

States via the import of semen is much less than the one estimated in the risk analysis, based on the following reasons:

- Although the swine semen simulation model used in the risk analysis assumes that an outbreak of CSF occurs each 2 years in a semen collection center in the region being analyzed, between 1991 and 2002 only one CSF outbreak occurred in a semen collection center in the region in question.
- Although the risk analysis assumed that the “risky period” in the case of an outbreak in a semen collection center would last as long as in any other pig holding—*i.e.*, 3–4 weeks on average—this does not correspond to what actually happened in the Netherlands in 1997, when CSF was introduced into a swine semen center and was recognized in other swine holdings in the vicinity of the center well before confirmation of the disease in the center itself.
- Improvements have been made through EC legislation to reduce the risk of spreading CSF through swine semen. This legislation took into account the experiences of the 1997–1998 outbreak.

The commenter requested that APHIS eliminate the requirement that semen collected in the EU region in question be held for 40 days before being exported to the United States. The commenter further requested that, if APHIS believes that some mitigating measures on the importation of semen are necessary, it consider alternative measures such as the testing of semen before exportation by virological tests.

We are making no changes based on this comment. The application of a 40-day hold on semen was based on the results of the risk assessment we conducted for the proposed rule, which indicated that, without mitigation, the importation of swine semen from the EU region in question would present a disproportionate risk of introducing CSF into the United States. The 40-day hold was determined to be an effective mitigation measure. If we receive a request from a member of the public to consider an alternative means of mitigation, along with supporting information with which to evaluate such a request, or if we receive information that indicates that no mitigation measures may be necessary, we will conduct an assessment of the risk of importing swine semen into the United States under the conditions suggested. If such an assessment indicates that the change would be appropriate, we will publish, in accordance with the Administrative Procedure Act (APA), a proposal in the **Federal Register** to change the

regulations accordingly, and provide an opportunity for other members of the public to comment on the proposed action.

The commenter also stated that the provisions of the final rule should reflect the current CSF situation in the EU, not the situation in 1999.

We published our June 1999 proposal in response to a request from the EC that we consider a multi-country area in the EU as one region, and we conducted an analysis of the risk of the introduction of CSF from that region at that time. In accordance with the APA, we invited comments on the proposed rule and are addressing in this final rule the comments we received. We are receptive to requests for further changes to the regulations and will address such changes through notice and comment rulemaking in accordance with the APA. If the existing situation appears to warrant a new analysis, we will conduct one.

One commenter raised a number of issues regarding our proposed rule and specific provisions of the risk analysis. We address below the issues raised by that commenter in a comment/response format.

*Comment:* APHIS’ scientific approach toward the regionalization of the EU and its member States and sublevels seems to differ from APHIS’ approach to other countries or regions. Continuing outbreaks of CSF in the EU call into question the ability of the EU to apply appropriate disease control measures and how APHIS can evaluate risk in a dynamic situation.

*Response:* We agree that the approach we proposed to regionalizing the EU is somewhat different from the way we have historically approached other regionalization actions. This is due to the nature of the request from the EU, which asked that multiple countries be considered as one region, and the infrastructure and regulatory factors specific to the region in question. In recognition of what the commenter refers to as a “dynamic situation,” the risk analysis we developed recognized the possibility of continuing sporadic CSF outbreaks in the EU region in question, and the risks associated with these outbreaks, rather than looking at a specific geographic area as free of the disease. Risk was defined as a quantitative probability based on the disease history of the region and was approached on a commodity basis, rather than as an evaluation of disease status. The approach in our risk analysis and proposed rulemaking is consistent with APHIS’ obligation under the World Trade Organization Agreement on Sanitary and Phytosanitary Measures

(WTO–SPS Agreement) to recognize not only disease-free areas, but also areas of low disease prevalence for which mitigations can be established to reduce risk.

*Comment:* CSF has been diagnosed in numerous locations in the EU since the data for the revised risk analysis was collected, and these new data should be incorporated into a risk analysis to allow for an accurate conclusion. We believe an outbreak in domestic swine in France in 2002 due to exposure to wild boar contradicted an assumption in the risk analysis that CSF outbreaks in domestic swine in France do not occur due to exposure to wild boar. The descriptive observations in the risk analysis do not predict clearly where outbreaks may occur and, although APHIS stated in its risk analysis that an historical reduction in the spread of CSF from wild boar could be attributed to EU surveillance and control activities, those activities were considered inadequate by the EU to counter outbreaks that occurred after publication of the June 1999 proposed rule, as evidenced by the EC’s decision in May 2002 to take further measures for the control of CSF.

*Response:* Much of the data used in the risk analysis were generated during an extremely severe CSF epidemic that occurred in the EU in 1997 and 1998. As discussed in the risk analysis, this CSF epidemic is considered the most severe the EU has ever experienced. The risk estimates generated in the analysis took into account the effectiveness of EU control measures, and where these measures failed, under these severe conditions. The risk analysis, therefore, anticipates future CSF epidemics of the same magnitude and the same level of detection and control failures as occurred during the 1997–98 epidemic. Given that recent CSF epidemics have been of a lesser magnitude and reflect fewer failures in detection and control, they fall within the expectations of the current risk analysis. Incorporating the data from these recent epidemics into the analysis would likely reduce the estimated risk.

We do not agree that our risk analysis assumed that CSF outbreaks in domestic swine in France do not occur due to exposure to wild boar. The statement that, at the time of the risk analysis, there had not been a CSF outbreak in France was not meant to imply that outbreaks in domestic swine do not occur due to exposure to wild boar, but was simply an observation of what had or had not occurred. The risk analysis recognized the possibility of continuing sporadic outbreaks anywhere in the EU. As discussed above, given that recent CSF epidemics are of a lower magnitude