection or Acceptable Level of Risk (ALOP or ALOR). Rather, APHIS used these results to assess the probable range or degree of the likelihood of introducing CSF from the EU and what mitigating importation conditions, if any, need to be imposed to further decrease the degree of such likelihood. In this particular case, irrespective of the precise frequency of events estimated by the model, the numerical values suggested that the frequency of CSF introduction by breeding swine and pork from the EU would be extremely low, as would be the case with swine semen with mitigation. Using the information available to it, APHIS was able to determine the likelihood of introducing CSF from the EU, assess the different risk levels, and decide if any mitigation measures were necessary without having to pinpoint an exact ALOP or ALOR.

Comment: The OIE Code describes four components of risk analysis-release assessment, exposure assessment, consequence assessment, and risk estimation— but APHIS did not conduct a consequence assessment because APHIS considered the risks estimated for release and exposure ''very small.'' APHIS should complete all four steps in its risk analysis, due to the extremely wide margins around the most likely risk estimates, as well as different risks to the U.S. swine populations depending on the route of exposure (*e.g.*, infected meat vs. infected semen).

Response: OIE guidelines state that, if the release or exposure assessment demonstrates no significant risk, the risk assessment may conclude. APHIS addressed consequences in its analysis. However, because the risk values for both release and exposure were very small, it did not conduct a detailed consequence assessment. However, the risk analysis does address all components listed in the OIE guidelines.

Comment: In conducting its risk analysis, did APHIS consider assessing CSF risk from specific discrete areas in the EU countries, rather than in the EU region as a whole? Perhaps this type of analysis would have identified specific areas with higher risk levels and the need for additional mitigation measures. APHIS should discuss the appropriateness of establishing different levels of risk for different areas.

Response: The risk analysis that APHIS conducted considered multiple Member States of the EU as one region. This approach was in response to a request by the EC that the countries in question be considered together as one region. The approach we have taken is actually a conservative one with regard to disease risk, in that we are continuing to prohibit imports of swine and swine products from parts of or entire Member States that had an outbreak of CSF either shortly before we published our 1999 proposed rule or since that time. In those parts of the EU where we are removing prohibitions on imports due to CSF, we are also applying mitigating measures with regard to the importation of swine semen, in recognition of the trade practices among the EU Member States in the region.

Comment: It was not clear from the risk analysis how primary and secondary outbreaks are factored into the evaluation of risk. It appears that any infected herd, regardless of whether its infection was considered primary or secondary, could contribute to CSF risks prior to detection. In the report from the APHIS 2000 site visit to the EU, it was not clear whether the EU was immediately notifying the United States of secondary outbreaks of CSF. The United States might be exposed to CSF from animals or products from areas of secondary outbreaks.

Response: In the December 2000 risk analysis (Section II, ''Spatial and Temporal Considerations,'' in ''Temporal Trends in Primary versus Secondary Outbreaks''), we used the following definitions for primary and secondary outbreaks: ''For purposes of this discussion, APHIS is defining a primary outbreak as one that occurred in domestic swine in a previously free area. The smallest area under consideration by APHIS in this definition is a county-level equivalent (*e.g., kreis*) that had not recently reported a CSF outbreak attributed to wild boar, swill feeding, or any other (including unknown) cause. Secondary outbreaks are defined as other outbreaks and are generally attributed to causes such as the purchase of animals or contacts with persons or transport equipment from other premises with infected domesticated swine.'' The commenter is correct that any herd, regardless of whether it was considered a primary or secondary outbreak could contribute to risks prior to detection. However, even considering changes in the levels of secondary spread from recent outbreaks in areas like Germany, the magnitude and scope of this spread is far less than occurred in the Netherlands in 1997–98, which was the most severe outbreak in the region in question in recent history.

The practice of the EC is to consider any disease outbreak a primary outbreak if it occurs outside the administrative unit where another primary outbreak has already occurred. Therefore,

notification must be given of outbreaks in any areas that are not currently under restriction, even if they are epidemiologically linked to outbreaks that have already occurred in another administrative unit. Where secondary outbreaks occur in areas that have already had a primary outbreak, movement from that area will have already been shut down due to the primary outbreak.

Comment: It may be difficult to detect CSF quickly, as witnessed by the 1997 outbreaks in the Netherlands, where it was estimated the CSF virus was detected approximately 6 weeks after it was introduced. Quick detection may be hindered by presumption that clinical symptoms are caused by a disease other than CSF, such as when diagnosis of CSF in the United Kingdom was delayed due to confusion of CSF with Postweaning Multi-Systemic Wasting Syndrome (PMWS) and Porcine Dermatitis and Nephropathy Syndrome (PDNS).

Response: With regard to outbreaks in the Netherlands, the risk analysis took into account the actual detection delays that occurred during the 1997–98 epidemic, including the 6-week time period the commenter mentioned for the Netherlands. With regard to the potential of misdiagnosing CSF as PMWS or PDNS, since the CSF outbreak in the United Kingdom, the EC has adopted a CSF Diagnostic Manual, taking into account the experience gained during outbreaks in the United Kingdom and in other EU Member States. Additionally, recent improvements in CSF diagnosis have been made through the development of polymerase chain reaction techniques, which are particularly useful in combination with postmortem examination and histopathology when CSF might otherwise be confused with other diseases.

Comment: How does APHIS intend to enforce its prohibition on the importation of products and animals from EU areas that APHIS considers to be affected with CSF, if the EU allows movement among its member States from such areas before APHIS recognizes the areas as CSF-free? How will movements within the EU be monitored to ensure that products and animals are not moved from areas considered restricted regions by the EU?

Response: In determining which areas in the EU are considered ''CSF-affected,'' APHIS will apply the criterion of whether at least 6 months have elapsed since the last incidence of CSF in the area, and will prohibit imports of swine and swine products from areas that APHIS does not consider CSF-free. This should be verifiable from the certification provided by the exporting region. For regions from which importation is not prohibited due to CSF, APHIS will require certification of region of origin by the exporting country.

Comment: The proposed rule did not describe how animal products would be traced if there were an outbreak outside the areas in which CSF is considered to exist, and how such an outbreak would affect products already in the United States or in transit to the United States. How will APHIS track and keep its port inspectors notified as to which areas in the EU are allowed to export swine, swine products, and swine semen to the United States?

Response: In the event a trading partner should have an outbreak of CSF, we would follow the same notification procedures that we follow for any disease of concern. Any prohibited or restricted articles in transit would be stopped at the port of importation into the United States. If a product had already passed through a port of entry, we would trace the product by means of the importer's distribution records.

Comment: APHIS should discuss in the final rule any comments on its June 1999 risk analysis that were generated by peer review of the analysis.

Response: The peer review comments focused on lack of transparency, identification of data sources, sensitivity analysis, listing of mitigation options, and conformance with OIE format. The comments suggested further that the analysis be revised to expand its hazard characterization, taking into account the spatial and temporal nature of the outbreaks that had occurred in the EU, including analysis of risk patterns, primary outbreaks versus secondary or tertiary ones, and pathways of disease spread.

In response to these comments, APHIS revised the presentation of the quantitative model. These revisions appear in Section I of the 2000 analysis. The document was reformatted to conform more closely with OIE guidelines, and includes a list of mitigation options. APHIS also clarified the description of the quantitative model and clearly identified data sources. Sensitivity analysis was conducted on some input values.

In addition, APHIS requested additional data from the EU to support a spatial and temporal analysis. Data collected included an update of the epidemiological information on which the 1999 analysis was based, as well as new information on the origin of outbreaks in space and time, disease surveillance in feral swine and wild boars, patterns of animal movement, maps of local veterinary administrative units in areas where outbreaks occurred, and information on herd and animal density. APHIS performed a spatial and temporal analysis that was presented as Section II of the revised analysis.

Comment: Will the risk analysis be reviewed and updated by APHIS in the event additional countries join the EU?

Response: In the event additional countries join the EU, we will initiate an assessment of CSF risk from those countries upon request by the EC. If, based on such a risk assessment, we believe restrictions from those countries with regard to CSF could safely be relieved, we would propose such a change through notice and comment rulemaking.

Comment: In calculating risk, the risk analysis factored in a ''risky period'' of 35 days following an outbreak, during which the disease may or may not be identified. Because the clinical signs of CSF are the same as for a number of other swine diseases, identification of CSF could be delayed. How would the probabilities of CSF introduction into the United States change if a 42-day risky period is used?

Response: The analysis incorporated the actual difficulties the Netherlands encountered in detecting CSF in 1997 as well as the actual detection difficulties of other EU Member States throughout the epidemic. The risky periods included in the analysis and described under variable ''b'' for each of the three models of the risk analysis were: (a) the Netherlands, 35 days; (b) the Lerida province in Spain, 53 days; (c) the Segovia, Madrid, and Toledo provinces in Spain, 7 to 21 days (most likely 10 days); (d) Belgium, 42 days; (e) Italy, 21 days; (f) Germany, 7 to 21 days (most likely 10 days). Therefore, the maximum risky period considered in the analysis was 53 days based on Spain's experience, which is greater than the 42 days suggested by the commenter. The risky period for any specific Member State was not analyzed individually, but rather was incorporated into an overall probability distribution of the risky period for all of the EU Member States under consideration. This probability distribution and its derivation are described in the risk analysis document. While the commenter is correct that problems with detection ability could be compounded even further in the United States, it is only the EU's ability to detect CSF that is being examined in the risk analysis.

Comment: In the EU in 1997, 611 outbreaks of CSF were confirmed, and 103 of the 611 were in farms outside protection zones established during the

outbreaks. Although, in its risk analysis, APHIS considered the remaining 508 herds as not contributing to further spread of the disease during the ''risky period,'' experience with disease movement through a variety of pathways indicates that CSF would be expected to spread from the protection zones.

Response: The 103 outbreaks occurring outside protection zones include any spread that occurred from the 508 outbreaks inside the protection zones to outside the protection zones.

Comment: APHIS stated in its risk analysis that an area can be designated as CSF-free if a case of CSF has not been detected for at least 6 months. What changes in the risk analysis would result if new criteria with a shorter length of time were established as the standard APHIS would use?

Response: The 6-month period referred to by the commenter is longer than the time that actual protection zones were maintained in the EU after the last case of CSF occurred in the zone. The risk analysis was based on the actual times the protection zones were maintained. Therefore, if a 6-month waiting period were applied, the risk would be reduced to levels below those estimated in the analysis. The additional mitigative effect of the longer 6-month waiting period could not be explicitly incorporated into the risk estimates because of the lack of actual observations on which to base such estimates.

Comment: In its risk model for breeding swine, APHIS assumed that each shipment of breeding swine for export originated from only a single farm. Is this a valid assumption? How would the probability of disease introduction change if this assumption were not made?

Response: APHIS made the assumption based on data available from the United Kingdom and Denmark. Import records showed that most shipments from these EU Member States originated from a single herd. APHIS was unable to obtain specific information for other Member States, so we assumed for the purposes of the risk analysis that each shipment was represented by one breeding herd. For a given number of imported breeding animals, any increase in risk caused by increasing the number of herds would be largely offset by the decrease in risk resulting from decreasing the number of animals selected per herd. The overall effect of a small increase in the number of herds of origin would be expected to be negligible, given the following: (1) The low within-herd prevalence that is likely for an undetected infected herd; (2) breeding animals would not likely be shipped if there were evidence of any type of infection in the shipment, regardless of whether an animal had been specifically identified as being infected with CSF; and (3) the overall number of imported animals is held constant.

Comment: Will this final rule change the quarantine and testing protocols for breeding swine imported into the United States?

Response: This final rule will change the listing of regions we consider to be affected with CSF and will affect the requirements an exporting region would have to meet in the absence of any other disease restrictions applicable to swine and swine products. It will not affect the current quarantine and testing protocols for breeding swine imported into the United States. If breeding stock is imported into the United States from regions in the EU considered to be free of CSF, the animals would still be required to undergo preembarkation and post-importation quarantine to ensure that they are not affected with brucellosis, tuberculosis, or pseudorabies.

Comment: In its sensitivity analysis, APHIS appeared to gauge changes in one variable independently of changes in another. For instance, the analysis determined the effect of varying the proportion over time of infected breeding farms exporting to the United States independently of determining the effect of varying the probability that an animal in a CSF-infected herd is infected with CSF. APHIS should evaluate concurrently these changes to the model to determine their simultaneous effect on the probability of one or more CSF incursions in a year.

Response: The purpose of the sensitivity analysis was to demonstrate the effect of changing individual input values in the model. The most likely risk estimates changed only minimally as a result of changing either of the two input values mentioned by the commenter, and changing both simultaneously would not be expected to result in a more substantial change. Although the range of uncertainty in the risk estimates did change substantially (a nine-fold change) by changing the distribution used for the input value ''Effect of varying the proportion over time of infected breeding swine farms exporting to the United States,'' this change too would not be substantively affected by changing both input values simultaneously.

Comment: The beta distribution (a probability distribution that is used to estimate the variability around a proportion) used to describe the relationship of the model term g/h (the probability that a randomly selected breeding herd has undetected CSF) in the breeding swine model could be viewed as too conservative to adequately describe the expected outbreak frequency, and a triangular distribution (a calculation of the minimum, most likely, and maximum estimate) that uses a more realistic description of the 1997 outbreak in the Netherlands is required. The analysis underestimated the number of herds that would become infected before the disease was diagnosed. An estimate of the number of herds infected during this ''risky period'' should be used for ''g'' (the number of infected breeding herds with undetected CSF) and provide a basis for determining the parameters of the triangular distribution.

Response: We disagree with the commenter's suggestion to use a triangular rather than a beta distribution to represent the variability around the proportion g/h. The use of a beta distribution to represent this variability is consistent with well-established statistical theory. A triangular distribution is generally used to represent a rough guess in the absence of actual observational data and has no theoretical foundation.

Comment: The risk analysis indicated a ''maximum'' result of one CSF incursion in breeding swine every 4,880 years, but a ''most likely'' result of one CSF incursion every 33,700 years. How does APHIS view the differences in the values?

Response: As noted above, the numerical values suggest that frequency of introduction by any commodity that was considered in the analysis, even with no import mitigations applied, was extremely low.

Comment: What does APHIS consider the estimated sensitivity of the serologic assay(s) being considered in the model? If the sensitivity is anything less than 100 percent, it should be included in the development of the model.

Response: The sensitivity of the serological assay for CSF in the EU is estimated at between 85 and 95 percent. However, since serological testing was not considered in the risk analysis as a potential mitigation for imported breeding swine, there was no need to include such an estimate in the model. If the commenter's question is regarding the EU's ability to detect CSF in its surveillance activities, it should be noted that risk analysis was based on a retrospective evaluation of the EU's actual detection success in the 1997–98 epidemic. Therefore, an estimate of the sensitivity of the serological assay was not required. Only evidence of the

observed success rate in detection and control, or, in other words, the measurements of the risky periods, was needed.

Comment: In its June 1999 risk analysis, APHIS stated that the starting risk level of CSF introduction by swine semen was 1 or more incursions in an average of 1,842 years, but that holding semen donor boars and observing them clinically for 40 days after semen collection reduced this likelihood to 1 or more outbreaks in 257.7 million years. In its December 2000 risk analysis, APHIS states that holding the swine for 40 days would result in a risk estimate of 1 or more incursions in an average of 8,090 years. How does APHIS explain the discrepancy between the first and the second analysis?

Response: In the June 1999 risk analysis, the 40-day holding period included the additional estimated mitigative effect of multiple animals being held together during the 40-day period. In other words, the June 1999 analysis incorporated a sentinel effect that required only one of the group of animals being held together to show observable signs of infection for detection to occur. In the revised December 2000 risk analysis, this sentinel effect was dropped from the analysis. The December 2000 risk analysis assumes that only one animal is held and is based on whether this specific animal shows observable signs. Dropping the sentinel effect from the analysis results in a substantial increase in the estimated risk. Although we believe this overestimates the risk, the sentinel effect was dropped from the analysis because there were no substantiated data available to support an estimate of the number of animals that might be held together. The assumption of no sentinel effect is described in the analysis in the discussion of variable ''k''.

Comment: APHIS stated in its risk analysis that additional mitigation could be accomplished by employing serological testing. APHIS, therefore, should evaluate the change in risk that would occur if such testing were required. During the 1997 CSF outbreak in the Netherlands, some boars in a semen collection center that were initially considered not to be infected with CSF, based on the absence of clinical signs, were tested the following day and found to be infected. It appears an outbreak of CSF in the semen collection center followed the transport of some boars into the center in the same means of conveyance used earlier for sows from a presumed infected farm. This apparent biosecurity problem raises questions about the assumptions used in the model in the risk analysis.

Response: The risk analysis included the fact that the CSF agent was introduced into the semen collection center during the risky period-*i.e.*, prior to CSF detection and control in the Netherlands. This information was incorporated into variable ''g'' (the number of affected swine semen collection centers with undetected CSF) in the swine semen model. Therefore, the breakdown in biosecurity that occurred and the unclear clinical signs that were presented were already accounted for in the risk analysis model, which prompted the proposed inclusion of a 40-day holding period on swine semen before export. Based on the reduced level of risk when such a holding period is required, we see no reason to additionally evaluate the effect of requiring the serological testing referred to by the commenter.

Comment: Many of the approved swine semen collection centers in the EU are located in Spain, Germany, and France, all countries in which CSF outbreaks have occurred relatively recently.

Response: As noted above, we are continuing to apply import prohibitions due to CSF on those parts of countries or entire countries where a CSF outbreak has occurred since our June 1999 proposal. As we discussed earlier, included in such areas are Spain, France, parts of Germany, and Luxembourg.

Comment: In establishing the eligibility of the semen of a boar for export to the United States, is it required that no new boars enter the stud (the semen collection facility) during the 30-day isolation period and 40-day incubation period of the specific donor boar in question. Is serologic testing a component of the isolation and incubation protocol?

Response: Serologic testing and isolation of boars is required by the EU prior to the boars entry into the semen collection center. Once the semen is collected, whether the boars are kept isolated will not have any significant effect on import risk.

Comment: In evaluating the sensitivity of its risk model (*i.e.*, its determination of how variations in input data affect probability outcomes), APHIS stated that it ''considered a distribution to address uncertainty unnecessary since the assumptions used reflected a situation worse than there were data to support.'' This statement seems to contradict itself, because a major justification for conducting a sensitivity analysis is the lack of a good estimate for a variable.

Response: The statement in the risk analysis that the commenter is referring to was in regard to only one scenario of the sensitivity analysis. In that scenario, the point estimate of the number of infected semen centers exporting semen to the United States was doubled in order to see the effect on the risk estimates. This scenario was created to isolate the effect of altering the number of semen centers that were infected, which could best be accomplished by comparing the model results using two alternative point estimates. However, another scenario was also run, and is documented in the risk analysis, where a probability distribution (specifically a beta distribution) was used to represent the number of infected semen centers. We devoted attention to running multiple scenarios for the number of infected semen centers because we viewed this factor as a critical model variable.

Comment: If the risk ''maximum result'' were selected in the analysis, the result would be an expected frequency of a CSF incursion due to imported semen every 694 years, in contrast to every 1,840 years for the ''most likely value.'' The sensitivity analysis varying the probability of an animal as CSF infected in a CSF-infected center results in a ''most likely value'' of one or more incursions every 903 years, and a ''maximum value'' of one or more incursions every 278 years, which are similar to the values for the scenario of an approved semen center becoming infected with CSF every year. Considering this level of risk, what would be the impact on risk to assume mitigation measures in addition to the 40-day hold on semen included in the proposed rule?

Response: The value referred to by the commenter was determined before any mitigating measures were introduced into the risk calculations. With the introduction of a 40-day waiting period before semen may be exported, even the maximum value is no more than one or more incursions every 2,430 years. However, the most likely value for the expected frequency is one or more incursions every 8,090 years.

Comment: Because semen seems to pose the highest risk of all swine commodities considered for export to the United States, it could be considered important to survey the U.S. industry regarding the types of importations that are likely in the future, in order to ensure that the assumptions that were used in the model are appropriate for future importations. The commenter suggested such survey information might include countries and other regions from which imports would be

requested, the number of doses likely, and the number of boars per shipment.

Response: In compiling data for the risk analysis, APHIS contacted several major breeding companies regarding their plans for importation. Although the companies gave no indication at the time of significant plans for importations, the risk analysis nonetheless assumed that such importations would occur.

Comment: APHIS stated that requirements for inspection by the Department's Food Safety and Inspection Service (FSIS) would reduce the risk of importing infected product into the United States even further than estimated in the risk analysis. Are there any rapid testing protocols, or pathognomonic (distinctly characteristic) lesions or clinical signs, that would lead an FSIS inspector to be concerned about CSF infection in a particular animal or pork product?

Response: There is no commercially practical test for the CSF virus in meat and meat products. Our statement in the proposed rule addressed ante- and post-mortem inspection of animals. Such inspection evaluates the general health of the animal to be slaughtered. One of the common characteristics of CSF is a high percentage of a swine herd sick at the ante-mortem stage. In addition, high temperature and purplish discoloration of the abdominal skin may be noticed. CSF does cause lesions on various organs that can be detectable post-mortem. Although we noted the benefit of inspection, the effect of such inspection was not considered in our risk analysis.

Comment: APHIS should explain why more emphasis was not applied to interpreting the ''maximum likelihood'' estimates regarding the risk of CSF introduction into the United States in addition to or rather than the ''most likely'' estimates. In risk evaluations, an evaluation of the range around the ''most likely'' estimate should carry as much weight as an evaluation of the ''most likely'' estimate itself.

Response: The most likely risk estimates were highlighted as the central tendencies of the model output distributions. However, maximum risk estimates (as well as minimum, mean, and median estimates) were also presented as part of the output of each scenario that was run for each model. In this way, readers had full information about the central tendencies and the ranges of the model outputs. However, the maximum risk estimates are obtained from the extreme tail of the probability distribution. The tail of the distribution represents an extremely small area relative to the area representing the central mass of the distribution from which the most likely estimate is obtained.

Comment: Given the difficulty and subjectivity involved in determining the value of variables for use in the risk model, and the magnitude of the effect of the variables on the final risk estimate, it may be useful to conduct a Delphi Survey (a survey of the opinions of experts on a particular topic) to ascertain ranges of estimates for prospective risk A sensitivity analysis could then be completed that combines the range of estimates (and the variation around the estimates) for the model inputs. This would allow APHIS to use data regarding CSF outbreaks since the December 2000 risk analysis was written, which would, in turn, allow the model to have more value for application to potential future CSF situations in the EU.

Response: Most of the data used in the risk analysis were generated during an extremely severe CSF epidemic that occurred in the EU in 1997 and 1998. As discussed in the risk analysis, this CSF epidemic is considered the most severe the EU has ever experienced. By using actual data from this epidemic rather than using estimates based on expert opinions obtained through a Delphi Survey, the risk assessment provides a more cautious estimation of the potential risk. The risk estimates generated in the analysis took into account the effectiveness of EU control measures, and if and where those measures failed, under these severe conditions. The risk analysis therefore anticipates future situations in the EU where CSF epidemics reach up to the same magnitude and the same level of detection and control failures as occurred during the 1997–98 epidemic. Given that recent CSF epidemics are of a smaller magnitude and have fewer failures in detection and control, they fall within the expectations of the current risk analysis. Incorporating the data from these recent epidemics into the analysis would likely reduce the estimated risk.

Comment: APHIS acknowledges the impact of the sensitivity analysis on the models but does not present the final risk estimations resulting from the sensitivity analysis. APHIS should publish the final risk estimates for the three models.

Response: A summary of the final risk estimates for all three models is presented in the executive summary of the risk analysis report. The full details of these estimates are presented throughout the text of the report. The risk estimates for each sensitivity analysis are reported in the sensitivity analysis section. The sensitivity analyses were conducted to show how the final risk estimates might change under alternative assumptions regarding input values. As such, the results of the sensitivity analyses stand alone rather than as adjustments to the final models.

Commenter: The model does not account for the impact of intraregional spread (such as five herds being infected at one time). This, combined with the use of a conservative beta distribution to describe the proportion of infected herds from which animals are exported to the United States over time (g/h), biases the model toward underestimating the true risk to the United States. Is APHIS considering this aspect?

Response: As we discussed in the sensitivity analysis section of the risk analysis regarding swine semen, the beta distribution for the input value g/h is considered conservative in the sense that it likely contributes to overestimating the risk. Also, as discussed in the risk analysis, the CSF epidemic that provided the data for the analysis is considered the most severe the EU has ever experienced. Incorporated into the risk estimates based on this epidemic are six different risky periods representing index cases in six discrete locations in the EU: the Netherlands, Italy, Belgium, Germany, and two separate locations in Spain (the risky period is documented under input value b in the models). Since the models are exclusively based on the time period during which this severe epidemic occurred and do not incorporate any ''peace time'' periods, the model is actually biased toward overestimating the risk.

Comment: The risk analysis report, despite referring to the importance of the wild boar reservoir in maintaining the CSF virus in a region, concludes that the ''risk of importing CSF-infected material from areas of the EU that are in close proximity to infected wild boar is not greater than the risk of importing infected material from areas that are geographically distant from primary outbreaks caused by wild boar.'' Have statistical tests been applied to the available data to provide a quantitative assessment of the risk posed by wild boar to EU herds? APHIS should review its previous assumptions about the role of wild boars with regard to the risk of importing infected or contaminated animals or products.

Will semen be allowed to be imported into the United States from an area in the EU that is designated by the EU to be ''wild boar control area'' (*i.e.*, an area in which CSF has been diagnosed in feral swine and in which domestic

swine have consequently been placed under surveillance and in which specified measures are being taken to protect domestic swine from infection by feral swine)? How will APHIS requirements change as EU wild boar control areas change?

The site visit report notes that a seropositive wild boar was detected in 1999 in the Netherlands. Are there wild boar control areas in that country? Additionally, Italy has a significant wild boar population that overlays the main pig-producing areas. Although Italy has had no reported CSF outbreaks in 2002, it had several outbreaks each year previously.

Response: Swine semen will be allowed to be imported into the United States from a wild boar control area. As discussed in the spatial and temporal section of the risk analysis, some of the outbreaks in domestic swine follow domestic animal movement or related pathways in the EU. The analysis documented that the number of outbreaks and the extent of undetected CSF spread associated with these pathways are actually greater than those that have been associated with disease originating from direct contact with infected wild boar and any associated proximity spread.

The clearest examples of these associations are evident in the outbreaks that occurred in the Netherlands and in Germany. The primary outbreak for the epidemic in the Netherlands actually occurred in Paderborn, Germany. The Netherlands outbreaks were linked to infectious material from Germany that contaminated a Dutch lorry. The improperly disinfected truck carried infectious material back to the Netherlands after transporting pigs in the Paderborn area of Germany. In this epidemic, secondary spread occurred through the movement of an empty truck into the Netherlands, where additional spread took place from a variety of causes, including the movement of swine, people, equipment, and semen for artificial insemination. Due in part to the Netherlands' relatively long risky period (the period before the disease was detected and controls implemented), a total of 429 outbreaks occurred in the Netherlands during this epidemic.

In contrast, in Germany during the same time period there were 56 outbreaks. Fourteen of these were primary outbreaks (due to either contact with wild boar or unknown causes that may have been contact with wild boar) with very little secondary spread, in contrast to the enormous secondary spread that occurred in the Netherlands. The outbreaks in Germany occurred primarily in areas that were already under EU restriction because disease had been detected in wild boar. As discussed in the analysis, APHIS attributed the relative lack of disease spread in Germany to movement restrictions and increased surveillance and control mechanisms, which were required by EU legislation and also conducted in part due to the presence of infected wild boar. During 1997 and 1998, Germany had a much shorter risky period than the Netherlands, with far less undetected and uncontrolled secondary spread. APHIS requirements will not change as wild boar control areas change. In response to the commenter's question, there are no wild boar control areas in the Netherlands.

All of these factors led to the conclusion that the risk to the United States of importing CSF-affected swine or swine products is not greater for imports from areas in close proximity to wild boar than it is from areas like the Netherlands that had more difficulty detecting a CSF incursion and had substantially greater secondary spread before the disease was detected and controls implemented. In short, CSF is found and controlled more quickly in areas of the EU where it is expected to be found, such as in close proximity to wild boar in Germany, than it is in areas where it is not expected to be found, such as in the Netherlands. The greater risk to the United States is from those areas with longer risky periods and substantially greater undetected secondary spread.

No statistical or quantitative methods have been applied to estimate the risk to EU herds from wild boar, because the focus of the risk analysis was on the risk to U.S. herds rather than EU herds.

Comment: Local veterinary units are important in local CSF eradication efforts. Are methods employed by the local veterinary units standardized and monitored by a central authority?

Response: Local veterinary units are subject to the national rules and regulations of the EU Member State in which they are located, as well as the relevant EU animal health legislation. National contingency plans must be reviewed and approved by EC authorities. Within these constraints, protection zones and surveillance zones are often established based on the boundaries of the local veterinary units.

Comment: Are reports from the EU Standing Veterinary Committee the best source of current listings of EU restrictions on swine movement due to a high prevalence of seropositive wild boars? What information will be made available to APHIS to allow it to adjust its listing of infected regions?

Response: As standard practice, there is direct communication between the EC and APHIS within 24 hours of an outbreak. Such information is then compiled in the reports of the EU Standing Veterinary Committee.

Comment: It would be helpful if all documentation submitted in support of a regionalization request that is posted to the APHIS Internet website be in English.

Response: We agree with the commenter. Under § 92.2, submission of information required by the regulations to accompany a regionalization request must be in English. We are encouraging countries requesting regionalization to provide English translations of all supporting documentation.

Comment: In its site visit report, APHIS noted that detailed reports on six CSF outbreaks that occurred in 1999 were reviewed and that all six occurred within previously established protection or surveillance zones. The report also notes that data from 2000 was presented but was not detailed. Was there anything of interest in the information from the 2000 outbreaks?

Response: Two CSF outbreaks occurred in domesticated swine in Germany in 2000. The two outbreaks were in Kreis Bernkastel-Wittlich (landers of Rhineland Palatinate) and were included on the maps in the spatial and temporal section of the risk analysis. Both outbreaks were situated in an area where there had been long-standing movement restrictions on domesticated swine due to CSF in wild boar. Therefore, these outbreaks would have posed no substantive risk to the United States.

Comment: Since January 2002, the EU has been responding to continuing CSF outbreaks in Germany by increasing the size of the areas from which exports of live swine and semen are not allowed. In light of such an evolving situation, has APHIS considered conducting a ''test exercise'' to review how the agency would apply its import restrictions and procedures? Has the evolving situation altered APHIS'' view of the adequacy of the EU disease control procedures?

Response: With regard to the recommendation of a ''test exercise,'' APHIS has ongoing experience in responding to outbreaks of animal diseases of concern in foreign regions, including such serious diseases as CSF and FMD, and will continue to take the measures necessary to ensure that such diseases are not introduced into the United States. With regard to how the evolving disease situation in the EU affects APHIS' conclusions regarding disease risk, as noted earlier, the risk

analysis upon which the June 1999 proposed rule was based took into consideration the most serious CSF situation in EU history. Any disease outbreaks since then have not been of the severity of the 1997–1998 outbreaks.

Comment: Although EU regulations restrict trade in domestic pigs from specified wild boar areas in Germany to other EU Member States, trade is allowed to other regions of Germany with some restrictions. How does the risk analysis account for the risk of the spread of CSF within Germany from such movement?

Response: The risk analysis took into account all CSF outbreaks in Germany that occurred outside of any established restriction zones. Therefore, any undetected outbreaks outside such zones that resulted from domesticated swine movement within Germany were considered to be part of the population of herds from which the United States could potentially import. These outbreaks were included in the risk estimates as part of variable ''g'' in the breeding swine and swine semen models, and variable ''P_1'' in the pork model.

Comment: Does a 2002 outbreak in France in domestic swine exposed to infected wild boar change APHIS'' conclusion in the risk analysis that areas containing infected wild boar can be considered CSF-free for export? The outbreak in France additionally calls into question the statement made in the risk analysis report that no CSF outbreaks in France had been attributed to wild swine during the 7 years prior to development of the risk analysis.

Response: Obviously, areas that have had recent outbreaks of CSF in domesticated swine, such as the area in France, would not be considered for recognition of CSF freedom until the waiting periods discussed in the proposed rule had elapsed. The risk analysis itself did not deal directly with declarations of disease freedom, but rather dealt with the risk to the United States of outbreaks that occurred outside any established EU restriction zones. As discussed in responses to comments above, the risk analysis anticipates future situations in the EU where CSF epidemics reach the same magnitude and the same level of detection and control failures as occurred during the 1997–98 epidemic. Given that recent CSF epidemics are of a smaller magnitude and have fewer failures in detection and control, they fall within the expectations of the current risk analysis.

Comment: How can APHIS support its statement in the risk analysis that the 1997–98 CSF outbreak in the Netherlands was ''unique'' and did not serve as a very good model of how CSF can be introduced into or spread within the region? What made this situation and a 2000 outbreak in East Anglia in the United Kingdom unique and unlikely to recur? Many of the factors that APHIS considered in judging the Netherlands outbreak to be unique have not and will not change, such as highly concentrated production, dependence on pig transport between farm sites and regions, and insufficient rendering capacity.

Response: The 1997–98 EU CSF epidemic is considered unique in its magnitude and scope because nothing comparable has occurred before or since. As noted above, this CSF epidemic is considered the most severe the EU has ever experienced. The computer model for the risk assessment alone is not intended to predict all possible future scenarios. APHIS intends to monitor the animal health situation in the EU and periodically review the parameters of the risk assessment model to determine if the situation in the EU has changed sufficiently to alter the findings of the assessment.

Comment: Although the site visit report indicates the Netherlands has instituted additional restrictions on handling semen, transporting live animals, and biosecurity practices, no information was presented on the measures taken at semen centers in other countries or regions.

Response: The risk analysis regarding CSF in the EU region, and the additional mitigations we proposed for the importation of swine semen, were based on the situation prior to any changes in biosecurity measures in the Netherlands. Any increases in biosecurity there and in other countries will serve to lower the assessed risk, but were not depended upon to bring the risk of CSF to an acceptable level.

Comment: The site visit report noted that a surveillance zone was established in Luxembourg in 1999 due to CSF in a neighboring area in Germany. It is not clear if movement restrictions are in place for domestic swine in the surveillance zone.

Response: Movement restrictions are in place for domestic pigs in the surveillance zone, and swine are not permitted to be moved until they are tested by both serology and virology.

Comment: Although the United Kingdom had originally been considered a low-risk area, a CSF outbreak there in 2000, coupled with the FMD outbreak in 2001, indicates disease control measures there are not adequate.

Response: The United Kingdom was not included in the region under consideration in our June 1999 proposal. We have addressed the disease outbreaks in the United Kingdom separately from the those in the region under consideration.

Comment: The commenter stated that because of recent CSF outbreaks in Spain, the EU extended its implementation of restrictive measures in that country.

Response: As we discussed above, CSF outbreaks in the EU region in question since publication of the proposed rule have been of a smaller magnitude, and have had fewer failures in detection and control, than during the 1997–1998 epidemic and fall within the expectations of our risk analysis. It should be noted, however, that because the outbreaks in Spain occurred after the publication of the proposed rule, and the public has not had the opportunity to formally comment on any CSF classification of Spain following those outbreaks, we are not including Spain in this final rule as a country in which CSF is not known to exist.

Comment: Will any of the risk mitigation measures in the proposed rule be applied to countries that have already been recognized as free of CSF?

Response: The scope of the risk analysis explicitly excluded those EU Member States that APHIS had already recognized as CSF free.

Comment: Would APHIS prohibit imports from areas under EU restrictions due to wild boar infections when the EU allows trade with restrictions within the country in question, even though it prohibits trade to other Member States?

Response: In this final rule, we are amending part 92 of the regulations to add a new § 92.3, as proposed, that provides that whenever the EC establishes a quarantine for a disease in the EU in a region that APHIS recognizes as one in which the disease is not known to exist, and the EC imposes prohibitions or other restrictions on the movement of animals or animal products from the quarantined area in the EU, such animals and animal products are prohibited importation into the United States.

Change in Terminology

We are making a change in this final rule to reflect current terminology regarding who receives certificates at the port of arrival. In § 94.23(c), instead of referring to ''collector of customs,'' we refer instead to ''appropriate Customs and Border Protection Officer.''

Therefore, for the reasons given in the proposed rule and in this document, we are adopting our June 1999 proposed rule as a final rule, with the changes discussed in this document.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

This rule recognizes a region of the EU as one in which CSF does not exist. Additionally, it recognizes Greece and certain regions of Italy as areas in which SVD does not exist. Although restrictions on the importation of animals and animal products from these regions may continue because of other diseases, a number of restrictions due to CSF and SVD are no longer warranted for imports from the areas. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon publication in the **Federal Register**.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

This rule recognizes a region in the EU as one in which CSF is not known to exist, and from which breeding swine, swine semen, and pork and pork products may be imported into the United States under certain conditions. Additionally, it recognizes Greece and four Regions in Italy as free of SVD. These actions are based on a request from the EC's Directorate General for Agriculture and on our review of the supporting documentation supplied by the EC and individual EU Member States. These actions will relieve some restrictions on the importation into the United States of certain animals and animal products from those regions that are imposed because of CSF and SVD.

In considering this rulemaking, we considered three options. The first, which we could have applied to all the diseases addressed by this rule, was to retain the current regulations and make no changes. We did not consider this an acceptable option because it was not warranted by the disease situation in the regions in question and such inaction would have been contrary to U.S. obligations under international trade agreements. A second option, specific to CSF, was to allow free movement of swine, swine semen, and pork from the region we are recognizing as one in which CSF does not exist. Based on our risk analysis, however, we concluded that adopting that option would lead to an unacceptable risk of introducing CSF into the United States. Therefore, we chose our third option, which was to adopt the provisions of this rule.

Below is a summary of the economic analysis prepared for this rule. The economic analysis provides a cost-benefit analysis as required by E.O. 12866 and an analysis of impacts on small entities as required by the Regulatory Flexibility Act. A copy of the full economic analysis is available by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Recognition of an EU Region as One in Which CSF Does Not Exist

The analysis with regard to CSF examines the economic impact of the potential importation of fresh (chilled or frozen) pork, breeding swine, and swine semen from a region in the EU that this rule recognizes as one in which CSF is not known to exist.

This is in accordance with the policy of ''regionalization,'' whereby import requirements are tailored to regions that are determined by science-based risk factors, rather than political boundaries.

Five EU Member States that are already recognized in the current regulations as being regions in which CSF is not known to exist are excluded from this analysis, because the regulations governing CSF do not currently restrict their pork, live swine, and swine semen exports to the United States.

Potential Importations of Pork

Potential exports to the United States from the seven EU Member States considered (Austria, Belgium, parts of Germany, Greece, parts of Italy, the Netherlands, and Portugal) constitute the trade volumes used in the analysis, assuming no risk of disease introduction. For pork, the import levels used in the analysis are based on the proportion of Denmark's global pork exports that are imported into the United States. It is assumed that a similar percentage of the global pork exports of each of the EU Member States will be exported to the United States. The total quantity of pork assumed is about 15,158 metric tons. For breeding swine and swine semen imports, the import levels used in the analysis are based on historical data and prior U.S. demand for EU swine genetic stock.

Current U.S. pork import levels suggest that imports resulting from this rule are likely to be minimal. The import levels used in the analysis allow for an analysis of potential economic effects if market conditions were to change in favor of U.S. imports of EU swine and pork and pork products. Estimated effects on producers and consumers reflect the expected effects of these imports, assuming no disease risks.

Although we expect that the economic effect of this rule will be minimal, we used a net trade benefit model to evaluate what would happen should trade occur. Benefits to the United States of pork imports from the EU Member States considered are calculated as the net change in consumer surplus and producer surplus. Assuming an import volume of 15,158 metric tons of pork, the annual net trade benefit is estimated to be about $228,000 (2001 dollars). Based on data on domestic pork production and prices for the period 1997 to 2001, the welfare changes in consumer surplus and producer surplus would reflect about a 0.1 percent decrease in U.S. pork production, a 0.1 percent increase in pork consumption, and a 0.1 percent decrease in the farmgate price of pork.

Potential Imports of Breeding Swine

The marginal benefit, in terms of productivity gains, from future imports of EU breeding swine is expected to be minimal, given the ready availability of improved genetic lines in both the United States and Canada. Over the 8-year period from 1994–2001, over 98 percent of breeding swine imports into the United States came from Canada, and only about 1.2 percent came from the European Union. The breeding swine that were imported from the EU came almost entirely from Denmark and the United Kingdom, countries that are unaffected by this rule. We used the number of breeding swine imported from Denmark and the United Kingdom to establish a recent average and a reasonable upper bound for potential imports from the EU Member States of concern. The average number of breeding swine imported annually from Denmark and the United Kingdom is 440. The minimum number imported was zero in 2001, and the maximum was 1,299 imported in 1997. It is assumed that 200 breeding swine per year may be imported from the newly recognized region in which CSF is not known to exist.[2]

APHIS does not record the percentages of imported breeding swine that are boars and gilts. For the purposes

[2] Although projected import quantities for breeding swine and swine semen used in this analysis were approximated independently of those used in the risk assessment, similar assumptions were followed in both analyses.

of benefits estimation, we assume that one-third of imports are boars and two-thirds are gilts. Therefore, the most likely future annual average of imported boars is assumed to be 67, and of gilts is assumed to be 133. Assuming minimal expected benefits from productivity gains, benefits to the United States from importation of EU breeding swine can most readily be quantified in terms of the unit values of the imports. It is assumed that, at a minimum, producers would expect to pay about $1,000 to import a single EU breeding gilt and possibly $2,800 to import a single EU breeding boar, including transportation and quarantine costs. There is a great deal of variability in both the prices of individual animals, due to product differentiation, and in the cost of transportation, which may be negotiated with individual contract carriers. Multiplying assumed quantities and unit values yields a most likely import value of $187,600 for breeding boars and a most likely value of $133,000 for breeding gilts imported from the EU region affected by this rule.

Potential Imports of Swine Semen

During the period 1997–2001, the source countries and quantities of swine semen varied widely from one year to the next. The single largest exporter to the United States during this period was Australia, which averaged 1,045 doses per year, or 43 percent of the total. Canada supplied an average of about 672 doses per year, or 28 percent of the total. An average of about 680 doses were imported each year from the EU–28 percent of the total. In 2001, 1,736 doses came from Germany, one of the Member States that constitute the region affected by this rule. During the first 9 months of 2002, the only swine semen imports from the EU were 780 doses imported from Denmark.

A wide range of prices for swine semen reflects considerable product differentiation in the market for swine genetics. Quoted prices for swine semen from a small sampling of producers range from $6 to $50 per dose. It is presumed that the higher priced semen represents the greater perceived benefit to U.S. swine products. In addition to the price per dose, buyers must pay for packaging materials and shipping costs, although these costs constitute a small fraction of the overall cost. A typical shipment of swine semen would be 30 doses packed in a cooler. Packing materials, including cooler, are available for about $15 per shipment. A 15-pound packed cooler can be shipped between the United States and the EU for about $200. The value of a 30-dose shipment of swine semen is therefore assumed to be $1,715. Using that value, annual values of swine semen imported from the region affected by this rule are expected to be approximately $40,000.

Regarding the effects of the rule on small entities, more than 88 percent of all U.S. hog farms meet the U.S. Small Business Administration size criterion for small entities of annual revenues of less than $750,000. Pork, breeding swine, and swine semen imports from the region in question are unlikely to be significantly affected by this regulatory change, which could cause an average annual effect on small entities of less than 0.1 percent of average gross revenue.

Recognition of Greece and Certain Regions in Italy as Free of SVD

We are also recognizing Greece and four Regions in Italy as free of SVD. Recognition of Greece and certain Regions in Italy as free of SVD will remove U.S. import restrictions because of this disease with respect to pork and live swine. This analysis examines potential effects of this rule on U.S. entities by comparing global trading patterns of Greece, Italy, and the United States for these commodities.

International trade statistics for swine, pork, and pork products are available for Greece and the United States, but not specifically for the four Regions in Italy. Given the unavailability of individual regional trade statistics for the Regions in question, we based our analysis on swine, pork, and pork products for Italy as a whole. Because Italy has a total of 20 Regions, conclusions regarding likely minimal export effects for the four Regions are all the more valid.

Both Greece's and Italy's swine, pork, and pork imports far outweigh their exports. During the period 1996 to 2000, the annual value of Italy's imports of swine, pork, and pork products averaged more than $1.2 billion more than the value of its exports of swine, pork, and pork products. For Greece, the annual value of its imports of swine, pork, and pork products averaged more than $250 million more than the value of its exports. In contrast, during the same period, the United States annually averaged approximately $6.2 million more in exports of breeding swine than in imports, and over $475 million more in exports of pork and pork products than imports. The United States is a net importer of swine other than breeding swine, with average annual imports, virtually all of which are supplied by Canada, valued at close to $274 million more than annual exports.

Small entities that might be directly affected by the SVD provisions of this rule are buyers and wholesalers of swine and pork products, and, indirectly, U.S. pork producers. However, as discussed above, prevailing trade patterns indicate that this rule will have little economic effect on U.S. entities, large or small.

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

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact were prepared for this rule. The assessment provides a basis for the conclusion that the importation of swine, swine semen, and other swine products from specified regions in Europe under the conditions specified in this rule 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 (NEPA), as amended (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 contacting 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 0579–0218.

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 71

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

9 CFR Part 92

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

9 CFR Part 93

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

9 CFR Part 94

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

9 CFR Part 98

Animal diseases, Imports.

9 CFR Part 130

Animals, Birds, Diagnostic reagents, Exports, Imports, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Tests.

■ Accordingly, we are amending 9 CFR parts 71, 92, 93, 94, 98, and 130 as follows:

PART 71—GENERAL PROVISIONS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 71.3 [Amended]

■ 2. In § 71.3, paragraph (b) is amended by removing the words ''hog cholera'' and adding the words ''classical swine fever'' in their place.

PART 92—IMPORTATION OF ANIMALS AND ANIMAL PRODUCTS: PROCEDURES FOR REQUESTING RECOGNITION OF REGIONS

■ 3. The authority citation for part 92 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.

■ 4. In § 92.1, a definition of *European Union* is added, in alphabetical order, to read as follows:

§ 92.1 Definitions.

* * * * *

European Union. 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).

* * * * *

■ 5. A new § 92.3 is added to read as follows:

§ 92.3 Movement restrictions.

Whenever the European Commission (EC) establishes a quarantine for a disease in the European Union in a region the Animal and Plant Health Inspection Service recognizes as one in which the disease is not known to exist and the EC imposes prohibitions or other restrictions on the movement of animals or animal products from the quarantined area in the European Union, such animals and animal products are prohibited importation into the United States.

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

■ 6. 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.

§ 93.505 [Amended]

■ 7. In § 93.505, paragraph (a) is amended by removing the words ''hog cholera'' and adding the words ''classical swine fever'' in their place.

§ 93.517 [Amended]

■ 8. In § 93.517, paragraph (a) is amended by removing the words ''hog cholera'' and adding the words ''classical swine fever'' in their place.

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

■ 9. The title of part 94 is revised to read as above.

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

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

■ 11. Section 94.9 is amended as follows:

■ a. By revising the section heading and paragraph (a) to read as set forth below.

■ b. By removing the words ''hog cholera'' and adding in their place the words ''classical swine fever'' in following places:

■ i. Paragraph (b), introductory text.

■ ii. Paragraph (b)(1)(iii)(C).

■ iii. Paragraph (b)(1)(iii)(C)(1), both times they appear.

■ iv. Paragraph (b)(1)(iii)(C)(2), both times they appear.

■ v. Paragraph (c).

§ 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; Denmark; England, except for East Anglia (Essex, Norfolk, and Suffolk counties); Fiji; Finland; Iceland; Isle of Man; New Zealand; Northern Ireland; Norway; the Republic of Ireland; Scotland; Sweden; Trust Territory of the Pacific Islands; Wales; and a single region in the European Union consisting of Austria, Belgium, Germany (except for the Kreis Uckermark in the Land of Brandenburg; the Kreis Oldenberg, the Kreis Soltau-Fallingbostel, and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Pŕm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsr̈che, the Kreis S̈dliche Weinstrasse, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the Land of Saxony-Anhalt); Greece; Italy (except for the Regions of Emilia-

Romagna, Piemonte, and Sardegna); the Netherlands; and Portugal.[10]

* * * * *

■ 12. Section 94.10 is amended by revising the section heading and paragraph (a) 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; Denmark; England, except for East Anglia (Essex, Norfolk, and Suffolk counties); Fiji; Finland; Iceland; Isle of Man; New Zealand; Northern Ireland; Norway; the Republic of Ireland; Scotland; Sweden; Trust Territory of the Pacific Islands; Wales; and a single region in the European Union consisting of Austria, Belgium, Germany (except for the Kreis Uckermark in the Land of Brandenburg; the Kreis Oldenberg, the Kreis Soltau-Fallingbostel, and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Prüm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsrücke, the Kreis Südliche Weinstrasse, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the Land of Saxony-Anhalt); Greece; Italy (except for the Regions of Emilia-Romagna, Piemonte, and Sardegna); the Netherlands; and Portugal. No swine that are moved 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 (b) of this section.

* * * * *

■ 13. In § 94.12, paragraph (a) is revised to read as follows:

§ 94.12 Pork and pork products from regions where swine vesicular disease exists.

(a) Swine vesicular disease is considered to exist in all regions of the world except Australia, Austria, the Bahamas, Belgium, Bulgaria, Canada, Central American countries, Chile, Denmark, Dominican Republic, Fiji, Finland, France, Germany, Greece, Greenland, Haiti, Hungary, Iceland, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Panama, Portugal, Republic of Ireland, Romania, Spain, Sweden, Switzerland, Trust Territories of the Pacific, the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland), Yugoslavia, and the Regions in Italy of Friuli, Liguria, Marche, and Valle d'Aosta.

* * * * *

■ 14. In § 94.13, the undesignated introductory text is revised to read as follows:

§ 94.13 Restrictions on importation of pork or pork products from specified regions.

Austria, the Bahamas, Belgium, Bulgaria, Chile, Denmark, France, Germany, Hungary, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Switzerland, the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland), Yugoslavia, and the Regions in Italy of Friuli, Liguria, Marche, and Valle d'Aosta are declared free of swine vesicular disease in § 94.12(a) of this part. These regions either supplement their national pork supply by the importation of fresh (chilled or frozen) meat of animals from regions where swine vesicular disease is considered to exist, have a common border with such regions, or have trade practices that are less restrictive than are acceptable to the United States. Thus, the pork or pork products produced in such regions may be commingled with fresh (chilled or frozen) meat of animals from a region where swine vesicular disease is considered to exist, resulting in an undue risk of swine vesicular disease introduction into the United States. Therefore, pork or pork products and ship's stores, airplane meals, and baggage containing such pork, other than those articles regulated under part 95 or part 96 of this chapter, produced in such regions shall not be brought into the United States unless the following requirements are met in addition to other applicable requirements of part 327 of this title:

* * * * *

§ 94.17 [Amended]

■ 15. Section 94.17 is amended by removing the words ''hog cholera'' and adding in their place the words ''classical swine fever'' in the following places:

■ a. The section heading.

■ b. Paragraph (b).

■ c. Paragraph (c).

§ 94.20 [Amended]

■ 16. In § 94.20, paragraph (c) and the introductory text of paragraph (e) are amended by removing the words ''hog cholera'' and adding in their place the words ''classical swine fever''.

■ 17. A new § 94.23 is added to read as follows:

§ 94.23 Restrictions on the importation of swine, pork, and pork products from parts of the European Union.

In addition to meeting all other applicable provisions of this part, live swine, pork, and pork products imported from the region of the European Union consisting of Austria, Belgium, Germany (except for the Kreis Uckermark in the Land of Brandenburg; the Kreis Oldenberg, the Kreis Soltau-Fallingbostel, and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Prüm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsrücke, the Kreis Südliche Weinstrasse, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the Land of Saxony-Anhalt), Greece, Italy (except for the Regions of Emilia-Romagna, Piemonte, and Sardegna), the Netherlands, and Portugal must meet the following conditions:

(a) *Pork and pork products.* (1) The pork or pork products must not have been commingled with pork or pork products derived from swine that have been in any region when the region was classified in § 94.10(a) as one in which classical swine fever is known to exist;

(2) The swine from which the pork or pork products were derived must not have lived in a region when the region was classified in § 94.10(a) as one in which classical swine fever is known to exist, and must not have transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination; and

(3) The pork and pork products must be accompanied by a certificate issued by an official of the national government of the region of origin who is authorized to issue the foreign meat inspection certificate required by § 327.4 of this title, stating that the provisions of paragraphs (a)(1) and (a)(2) of this section have been met.[19]

(b) *Live swine.* (1) The swine must be breeding swine and must not have lived in a region when the region was classified in § 94.10(a) as one in which classical swine fever is known to exist, and must not have transited such a region unless moved directly through the region in a sealed means of

[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 importation of swine and swine products.

[19] 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.

conveyance with the seal determined to be intact upon arrival at the point of destination;

(2) The swine must never have been commingled with swine that were in a region at a time when the region was classified in § 94.10(a) as one in which classical swine fever is known to exist;

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

(4) The swine must be accompanied by a certificate issued by a salaried veterinary officer of the national government of the country of origin, stating that the provisions of paragraphs (b)(1) through (b)(3) of this section have been met.[20]

(c) The certificates required by paragraphs (a)(3) and (b)(4) of this section must be presented by the importer to the appropriate Customs and Border Protection officer at the port of arrival, upon arrival of the swine, pork, or pork products at the port, for the use of the veterinary inspector at the port of entry.

(Approved by the Office of Management and Budget under control number 0579–0218)

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

■ 18. 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.

§ 98.15 [Amended]

■ 19. Section 98.15 is amended by removing the words ''hog cholera'' and adding in their place the words ''classical swine fever'' in the following places:

■ a. Paragraph (a)(1)(ii).
■ b. Paragraph (a)(2)(ii).
■ c. Paragraph (a)(5)(ii)(B)
■ d. Paragraph (a)(7)(i)(B).
■ e. Paragraph (a)(8)(i)(B).

§ 98.34 [Amended]

■ 20. Section 98.34 is amended as follows:

■ a. By removing the words ''hog cholera'' and adding in their place the words ''classical swine fever'' in the following places:

■ i. Paragraph (c)(7)(ii).
■ ii. Concluding text of paragraph (c)(7)(iii) (following paragraph (c)(7)(iii)(G)).

■ b. In paragraph (c)(7)(iii)(D), by removing the words ''Hog cholera'' and adding in their place the words ''Classical swine fever''.

■ 21. A new § 98.38 is added to read as follows:

§ 98.38 Restrictions on the importation of swine semen from parts of the European Union.

In addition to meeting all other applicable provisions of this part, swine semen imported from the region of the European Union consisting of Austria, Belgium, Germany (except for the Kreis Uckermark in the Land of Brandenburg; the Kreis Oldenberg, the Kreis Soltau-Fallingbostel, and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Prüm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsrücke, the Kreis Südliche Weinstrasse, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the Land of Saxony-Anhalt); Greece, Italy (except for the Regions of Emilia-Romagna, Piemonte, and Sardegna), the Netherlands, and Portugal must meet the following conditions:

(a) The semen must come only from a semen collection center approved for export by the veterinary services of the national government of the country of origin;

(b) The donor boar must not have lived in a region when the region was classified in § 94.10(a) as one in which classical swine fever is known to exist, and must not have transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination;

(c) The donor boar must never have been commingled with swine that have been in a region when the region was classified in § 94.10(a) as one in which classical swine fever is known to exist;

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

(e) No more than 30 days prior to being held in isolation as required by paragraph (d) 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;

(f) 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 has first been cleaned and disinfected;

(g) The donor boar must be observed at the semen collection center by the center veterinarian, and exhibit no clinical signs of classical swine fever;

(h) Before the semen is exported to the United States, the donor boar must be held at the semen collection center 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; and

(i) The semen must be accompanied to the United States by a certificate issued by a salaried veterinary officer of the national government of the country of origin, 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 number 0579–0218)

PART 130—USER FEES

■ 22. The authority citation for part 130 continues to read as follows:

Authority: 5 U.S.C. 5542; 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 3701, 3716, 3717, 3719, and 3720A; 7 CFR 2.22, 2.80, and 371.4.

§ 130.14 [Amended]

■ 23. In § 130.14, paragraph (b), the table is amended in the column titled ''Test'' by removing the words ''(hog cholera)'' in the entry for Fluorescent antibody neutralization and adding in their place the words ''(classical swine fever)''.

■ 24. In § 130.18, paragraph (b), the table is amended by removing the entry for Hog Cholera tissue sets and adding a new entry in alphabetical order to read as follows:

§ 130.18 User fees for veterinary diagnostic reagents produced at NVSL or other authorized site (excluding FADDL).

* * * * *

(b) * * *

[20] 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.

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

Reagent	User fee	Unit
* * * * * *		
Classical swine fever tissue sets	81.50	Tissue set.
* * * * * *		

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Done in Washington, DC, this 2nd day of April 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

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