

1997). The regulations set out the process by which a foreign government may apply to have all or part of a country recognized as a region or for approval to export animals or animal products to the United States under conditions based on the risk associated with animals or animal products from that region. Our intention was for these regulations to tell veterinary officials of foreign governments that have different risk levels within the country or extending across national boundaries and that wish to begin exporting animals or animal products to the United States how to request an initial evaluation of animal disease status or conditions for import of commodities. We did not intend for these regulations to apply in circumstances where an outbreak of a disease in a region previously recognized as disease-free, or an increased incidence of disease in a foreign region makes it necessary for the United States to take interim measures to protect its livestock from the foreign animal disease. In these cases, APHIS must take immediate action to prohibit or restrict imports from the region that now presents a disease concern, and the scope of that action may be limited to the portion of the region that presents the disease risk. Such action may include publishing an interim rule to provide an appropriate basis for enforcing prohibitions or restrictions that may initially be announced administratively. In these circumstances, APHIS has a responsibility to take whatever measures appear necessary to prevent the introduction of disease. We believe that publishing a proposed rule for comment would be contrary to the public interest because doing so would delay our taking protective actions. We also believe that making the information upon which we base our decisions for establishing a region via an interim rule available to the public for comment prior to publishing the interim rule would also be contrary to the public interest for the same reason. In the case of East Anglia, we felt that risk considerations justified our regionalization approach. However, we understand the commenter's concerns, and we have taken actions to address them. One of the actions we took in this case was the preparation of a risk assessment on the disease status of East Anglia, which we made available to the public for comment prior to this final rule.

We took action at a regional level in the case of East Anglia because we believed that the disease situation warranted it. We already had extensive

information about the region, including information on the authority, organization, and infrastructure of the veterinary services organization of the region; the extent to which movement of animals and animal products is controlled from regions of higher risk, and the level of biosecurity for such movements; livestock demographics and marketing practices in the region; the type and extent of disease surveillance conducted in the region; diagnostic laboratory capabilities in the region; and the region's policies and infrastructure for animal disease control, *i.e.*, the region's emergency response capacity. This information provided the basis for our previous recognition of the region as free of the disease. Our obligations under international trade agreements compel us to take no more restrictive actions than necessary to prevent the introduction of disease. Unless we determine that this information is no longer reliable, it should provide a rational basis for believing that the region can effectively control an outbreak within a smaller region.

#### **Unjustified Emergency Action**

*Comment:* While the CSF outbreak in East Anglia presented an emergency situation justifying the issuance of an interim rule in order to protect against the introduction of CSF into the United States, the specific action APHIS took was not justified. The emergency situation only justified an interim rule removing all of Great Britain from the list of CSF-free regions, and any action with respect to regionalizing East Anglia should have been handled according to the procedures in § 92.2.

*Response:* As explained previously, we believe that it was appropriate to limit the scope of our action to the specific region of East Anglia, given the specific disease situation and the extensive information we already possessed about East Anglia and Great Britain as a whole. Given these factors, we are confident that we had sufficient justification for taking action with respect to East Anglia on an emergency basis to protect against the introduction of CSF into the United States. We believe that any action to remove all of Great Britain from the list of CSF-free regions would have been unnecessary and unjustified.

#### **Veterinary Equivalency Agreement**

*Comment:* The Veterinary Equivalency Agreement (VEA) signed by the United States and the European Union (EU), which includes provisions concerning the recognition of regionalization decisions taken by the parties with respect to certain diseases,

does not supercede or change U.S. statutory or regulatory law regarding regionalization. Thus, APHIS should have followed its procedures in part 92 in regionalizing East Anglia for CSF.

*Response:* The action that we took regarding East Anglia was not related to the VEA. As noted elsewhere in this document, we believe our action was consistent with our regulations and statutory authority, neither of which was affected by the VEA.

#### **Inconsistency With Other Regionalization Requests**

*Comment:* APHIS has received requests from the EU to recognize certain regions in the EU as free of specified animal diseases, but has not yet made any decisions or changes to the regulations based on these requests. How was APHIS able to reach a decision about the disease-free status of Great Britain with the exception of East Anglia while the other regionalization requests it had received from the EU have been under consideration since June 1999?

*Response:* The request that we received from the EU related to a much larger region that was not already recognized as free of CSF. In addition, that request related to establishing a single region composed of multiple countries, some of which continue to experience outbreaks of CSF. Immediate action at a regional level was not necessary in the case of the EU as it was for East Anglia. The amount of time necessary to reach a decision in these two situations is not comparable because the two situations are not comparable.

One factor that influenced the comparative speed of the evaluation of Great Britain in comparison with the evaluation of other EU regions was that Great Britain was already recognized individually as disease-free. In comparison, other EU regions under consideration were not previously recognized as disease-free, and several of these regions continue to experience periodic outbreaks of CSF. In addition, our long-standing trade relationship with Great Britain provided us with the information necessary to reach a decision about the disease status of the entire country. This particular outbreak was a temporary emergency situation that was ultimately limited to 16 sites in a particular region of the country and was contained and eradicated quickly.

#### **Future Procedures**

*Comment:* Veterinary infrastructure and animal health authorities of the United Kingdom are highly professional and extremely conscientious, and