

though the prevalence of CSF in wild boars in Brandenburg had been determined to be under 1 percent, that apparently was enough to lead to infection of the domestic population. The commenter concluded that there is insufficient control of the potential sources of the introduction of CSF into herds in Germany to allow that country to be regionalized.

When we developed the risk analysis on which we based our proposed rule, we included among our assumptions the probability that CSF outbreaks would continue to occur in the EU, just as we must assume there is some chance of an outbreak of a particular disease in any country we currently consider free of that disease. Starting from the assumption that future outbreaks of CSF would occur, we evaluated the risk of disease spread based on the length of time between the occurrence of CSF infections and the time that control efforts, such as implementation of new restriction zones, took effect. We concluded that breeding swine, swine semen, and pork and pork products could be imported with extremely low risk from the region we were proposing to establish in the EU, under the conditions set forth in the proposal. It should be noted that the information and data we used for our risk analysis were from outbreaks that occurred in 1997–1998, which constituted one of the worst CSF epidemics in the EU in recent history.

#### *CSF in Germany*

One commenter stated that no scientific justification was provided in the proposed rule for identifying the Kreis Vechta, the Kreis Warendorf, and the Kreis Altmarkkreis Salzwedel as those regions in which CSF is considered to exist, or for how the risk from other areas in Germany was assessed.

As we explained in our proposed rule, in establishing geographic boundaries for the regions, we used the boundaries of the smallest administrative jurisdiction that has effective oversight of normal animal movements into, out of, and within that jurisdiction, and that, in association with national authorities if necessary, has the responsibility for controlling animal disease locally. In Germany, this administrative unit is a *kreis*.

We proposed to continue to consider the *kreis* listed above as regions in which CSF is known to exist because each had an outbreak of CSF during the 6 months prior to the time we developed our proposed rule. In assessing the risk from the remaining areas of Germany, we assumed, as

described above, that CSF outbreaks would continue in the EU, and we evaluated risk based on the length of time between the occurrence of infection in a region previously considered free of CSF by the EC and the time that control efforts took effect.

#### *Delay in Disease Detection*

In our proposed rule, we stated that, in 1997, an estimated 103 of 611 CSF outbreaks in the EU occurred outside any zones that were under restrictions because of CSF, and that, of those 103, only 1 was a swine semen collection center approved for export, and only 1 was a breeding operation that engaged in export sales. We stated further that epidemiological evidence suggests that the disease was present in various regions for 7 days to nearly 8 weeks before it was detected and the region was placed under restrictions. One commenter expressed concern that this demonstrated that several importations into the United States of semen and breeding stock could occur before a CSF outbreak is detected.

The commenter is correct in concluding that, with unmitigated importation, there is a significant risk of introducing CSF into the United States. Our risk analysis calculated that risk as a probability, and also calculated the probability if mitigation measures were applied. We evaluated the likely volume of imported products and the prevalence of infected versus noninfected products in the estimate of the probability that infected products would be imported. The risk of importing CSF-infected products is not zero but, as discussed in the risk analysis, is quite low. Of the products evaluated, the risk analysis identified swine semen as presenting the greatest risk. Therefore, we proposed that, in addition to the EU's routine biosecurity measures, before swine semen can be exported to the United States from the region in question, the donor boar must be held at the semen collection center for at least 40 days following collection of semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF.

#### *Compliance With Office International des Epizooties (OIE) Guidelines*

In discussing the quantitative risk analysis that we used as a basis for our proposed rule, we stated that one of the starting point assumptions we made was that OIE export guidelines are applied to the movement of animals and animal products within the EU. One commenter stated that, elsewhere in our proposal, we indicated we had to take into account that the EC released certain

areas from restrictions prior to completion of a 6-month waiting period. The commenter expressed concern that our risk analysis appeared to be using an assumption that is not supported by current practice in the EU, and requested further documentation of adherence to the OIE standard before the proposed rule was made final.

Although we stated that we expected that OIE export guidelines would be applied to movement of animals and animal products within the EU, we did not build that assumption into our quantitative risk assessment. The quantitative assessment was based on the waiting periods actually used by the EU during the 1997–1998 epidemic. With regard to guidelines for export to the United States, whether a region is certified as being free of CSF must be based on U.S. criteria (*i.e.*, at least 6 months must have passed since eradication of the last outbreak of the disease).

One commenter stated it was not possible to determine from the site visit reports done prior to the proposed rule whether movement and import controls complied with EU directives. Additionally, said the commenter, information was not presented regarding compliance with directives regarding truck washing.

When conducting its site visit, the review team observed compliance with EC directives, truck washing, and tracking of swine movements through the “SANITEL–V” and “ANIMO” databases. (The SANITEL–V database is a computerized database in Belgium that contains information on animal identification, farm registration, and animal movements. The ANIMO database is an EU-wide database that contains origin, destination, and movement information regarding animal movements within the EU.)

#### *Notification of Change in Disease Status*

One commenter stated that the proposed rule did not describe the process by which the EU would notify APHIS of a change in regionalization status and how timely we expected that notification to be. The commenter stated additionally that the proposed rule included no discussion of the process by which APHIS would accept or reject a regionalization decision and the impact of that process on EU exports of animals and animal products to the United States.

The U.S.-EU Equivalency Agreement (an agreement covering sanitary measures affecting U.S.-EU trade in all animals and animal products) requires written notification, within 24 hours, of a change in disease status. If the EU