

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