Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 98

[Docket No. 02–046–1]

RIN 0579–AB79

Importation of Swine and Swine Products From the European Union

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations for importing animals and animal products into the United States to apply a uniform set of importation requirements related to classical swine fever (CSF) to a region consisting of all of the 15 Member States of the European Union (EU) that comprised the EU as of April 30, 2004 (the EU–15) and prohibit for a specified period of time the importation of live swine and swine products from any area in the EU–15 that is identified by the veterinary authorities of the region as a restricted zone. We believe these changes are necessary to help prevent the introduction of CSF into the United States while increasing our responsiveness to changes in the CSF situation in the EU.

DATES: We will consider all comments that we receive on or before June 7, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. 02–046–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–046–1.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Chip Wells, Senior Staff Veterinarian, Regionalization Evaluation Services Staff, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country. The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including classical swine fever (CSF), rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, swine vesicular disease, and African swine fever.

Sections 94.9 and 94.10 of the regulations state that CSF is known to exist in all regions of the world, except for those regions listed in §§ 94.9(a) and 94.10(a). The importation of live swine and swine products from regions not recognized as free of CSF is restricted or prohibited. In addition, the importation of live swine and swine products from a region consisting of certain Member States and portions of Member States of the European Union (EU) is restricted with regard to CSF, even though that region is listed as free of the disease. The restrictions on imports from that region were established in a final rule published in the **Federal Register** on April 7, 2003 (68 FR 16922–16941, Docket No. 98–090–5).

We based our final rule primarily on two risk analyses conducted by APHIS.[1] [2] The risk analyses examined a region consisting of EU countries (Member States) that the European Commission (EC) asked us to recognize as free of CSF. (The EC is the EU institution responsible for representing the EU as a whole. It proposes legislation, policies, and programs of action and implements decisions of the EU Parliament and Council.) The Member States identified were Austria, Belgium, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, and Spain. Five other EU Member States—Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom—were already recognized by APHIS as being free of CSF.

The first risk analysis was made available to the public in 1999 at the time of publication in the **Federal Register** of the proposed rule (64 FR 34155–34168, Docket No. 98–090–1) upon which we based our April 2003 final rule. The second risk analysis was released in 2002 for public comment (67 FR 22388–22389, Docket No. 98–090–2) and represented a revision and supplementation of the 1999 risk analysis. Data used in both risk analyses represented events that occurred during a CSF epidemic in Europe during 1997 and 1998. That outbreak is considered to be the most severe CSF epidemic ever experienced in Europe. Both risk analyses are available by calling or writing to the person listed in this

[1] Biological Risk Analysis: Risk assessment and management options for imports of swine and swine products from the European Union—June 2, 1999.

[2] Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union—December 2000.

document under **FOR FURTHER INFORMATION CONTACT.** The analyses are also available on the Internet at *http://www.aphis.usda.gov/vs/ncie/reg-request.html.* At the bottom of that Web site page, click on ''Information previously submitted by Regions requesting export approval and supporting documentation.'' At the next screen, click on the triangle beside ''European Union/Not Specified/Classical Swine Fever,'' then click on the triangle beside ''Response by APHIS,'' which will reveal links to the risk analyses.

The analyses took into account, among other things, the CSF history of the EU region consisting of the 10 Member States in the EC's request, the CSF history of countries adjacent to the region, the veterinary infrastructure and policies of the region, and the historical volumes of imports into the United States of breeding swine, swine semen, and pork and pork products from the region.

Based on the analyses, we considered it necessary to establish certain mitigation measures for the importation of live swine, pork and pork products, and swine semen from the region. Although there were no CSF outbreaks in EU domestic swine within the defined region at the time, the risk analyses assumed that, because CSF was endemic in wild boar in several parts of the EU, it was likely CSF would continue to occur in domestic swine in the region. Further, the risk analyses considered the open borders among EU Member States. To address these situations, the final rule required that commodities from the region of the EU that was considered to be unaffected with CSF be segregated from those from CSF-affected regions of the EU and other CSF-affected regions, and that measures be taken to ensure that donor boars providing semen for export to the United States are truly free of CSF. These requirements are described below under the heading ''Importation Conditions Established in April 2003.''

Importation Conditions Established in April 2003

Specifically, our April 2003 final rule required that the following conditions be met before the commodity in question could be imported into the United States (in the absence of any other diseases of swine that would otherwise prohibit importation):

- *For pork and pork products:* (1) The articles have not been commingled with pork or pork products derived from swine that have been in a region listed at the time as one in which CSF is known to exist; (2) the swine from which the pork or pork products were derived have not lived in a region listed at the time as one in which CSF is known to exist, and have not transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination; and (3) the articles are accompanied by a certificate, issued by an official of the national government of the region of origin, stating that the above provisions have been met.
- *For breeding swine:* The swine (1) have never lived in a region listed at the time as one in which CSF is known to exist; (2) have never transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination; and (3) have never been commingled with swine that have been in a region listed at the time as one in which CSF is known to exist. Additionally, no equipment or materials used in transporting the swine may have previously been used for transporting swine ineligible for export to the United States unless the equipment or materials first were cleaned and disinfected. Lastly, the swine have to be accompanied by a certificate, issued by a salaried veterinary officer of the national government of the country of origin, stating that the above provisions have been met.
- *For swine semen:* The donor boar meets the same conditions as those listed above for breeding swine. Additionally, the following conditions must be met: (1) The semen comes from a semen collection center approved for export by the veterinary services of the national government of the country of origin; (2) the donor boar is held in isolation for at least 30 days prior to entering the semen collection center, and, no more than 30 days prior to being held in isolation, is tested with negative results using a CSF test approved by the Office International des Epizooties (OIE) [also referred to as the World Organisation of Animal Health]; and (3) the donor boar is observed by the semen collection center veterinarian while at the center (including at least a 40-day holding period at the center following collection of the semen) and, along with all other swine at the center, exhibits no clinical signs of CSF.

Under these conditions, we estimated that the risk of introducing CSF through imports from the defined region would be as follows:

- By importing breeding swine, most likely one incursion in an average of 33,670 years.
- By importing fresh pork, most likely one incursion in an average of 22,676 years.
- By importing swine semen, most likely one incursion in an average of 8,090 years.

APHIS considered each of these risks to be low.

We continue to consider the mitigation measures established in our April 2003 final rule to be necessary for the importation of breeding swine, pork and pork products, and swine semen from the EU region we recognized in that final rule, and to France and Spain, which were added to that region following publication of the April 2003 final rule in a final rule published on April 20, 2004 (69 FR 21042–21047, Docket No. 98–090–7). Under this proposed rule, those requirements would continue to apply.

Additionally, we are proposing to apply the measures established in our April 2003 final rule to importations from five additional EU Member States whose exports to the United States are free of CSF-related restrictions (Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom [consisting of England, Scotland, Wales, the Isle of Man, and Northern Ireland]), as well as to Luxembourg (which is currently listed as a region in which CSF exists, due to an outbreak of the disease following our June 1999 proposal) and all of Germany and Italy. Currently, only portions of Germany and Italy are recognized as free of CSF in our regulations. We would apply the same mitigation measures to each of the areas described above because we would recognize the combination of all of those areas of the EU as a single region of low-risk for CSF, discussed below. The region would be comprised of the 15 Member States comprising the EU as of April 30, 2004, which we refer to as the *European Union–15 (EU–15).* We would add a definition of *European Union–15 (EU–15)* to §§ 93.500, 94.0, and 98.30.

We discuss below, under the heading ''Uniform Conditions for Imports from the EU–15,'' our proposed application of uniform import conditions to the EU–15 with regard to CSF. We then discuss the reasons we believe the EU–15 qualifies as a region of low-risk for CSF under the heading ''Basis for Recognition of an EU Region.''

Uniform Conditions for Imports From the EU–15

As noted above, we are proposing to recognize a single region for CSF (the EU–15) that would consist of the following areas: (1) That region of the EU we now recognize as being free of

CSF but from which imports of swine and swine products are subject to specified restrictions; (2) Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom (consisting of England, Scotland, Wales, the Isle of Man, and Northern Ireland); and (3) Luxembourg and all of Germany and Italy. Currently, only portions of Germany and Italy are recognized as free of CSF in our regulations.

In our April 2003 final rule, we did not include Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom in the EU region we defined as free of classical swine fever but from which the importation of swine and swine products are subject to certain restrictions. Those five Member States had already been recognized in previous rulemakings as regions in which CSF is not known to exist and from which swine and swine products may be imported into the United States without restriction related to CSF. We continued to treat those Member States in the same way we had been treating them since the time we recognized them as free of CSF; that is, we did not apply to them the additional mitigation measures we were applying to the EU region we recognized in the April 2003 final rule.

However, because we had recognized those five Member States as free of CSF before the EU was established, the evaluations we had conducted that supported such a classification of freedom did not take into account the opening of national borders within the EU and the possibility that the five CSF-free Member States would trade freely with EU Member States that we considered CSF-affected.

As part of the EU, those five Member States carry out trade with the rest of the EU under what is essentially an open-border trading policy. There is no substantive difference between the way trade is carried out within the EU by those five Member States compared to the way it is carried out by other Member States. Because of these open-border policies, we believe the CSF risk from the five member States must be considered the same as from the EU region we recognized as subject to additional mitigation measures in our April 2003 final rule, and the same importation conditions would be applied to both areas under this proposed rule.

Additionally, we are proposing to apply those importation conditions to parts of the EU that we have not yet recognized as CSF-free. In our April 2003 final rule, we excluded certain parts of the EU—in some cases entire Member States—from the region we recognized as CSF-free, either because those areas were not eligible for recognition as CSF-free at the time we published the proposal for our April 2003 final rule, or because they experienced an outbreak of CSF in domestic swine following publication of that proposed rule. Those areas included all of France and Spain—which have since been added to the region of the EU we consider free of CSF with restrictions—all of Luxembourg, and parts of Germany and Italy. In Germany, we excluded the following kreis: the Kreis Uckermark in the Land of Brandenburg; the Kreis Oldenberg, the Kreis Soltau-Fallingbostel, and the Kreis Vechta in the Land of Lower Saxony; the Kreis Heinsberg and the Kreis Warendorf in the Land of Northrhine-Westphalia; the Kreis Bernkastel-Wittlich, the Kreis Bitburg-Prüm, the Kreis Donnersbergkreis, the Kreis Rhein-Hunsrüche, the Kreis Südliche Weinstrasse, and the Kreis Trier-Saarburg in the Land of Rhineland Palatinate; and the Kreis Altmarkkreis in the Land of Saxony-Anhalt. In Italy, we excluded the Regions of Emilia-Romagna, Piemonte, and Sardegna.

Whether we excluded an entire Member State or a smaller administrative unit depended on whether we had identified in the June 1999 proposed rule the administrative unit we would recognize as a region within a particular Member State in the event of a CSF outbreak. We had identified such administrative units for Germany and Italy (the ''kreis'' in Germany and the ''region'' in Italy), but not for the other Member States of the EU.

We are now proposing to apply the certification requirements established by our April 2003 final rule to all the areas in Italy and Germany listed above and to Luxembourg. In addition, we would require the EC to certify that commodities (breeding swine, swine semen, and fresh pork and pork products) are not exported from—and have not been commingled with swine from—restricted zones in the EU during the following time periods: (1) A period of 6 months after the last case of CSF in domestic swine in the restricted zone; or (2) until restrictions put in place by the EU because of CSF in wild boar in the restricted zone are released. We consider this action warranted because we consider the EU to be an homogeneous region of low CSF risk (although one in which CSF outbreaks may continue to occur) and because the EC has appropriate control measures in place to mitigate the risk of continuing outbreaks.

We consider the EU to be homogeneous with regard to CSF despite the fact that we have treated certain kreis in Germany and Regions in Italy slightly differently from the rest of those countries during our rulemaking process. Our June 1999 proposed rule excluded three kreis in Germany and three Regions in Italy from consideration as part of the region recognized in our April 2003 final rule. Because these areas had experienced outbreaks within 6 months before collection of data for the 1999 risk analysis, the model excluded consideration of exports from those areas. Exclusion of those areas was a policy decision based on the regionalization approach being used by APHIS at the time.

However, the model used for the risk analysis was based on the assumption that outbreaks would continue to occur in the EU. Even with this assumption, the risk analysis concluded that the risk of exporting CSF from the EU in breeding swine, swine semen, and fresh pork was low. Outbreaks did, in fact, occur in some German kreis other than the three excluded from the June 1999 proposed rule—as well as in France, Spain, and Luxembourg, which were subject to the June 1999 proposed rule—and to provide the public an opportunity to comment upon the outbreaks, we did not include those kreis and Member States in our April 2003 final rule. However, we consider the CSF risk posed by commodities from the German kreis and Italian Regions that were excluded from the proposed rule, as well as from those areas and Member States that had outbreaks subsequent to the proposed rule, to be equivalent to the CSF risk from the other EU–15 Member States (as discussed above, in April 2004 we added France and Spain to the EU region we recognized in April 2003). We consider the risk from the EU–15 as a whole to be within the parameters of the risk analysis, and believe the risk from continuing CSF outbreaks in any part of the EU–15 would be adequately mitigated by the control mechanisms implemented in the EU.

Thus, we are proposing to apply the same import conditions for swine and swine products with regard to CSF to a region consisting of all of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, the Republic of Ireland, Spain, Sweden, and the United Kingdom. The conditions for pork, pork products, and live swine would be set forth in § 94.24. The conditions for swine semen would be set forth in § 98.38.

The EU–15 as a Region of Low Risk for CSF

In evaluating the CSF risk from imports of breeding swine, swine semen, and swine products from the EU–15, we took into consideration the following characteristics of that region:

- The region contains a known source of CSF risk (*e.g.*, infected wild boar) that may spread the disease virus to EU domestic swine, resulting in continuing outbreaks of CSF in the region, but veterinary officials in the region have established risk mitigation measures adequate to prevent widespread exposure and establishment of the disease;
- Specific mitigation measures in place include surveillance, epidemiological investigations, diagnostic capability, and emergency response capacity that are sufficient to identify the disease, establish appropriate control zones, and implement all measures necessary to effectively limit the spread of CSF from the region; and
- Veterinary officials maintain contingency plans defining proactive approaches to CSF control: The veterinary officials have sufficient legal powers, a detailed chain-of-command, and appropriate resources, including emergency funds, laboratory staff, equipment and infrastructure, to carry out a rapid and effective eradication campaign; there is an instruction manual detailing all procedures, instructions, and measures, including emergency vaccination plans if deemed necessary, to be implemented in the event of a CSF outbreak; and appropriate staff regularly receive training and conduct drills in CSF diagnosis, control measures, and communication techniques.

Included in the EC request to APHIS that resulted in our April 7, 2003, final rule was a request that was made in the context of the Veterinary Equivalence Agreement (VEA) between the United States and the EU, which was enacted in 1998. (The stated objective of the VEA is to facilitate trade in live animals and animal products between the EU and the United States by establishing a mechanism for the recognition of equivalence of sanitary measures, consistent with the protection of public and animal health, and improve communication and cooperation on sanitary issues.) The EC requested that APHIS adopt the EC approach to regionalization for CSF. This would require APHIS to establish a new approach to dealing with outbreaks of CSF in the EU–15. As a result of our review of the information provided, we are proposing to establish a new approach that will adopt many elements of the EC approach to dealing with outbreaks of CSF in the EU–15. Rather than responding to outbreaks through rulemakings specific to each outbreak, we are proposing in this document to establish actions that we would take in the event of a CSF outbreak in the region. Our proposal and the way in which it differs from current practice is explained below. While the approach we are proposing would, in this case, apply specifically to the EU–15, we would accept requests and supporting information from other regions interested in being considered for a similar approach.

Currently, § 92.3 of the regulations provides that whenever the EC establishes a quarantine for a disease in the EU in a region APHIS recognizes as one in which the disease is not known to exist and the EC imposes prohibitions or other restrictions on the movement of animals or animal products from the quarantined area in the EU, such animals and animal products are prohibited importation into the United States. Additionally, APHIS published a final rule on May 4, 2004 (69 FR 25817–25820, Docket No. 02–001–2) that established procedures to follow when a region that we recognize as free of an animal disease experiences an outbreak of that disease. If a region of the world that is considered free of CSF experiences an outbreak of CSF, APHIS will prohibit or restrict immediately the importation of live swine, fresh pork and pork products, and swine semen from that region into the United States. We then may publish an interim rule in the **Federal Register** as soon as possible that removes that region from the lists in §§ 94.9 and 94.10 of the regulations of regions in which CSF does not exist and that prohibits or restricts, by regulation, the importation of live swine, fresh pork and pork products, and swine semen. We accept public comment on the interim rule for a specified period of time. If the outbreak is eliminated in the region in question and a sufficient amount of time passes (generally defined as consistent with OIE recommendations) to ensure that the disease has been eradicated, we evaluate the risk of resuming imports from the region. If we believe the results of the risk evaluation support reinstatement of the region's previous CSF-free status and resumption of the importation of the prohibited swine and swine products into the United States, we make the evaluation available to the public and solicit public comment on it. If, after considering the public comments, we still consider it warranted to reinstate the region's CSF-free status, we publish a final rule in the **Federal Register** listing the region as free of CSF, and we allow importations of swine and swine products to resume.

We are proposing in this document that, whenever an outbreak of CSF occurs in the EU–15 and the competent veterinary authority of the EU–15 Member State establishes a quarantined area for CSF (also referred to in this document as a ''restricted zone''), swine and swine products will be prohibited importation into the United States from that zone. No action would be required by APHIS; the prohibition would take effect immediately. Swine and swine products would not be allowed importation from the region unless they are accompanied by certification by an official of the competent veterinary authority of the EU–15 Member State that the prohibitions set forth in this proposed rule regarding restricted zones (discussed below) have been met.

In the case of an outbreak of CSF in EU domestic swine, the importation prohibitions would remain in effect for 6 months following the depopulation of swine and the cleaning and disinfection of the last infected premises in the restricted zone, even if the competent veterinary authority of the EU–15 Member State removes its designation of the area as a restricted zone before 6 months have elapsed. In the case of a restricted zone established because of the detection of CSF in wild boar, the importation prohibitions would remain in place until the competent veterinary authority of the EU–15 Member State removes its designation of the area as a restricted zone. (The issue of wild boar is discussed further in this document under the heading ''Wild Boar.'') The lifting of the prohibitions on imports into the United States from a restricted zone would take effect at the times described above. No action by APHIS would be required. However, APHIS would reserve the right to make site visits and review documentation related to the outbreak and eradication activities. In considering the CSF risk in the EU–15, we evaluated both the ability of officials in that region to ensure that such restricted zones would be effectively established and maintained and the ability of the officials to ensure that prohibitions on the importation into the United States of swine and swine products from the restricted zones would be effectively enforced.

In §§ 94.0 and 98.30, we would define *restricted zone for classical swine fever* to mean an area, delineated by the relevant competent veterinary authorities of the region in which the

area is located, that surrounds and includes the location of an outbreak of CSF in domestic swine or detection of the disease in wild boar, and from which the movement of domestic swine is prohibited. We are not proposing to specify how far from an outbreak a restricted zone must extend because factors such as geographic boundaries could influence the necessary distance. However, we did evaluate the policies of the EC for establishing restricted zones when considering whether to consider the EU–15 as a region of low-risk for CSF. This is discussed in more detail below under ''EU Animal Health Controls.''

We believe this new approach is warranted for the EU–15 because that region has demonstrated the capability to effectively prevent the spread of CSF from areas where outbreaks occur. Plus, as a precautionary measure, imports of swine and swine products from the EU–15 into the United States will be restricted to address the recognized probability of these outbreaks occurring from time to time.

Because we are proposing to recognize the EU–15 as a single region that poses a low risk for CSF, we would remove from §§ 94.9(a) and 94.10(a) of the regulations the EU–15 Member States currently listed as regions in which CSF is not known to exist. The EU–15 would be included in proposed §§ 94.9(b) and 94.10(b) as a single region of low-risk for CSF.

Basis for Consideration of the EU–15 as a Region of Low-Risk for CSF

We believe that consideration of the EU–15 as a single low-risk region for CSF is warranted based on the risk analyses described above, upon which we based on our April 2003 final rule, and on our knowledge of the veterinary infrastructure and legislation in the EU. These considerations are discussed in detail in an APHIS document titled ''APHIS Risk Considerations on Importation of Classical Swine Fever (CSF) Virus in Breeding Swine, Swine Semen, and Fresh Pork from a European Union Region of Fifteen Member States.'' The document can be obtained by calling or writing to the person listed in this document under **FOR FURTHER INFORMATION CONTACT**. It is also available on the Internet at *http://www.aphis.usda.gov/vs/ncie/reg-request.html.* At the bottom of that Web site page, click on ''Information previously submitted by Regions requesting export approval and supporting documentation.'' At the next screen, click on the triangle beside ''European Union/Not Specified/Classical Swine Fever,'' then click on the triangle beside ''Response by APHIS,'' which will reveal a link to the document.

The estimates of risk in the analyses we conducted regarding CSF in the EU–15 suggest that the EU's control mechanisms, combined with the risk mitigation measures we established in the April 2003 final rule, are sufficiently effective to mitigate the risk of introducing the CSF virus to the United States via exports of the swine and swine products that would be eligible for importation into the United States under this rule.

The risk estimated in the risk analyses regarding the EU that we conducted in 1999 and 2000 was based on quantitative data reflecting the effects of EU regulations that were in place during a severe CSF outbreak in 1997 and 1998 that occurred extensively in the Netherlands and that spread to other EU Member States. Although the outbreak was considered the most severe the EU ever experienced and CSF did spread during that outbreak, our quantitative estimates of risk showed that the risk to the United States of CSF introduction due to that most severe outbreak was low. Since that outbreak, the EU has implemented measures to strengthen its response to a CSF outbreak. Therefore, with the continued application of EU regulations, any risk from future CSF outbreaks in the EU–15 is expected to also be low, unless an outbreak occurs that is more severe than the one in 1997–1998—*i.e.*, that poses a risk greater than that evaluated in the analysis. In the event of a more severe outbreak or any other circumstance the Administrator considers to pose a risk (such as evidence of unreported CSF outbreaks or significant deterioration of veterinary infrastructure or control in the region), the APHIS Administrator would reserve the right to take whatever action is necessary to ensure that CSF is not introduced into the United States.

EU Animal Health Controls

In general, our proposed classification of the EU–15 as a region of low risk for CSF is based on continued adherence in the Member States to EU animal health controls, some of which are described below, as well as on the measures we established in our April 2003 final rule. However, in one way, we believe it is necessary to require a measure that exceeds the EU controls. This measure has to do with the length of time the prohibition on the importation into the United States of swine and swine products from a restricted zone is maintained. We discuss this measure at greater length below, under the heading ''Prohibition of Importations from a Restricted Zone.''

Animal health regulations imposed in the EU are harmonized and binding upon all Member States. Requirements include compulsory notification of OIE List A diseases, including CSF, and laboratory testing for CSF on all sick swine if CSF is suspected. Member States are required to have CSF contingency plans and, if applicable, eradication plans for CSF in wild boar populations.

Swine are moved freely among EU Member States and within Member States. Swine born in one Member State are routinely fattened or slaughtered in another. Animals moving between Member States are required to be accompanied by an official health certificate issued by an official veterinarian appointed by the competent veterinary authority of the Member State. Prior notification of the movement is reported electronically through an electronic network linking authorities of the EC and Member States.[3]

Farm registration is mandatory, and each holding is assigned a unique identification number by the competent veterinary authority of the Member State. Animal identification is compulsory. Breeding swine must be identified with a unique identification number (either by ear tag or tattoo), and fattening swine must be identified by the holding registration number. This information is maintained by each Member State.

If CSF is detected anywhere in the EU, control mechanisms are activated in accordance with EU legislation. When CSF is suspected on a swine holding, a clinical investigation is conducted by the competent veterinary authority of the Member State to confirm or rule out the disease, and an epidemiological investigation is carried out. Movement of swine from the holding under suspicion is prohibited, and biosecurity measures are implemented to prevent spread of the disease.

If CSF is confirmed, all swine on the holding containing infected swine must be depopulated, and the carcasses must be disposed of after being treated to inactivate the CSF virus under official supervision. Two types of zones are

[3] TRACES (Trade Control and Export System) is replacing ANIMO by the end of 2004 as the computerized system mandated by EU law to track animal and animal product movement between Member States, as well as to track imports from non-EU countries into the EU. Data are entered by local veterinary authorities in each Member State and are shared over a network with the rest of the EU. The system is administered by a private contractor under the oversight of the EC and the EU Court of Auditors.

established around an outbreak of CSF in EU domestic swine—''protection zones'' and ''surveillance zones.'' The protection zone extends at least 3 kilometers from the outbreak. The surveillance zone extends at least 10 kilometers from the outbreak. For the purpose of our regulations, we would consider the combination of an EU protection zone and surveillance zone to constitute a restricted zone. When establishing zones, the competent veterinary authority of the Member State is required by EU legislation to take into account the following:

- The results of the epidemiological investigation;
- The geographical situation, particularly natural or artificial boundaries;
- The location and proximity of holdings;
- Patterns of movements and trade in swine and the availability of slaughterhouses;
- The facilities and personnel available to control any movement of swine within the zones, in particular if the swine to be killed need to be moved away from their holding of origin.

Veterinary authorities are required to take all necessary measures, including posting signs and alerting the media, to inform the public of the imposed restrictions and must use appropriate measures to enforce the restrictions. Veterinary authorities of Member States collaborate in establishing zones that overlap their borders.

In accordance with EU regulations, premises located within the protection zone are prohibited by the Member State from moving swine out of that zone for at least 30 days following the depopulation of swine and the cleaning and disinfection of the last premises in the zone infected with CSF. Premises within the surveillance zone are prohibited by the Member State from moving swine out of that zone for at least 20 days following the depopulation of swine and the cleaning and disinfection of the last premises in the protected zone infected with CSF. A census is conducted of all swine in both the protection and surveillance zones. Clinical examinations are conducted of all swine within the protection zone.

An epidemiological inquiry is made into the origin of the virus in the infected swine, and contacts are identified for traceback and traceforward investigations. Isolates of the virus are genetically typed by the EU Reference Laboratory in Hanover, Germany.

Under official supervision of the competent veterinary authority of the Member State, meat of swine slaughtered during the period between the probable introduction of disease and the implementation of control measures is traced and processed in such a way as to destroy or inactivate the CSF virus. Likewise, swine genetic products collected during this time are traced and destroyed under official supervision in such a way as to avoid the risk of spread of the CSF virus.

After the depopulation of swine, the buildings, equipment, vehicles, and other articles that may have been contaminated with the CSF virus must be cleaned and disinfected under official supervision using approved disinfectants.

Swine may not be reintroduced onto a holding that contained infected swine until at least 30 days after the required cleaning and disinfection. Any swine reintroduced onto the holding must be monitored to make sure that none develop antibodies to CSF.

The EU does not vaccinate domestic swine for CSF. However, with EC approval, emergency vaccination may be used in cases where CSF has been confirmed and epidemiological data suggest that the disease threatens to spread.

Whenever CSF is detected in a wild boar, the competent veterinary authority of the Member State, in consultation with an expert panel of veterinarians, hunters, wildlife biologists, and epidemiologists, defines the infected area, implements appropriate measures to reduce the spread of the disease, develops and submits for EC approval an eradication plan, and audit the effectiveness of measures adopted to eradicate CSF from the infected area. These measures require that all holdings of domestic swine in the infected area be placed under official surveillance, an official census of swine be conducted, swine movement be restricted, biosecurity measures be implemented, and testing for CSF be conducted on all sick or dead swine. Further, all wild boar shot or found dead must be examined and tested for CSF by an official veterinarian designated by the competent veterinary authority of the Member State. In addition, the measures taken may include suspension of hunting and a ban on feeding wild boar. The veterinary authority must also ensure that the CSF isolate is genetically typed. Adjacent Member States collaborate in establishing control measures in cases where the infected wild boar are found close to common borders.

As part of an approved eradication plan, emergency vaccination of wild boar may be conducted in situations where CSF has been confirmed and epidemiological data suggest that the disease threatens to spread. The vaccination area must be part of the defined infected area, and appropriate measures must be taken to prevent spread of the vaccine virus to domestic swine. Currently, there is an ongoing emergency vaccination program for wild boar in infected areas within Germany and Luxembourg.

Requirement in Addition to EU Controls

As we stated above, we believe it is necessary to require a CSF control measure in the EU–15 that exceeds EU controls and the conditions imposed by our April 2003 final rule. This measure is the length of time the prohibitions on the exportation of swine and swine products to the United States are maintained. We discuss this measure below.

Prohibition of Importations From a Restricted Zone

Current EU regulations allow CSF restrictions in a protection zone (that area extending at least 3 kilometers from an infected holding of domestic swine) to be removed 30 days after completion of preliminary cleaning and disinfection measures on the infected holding. Restrictions in a surveillance zone must stay in place at least 20 days after such cleaning and disinfection. Restrictions are removed only after clinical examinations and serology indicate that any swine remaining in the area are free of CSF. Presumably, after restrictions are released, swine from the area could be moved throughout the EU.

We are concerned by observations of recurrence of CSF in certain areas shortly after such restrictions have been removed by the EU and swine movement from the areas has commenced. For example, in December 2001, an outbreak was confirmed in Osoma, Spain, 22 days after release of movement restrictions by the EU. In another case, an outbreak in Luxembourg in August 2002 was epidemiologically linked to an outbreak that occurred in June 2002, and occurred 27 days after release of movement restrictions by the EU. During the 1997–1998 epidemic, veterinary authorities in the EU usually found it necessary to maintain movement restrictions for more than 30 days following an outbreak. These observations suggest that restricting movement for only 30 days may be insufficient to ensure that the region remains unaffected.

Further, as discussed below, we believe that OIE standards support restriction of movement for more than 30 days. As discussed above, we are

proposing to consider the EU–15 as a region of low risk for CSF, rather than as a region in which CSF is not known to exist. The OIE standard that would be relevant to such a region is the standard for a country or zone free of CSF in domestic swine but with infection in the wild swine population.[4] In such situations, OIE recommends that, where a stamping out policy without vaccination has been implemented for CSF control, recognition of the region as CSF-free may be acquired 6 months after the last outbreak in domestic swine.

We are in agreement with the OIE recommendation that restrictions on the movement of swine and swine products from a CSF quarantined area be maintained for 6 months, and consider it consistent with our proposed consideration of the EU–15 as a region that poses a low risk of CSF. Further, maintenance of such restrictions for 6 months is consistent with our stated intent in our December 2000 risk analysis to accept exports only from regions that have not experienced a CSF outbreak within the previous 6 months.[5] This is why we are proposing to provide that our prohibition on the importation of swine and swine products from a restricted zone established because of an outbreak of CSF in domestic swine remain in place for at least 6 months following the depopulation of swine and the cleaning and disinfection of the last infected premises in the zone. As noted above, the prohibition of the importation of swine and swine products from a restricted zone established because of the detection of CSF in wild boar would remain in place until the restricted zone status of the area is removed by the competent veterinary authority of the EU–15 Member State.

Wild Boar

Under our current regulations, we do not remove a region from the lists in §§ 94.9(a) and 94.10(a) of regions considered free of CSF if the disease is detected in wild boar in the region but not in domestic swine. This approach is consistent with APHIS domestic regulations, which do not regulate wild boar in the United States for swine diseases. However, under this proposed rule, we would prohibit importations of swine and swine products from areas in the EU–15 placed under quarantine by the competent veterinary authority of an EU–15 Member State because of the detection of CSF in wild boar, even if CSF has not been detected in domestic swine in the area. Although the estimates of CSF risk from the region identified in our 1999 and 2000 risk analyses were based on data related only to outbreaks and control measures in EU domestic swine (*i.e.*, data from wild boar outbreaks were not included), we recognize that EU control measures implemented in response to outbreaks in wild boar had a mitigating effect on the spread of CSF in domestic swine. Therefore, we believe that EU control measures for CSF in wild boar are a critical component of the overall EU controls for CSF. Data indicate that wild boar continue to be a potential source of infection in domestic swine. For example, infected wild boar are the suspected source of virus linked to an August 2003 outbreak in Luxembourg, an April 2002 outbreak in France, and multiple outbreaks in Germany. The EU recognizes the risk to its domestic swine population because of the endemic CSF infection in wild boar and has implemented eradication plans and contingency measures to deal with this problem. To protect domestic swine herds throughout the region, the EC has placed restrictions on movement of domestic swine from infected wild boar areas. It is likely that the EU restrictions on regions containing infected wild boar contribute significantly to the effectiveness of EU control measures.

Certificate for Swine

Section 93.505 of the regulations requires that, except for swine from Canada, all swine intended for importation into the United States be accompanied by official certification regarding the health status of the swine and the disease status of the region of origin. Paragraph (a) of § 93.505 requires that the certificate accompanying the swine show that the entire region of origin of the swine is free of CSF. In accordance with our proposed action to allow the importation of breeding swine from the EU–15, we are proposing to change the language in § 93.505 accordingly, to allow for the importation of live swine from the EU–15.

Application of this Approach to Other Regions

Section 92.2 of the regulations defines the type of information that must be included with the request of a country or countries to APHIS for recognition of the animal health status of a region. Evaluation of this information would constitute the first step in consideration of a new regulatory approach for the region. As part of its consideration, APHIS would determine whether it might be appropriate to revise its approach dealing with outbreaks in the region that made the request. The results of these considerations will be reflected in regulatory changes made through rulemaking. Aspects of the rulemaking process are discussed in § 92.2.

Authorized Inspectors

Currently, there is a requirement in § 94.24(c) that certificates required under § 94.24 be presented by the importer of swine and swine products to the appropriate Customs and Border Protection officer at the port of arrival. We are proposing to require instead that the certificates be presented to an authorized inspector, which is defined in § 94.0 as any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations. This change would reflect the fact that, for some imports, it is an APHIS employee who accepts the certificate at the port of arrival.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) the Secretary of Agriculture is authorized to promulgate regulations to prevent the introduction into the United States or dissemination of any pest or disease of livestock. Under this authority, APHIS is proposing to establish provisions for imports of swine and swine products from the EU–15 under conditions we believe will guard against the introduction of CSF into the United States from that region.

Below is the economic analysis for the changes proposed in this document. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866 and an analysis of the potential economic effects on small entities as required by the Regulatory Flexibility Act.

We do not have enough data for a comprehensive analysis of the economic effects of this proposed rule on small entities. Therefore, in accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis for this proposed rule. We are inviting comments about this proposed rule as it relates to small entities. In particular, we are interested in determining the number and kind of small entities who

[4] OIE, Terrestrial Animal Health Code-2003, Part 2, Chapter 2.1.13.

[5] Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union—December 2000.

may incur benefits or costs from implementation of this proposed rule and the economic impact of those benefits or costs.

CSF is a highly contagious and fatal disease of swine. It was eradicated from the United States in 1976 after a 16-year effort, at a cost to USDA and individual States of about $140 million ($455 million in 2003 dollars). The potential for reintroduction of CSF into the United States remains a major concern, not only because of production losses and eradication costs, but also because of the adverse effects reintroduction would have on U.S. swine and pork exports.

APHIS determines, based on disease risk evaluations, whether animals and animal products may be exported from foreign regions to the United States. If a region recognized by APHIS as free of a specific animal disease experiences an outbreak, generally an interim rule is issued prohibiting or restricting potentially infected imports. Once the outbreak has been eliminated, and a period of time has elapsed sufficient to allow the animal disease situation in the region to stabilize, the region's previous disease-free status may be restored. APHIS personnel conduct a site visit and reevaluate the risk by conducting a risk analysis. If, based on the analysis, APHIS believes it is appropriate to once again consider the region free of the disease, APHIS publishes a notice in the **Federal Register** soliciting public comments on the analysis. Any comments received are reviewed and each issue raised by commenters is considered. If, after review of the comments, APHIS continues to consider it appropriate to once again recognize the region free of the disease, a final rule is published in the **Federal Register** giving notice of such recognition.

We believe this proposed rule would enable APHIS to respond more quickly to changes in CSF conditions within the EU–15, while maintaining the Agency's sanitary standards. The proposed rule would change the procedure by which imports of swine, pork and pork products, and swine semen would be allowed to resume following the elimination of a CSF outbreak in the EU–15. Separate rulemaking would no longer be required each time an area within the region experiences a CSF outbreak and the disease is subsequently eliminated. Rather, APHIS would recognize quarantine decisions made by the competent veterinary authority of an EU–15 Member State and prohibit the importation of swine and swine products from restricted zones in the EU–15 established by the competent veterinary authority of an EU–15 Member State. As an additional safeguard, imports of swine, fresh pork and pork products, and swine semen into the United States from the restricted zone would be prohibited for a period of 6 months following the depopulation of swine and the cleaning and disinfection of the last infected premises in the zone. Restrictions and prohibitions we would establish because of the detection of CSF in wild boar would remain in place until the restricted zone status of the area is removed by a competent veterinary authority of the EU–15 Member State.

An alternative to the proposed rule would be to not change the regulations—*i.e.*, to continue to initiate rulemaking whenever the CSF situation within the EU–15 changes. Continuing with the current procedures would not achieve the Agency objective of improving the Agency's responsiveness to CSF situation changes while maintaining adequate disease prevention measures. A second alternative would be to consider the EU–15 as a single region of low risk for CSF, but not require that at least 6 months elapse after eradication of a disease outbreak in the region before the importation of swine and swine products into the United States could resume. This alternative would forfeit the additional sanitary assurance that the 6-month period is intended to provide to the U.S. swine industry that the reestablished imports would be CSF-free. We believe that this proposed rule would be preferable in allowing resumption of imports in a timelier manner, while ensuring that sanitary standards are maintained. As noted above, we invite public comment on this proposed rule, including comment on how the proposed rule could be modified to reduce expected costs or burdens for small entities consistent with its objectives. Any comment suggesting changes to the proposed criteria should be supported by an explanation of why the changes should be made.

Expected Effects of the Proposed Rule

This proposed rule could affect U.S. imports of swine, pork and pork products, and swine semen from the EU–15 in several ways. One of the effects would be potential additional restrictions on the importation of swine semen from certain EU–15 Member States. Additionally, the regulatory process used to establish import restrictions for areas affected by CSF, and to remove those restrictions when the disease is eliminated, would be simplified and made timelier. We believe the proposed rule would also result in more efficient use of APHIS resources. These areas of potential effects are discussed in turn.

Change in Swine Semen Requirements

The EU–15 consists of the following Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, the Republic of Ireland, Spain, Sweden, and the United Kingdom. APHIS considered five of the Member States—Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom—to be free of CSF even before publication of our April 2003 final rule. In that final rule, we recognized—with the exception of specified regions in Germany and Italy—the countries of Austria, Belgium, Germany, Greece, Italy, the Netherlands, and Portugal as a single region in which CSF is not known to exist. That final rule also set forth conditions under which breeding swine, pork and pork products, and swine semen could be imported into the United States from that region.

The remaining three Member States-France, Luxembourg, and Spain-as well as specified regions in Germany and in Italy, were not included in the region recognized by the final rule because of outbreaks of CSF either before or after publication of the June 1999 proposed rule on which the April 2003 final rule was based. However, as discussed above, we published a final rule in the **Federal Register** in April 2004 that recognized France and Spain as part of the CSF-free region we had established in our April 2003 final rule.

This proposed rule would consider the EU–15 to be a single region of low-risk for CSF. Therefore, that region would include the seven Member States we recognized in whole or in part as CSF-free in the April 2003 final rule (Austria, Belgium, Germany, Greece, Italy, the Netherlands, and Portugal), the five Member States we already considered CSF-free before the April 2003 final rule (Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom), the two Member States we recognized as CSF-free in our April 2004 final rule (France and Spain), and Luxembourg. Under the provisions of this proposed rule, each of the 15 Member States would be subject to the import conditions set forth in the April 2003 final rule and to the restrictions added in this document concerning waiting periods before release of restrictions on zones where outbreaks have occurred. In considering the effects of these changes, the key questions are: (1) In what ways do the current import requirements for

Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom differ from the import requirements set forth in this proposed rule; and (2) what effects would result for those five Member States due to the changes in requirements for export to the United States?

This proposed rule prescribes conditions for the importation of breeding swine, swine semen, and pork and pork products from areas classified as low risk for CSF. Movement restrictions require that there be no commingling of commodities intended for export to the United States (or of the donor boars of swine semen intended for export to the United States) with like commodities from areas where CSF is known to exist. Movement of commodities intended for export to the United States through areas where CSF is known to exist is permitted only by sealed means of conveyance. Sanitary certification that these provisions have been met is required.

Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom are already complying with the proposed conditions for pork, pork products, and breeding swine, and, in fact, were meeting these conditions before our April 2003 final rule. However, with respect to swine semen, the proposal would require that before the semen is exported to the United States, the donor boar must be held at the semen collection center for at least 40 days following semen collection, to ensure that the boar does not exhibit any clinical signs of CSF. This would be a new risk mitigation measure for swine semen exported to the United States from these five Member States.

Three of the five Member States, Denmark, the Republic of Ireland, and the United Kingdom, have histories of swine semen exports to the United States. From 1994 through 2002, the United States imported an average of 2,474 straws of swine semen annually. The average yearly share of U.S. swine semen imports supplied by the three Member States over the 9-year period was about 26 percent. The United Kingdom was the major source among the three Member States, supplying all of the three Member States' swine semen exports to the United States in 5 of the 9 years.

Reportedly, donor boars are largely resident at swine collection centers, so costs associated with the animals' maintenance would be affected little by the 40-day holding period. A potential issue is whether storage for 40 days before exportation would affect the quality of the collected semen and therefore affect import demand. APHIS welcomes information on this issue that may help in evaluating the effect on swine semen importers.

More Timely Reestablishment of CSF-Free Status

The proposed procedure for reestablishing CSF-free status for an area that has been under quarantine is expected to require less time than current procedures, notwithstanding the 6-month restriction following the last case of CSF and completion of disinfection measures. More timely recognition of an area's CSF-free status would allow imports of swine and swine products from the area to resume sooner than at present. The effect of this procedural change would depend on the difference in time required by the two regulatory approaches, and the additional swine, swine meat, and swine genetics that would be imported because of more timely recognition of an area's reestablished CSF-free status.

APHIS published a final rule on May 4, 2004 (69 FR 25817–25820, Docket No. 02–001–2) that codifies the procedures APHIS follows when a region free of a particular disease has an outbreak and APHIS responds to that outbreak by publishing an interim rule prohibiting or restricting imports from that region. APHIS will reassess the disease situation in that region, and, before taking any action to relieve or finalize prohibitions or restrictions imposed by the interim rule, will make information regarding its reassessment of the region's disease status available to the public for comment. Based on that reassessment, including comments received regarding the reassessment information, APHIS will either publish a final rule reinstating the disease-free status of the area, or a portion of the area covered by the interim rule; publish an affirmation of the interim rule that imposed prohibitions or restrictions on imports of animals and animal products from that area; or publish another document for comment. Under procedures in place previously, APHIS affirmed the initial interim rule, and then conducted new notice-and-comment rulemaking (proposed rule, comment period, final rule) in order to restore a region's disease-free status.

The new procedures the Agency codified allow for more timely reinstatement of an area's disease-free status, while protecting the U.S. swine sector. We believe the rule we are now proposing would further improve the timeliness of APHIS's recognition of changes in CSF status in the EU–15.

As noted in the economic analysis for the May 2004 final rule, quantities of animals and animal products imported by the United States are relatively small in comparison to the total quantities available domestically. In addition, the majority of the imports come from a small fraction of the world's disease-free regions. Also, it is very difficult to quantify the potential economic effects of more timely recognition of changes in CSF status. We believe the major benefit of this proposed rule would be improved trade relations between the United States and the EU. Less than 6 percent of domestically available swine (U.S. production plus imports minus exports) and less than 3 percent of domestically available pork are imported. The majority of swine imports come from one country, Canada, and the majority of swine product imports come from two, Canada and Denmark. We cannot predict the number of swine or quantity of swine products that this proposed rule would affect, but they are unlikely to be significant. One or more of the areas not yet recognized by the United States as free of CSF-Luxembourg and parts of Germany and Italy—may be among the first to benefit from this rule.

More Efficient Use of APHIS Resources

A third area of impact would be the effect of the proposed rule on APHIS operations. Just as the proposed rule could enable imports of swine, swine meat, and swine genetics to resume more quickly from areas that experience and then eradicate outbreaks of CSF, so too would it result in fewer site visits, risk analyses, **Federal Register** publications and other rulemaking tasks for APHIS. Resources that are devoted to tasks currently required for changing the CSF status of areas in the European Union would become available for other uses.

As with the impact on imports, expected gains in the efficient use of Agency resources cannot be quantified. They would be realized in terms of the additional time APHIS staff would have for other tasks, and would depend on the frequency with which CSF quarantines and CSF-free status reinstatements occur within the European Union.

We believe that the benefits that would accrue from this rule—*i.e.*, improved trade relations with the EU through more timely recognition of changes in CSF status, as well as increased efficiency in use of APHIS resources—would outweigh any increased costs to importers of swine semen from certain EU Member States that would result from an extended waiting period between when the semen is collected and when shipment may occur.

Effects on Small Entities

As a part of the rulemaking process, APHIS evaluates whether proposed regulations would likely have a significant economic impact on a substantial number of small entities. U.S. entities that could be affected by the proposed rule would be swine and pork producers and swine product wholesalers.

The size of the potentially affected entities is unknown. However, it is reasonable to assume that most are small in size under the U.S. Small Business Administration's (SBA) standards. The SBA defines small hog and pig farms as those earning not more than $750,000 in annual receipts. National Agricultural Statistics Service data on hog farm inventories include farm size categories, including the number of farms with more than 1,000 head. Only those swine operations with inventories well in excess of 3,000 animals would likely earn more than $750,000 in yearly sales. About 85 percent of 78,895 hog and pig farms in 2002 held inventories of fewer than 1,000 head. The number of operations with fewer than 3,000 is very likely to be much higher than 85 percent of all hog and pig farms. An earlier Census of Agriculture (1997) had more detail on farm size and showed that over 95 percent of U.S. swine operations held inventories of less than 2,000 head. Clearly, most swine and pork producers are small entities.

Likewise, swine product wholesalers are also mainly small entities. The SBA small entity definition for these businesses is not more than 100 employees. We do not know the size distribution of meat wholesalers, but the 2002 Economic Census indicates that the 2,889 establishments in that category had an average of 15 employees.

We invite comment from the public that would clarify the number of swine operations and swine product wholesalers that are small entities that would be affected by this rule.

Although the industries that would be affected by the proposed rule are largely composed of small entities, the effects are not expected to be significant. Imports of swine semen from Denmark, Finland, the Republic of Ireland, Sweden, and the United Kingdom may be affected if the 40-day holding period for donor boars before the semen may be imported influences U.S. demand. However, even if there is an effect, most swine semen that is imported comes from other countries—Canada, in particular. The more timely reestablishment of an area's CSF-free status may affect individual entities that have arranged for imports from that area, but, as described, such effects are expected to be minor.

This proposed rule contains various recordkeeping and reporting requirements. These requirements are described in this document under the heading ''Paperwork Reduction Act.''

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 02–046–1. Please send a copy of your comments to: (1) Docket No. 02–046–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

Under this proposed rule, we would apply a uniform set of importation requirements related to CSF to the EU–15 and prohibit for a specified period of time the importation of live swine and swine products from any area in the EU–15 that is identified by the competent veterinary authority of an EU–15 Member State as a restricted zone.

These importation requirements would necessitate the use of additional certification statements in connection with the importation of live swine, pork and pork products, and swine semen imported into the United Sates from the EU–15.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 1 hour per response.

Respondents: Federal animal health authorities in the European Union who will complete certificates to export swine, pork and pork products, and swine semen to the United States.

Estimated annual number of respondents: 115.

Estimated annual number of responses per respondent: 8.695.

Estimated annual number of responses: 1,000.

Estimated total annual burden on respondents: 1,000 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Accordingly, we are proposing to amend 9 CFR parts 93, 94, and 98 as follows:

List of Subjects

9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 98

Animal diseases, Imports.

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 would continue to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. In § 93.500, a new definition of *European Union–15 (EU–15)* would be added, in alphabetical order, to read as follows:

§ 93.500 Definitions.

* * * * *

European Union–15 (EU–15). The organization of Member States consisting of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

3. In § 93.505, paragraph (a), the second sentence would be removed and two sentences would be added in their place to read as follows:

§ 93.505 Certificate for swine.

(a) * * * For domestic swine, the certificate shall also show that the entire region of origin is free of African swine fever and swine vesicular disease and that, for 60 days immediately preceding the time of movement from the premises of origin, no swine erysipelas or swine plague has existed on such premises or on adjoining premises. Additionally, except for the region consisting of the EU–15 for the purposes of classical swine fever, for which alternative certification is required under § 94.24(b)(4), for domestic swine the certificate shall show that the entire region of origin is free of classical swine fever.

* * * * *

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

4. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

5. In § 94.0, definitions of *European Union–15 (EU–15)* and *restricted zone for classical swine fever* would be added, in alphabetical order, to read as follows:

§ 94.0 Definitions.

* * * * *

European Union–15 (EU–15). The organization of Member States consisting of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

Restricted zone for classical swine fever. An area, delineated by the relevant competent veterinary authorities of the region in which the area is located, that surrounds and includes the location of an outbreak of classical swine fever in domestic swine or detection of the disease in wild boar, and from which the movement of domestic swine is prohibited.

* * * * *

6. Section 94.9 would be amended as follows:

a. Paragraph (a) and footnote 10 would be revised to read as set forth below.

b. Paragraphs (b) and (c) would be redesignated as paragraphs (c) and (d), respectively.

c. A new paragraph (b) would be added to read as set forth below.

d. The introductory text of newly designated paragraph (c) would be revised to read as set forth below.

e. In newly redesignated paragraph (c)(1)(iii)(C)(*2*), the words ''paragraph (b)'' would be removed each time they occur and the words ''paragraph (c)'' would be added in their place.

f. In newly redesignated paragraph (c)(2), the words ''paragraph (b)'' would be removed and the words ''paragraph (c)'' would be added in their place.

g. In newly redesignated paragraph (c)(3), the words ''paragraph (b)'' would be removed each time they occur and the words ''paragraph (c)'' would be added in their place.

h. In newly redesignated paragraph (d), the words ''paragraph (b)'' would be removed and the words ''paragraph (c)'' would be added in their place.

§ 94.9 Pork and pork products from regions where classical swine fever exists.

(a) Classical swine fever is known to exist in all regions of the world except Australia; Canada; Chile; Fiji; Iceland; the Mexican States of Baja California, Baja California Sur, Chihuahua, and Sinaloa; New Zealand; Norway; and Trust Territory of the Pacific Islands.[10]

(b) The EU–15 is a single region of low-risk for CSF.

(c) Except as provided in § 94.24 for the EU–15, no fresh pork or pork product may be imported into the United States from any region where classical swine fever is known to exist unless it complies with the following requirements:

* * * * *

7. Section 94.10 would be revised to read as follows:

§ 94.10 Swine from regions where classical swine fever exists.

(a) Classical swine fever is known to exist in all regions of the world, except Australia; Canada; Chile; Fiji; Iceland; the Mexican States of Baja California, Baja California Sur, Chihuahua, and Sinaloa; New Zealand; Norway; and Trust Territory of the Pacific Islands.

(b) The EU–15 is a single region of low-risk for CSF.

(c) Except as provided in § 94.24 for the EU–15, no swine that are moved from or transit any region where classical swine fever is known to exist may be imported into the United States, except for wild swine imported into the United States in accordance with paragraph (d) of this section.

(d) Wild swine may be allowed importation into the United States by the Administrator upon request in specific cases under § 93.501 or § 93.504 (c) of this chapter.

8. Section 94.24 would be revised to read as follows:

§ 94.24 Restrictions on the importation of pork, pork products, and swine from the EU–15.

(a) *Pork and pork products.* In addition to meeting all other applicable provisions of this part, fresh pork and

[10] See also other provisions of this part and parts 93, 95, and 96 of this chapter, and part 327 of this title, for other prohibitions and restrictions upon the importation of swine and swine products.

pork products imported from the EU–15 must meet the following conditions:

(1) The pork and pork products must not have been commingled with pork or pork products derived from swine that have been in any of the following regions or zones:

(i) Any region when the region was classified in §§ 94.9(a) and 94.10(a) as one in which classical swine fever is known to exist, except for the EU–15; and

(ii) During the following time periods in any restricted zone in the EU–15:

(A) In a restricted zone established because of an outbreak of classical swine fever in domestic swine, during the 6 months following depopulation of the swine in the restricted zone and the cleaning and disinfection of the last infected premises in the zone; or

(B) In a restricted zone established because of the detection of classical swine fever in wild boar, until the designation of the zone as a restricted zone is removed by the competent veterinary authority of an EU–15 Member State.

(2) The swine from which the pork or pork products were derived must not have lived in any region or zone listed in paragraph (a)(1)(i) or (ii) of this section, and must not have transited any such region or zone unless moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination.

(3) The pork and pork products must be accompanied by a certificate issued by an official of the competent veterinary authority of the EU–15 Member State who is authorized to issue the foreign meat inspection certificate required by § 327.4 of this title, stating that the applicable provisions of paragraphs (a)(1) and (a)(2) of this section have been met.[19]

(b) *Live swine.* In addition to meeting all other applicable provisions of this title, live swine imported from the EU–15 meet the following conditions:

(1) The swine must be breeding swine;

(2) The swine must not have lived in any region or zone listed in paragraph (a)(1)(i) or (ii) or this section, must not have transited any such region or zone unless moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, and must never have been commingled with swine that were in such a region.

(3) No equipment or materials used in transporting the swine may have previously been used for transporting swine that do not meet the requirements of this section, unless the equipment and materials have first been cleaned and disinfected; and

(4) The swine must be accompanied by a certificate issued by a salaried veterinary officer of the competent veterinary authority of the EU–15 Member State, stating that the conditions of paragraphs (b)(1) through (b)(3) of this section have been met.[20]

(c) The certificates required by paragraphs (a)(3) and (b)(4) of this section must be presented by the importer to an authorized inspector at the port of arrival, upon arrival of the swine, pork, or pork products at the port.

(Approved by the Office of Management and Budget under control number 0579–0218)

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND SEMEN

9. The authority citation for part 98 would continue to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

10. In § 98.30, definitions of *European Union–15 (EU–15)* and *restricted zone for classical swine fever* would be added, in alphabetical order, to read as follows:

§ 98.30 Definitions.

* * * * *

European Union–15 (EU–15). The organization of Member States consisting of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

Restricted zone for classical swine fever. An area, delineated by the relevant competent veterinary authorities of the region in which the area is located, that surrounds and includes the location of an outbreak of CSF in domestic swine or detection of the disease in wild boar, and from which the movement of domestic swine is prohibited.

* * * * *

11. Section 98.38 would be revised to read as follows:

§ 98.38 Restrictions on the importation of swine semen from the EU–15.

In addition to meeting all other applicable provisions of this part, swine semen imported from the EU–15 must meet the following conditions:

(a) The semen must come from a semen collection center approved for export by the competent veterinary authority of the EU–15 Member State;

(b) The donor boar must not have lived in any region or zone listed in paragraph (b)(1) or (b)(2) of this section, must not have transited any such region or zone unless moved directly through the region or zone in a sealed means of conveyance with the seal determined to be intact upon arrival at the point of destination, and must never have been commingled with swine that were in such a region:

(1) Any region when the region was classified in §§ 94.9(a) and 94.10(a) of this chapter as one in which classical swine fever is known to exist, except for the EU–15; and

(2) During the following time periods in any restricted zone in the EU–15:

(i) In a restricted zone established because of an outbreak of classical swine fever in domestic swine, during the 6 months following depopulation of the swine in the restricted zone and the cleaning and disinfection of the last infected premises in the zone; or

(ii) In a restricted zone established because of the detection of classical swine fever in wild boar, until the designation of the zone as a restricted zone is removed by the competent veterinary authority of the EU–15 Member State.

(c) The donor boar must be held in isolation for at least 30 days prior to entering the semen collection center;

(d) No more than 30 days prior to being held in isolation as required by paragraph (c) of this section, the donor boar must be tested with negative results with a classical swine fever test approved by the Office International des Epizooties (World Organisation for Animal Health);

(e) No equipment or materials used in transporting the donor boar from the farm of origin to the semen collection center may have been used previously for transporting swine that do not meet the requirements of this section, unless such equipment or materials has first been cleaned and disinfected;

(f) Before the semen is exported to the United States, the donor boar must be held at the semen collection center and observed by the center veterinarian for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center,

[19] The certification required may be placed on the foreign meat inspection certificate required by § 327.4 of this title or may be contained in a separate document.

[20] The certification required may be placed on the certificate required by § 93.505(a) of this chapter or may be contained in a separate document.

exhibit no clinical signs of classical swine fever; and

(g) The semen must be accompanied to the United States by a certificate issued by a salaried veterinary officer of the EU–15 Member State, stating that the provisions of paragraphs (a) through (f) of this section have been met.[3]

[Approved by the Office of Management and Budget under control number 0579–0218]

Done in Washington, DC, this 4th day of April 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–7013 Filed 4–7–05; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Notice No. 39]

RIN 1513–AA95

Proposed Establishment of the Shawnee Hills Viticultural Area (2002R–345P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau proposes to establish the Shawnee Hills viticultural area in southern Illinois. This proposed 1,268,960-acre viticultural area is approximately 80 miles long east to west and approximately 20 miles wide from north to south. We designate viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. We invite comments on this proposed addition to our regulations.

DATES: We must receive your written comments on or before June 7, 2005.

ADDRESSES: You may send comments to any of the following addresses:

- Chief, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, Attn: Notice No. 39, P.O. Box 14412, Washington, DC 20044–4412.
- 202–927–8525 (facsimile).
- *nprm@ttb.gov* (e-mail).
- *http://www.ttb.gov/alcohol/rules/index.htm.* An online comment form is posted with this notice on our Web site.
- *http://www.regulations.gov* (Federal e-rulemaking portal; follow instructions for submitting comments).

You may view copies of this notice, the petition, the appropriate maps, and any comments we receive about this notice by appointment at the TTB Library, 1310 G Street, NW., Washington, DC 20220. To make an appointment, call 202–927–2400. You may also access copies of the notice and comments online at *http://www.ttb.gov/alcohol/rules/index.htm.*

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

FOR FURTHER INFORMATION CONTACT: Rita Butler, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Washington, DC 20220; telephone 202–927–8210.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (the FAA Act, 27 U.S.C. 201 *et seq.*) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's identity and prohibits the use of misleading information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out its provisions. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers these regulations.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) contains the list of approved viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been recognized and defined in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that supports setting the boundary of the proposed viticultural area as the petition specifies;
- Evidence relating to the geographical features, such as climate, soils, elevation, and physical features, that distinguish the proposed viticultural area from surrounding areas;
- A description of the specific boundary of the proposed viticultural area, based on features found on United States Geological Survey (USGS) maps; and
- A copy of the appropriate USGS map(s) with the proposed viticultural area's boundary prominently marked.

Shawnee Hills Petition

TTB received a petition from Dr. Theodore F. Wichmann, president of Owl Creek Vineyard, Inc., and Dr. Imed Dami, Illinois State Viticulturist, proposing the establishment of a new viticultural area in southern Illinois to be called ''Shawnee Hills.'' The proposed Shawnee Hills viticultural area lies largely within the Shawnee National Forest in Alexander, Gallatin, Hardin, Jackson, Johnson, Pope, Pulaski, Randolph, Saline, Union, and William counties. Encompassing a region of unglaciated hills between the Ohio and Mississippi Rivers, the proposed viticultural area is about 80 miles long east to west and 20 miles wide north to south, and it covers about 2,139 square miles or 1,268,960 acres.

People have raised grapes, including such important present-day wine varieties as Norton, in the proposed Shawnee Hills viticultural area since 1860, according to the petition, citing ''Grape Culture'' by W.E. Gould (1891). The proposed area contained 1,250 acres of vineyards in 1890, and vintners produced 19,750 gallons of wine in 1891, the petition adds, citing ''Grape and Wine Production in Illinois from 1983 to Present,'' by R.M. Skirvin, *et al.*, in ''Illinois Grape Growers and Vintners

[3] The certification required may be placed on the certificate required under § 98.35(c) or may be contained in a separate document.