

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