

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