

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,