

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