

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. APHIS–2008–0043]

RIN 0579–AD20

Importation of Live Swine, Swine Semen, Pork, and Pork Products; Estonia, Hungary, Slovakia, and Slovenia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of animals and animal products to add Estonia, Hungary, Slovakia, and Slovenia to the region of the European Union that we recognize as a low-risk region for classical swine fever (CSF). Swine, swine semen, pork, and pork products may be imported into the United States from this region under certain conditions. We are proposing to remove one of these conditions, a 40-day holding period for swine semen and donor boars after the collection of swine semen, based on our determination that it is unnecessary. We are also proposing to add Estonia, Slovakia, and Slovenia to the list of regions we consider free of swine vesicular disease (SVD) and to add Slovakia and Slovenia to the list of regions considered free of foot-and-mouth disease (FMD) and rinderpest. These proposed actions would relieve some restrictions on the importation into the United States of certain animals and animal products from those regions, while continuing to protect against the introduction of CSF, SVD, FMD, and rinderpest into the United States.

DATES: We will consider all comments that we receive on or before April 12, 2011.

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

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov/fdmspublic/>

component/main?main=DocketDetail&d=APHIS-2008-0043 to submit or view comments and to view supporting and related materials available electronically.

- **Postal Mail/Commercial Delivery:** Please send one copy of your comment to Docket No. APHIS–2008–0043, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0043.

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: Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Donald Link, Import Risk Analyst, Regionalization Evaluation Services, National Center for Import and Export, VS, APHIS, 920 Main Campus Drive Suite 200, Raleigh, NC 27606; (919) 855–7730.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) 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), foot-and-mouth disease (FMD), swine vesicular disease (SVD), and rinderpest. These are dangerous and communicable diseases of ruminants and swine.

The regulations in 9 CFR part 98 govern the importation of animal

germplasm to prevent the introduction of contagious diseases of livestock and poultry into the United States. Subparts A and B of part 98 apply to animal embryos, and subpart C (§§ 98.30 through 98.38) applies to animal semen.

Sections 94.9 and 94.10 of the regulations list regions of the world that are declared free of, or low-risk for, CSF. The APHIS-defined EU CSF region, consisting of the 19 Member States of the EU that we currently recognize as a single region with regard to CSF, is currently the only region we consider low-risk for CSF. Sections 94.24 and 98.38 specify restrictions necessary to mitigate the risk of introducing CSF into the United States via pork, pork products, live swine, and swine semen from that region. We will discuss the restrictions on swine semen, found in § 98.38, at greater length later in this document.

Section 94.12 of the regulations lists regions that are declared free of SVD, and § 94.13 of the regulations lists regions that have been determined to be free of SVD, but that are subject to certain restrictions because of their proximity to, or trading relationships with, SVD-affected regions.

Section 94.1 of the regulations lists regions of the world that are declared free of rinderpest or free of both rinderpest and FMD. Section 94.11 of the regulations lists regions that have been determined to be free of rinderpest and FMD, but that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected regions.

On May 1, 2004, Estonia, Hungary, Slovakia, and Slovenia became Member States of the EU. As part of the accession process, these new EU Member States adopted the legislation of the European Commission (EC)¹ regarding animal health, welfare, and identification, including legislation pertaining to CSF, FMD, and SVD. This legislation became the basis for new standard operating procedures for domestic animal health matters in Estonia, Hungary, Slovakia, and Slovenia by the time of their accession. Estonia, Hungary, Slovakia, and Slovenia also adopted the harmonizing

¹ 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.

EC legislation regarding sanitary measures applicable to import and trade in live animals and animal products.

Prior to joining the EU in 2004, the Government of Slovakia requested APHIS to evaluate its animal health status with respect to CSF in 1997, to SVD in 2001, and to FMD and rinderpest in 2002. Likewise, the Government of Hungary requested that APHIS evaluate its animal health status with respect to CSF in 2001. After joining the EU, the Government of Estonia made a similar request with respect to CSF and SVD in 2005, and, that same year, the Government of Slovenia made a request for APHIS to evaluate its animal health status with respect to CSF, SVD, FMD, and rinderpest. APHIS had previously listed Estonia as free of FMD and rinderpest in a final rule published in the **Federal Register** on May 30, 2002 (67 FR 37663–37664, Docket No. 01–041–2), and had listed Hungary as free of FMD and rinderpest in a final rule published in the **Federal Register** on June 1, 1994 (59 FR 28216–28218, Docket No. 93–172–2), and SVD in a final rule published in the **Federal Register** on August 2, 1973 (38 FR 20610–20611).

Summary of Proposed Changes

In this document, we are proposing to add Estonia, Hungary, Slovakia, and Slovenia to the APHIS-defined EU CSF region. We are also proposing to remove one of the conditions pertaining to the importation of swine semen from that region. With the exception of semen collected from swine in Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom, we require that, before swine semen may be exported to the United States, the semen and donor boars be held at the semen collection center for at least 40 days following collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF. For reasons discussed later in this document, we have determined that this requirement is unnecessary.

We are also proposing to add Estonia, Slovakia, and Slovenia to the list of regions recognized as free of SVD, and to the list of SVD-free regions whose exports of pork and pork products to the United States are subject to certain restrictions to prevent the introduction of SVD into this country.

Additionally, we are proposing to add Slovakia and Slovenia to the list of regions recognized as free of FMD and rinderpest. We are also proposing to add Slovakia and Slovenia to the list of FMD and rinderpest-free regions whose exports of ruminant and swine meat and products to the United States are subject

to certain restrictions to prevent the introduction of FMD and rinderpest into this country.

As part of our evaluation of their disease status, APHIS identified the smallest administrative units (AUs) within each of these EU Member States that we would consider designating as regions in the event of future animal disease outbreaks. See the discussion of these AUs under the section titled “Administrative Units.”

The Low-Risk CSF Region in the EU; History

Before discussing our assessments of the animal health status of Estonia, Hungary, Slovakia, and Slovenia with regard to CSF and other diseases, and our determination that Estonia, Hungary, Slovakia, and Slovenia can be added to the APHIS-defined EU CSF region, we consider it helpful to explain how the region came about and how countries were added to that region. Later in this document, we will discuss under what conditions swine semen may currently be imported into the United States from that region, in order to provide context for the provision that we are proposing to remove from those requirements.

Traditionally, we have recognized countries either as affected with CSF or free of CSF. Pork and pork products from a country affected with CSF could be imported into the United States only after meeting rigorous processing and certification requirements; live swine, with a few, limited exceptions, could not be imported into the United States from such countries. Conversely, swine, pork, pork products, and semen from countries that we considered free of CSF could be imported into the United States under certain conditions.

In 1999, we prepared a risk analysis, titled “Biological Risk Analysis: Risk assessment and management options for imports of swine and swine products from the European Union—June 2, 1999,” in response to a request from the EC that we recognize a region of 10 EU Member States as free of CSF. That analysis, along with another, supplemental risk analysis, “Risk Analysis for Importation of Classical Swine Fever Virus in Swine and Swine Products from the European Union—December 2000,” took into consideration the CSF history of the 10 Member States in the EC’s request, the CSF history of countries adjacent to this region, the veterinary infrastructure and policies of the region, and the historical volumes of imports into the United States of breeding swine, swine semen, pork, and pork products from the region. Moreover, the analyses also took into

consideration the open borders among Member States of the EU, and the possibility of commingling of pork products from a CSF-free region and a CSF-affected region prior to their importation into the United States.

The analyses concluded that, because of this open-border policy, and because CSF was endemic in wild boar in several parts of the EU, it was likely that limited outbreaks of CSF would continue to occur in domestic swine in the region.

Based on the analyses, we decided that the unrestricted importation of swine, swine semen, pork, and pork products from the region could present a risk of introducing CSF into the United States. However, we also decided that this risk was low, and that the application of certain risk mitigation measures on the importation of these products would further reduce the risk of introduction of CSF into the United States. Therefore, we initiated a rulemaking that we finalized on April 7, 2003 (68 FR 16922–16941, Docket No. 98–090–5), to recognize a single region of 10 Member States or parts of Member States of the EU that we determined to present a low risk of introducing CSF into the United States.

In that rule, we mentioned that we considered the control mechanisms for CSF employed by the EU to be sufficient to mitigate any risk that continuing outbreaks of CSF in the EU could pose to swine, swine semen, pork, or pork products destined for export to the United States. We outlined these EU-imposed mitigation measures, which included measures to prevent widespread exposure and establishment of the disease; specific mitigation measures, such as wildlife surveillance and epidemiological investigations; and contingency plans establishing proactive approaches to CSF control. In sum, we stated that we considered the EU as a whole to be homogeneous with regard to CSF risk, regardless of individual outbreaks within Member States.

Accordingly, in a rulemaking that we finalized on May 19, 2006 (71 FR 29061–29072, Docket No. 02–046–2), we recognized the EU–15.² We considered the EU–15 to be those 15 Member States comprising the EU as of April 20, 2004: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Portugal, Republic of Ireland, Spain, Sweden, and the United Kingdom (England, Scotland,

²To view this rule, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2005-0028>.

Wales, the Isle of Man, and Northern Ireland).

Second, in recognition of the presence of CSF within the EU, and the possibility of future outbreaks of the disease, we also recognized “restricted zones,” or quarantined areas for CSF within the Member States of the EU–15. We defined a *restricted zone* in the regulations as “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 stated that, once a restricted zone was established, a prohibition on the importation of swine and swine products from that region into the United States would be immediate, with no action required by APHIS.

Finally, on November 28, 2007, we issued a final rule (72 FR 67227–67233, Docket No. APHIS–2006–0106)³ that amended the regulations to add the Czech Republic, Latvia, Lithuania, and Poland to the low-risk region for CSF. The rule also removed the term “EU–15” and added “APHIS-defined EU CSF region” in its place, since the addition of these countries had rendered the former term obsolete.

We will now discuss the analyses that have led us to propose to include Estonia, Hungary, Slovakia, and Slovenia in the EU CSF region, to conclude that Estonia, Slovakia, and Slovenia are free of SVD, and to conclude that Slovakia and Slovenia are free of FMD and rinderpest.

APHIS Evaluations Regarding the CSF and SVD Status of Estonia, the CSF Status of Hungary, and the CSF, SVD, FMD, and Rinderpest Statuses of Slovakia and Slovenia

APHIS has conducted an evaluation regarding the CSF and SVD status of Estonia; an evaluation regarding the CSF status of Hungary; an evaluation regarding the CSF, SVD, FMD, and rinderpest status of Slovakia; and an evaluation regarding the CSF, SVD, FMD, and rinderpest status of Slovenia. The evaluations regarding Estonia and Slovakia were finalized in January 2011, the evaluation regarding Hungary in May 2009, and the evaluation regarding Slovenia in October 2007. Each evaluation may be viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for

accessing Regulations.gov). In the following paragraphs, we summarize our findings for each of the 11 factors set out in our procedures for requesting recognition of regions in 9 CFR 92.2 and summarize our risk considerations of these findings following our discussion of the factors.

Authority, Organization, and Veterinary Infrastructure

As stated above, Estonia, Hungary, Slovakia, and Slovenia have adopted the legislation of the EC regarding animal health, welfare, and identification, as well as sanitary measures applicable to import and trade in live animals and animal products. At the time of accession, Commission Decisions and Regulations concerning CSF, SVD, and FMD became directly applicable in the new EU Member States, whereas Council Directives were implemented in national legislation. Our evaluations document that Estonia, Hungary, Slovakia, and Slovenia have, in fact, implemented these directives; this documentation was corroborated by site visits.

APHIS concludes that the official veterinary services of Estonia, Hungary, Slovakia, and Slovenia have sufficient legal authority, personnel, and financial resources to carry out animal health activities quickly and efficiently. The official offices are well-organized, with clear lines of command and reporting, as well as sufficient autonomy at the local level to carry out the tasks assigned. Internal and external auditing practices are adequate to monitor for compliance with the provisions of the pertinent animal health legislation.

Disease History

CSF: The most recent outbreak of CSF in domestic swine in Estonia occurred in 1994. In Hungary, the most recent outbreak of CSF in domestic swine occurred in 1993. In Slovakia, the last outbreak of CSF in domestic swine occurred in 2008. In Slovenia, the last outbreak in domestic swine occurred in 1996.

In both Hungary and Slovakia, CSF is endemic within the wild boar population. We discuss this at greater length later in this document.

SVD: SVD has never been reported to have occurred in either Estonia or Slovenia. In 1972, there were 16 cases of SVD reported in Slovakia; in each case, the swine had been imported into the country.

FMD: FMD was last reported in Slovenia in 1968, and in Slovakia in 1973.

Rinderpest: Rinderpest was last reported in Slovakia in 1881, and in

Slovenia in 1883; the countries are recognized by the World Organization for Animal Health (OIE) as being free of the disease.

Disease Status of Adjacent Regions

CSF: Estonia is bordered by Latvia to the south and Russia to the east. APHIS considers Latvia to be a low-risk region for CSF. APHIS has not evaluated Russia for its CSF status. However, Russia has experienced multiple outbreaks of CSF in domestic swine since 1996, and had its most recent outbreak in 2010. It is worth noting, in this regard, that APHIS considers any country that we have not evaluated for CSF as having a status equivalent to that of a CSF-affected country.

The risk analysis for Estonia considers the occurrence of CSF in Russia to be a potential risk factor for the introduction of CSF into that country. However, no region in Russia that borders Estonia has reported a CSF outbreak since 2000, and adequate control measures appear to be in place to prevent the possible spread of the disease to Estonia. Therefore, the analysis concludes that the Russian regions adjacent to Estonia do not appear to pose a high risk as potential sources of CSF introduction.

Hungary shares borders with seven countries. Of these, four are EU Member States: Austria, Slovakia, Romania, and Slovenia. The remaining three—Croatia, Serbia and Montenegro, and Ukraine—are EC-designated “third countries,” *i.e.*, countries that are approved by the EC to export certain live animals and animal products to EU Member States because they meet certain animal health standards that are at least equivalent to those required of EU Member States. None of these three countries, however, is approved to export live swine, swine semen, pork, or pork products to the EU at this time.

APHIS considers Austria to be a low-risk region for CSF. CSF has been enzootic, or persistently present, within Romania for the last few years, although it currently appears to be under control. Hungary continues to implement enhanced checks for forbidden pork products from Romania in passenger baggage at and near the Hungary/Romania border. The CSF disease histories of Slovakia and Slovenia are discussed earlier in this document.

APHIS has not evaluated Croatia, Serbia and Montenegro, or Ukraine for their CSF status. Between July 2006 and April 2008, Croatia reported a series of outbreaks in its domestic swine population—129 occurrences in total, over 11 counties—with several occurring between 20 and 50 kilometers (approximately 12.4 to 31 miles) from

³ To view this rule, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0106>.

the Hungarian border. In addition, according to the OIE, Serbia and Montenegro was known to have had widespread CSF in its domestic swine population as recently as 2005. Subsequently, Serbia and Montenegro implemented vaccination in the domestic swine population in order to control the outbreak. No evidence exists, however, to suggest that CSF has been eradicated in the country; in fact, there was a limited outbreak in domestic swine as recently as 2010. Finally, Ukraine reported its last CSF outbreak in 2001. In response to the outbreak, Ukraine undertook several disease control measures, including a quarantine of the area, depopulation of weak or sick animals, and vaccination of all domestic swine within a 3 kilometer (approximately 1.86 mile) radius.

Because five of the seven countries adjacent to Hungary have had recent CSF outbreaks, the risk analysis for that country considers these countries to be potential sources of infection of CSF. The analysis notes that Hungary has surveillance measures in place to detect CSF in its wild boar population and, because of the harmonized control measures that Hungary adopted at the time of its accession into the EU, the analysis considers the risk of CSF in its wild boar to be sufficiently mitigated.

Slovakia is bordered by Austria to the west, the Czech Republic to the northwest, Poland to the northeast, Ukraine to the east, and Hungary to the south. APHIS considers Austria, the Czech Republic, and Poland to be low-risk regions for CSF.

The analysis concludes that CSF could be introduced into domestic swine in Slovakia from a neighboring country, but that EC control measures serve to limit this risk, and that, accordingly, the risk is less immediate than that posed by native infected boar.

Slovenia is bordered by Austria to the north, Italy to the west, Hungary to the upper northeast, and Croatia to the south and lower northeast. APHIS considers Austria and Italy to be low risk regions for CSF. Croatia has experienced recent outbreaks of CSF.⁴ The CSF disease history of Hungary is discussed earlier in this document.

The risk analysis considers the occurrence of CSF in Croatia to present a potential risk factor for the introduction of CSF into Slovenia. However, APHIS recognizes that Slovenia, in response to outbreaks within Croatia, strengthened its CSF surveillance along the Croatian border,

and considers this a reasonable risk mitigation.

SVD: With regard to the SVD status of countries bordering Estonia, neither Latvia nor Russia has ever reported an outbreak of SVD. With regard to the status of those countries bordering Slovakia and Slovenia, APHIS considers Austria, the Czech Republic, Hungary, and Poland to be free of SVD. APHIS considers certain regions of Italy to be affected with SVD, and has not evaluated either Croatia or Ukraine for their SVD status. The risk analyses conclude that the regions adjacent to Estonia, Slovakia, and Slovenia appear to pose a low risk as potential sources of SVD introduction into these three countries.

FMD: With regard to the FMD status of countries bordering Slovakia and Slovenia, APHIS considers Austria, the Czech Republic, Hungary, Italy, and Poland to be free of FMD, but has not evaluated Croatia or Ukraine for their FMD status. The risk analysis concludes that the risk of introduction of FMD into Slovakia or Slovenia from neighboring countries is low, and mitigated by movement controls and border veterinary inspection.

Rinderpest: APHIS considers Austria, the Czech Republic, Hungary, Italy and Poland to be free of rinderpest, but has not evaluated Croatia or the Ukraine for their rinderpest status.

Degree of Separation From Adjacent Regions

Estonia is separated from most nearby regions by large bodies of water. It is bordered to the southwest by the Gulf of Riga, to the west by the Baltic Sea, to the north by the Gulf of Finland, and to the east by Lake Peipus, Lake Pskov, and the Narva River. Estonia shares land borders with only two countries: Latvia to the south, and Russia to the east. As mentioned above, APHIS considers Latvia to be a low risk for CSF, and Latvia has never reported an occurrence of SVD. There have been multiple outbreaks of CSF in Russia in recent years; however, there has not been an outbreak in the two administrative regions that border Estonia since 2000. Thus, land regions immediately adjacent to Estonia do not appear to pose a high risk for CSF and SVD.

There are few natural barriers to animal or human movement along the majority of Hungary's borders. The most significant natural barrier is the Danube River, which constitutes a portion of the border with Slovakia. Nonetheless, the analysis considers the risk of introduction of CSF into Hungary to be partially mitigated by border veterinary inspection and ongoing disease

surveillance efforts, which are concentrated on border counties.

There are few natural barriers to the introduction of CSF, FMD, SVD, or rinderpest via animal or human movement along the border between Slovakia and neighboring countries. As noted above, the Danube River forms part of the border between Slovakia and Hungary; it also runs along a portion of the Austro-Slovakian border. The Carpathian Mountains lie to the north, but are not high enough to substantially limit animal movement. Animals in neighboring countries that could serve as reservoirs for CSF, SVD, FMD, and rinderpest—deer, chamois, bison, and wild boar—tend to be nonmigratory, and all bordering countries except Ukraine are considered by APHIS to be free of FMD, SVD, and rinderpest. Accordingly, the analysis concludes that CSF, SVD, FMD, or rinderpest could be introduced into Slovakia through animal movement, but that the risk of such introduction is very low with regard to FMD, SVD, or rinderpest. There is a slightly greater risk of CSF introduction into Slovakia, since wild boars are the primary reservoir of the disease and may enter Slovakia from neighboring countries. Nonetheless, the risk of CSF introduction is still low, based on the risk-mitigation measures Slovakia has in place, including wildlife surveillance.

Slovenia is bordered by the countries of Austria, Italy, Hungary, and Croatia. The Adriatic Sea is on its southwestern border. The Julian Alps provide a natural barrier between Slovenia and Austria, and substantially limit animal movement at their highest points. The Alps also separate Slovenia from Italy, but are more passable along this border, particularly since their incline drops as they approach the Adriatic Sea. Slovenia is separated from Croatia and Hungary by a State border alone. Effective movement controls, border veterinary inspection, and enhanced disease surveillance in border regions mitigate the risk of introduction of disease from these two countries.

Extent of an Active Disease Control Program

Due to the absence of CSF and SVD outbreaks in recent years, there are no CSF and SVD control programs currently active in Estonia.

In response to the detection of CSF in wild boar along the border with Slovakia, Hungary has exercised disease control measures within the infected area. As pertains to the wild boar population, Hungary has implemented hunting restrictions and mandatory veterinary inspections for any boar shot

⁴ An evaluation of the disease status of Croatia with regard to CSF has been initiated.

or found dead within an affected county. As pertains to the domestic swine population, Hungary has implemented a census of all swine on premises within the quarantined area, standard procedures for cleaning and disinfection, and enhanced reporting requirements for swine exhibiting clinical signs of CSF infection.

Shortly before Slovakia's accession to the EU, the EC recognized that CSF was endemic in the wild boar population in a certain area of the country, and thus designated the area a restricted area. Accordingly, the EC imposed movement restrictions on swine and swine products from the area, and required Slovakia to undertake an eradication-based CSF vaccination program for wild boar within the area. Slovakia does not have active disease control programs for SVD, FMD, or rinderpest, as none of these diseases have been reported in the country in many years.

Control measures for CSF in Slovenia include active systematic monitoring, veterinary inspection, movement certificates, field investigations, and laboratory investigations. Due to the prolonged absence of SVD, FMD, and rinderpest in Slovenia, Slovenia does not have aggressive active disease surveillance programs for these diseases, but maintains interlocking safeguards in order to prevent, detect, and suppress them. These safeguards include veterinary certificates, standard procedures for cleaning and disinfection, training of veterinarians, veterinary technicians, and animal owners, indemnity and compensation for diseased animals, and incentives for compliance with animal health regulations.

Vaccination

General preventive vaccination against CSF and SVD is prohibited in Estonia; emergency vaccinations for CSF are permitted only under exceptional circumstances to prevent the spread of the disease in the event of an outbreak, and only if sanctioned by the EC.

Routine vaccination for CSF has been prohibited within Hungary since 1974. As noted above, the current outbreak of CSF in the wild boar population within the country is being managed through hunting restrictions, population control, and surveillance efforts.

Routine vaccination of domestic swine against CSF and SVD is currently prohibited in Slovakia, as is vaccination of any animal for FMD, although FMD vaccinations may be implemented in the event of an outbreak. As noted above, however, there is CSF vaccination of wild boar in the EC-designated restricted area within the country.

Moreover, since the last vaccination of domestic swine for CSF occurred in 2000, there is some potential of detecting vaccine titers during CSF slaughter surveillance. Finally, FMD vaccinations may be implemented in the event of an outbreak.

The last vaccination against CSF occurred in Slovenia in 2000; however, Slovenia has the authority to implement emergency vaccinations in the event of a CSF outbreak. SVD vaccination is prohibited. FMD vaccinations, although currently prohibited, may be implemented in the event of an outbreak.

Movement Control From Higher Risk Regions

Some forms of CSF, SVD, and FMD are difficult to detect in live animals or in post-mortem examinations without laboratory testing, and, in some instances, detection may be delayed due to deficiencies in active surveillance or diagnostic testing capabilities. Any such delay in detection of an outbreak could increase the risk that infected animals or animal products are exported to the United States. Consequently, the risk analyses analyze potential pathways for disease introduction into Estonia, Hungary, Slovakia, and Slovenia, such as importation and intra-Community trade in live animals and animal products, vehicular and human traffic, and commodities for human consumption.

Import Controls: Importations must occur at specified road, rail, air, and/or sea ports through a border inspection post (BIP) approved by the EC; inspections and veterinary checks occur at such BIPs. The EC conducts a rigorous inspection of each BIP prior to approval and carries out regular audits to monitor the efficacy of sanitary controls. APHIS considers EC-approved BIPs to be capable of performing appropriate inspections and veterinary checks on animals and animal products; this was corroborated by several site visits to Slovakian and Hungarian BIPs in November 2004 and by visits to two BIPs in Estonia in November 2005. Although the site visit to Slovenia did not include a visit to a BIP, Slovenia provided APHIS with information certifying that each Slovenian BIP is approved by the EC.

Swine, ruminants, and derived products such as meat, meat products, and genetic material are harmonized commodities under EC legislation, which means that the restrictions on imports from non-EU countries are generally standardized across all EU Member States. Binding EC legislation lists the non-EU countries, and

establishments within those countries, that are approved for export of certain commodities to the EU.

Slaughterhouses, cutting plants, semen collection centers, and other exporting establishments are subject to inspection prior to approval. Veterinary certificates required for export to the EU outline comprehensive animal health and testing requirements and must be endorsed by an official veterinarian of the exporting country.

At the time the analyses were conducted, four non-EU countries were authorized to export both live swine and fresh pork products to EU Member Countries: Chile, New Zealand, Norway, and Switzerland. Three additional countries (Australia, Canada, and the United States) were authorized to export fresh pork products alone, and one (Iceland) was authorized to export live swine, but not pork products. The United States is free of SVD, CSF, and FMD. APHIS recognizes all seven other countries to be free of SVD (although some are subject to the restrictions specified in § 94.13), and all but Switzerland to be free of CSF.⁵ APHIS also considers these countries to be free of FMD, although some are subject to the restrictions specified in § 94.11.

However, although the importation of swine and pork products into Estonia, Hungary, Slovakia, and Slovenia is currently limited to these eight countries, and although the import practices of Estonia, Hungary, Slovakia, and Slovenia have proven generally effective with regard to CSF, SVD, or FMD, EC legislation allows EU Member States to import fresh pork and pork products derived from swine from several regions that APHIS has not evaluated and therefore regards as having the same status as regions affected with these diseases. Moreover, EU Member States may also import bovine embryos and meat and meat products from both domestic and wild ruminants from regions that APHIS considers affected with FMD.

Veterinary inspectors at the entry BIPs check that the documentation accompanying commodities is in order, including appropriate health certificates and other movement control documents, and that the shipment is properly identified and the identification matches the documentation. Veterinary inspectors also conduct physical examinations of incoming shipments in accordance with EC legislation. However, because CSF, SVD, and FMD testing is generally not required at the BIPs, the mandated inspections would

⁵ An evaluation of the disease status of Switzerland with regard to CSF has been initiated.

not usually detect subclinical infection. The causal agents of CSF, SVD, and FMD could also remain viable through carcass maturation, transport, and storage, and could be present in genetic material.

Accordingly, the risk evaluations determined that there is some risk of CSF, SVD, and/or FMD introduction into Estonia, Hungary, Slovakia, and Slovenia through the importation of commodities from non-EU Member States. However, the evaluations also found that this risk is substantially mitigated by EC certification requirements for meat, meat products, and genetic material, such as veterinary inspection of live animals prior to shipment, restrictions on the sources (countries, regions, premises, or production facilities) from which trade is permitted, certification of disease status by an official veterinarian, veterinary inspection at BIPs, and requirements for processing meant to inactivate viral disease agents.

Trade Controls: As EU Member States, Estonia, Hungary, Slovakia, and Slovenia may engage in intra-Community trade with other Member States as governed by EC legislation that was transposed into national legislation prior to accession. Live animals and animal products must originate from a holding center or organization (e.g., market or assembly center) that is under State veterinary control, i.e., that has regular veterinary checks. The animals must be appropriately identified, must be accompanied by an appropriate health certificate signed by an official veterinarian of the country of origin, and must be segregated according to destination, if destined for shipment to multiple locations. Intra-Community trade in swine and swine products, including semen and embryos, from CSF- or SVD-affected regions of EU Member States is prohibited, and States with such regions must adhere to animal health control measures meant to control the spread of these diseases in order to engage in trade with other Member States. Because FMD is not known to be present in the EU, there are no current trade restrictions based on FMD; however, EC legislation authorizes the imposition of such restrictions in the event of an outbreak.

Establishments such as slaughterhouses, processing plants, milk processing plants, and semen collection centers must be approved by the Member State in which they reside according to criteria similar to those for exporting establishments in non-EU countries. The EC and official veterinary services of the Member State conduct periodic audits to monitor compliance

with approval criteria and certification requirements.

The risk analyses conclude that there is some risk of CSF, SVD and/or FMD and rinderpest being introduced into Estonia, Hungary, Slovakia, and Slovenia from other EU Member States, but this risk is low, based on the absence of FMD in the EU and the mitigation measures for CSF and SVD imposed through EC and transposed national legislation.

Veterinary Control of Passenger Traffic: Estonia shares a land border with only one non-EU country, Russia. Customs officials, rather than veterinary officers, control the majority of border crossings. Cars and buses are subject to inspections and random luggage checks; not all buses or pieces of luggage, therefore, are inspected. Cleaning and disinfection procedures are enforced for all transport vehicles carrying live animals; disinfection barriers also exist for vehicles and pedestrians at each BIP and point of entry.

Informational posters are hung at border crossing points, press releases are distributed, and information is disseminated to customs officers and customs clients to publicize regulations regarding prohibitions and restrictions on personal imports of meat. During visits by APHIS to two Estonian BIPs in 2005, APHIS found that prohibited food items were not often found in the luggage of individuals entering Estonia. However, at one of these BIPs, there was a high volume of road traffic from Estonia into Russia due to the comparatively low price of basic commodities in Russia.

In Hungary, BIP veterinary staff, employed by the county Agricultural Offices but under the direct supervisory and administrative responsibility of the central Ministry of Agriculture and Rural Development office in Budapest, oversee the operations of each BIP. These inspectors conduct searches, may seize prohibited goods, segregate live animals through a separate point of entry, and enforce cleaning and disinfection procedures.

There is, however, significant movement of passengers who do not pass through these BIPs from countries that are not part of the EU. The Hungarian Frontier Guard, which controls the frontier borders of Hungary, conducts random checks and other control activities at these points of entry in conjunction with customs officials. During our site visits, both the Frontier Guards and customs officials appeared familiar with EU requirements and prohibitions regarding importation of meat and dairy products transported in personal consignments.

In addition, while informational posters informing travelers of prohibitions on the importation of certain meat and dairy products were reported to be present at BIPs and other border crossings at the time of accession, APHIS found no such posters during our site visit.

The State Veterinary and Food Administration controls all border crossing points in Slovakia, including all BIPs. There are, however, several crossings for passenger traffic that do not have official veterinary inspection. All individuals attempting to enter the country with agricultural products are redirected to a BIP with veterinary inspection. Customs officials visually check all passenger luggage at BIPs on the Ukrainian border, and selected passenger luggage at Slovakia's airport BIP. Moreover, during our site visit, APHIS noticed wall notices informing travelers of prohibitions on the importation of certain meat and dairy products were present in many, but not all, BIPs.

The Veterinary Administration of the Republic of Slovenia (VARs) includes both an Internal Veterinary Inspection Sector (10 regional offices and 2 branch offices) and the Border Veterinary Inspection Service (BVIS). The annual disease control program issued by VARs outlines the frequency and location of inspections for the Regional Offices to undertake within Slovenia itself. The BVIS has administrative and supervisory responsibility for the 6 BIPs in Slovenia. BVIS veterinary inspectors are present at the BIPs during working hours, but do not conduct inspections outside normal working hours without prior notice.

Slovenian road border crossings are also staffed by customs officials from the Customs Administration of the Republic of Slovenia (CARS). Customs officials conduct searches of personal luggage at border crossings for prohibited meat and dairy products. The customs officials are not themselves veterinarians, but work in close coordination with the veterinary inspectors of VARs: VARs inspectors conduct their training and meet with them monthly to discuss areas for improvement. CARS produces posters, brochures, and Web site information to promote awareness of prohibitions on the importation of meat and other animal products.

Accordingly, the analyses conclude that there is a risk of introduction of CSF, FMD, SVD, or rinderpest into Slovakia or Slovenia, CSF or SVD into Estonia, and CSF into Hungary via passenger traffic, but that this risk is significantly mitigated by the control

measures in place at points of entry to the countries.

Livestock Demographics

As stated above, Estonia, Hungary, Slovakia, and Slovenia adopted EC legislation with regard to animal identification at the time of their accession. Each country has in place herd registration and animal identification requirements for ruminants and swine that include movement tracking through a centralized database or register. Health certificates and/or movement authorization certificates are required for all internal movements of ruminants and swine. We will discuss livestock demographics for swine first, then discuss demographics for ruminants, as warranted.

Between 2002 and 2004, the total number of swine holdings in Estonia was approximately 3,835. However, 30 large-scale confinement facilities, each with holdings of at least 2,000 swine, account for the majority of all swine production in the country. Outdoor production facilities are rare, although some small backyard farms do keep swine outdoors in the summer months.

In 2007, the domestic swine population in Hungary was 3.3 million. Approximately 70 percent of all pigs slaughtered in any given year, as well as the majority of pigs destined for commercial export, originate from large-scale facilities of more than 100 pigs. However, it was once common for Hungarians to raise swine for personal consumption, and, although such small-scale farms have declined greatly in number in recent years, they still are more numerous than the large-scale facilities within the country.

In 2006, there were 921,723 pigs on 6,806 holdings in Slovakia. The majority of holdings have between 1 and 450 pigs, although there are several large commercial confinement facilities of 7,000 to 10,000 pigs in the eastern and southwestern parts of the country.

In Slovenia, there were approximately 26,000 swine holdings and 608,000 pigs in 2004. Eight large-scale confinement facilities, each with between 500 and 5,700 sows, account for half of commercial pig production.

In all four countries, there is some overlap between the distribution of swine holdings and areas of concentration of wild boars; however, the majority of swine in Estonia, Hungary, and Slovenia are housed in confinement facilities, with minimal to no outdoor access, and are moved only for slaughter or export. This is not the case with Slovakia, where small to medium holdings constitute the

majority of the industry; however, many of these facilities either do not move swine or move them only for custom slaughter for personal consumption.

As part of our evaluations, APHIS conducted site visits of production facilities in Hungary and Slovakia and a rendering plant in Estonia, and determined that they adhered to State-mandated biosecurity measures that are adequate to prevent wild animal incursions into the facilities and the spread of communicable swine diseases by other routes. The risk analyses for Estonia, Hungary, and Slovenia therefore conclude that the prevalence of large commercial confinement facilities in these countries, the distribution of the wild boar population in each country in relation to these facilities, mandatory animal identification requirements, movement controls, and other biosecurity measures adequately mitigate the export risk to the United States. The risk analysis for Slovakia finds that the risk posed by the prevalence of smaller, outdoor production facilities is often mitigated by the lack of movement of swine from the facilities, or their movement only for custom slaughter.

In 2006, there were 524,247 cattle on 19,904 holdings, 326,322 sheep on 4,949 holdings, and 5,507 goats on 918 holdings in Slovakia. Ruminant holdings tend to be constructed in a manner that allows the animals space to graze, and rely on biosecurity measures, such as perimeter fencing and cleaning and disinfection techniques, that minimize but do not prevent contact with wildlife or disease introduction. That said, Slovakia has in place movement restrictions, isolation parameters, and assembly center requirements that APHIS considers sufficient to mitigate the risk that meat derived from FMD-infected ruminants could be exported to the United States.

Cattle are distributed throughout Slovenia, primarily on small- to medium-sized family farms. Family farms frequently maintain cattle for dairy production or breeding. There are large commercial breeding operations (of approximately 600 head apiece) in Slovenia, but most large commercial operations specialize in fattening and meat production. The majority of cattle or products from cattle that are exported from Slovenia originate from cattle held on large-scale commercial operations.

In 2006, there were 144,000 sheep and goats in Slovenia, on 8,600 sheep and goat holdings. As for cattle and swine, Slovenia has in place mandatory animal identification and registration for sheep and goats, which facilitates traceability. In addition, APHIS' regulations

governing bovine spongiform encephalopathy currently prohibit the importation of ruminant-derived products from Slovenia. These safeguards address the risk of FMD being introduced into the United States through the importation of ruminant-derived products from Slovenia.

Disease Surveillance

CSF: Estonia, Hungary, Slovakia, and Slovenia all have national surveillance programs in place for CSF in domestic swine and wild boar. Active surveillance is primarily based on serology for antibodies to the CSF virus, as is common throughout the world. Since antibodies usually occur late in CSF infection, serological surveillance would likely miss an early infection (e.g., in the first 21 days). In each country, training, the distribution of informational literature, and national surveillance exercises aid in passive surveillance for CSF by developing and maintaining the ability to quickly detect this disease. APHIS considers passive surveillance to be sufficient to detect overt clinical signs of CSF, but detection may be delayed in the case of moderate- or low-virulence strains.

SVD: Estonia conducts serological surveillance for SVD in domestic swine. Slovakia does not conduct active surveillance for SVD, but instead relies on passive surveillance similar to that employed to detect CSF. Due to the absence of SVD in the country, Slovenia relies primarily on passive surveillance strategies. Consequently, detection of SVD in Slovakia or Slovenia may be delayed in some instances based on the absence of overt clinical signs.

FMD: Slovakia and Slovenia conduct passive surveillance for FMD. As noted above, passive surveillance may delay the detection of the disease in some instances based on the absence of clinical signs of infection.

Diagnostic Capabilities

Estonia, Hungary, Slovakia, and Slovenia have established accredited national reference laboratories (NRLs) for animal diseases, including CSF, SVD, and FMD. In Slovenia, the National Veterinary Institute (NVI) at the University of Ljubljana is the NRL for a number of diseases, although there are nine regional laboratories that perform initial diagnostic and screening tests. Overall, the laboratories are well organized and equipped, with experienced scientific and technical staff. Standard operating procedures and quality control measures are in place throughout.

CSF: In each country, the NRL provides a range of tests for the

diagnosis and confirmation of CSF. Testing includes the virus isolation and antigen enzyme-linked immunosorbent assay (ELISA) tests, as well as the nested polymerase chain reaction, immunofluorescence, and immunoperoxidase methods.

During APHIS' site visit to the NRL in Hungary, we had some concerns regarding the lack of sensitivity of one of the assays employed, a fluorescent antibody test for wild boars. In response, Hungary implemented more sensitive assays that are consistent with OIE specifications. Moreover, APHIS notes that Slovenia's NVI Biohazard Level 3 containment center is not yet completed. Because the NVI cannot handle live CSF virus until this is constructed, it cannot perform all CSF diagnostic tests, and thus it has not yet been accredited by VARS and the EU. (Similar restrictions apply to FMD testing.) Finally, the NRLs of both Estonia and Slovenia rely in certain instances on corroborative testing that takes place outside of each country.

We do not believe that any of these issues decisively compromises the ability of Estonia, Hungary, or Slovenia to detect CSF in samples from domestic swine and wild boars in a timely manner; we have determined that, in each instance, other factors mitigate the risk associated with the issue of concern; and we have therefore concluded that the laboratory systems of Estonia, Hungary, Slovakia, and Slovenia, on the whole, have adequate diagnostic capabilities for CSF.

SVD: The NRL of Estonia currently conducts both serological and nucleic acid testing for SVD. Slovakia does not employ active surveillance for SVD, hence there is no required testing for the disease. However, the NRL of Slovakia does provide a partial range of diagnostic tests for the detection of SVD, as such testing is requested. The NRL of Slovenia has historically conducted limited ELISA testing for SVD: In 2004, there were 30 samples tested, each of which tested negative for SVD, while there were no samples tested in either 2005 or 2006. A monitoring program was designed for 2008. The NRL can, however, process up to 500 samples by ELISA each day.

FMD: The NRLs of Slovakia and Slovenia are capable of performing ELISA tests for FMD antigens. However, because the NRL of Slovakia cannot perform virus isolation tests, confirmatory testing is currently conducted in Riems, Germany. Similarly, because the NRL of Slovenia lacked accreditation for handling live FMD virus at the time of our analysis, samples were being sent instead to

Pirbright, United Kingdom, for virological testing. Should either of these procedures continue, they could result in a slight delay in confirming an outbreak in the two countries.

Emergency Response Capacity

Estonia, Hungary, Slovakia, and Slovenia all have contingency plans in place and supporting legislation to control and eradicate CSF outbreaks in domestic swine. In addition, Estonia has in place a contingency plan to control and eradicate SVD; Slovakia, SVD and FMD; and Slovenia, FMD. These contingency plans conform closely to the provisions of EC legislation. The EC has a stamping out policy with regard to CSF, SVD, and FMD. Eradication is carried out by compulsory depopulation of all animals on the affected premises with burial or incineration of the carcasses, as well as certain cleaning and disinfection protocols. All live animals, animal products, and genetic material moved from affected premises during the time between disease introduction and detection of the outbreak must be destroyed. Additionally, surveillance zones of at least a 10-kilometer radius from the affected premises are established, and the movement of live animals, animal products, and genetic material is suspended until the restrictions are lifted.

While Slovenia currently has no contingency plan for the control and eradication of SVD, the disease has never been reported to have occurred in that country. Furthermore, APHIS recognizes Slovenia's thorough contingency plans for CSF and FMD. In particular, the FMD contingency plan encourages the detection and reporting of vesicular diseases that could lead to an SVD diagnosis.

Release Assessment Conclusions

APHIS found no evidence to suggest CSF or SVD exists within Estonia. Moreover, we determined that there are measures or factors in place which mitigate the pathways through which these diseases could be introduced into Estonia: Migration of wild boar, trade of swine and swine products, vehicle and human traffic, and importation of swine products for personal consumption. APHIS concludes that the risk of introduction of these diseases into Estonia is therefore low. Moreover, APHIS concludes that the risk of introduction of CSF or SVD into the United States from products imported from Estonia is mitigated by additional import restrictions already specified in the regulations.

APHIS found that CSF exists in the wild boar population living within Hungary, as evidenced by a 2009 outbreak of CSF in wild boar. Moreover, APHIS has determined that, even if CSF were eradicated in wild boar within the country, there is a risk of reintroduction of the disease because the wild boar populations in neighboring countries are known to be affected with CSF. However, as noted earlier, APHIS does not consider the presence of CSF in wild boar within a country grounds for precluding that region's inclusion in the APHIS-defined EU CSF low-risk region. Moreover, APHIS has determined that swine operations within Hungary, especially larger commercial ones, adhere to biosecurity measures intended to preclude the introduction of CSF into their holdings.

Upon being added to the EU CSF region, Hungary would be subject to the requirement, under the existing regulations in § 94.24, that its veterinary authorities certify that live swine and swine products exported to the United States did not originate from the restricted zone in Hungary and have never been commingled with swine or swine products from that area. We consider this requirement, in conjunction with the risk mitigation measures imposed by Hungary and the EC, sufficient to mitigate the CSF risk associated with the importation of pork and pork products from Hungary.

APHIS found that CSF exists within Slovakia in wild boar in the EC-designated eradication zone. While surveillance and vaccination within this area have reduced the incidence of CSF in recent years, there is a clear risk of disease introduction to domestic swine via contact with such boars, although the risk of exposure to infected boars is substantially mitigated by commercial production and biosecurity practices on swine confinement operations. Exposure to wild boar is more likely on small farms without such measures; however, such farms often raise pigs only for personal consumption.

Upon being added to the EU CSF region, Slovakia would be subject to the requirement, under the existing regulations in § 94.24, that its veterinary authorities certify that live swine and swine products imported into the United States did not originate from the CSF-restricted zone in Slovakia, and have never been commingled with swine or swine products from that area. We consider this requirement, in conjunction with the risk mitigation measures imposed by Slovakia and the EC, sufficient to mitigate the CSF risk associated with the importation of pork and pork products from Slovakia.

APHIS has no evidence that SVD, FMD, or rinderpest currently exists in Slovakia. The most likely sources of introduction of these two diseases into Slovakia are migration of wild boar or smuggled agricultural products. Slovakia has adequate mitigation measures in place to detect the smuggling of agricultural products. It is possible that infected wild boar could enter Slovakia and come in contact with domestic swine; this risk is somewhat mitigated, but not altogether removed, by the biosecurity measures of commercial confinement facilities within Slovakia. However, the introduction of SVD, FMD, or rinderpest into the domestic herd in Slovakia would only pose a risk of disease introduction into the United States if diseased swine or animal products derived from diseased swine were not detected prior to export. APHIS regards the risk of this occurring to be low.

APHIS found no evidence to suggest that CSF, SVD, FMD, or rinderpest exists in Slovenia. The most likely source of introduction of CSF, SVD or FMD into Slovenia is wild boar from neighboring countries affected with the diseases. However, the introduction of these diseases into Slovenia's domestic herd would only pose a risk of disease introduction into the United States if diseased swine or animal products derived from diseased swine were not detected prior to export. APHIS regards the risk of this occurring to be low. Furthermore, should these diseases be introduced, APHIS has evaluated EC control measures and found them efficacious in detecting and controlling outbreaks of CSF, SVD, and FMD in domestic livestock.

As a result of our analyses, we have concluded that the risk profiles for Estonia, Hungary, Slovakia, and Slovenia are equivalent in CSF risk to the APHIS-defined EU CSF region. The region is defined in §§ 93.500, 94.0, and 98.30, and is recognized as a single region of low-risk for CSF in §§ 94.9 and 94.10. The region is subject to the import restrictions specified in § 94.24 for live swine, pork, and pork products, and § 98.38 for swine semen. Therefore, we are proposing to amend the definition of the APHIS-defined EU CSF region §§ 93.500, 94.0, and 98.30 in order to include Estonia, Hungary, Slovakia, and Slovenia in the region, and, accordingly, to allow the importation of live swine, swine semen, pork, and pork products into the United States from these four countries under the restrictions listed in the regulations.

We are proposing to recognize Estonia, Slovakia, and Slovenia as free of SVD, and Slovakia and Slovenia as

free of FMD and rinderpest. In addition to proposing to include Estonia, Slovakia, and Slovenia in the list in § 94.12(a) of regions declared free of SVD, and Slovakia and Slovenia to the list in § 94.1(a)(2) of regions declared free of both rinderpest and FMD, we are also proposing to add Estonia, Slovakia, and Slovenia to the list in § 94.13 of regions declared free of SVD whose exports of pork and pork products are also subject to restrictions and to add Slovakia and Slovenia to the list in § 94.11(a) of regions declared free of rinderpest and FMD whose exports of meat and other animal products to the United States are nevertheless subject to certain restrictions.

Risk Mitigation Measures for the Importation of Swine Semen From the APHIS-Defined EU CSF Region and the 40-Day Post-Collection Holding Period

Currently, the requirements for the importation of swine semen from the APHIS-defined EU CSF region, which are found in paragraphs (a) through (i) of § 98.38, provide, among other things, that semen must come from an approved semen collection center, that it must come from a donor boar that has never been in or transited a region where CSF is known to exist or a restricted zone for CSF, that it must come from a donor boar that has never commingled with swine that have been in such regions or zones, that the donor boar must be held in isolation for 30 days prior to semen collection, and that the boar must be tested for CSF prior to being held in isolation with negative results. In addition, paragraph (h) of the section currently requires that, except for semen collected from swine in Denmark, Finland, Sweden, the Republic of Ireland, and the United Kingdom, 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 collection of the semen, and, along with all other swine at the semen collection center, exhibit no clinical signs of CSF.

After reviewing relevant information, we are proposing to remove paragraph (h) from the regulations.

Three considerations, which are documented in a risk assessment titled "APHIS Risk Considerations on the Necessity of the 40-Day Post-Collection Holding Period for Swine Semen Imported from the European Union" (June 2008) that accompanies this proposed rule, led us to this conclusion. First, in recognizing the APHIS-defined EU CSF region, we decided that EC quarantine regulations with respect to areas affected by CSF would form the basis for the additional restrictions or

mitigation measures that we would impose upon imports of swine and swine products from that region. We will only impose additional restrictions in circumstances where we have determined that, in the absence of such restrictions, EC regulations would prove insufficient to adequately mitigate the risk of CSF being introduced into the United States by such animals and animal products. In other words, the restrictions that our regulations impose upon the EU CSF region are dependent on the restrictions in the EC regulations themselves; as the latter become more or less restrictive, our regulations should change accordingly.

Since we recognized the EU CSF region, significant changes have been made to the EC regulations to strengthen its controls for CSF introduction or dissemination via infected swine germplasm. These include additional controls on the intra-community trade of swine semen, the immediate halt of the movement of swine semen from collection centers within all restricted zones established during an outbreak of CSF, and additional testing requirements for all animals in swine semen centers prior to releasing an area from restrictions following an outbreak.

Second, since we conducted the 1999 risk analysis that suggested the need for the 40-day holding period, we have strengthened our regulations governing the importation of swine semen from a CSF-affected area within the EU CSF region and added additional mitigation measures for products imported from that region. For example, we have since added a 6-month restriction on the importation into the United States of swine and swine products from a restricted zone within the EU CSF region following an outbreak.

Finally, at the time we put the 40-day holding period in place, we believed that it would not be overly burdensome for exporters of swine semen or otherwise inhibit trade. However, we have since learned that artificial insemination of sows relies overwhelmingly on fresh boar semen or semen that has been chilled for no more than 5 days; indeed, such semen accounts for approximately 99 percent of all artificial insemination worldwide. Methods, such as freezing, exist to preserve swine semen for longer periods of time; however, swine semen is extremely sensitive to freezing and thawing, losing both potency and fertility in the process. Given the other increased restrictions on the importation of swine semen from the EU CSF region, continuing to require the 40-day hold, and thus to interfere with trade in swine semen, no longer appears

necessary. Accordingly, we are proposing to remove § 98.38(h), which requires the 40-day hold, from the regulations.

Administrative Units

On October 28, 1997, we published in the **Federal Register** a final rule (62 FR 56000–56026, Docket No. 94–106–9) and a policy statement (62 FR 56027–56033, Docket No. 941068) that established procedures for recognizing regions and levels of risk for the purpose of regulating the importation of animals and animal products. With the establishment of those procedures, APHIS can consider requests to allow importations from regions based on levels of risk, as well as to recognize entire countries as free of a disease. In subsequent rules, we identified the smallest administrative jurisdictions, referred to as administrative units (AUs), in the APHIS-defined EU CSF region that we would use to regionalize those Member States in the event of future animal disease outbreaks. As discussed in those documents, we believe that each of those jurisdictions is the smallest that can be demonstrated to have oversight of normal animal movements into, out of, and within that Member State, and that, in association with national authorities, if necessary, has effective control over animal movements and animal diseases locally.

We have identified the following AUs for each country addressed in this proposal: For both Estonia and Hungary, the AU would be the county; for Slovakia, the district; and for Slovenia, the region.

We have also reevaluated the AUs that we currently recognize for other countries in the EU to determine whether any modifications to these recognitions were necessary. Prior to July 29, 2005, the AU for Italy was the region. In a notice that we published in the **Federal Register** (70 FR 43838–43839, Docket No. 04–081–2) on that date, we advised the public that, among other things, we considered the *aziende sanitarie locali* (local health unit), a smaller administrative unit, the AU for Italy. Since that time, we have determined that this unit does not have sufficient control over local animal movements to fulfill the criteria established for an AU. Therefore, we intend to once again identify the region as the AU for Italy. We invite comments on that determination.

Accordingly, these AUs would be used to regionalize those Member States in the event of future animal disease outbreaks.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866, and has therefore not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (*see ADDRESSES* above for instructions for accessing Regulations.gov).

The analysis identifies hog and pig producers as the small entities most likely to be affected by this action and considers the effects on domestic prices associated with increased imports of swine, swine semen, pork, and pork products. Based on the information presented in the analysis, we expect that domestic pork producers would experience only a minimal loss in welfare as a result of this action. The analysis provides a basis for the APHIS Administrator's determination that this action would not have a significant economic impact on a substantial number of small entities.

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.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the proposed addition of Estonia, Hungary, Slovakia, and Slovenia to the list of EU countries considered to be a low risk CSF, Estonia, Slovakia, and Slovenia to the list of regions recognized as free of SVD, but that are subject to certain import restrictions, and Slovakia and Slovenia to the list of regions recognized as free of FMD and rinderpest, but that are subject to certain import restrictions, we have prepared environmental assessments for each country.

The environmental assessments were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C.

4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessments may be viewed on the Regulations.gov Web site or in our reading room. We invite the public to comment on those environmental assessments. Comments on the environmental assessments may be submitted using the same process as comments on the proposed rule.

Instructions for accessing Regulations.gov and for submitting comments and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule. In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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.

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

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

1. The authority citation for part 93 continues 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, the definition of *APHIS-defined EU CSF region* is revised to read as follows:

§ 93.500 Definitions.

* * * * *

APHIS-defined EU CSF region. The European Union Member States of Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Republic of Ireland, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

3. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

4. In § 94.0, the definition of *APHIS-defined EU CSF region* is revised to read as follows:

§ 94.0 Definitions.

* * * * *

APHIS-defined EU CSF region. The European Union Member States of Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Republic of Ireland, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

* * * * *

§ 94.1 [Amended]

5. In § 94.1, paragraph (a)(2) is amended by adding the words “Slovakia, Slovenia,” immediately after the word “Portugal.”

§ 94.11 [Amended]

6. In § 94.11, paragraph (a) is amended by adding the words “Slovakia, Slovenia,” immediately after the word “Portugal.”

7. In § 94.12, paragraph (a) is revised to read as follows:

§ 94.12 Pork and pork products from regions where swine vesicular disease exists.

(a) Swine vesicular disease is considered to exist in all regions of the world except Australia, Austria, the

Bahamas, Belgium, Bulgaria, Canada, Central American countries, Chile, the Czech Republic, Denmark, Dominican Republic, Estonia, Fiji, Finland, France, Germany, Greece, Greenland, Haiti, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Panama, Poland, Portugal, Republic of Ireland, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Trust Territories of the Pacific, the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland), Yugoslavia, and the Regions in Italy of Friuli, Liguria, Marche, and Valle d’Aosta.

* * * * *

8. In § 94.13 introductory text, the first sentence is revised to read as follows:

§ 94.13 Restrictions on importation of pork or pork products from specified regions.

Austria, the Bahamas, Belgium, Bulgaria, Chile, the Czech Republic, Denmark, Estonia, France, Germany, Hungary, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Republic of Ireland, Slovakia, Slovenia, Spain, Switzerland, the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland), Yugoslavia, and the Regions in Italy of Friuli, Liguria, Marche, and Valle d’Aosta are declared free of swine vesicular disease in § 94.12(a).

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PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

9. The authority citation for part 98 continues 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, the definition of *APHIS-defined EU CSF region* is revised to read as follows:

§ 98.30 Definitions.

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APHIS-defined EU CSF region. The European Union Member States of Austria, Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Republic of Ireland, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom (England, Scotland, Wales, the Isle of Man, and Northern Ireland).

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§ 98.38 [Amended]

11. Section 98.38 is amended as follows:

a. In the introductory text, by removing the words “, except as noted in paragraph (h) of this section with regard to swine semen imported from Denmark, Finland, the Republic of Ireland, Sweden, or the United Kingdom”.

b. By removing paragraph (h).

c. By redesignating paragraph (i) as paragraph (h).

d. In newly redesignated paragraph (h), by removing the words “through (h)” and adding the words “through (g)” in their place.

Done in Washington, DC, this 7th day of February 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R–1405]

RIN 7100–AD64

Definitions of “Predominantly Engaged in Financial Activities” and “Significant” Nonbank Financial Company and Bank Holding Company

AGENCY: Board of Governors of the Federal Reserve System (“Board”).

ACTION: Notice of proposed rulemaking and request for comment.

SUMMARY: The Board is publishing for comment proposed amendments to Regulation Y that establish the criteria for determining whether a company is “predominantly engaged in financial activities” and define the terms “significant nonbank financial company” and “significant bank holding company” for purposes of Title I of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the “Dodd-Frank Act” or “Act”). These terms are relevant to various provisions of Title I of the Dodd-Frank Act, including section 113, which authorizes the Financial Stability Oversight Council (“Council”) to designate a nonbank financial company for supervision by the Board if the Council determines that the company could pose a threat to the financial stability of the United States. The Council recently requested comment on a proposed rule to implement section 113 of the Dodd-Frank Act.

DATES: *Comments:* Comments should be received on or before March 30, 2011.

ADDRESSES: You may submit comments, identified by Docket No. R–1405 and