

# Review of the APHIS-defined European Classical Swine Fever Region

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# **Executive Summary**

Consistent with the regulations in 9 CFR 92, APHIS periodically reviews the animal health statuses of foreign regions to determine whether the conditions support the continuation of APHIS' recognition of those statuses. In 2019, the Animal and Plant Health Inspection Service (APHIS) reviewed the classical swine fever (CSF) statuses of thirteen of the twenty-eight European Union (EU) Members States that APHIS considers to be representative of the APHIS-defined European CSF region (henceforth referred to as the "European CSF Region" in this document). The selected countries were Belgium, the Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Poland, and Spain. 1

APHIS considers the European CSF Region to be low risk for classical swine fever (CSF). This region comprises twenty-eight countries in Europe: twenty-five EU Member States,<sup>2</sup> the United Kingdom, and two of the European Free Trade Association (EFTA) Member States, Switzerland and Liechtenstein.<sup>3</sup> APHIS adds countries to the European CSF Region after it conducts an evaluation of the country and finds that its CSF status is equivalent to that of the European CSF Region, i.e. low risk for CSF (and free of other swine diseases). Although Bulgaria and Romania are EU Member States, APHIS does not currently recognize the foot-and-mouth disease (FMD), classical swine fever (CSF), or swine vesicular disease (SVD) status of these two EU Member States. As such, APHIS prohibits the import of live swine, pork, pork products, and swine casings from Bulgaria and Romania and does not include them in the European CSF Region.

APHIS collected and reviewed information from the thirteen EU Member States and, in September 2019, conducted site visits to seven of the thirteen Member States to collect additional information, and to clarify and verify the information submitted for this review. Based on consideration of several factors, including geographical location, disease history, disease response activities, wild boar and domestic swine demographics, and trade practices, APHIS considers the seven EU Member States visited to be representative of the thirteen EU Member States under review, and by extension, the European CSF Region.

APHIS approached this review by individually reviewing the CSF status (as well as the statuses of three other diseases that affect swine) of each country. In this report, APHIS summarizes its observations and conclusions about the selected countries, which is then extrapolated to the whole European CSF Region. APHIS documents in separate reports its review of the animal health statuses of the thirteen individual countries.

The findings and conclusions for CSF in the individual EU Member States are summarized in this overarching report. The findings address each EU Member State's ability to reduce the risk of CSF introduction, to detect and control CSF if it were introduced, and, utilizing their existing

<sup>&</sup>lt;sup>1</sup> APHIS invited the Canadian Food Inspection Agency (CFIA) to participate in this review due to shared interests in safe trade of live breeding swine, pork, and pork products. Joint observations and conclusions are described in separate individual EU Member State reports. Since APHIS and CFIA follow different approaches to regionalizing Europe for CSF, this report describes only the conclusions of the review of the APHIS approach for the European CSF Region.

<sup>&</sup>lt;sup>2</sup> The twenty-five EU Member States in the European CSF Region are Austria, Belgium, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain and Sweden. APHIS includes in the European CSF Region the Republic of Cyprus *except for* those areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control. APHIS does not include Bulgaria and Romania in the European CSF Region.

<sup>&</sup>lt;sup>3</sup> The EFTA is the intergovernmental organization of Iceland, Liechtenstein, Norway, and Switzerland.

traceability systems, to certify and comply with APHIS' certification requirements for exporting live breeding swine, pork, and pork products to the United States. APHIS then considered the observations and conclusions derived from the individual country reviews to collectively draw conclusions about the status of the whole European CSF Region.

The incidence of CSF detections in the European CSF Region significantly declined since CSF outbreaks in wild boar and domestic swine impacted Europe from 1997 – 2010. The most recent detection of CSF in the region was in Latvia in 2015. APHIS found no evidence that CSF currently exists in any of the thirteen countries selected for review. Therefore, by extension, APHIS considers it unlikely that the disease is present in the European CSF Region.

The European Commission (EC) maintains legislation requiring competent EU Member State veterinary authorities be notified if CSF is detected in their country and outlining the control measures to implement when CSF is detected. The EC legislation was adopted by all countries that are included in the European CSF Region, thereby ensuring harmonization. The EC implements a CSF regionalization strategy to address potential reintroduction of CSF into regions of the EU identified as being at higher risk. As a precaution, the EC imposes additional measures on these higher risk regions in order to mitigate against potential spread of CSF via intra-Union trade that might occur during the period between disease introduction and subsequent detection. Currently, these measures apply in the whole territory of Romania and Bulgaria.

APHIS found the countries selected for review effectively implement CSF prevention and control measures and maintain traceability practices for live breeding swine, pork, and pork products in accordance with EC standards. The thirteen countries reviewed have demonstrated a history of promptly reporting CSF detections and taking appropriate measures to prevent exportation of infected or contaminated commodities.

APHIS concluded that the thirteen EU Member States, and by extension, the countries of the European CSF Region are capable of detecting CSF in both domestic swine and wild boar through their active and/or passive surveillance systems. APHIS further concluded that if CSF was introduced, the appropriate competent authorities could mount an effective emergency response against the disease and could safeguard against spreading CSF to third countries through the export of susceptible commodities.

<sup>&</sup>lt;sup>4</sup> In June 2002, Switzerland and Liechtenstein entered into an agreement with the European Union (EU) whereby they gradually adopted the EU's harmonized import and trade regulations for live animals and animal products. Although the United Kingdom ended its membership in the EU on February 1, 2020, they continue to enforce harmonized CSF regulations.

# Background

APHIS regulates the import of animals and animal products into the United States to guard against the introduction and spread of foreign animal diseases. In support of this goal, and in accordance with Title 9, Code of Federal Regulations, Part 92 (9 CFR 92), APHIS assesses import risk and conducts animal health status evaluations of foreign regions for several foreign animal diseases [1]. APHIS maintains a list of APHIS-recognized animal health statuses of foreign regions for specific animal diseases or pests on its website, and implements various approaches for recognizing those statuses [2].

In conducting animal health status evaluations, APHIS assesses eight factors related to animal health status and import risk. These factors, as listed in 9 CFR 92, include but are not limited to the organization and oversight of official veterinary services in the region; the region's livestock demographics, movement patterns and marketing controls; animal disease surveillance programs, including laboratory diagnostics; the region's animal disease prevention and control programs, including biosecurity measures, to reduce the risk of introduction into and spread within the region of animal diseases of concern; and other animal health matters and associated risks for international trade.

Consistent with the regulations in 9 CFR 92, APHIS periodically reviews the animal health statuses of foreign regions. APHIS assesses the animal health conditions in those regions to determine whether the conditions support the continuation of APHIS' recognition of those statuses.

In 2019, APHIS reviewed the CSF status, along with several other swine diseases, of thirteen EU Member States that are also part of the European CSF Region that is described in the next section. The thirteen EU Member States are Belgium, the Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Poland, and Spain. APHIS selected these countries as representative of the European CSF Region.

APHIS subsequently selected seven EU Member States for site visits—Belgium, the Czech Republic, Germany, Greece, Lithuania, Poland, and Spain. These countries provide a cross-section of old versus more recent EU membership; geographical diversity and varying swine husbandry, production, and marketing practices; swine commodities trade volumes with the United States; risk of CSF (and other swine disease) introduction; and veterinary infrastructure considerations that could potentially affect the ability of the central competent authority for animal health to effectively administer and capably oversee swine disease prevention, surveillance, and control programs, and to ensure the veterinary certification requirements of the United States are met. The site visits to these countries were conducted September 7-20, 2019.

Specific findings and conclusions for CSF are available in the respective individual EU Member State reports. The findings and conclusions for each country to prevent CSF introductions, to detect and control CSF if it was introduced, and to certify exports of live breeding swine, pork, and pork products are summarized in this report and extrapolated to generate conclusions about the European CSF Region as a whole.

# The APHIS-Defined European CSF Region (European CSF Region)

APHIS prohibits or otherwise restricts the importation of swine commodities from regions that APHIS does not recognize as either free of CSF or low risk for CSF. APHIS currently recognizes the European CSF Region as a single region of low risk for CSF [3]. It is defined in 9 CFR 94.0, 9 CFR 94.9(b), and 9 CFR 94.10(b) and on the web-based list of regions that APHIS has declared low risk for CSF [2, 3, 4, 5]. APHIS lists import restrictions on live swine, swine semen, pork, and pork products in 9 CFR. 94, with specific regulations on live breeding swine, swine semen, pork, and pork products from the European CSF Region in 9 CFR 94.31 and 98.38. APHIS prohibits importation of these commodities from any restricted zone established by the competent authority of countries of the European CSF Region due to detection of CSF in either domestic swine or wild boar during a specified period. Under this provision, APHIS accepts the CSF zoning decisions of the European CSF Region competent authorities and trusts them to only export commodities from zones that are free of CSF [6, 7].

The European CSF Region consists of countries beyond the EU, including the non-EU Member States of the United Kingdom, Switzerland, and Liechtenstein, <sup>5</sup> as well as 25 EU Member States [Austria, Belgium, Croatia, Republic of Cyprus, <sup>6</sup> Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain and Sweden]. APHIS adds countries in Europe to the European CSF Region after conducting an evaluation of the country to assess its ability to effectively implement the European Commission's (EC's) overarching legislative framework and requirements for CSF prevention, response, and control programs. If APHIS finds that the CSF status for the evaluated country is equivalent to that of the European CSF Region, then APHIS adds the evaluated country to the European CSF Region. Although Bulgaria and Romania are EU Member States, APHIS does not currently recognize the foot-and-mouth disease (FMD), classical swine fever (CSF), or swine vesicular disease (SVD) status of these two EU Member States. As such, APHIS prohibits the import of live swine, pork, pork products, and swine casings from Bulgaria and Romania and does not include them in the European CSF Region.

# CSF Epidemiological Situation in the European CSF Region

The incidence of CSF detections in the European CSF Region significantly declined since CSF outbreaks in wild boar and domestic swine impacted Europe from 1997 – 2010. The most recent occurrence of CSF in the European CSF Region occurred in Latvia, in 2015, when CSF detections were reported in both domestic swine and wild boar [8, 9].

APHIS collected CSF surveillance information from the thirteen EU Member States selected for review and found no evidence in the information that CSF currently exists in any of those countries.

# The European Commission CSF Framework

EU legislation to control CSF is promulgated in Council Directive 2001/89/EC of October 2001 on Community measures for the control of classical swine fever, and subsequent amendments

<sup>&</sup>lt;sup>5</sup> Switzerland and Liechtenstein are European Free Trade Association (EFTA) Member States. The EFTA is the intergovernmental organization of Iceland, Liechtenstein, Norway, and Switzerland.

<sup>&</sup>lt;sup>6</sup> Except for those areas of the Republic of Cyprus in which the Government of the Republic of Cyprus does not exercise effective control.

[10]. This legislation outlines the requirements that EU Member States report all suspected or confirmed cases of CSF, and the measures to be taken if CSF is suspected or confirmed. The legislation specifies measures to be taken in response to suspected or confirmed CSF occurrence, including quarantine and surveillance requirements for affected holdings; movement controls on live animals, products, and fomites; depopulation, cleaning, and disinfection of affected premises; establishing protection and surveillance zones, and the disease control measures therein; disease control measures taken at slaughterhouses and by animal transporters; disease control measures when CSF is suspected in feral pigs; and other emergency response activities, including emergency vaccination against CSF in domestic and feral pigs (the EC maintains an emergency CSF vaccine bank [11]), epidemiological investigations to confirm or exclude additional cases and repopulating premises after a CSF outbreak. The EC legislation and affiliated requirements are transposed into national legislation and programs by all countries that are included in the European CSF Region, including the non-EU Member States.

The EU also implements a separate legislation for CSF regionalization for those EU Member States where CSF introduction is more likely to occur. Commission Implementing Decision 2013/764/EU concerning animal health control measures relating to classical swine fever in certain Member States, as amended [12] lists CSF prevention and control measures to be taken in specified areas of certain EU Member States based on an assessment of risk rather than detection of CSF. Summarizing, it prohibits or otherwise restricts movement of live pigs; porcine semen, ova, and embryos; and both fresh and prepared pork products from the listed areas of these EU Member States to other EU Member States via intra-Union trade. It also outlines requirements for special health marks and certification requirements for certain products and stipulates additional biosecurity requirements for pig holdings and transport vehicles in the areas listed. The Annex of the legislation lists the EU Member States, or parts thereof, subject to its CSF prevention and control measures. Currently, the measures apply to all of Romania and Bulgaria.

This legislation was set to expire on December 31, 2019, but the EC recently extended the legislation and the preventative measures until April 21, 2021, via Decision (EU) 2019/1972, in November 2019 [13]. All of Romania and Bulgaria continue to be subject to this legislation. This signals that the EC remains concerned about and vigilant for CSF introduction, continues to identify areas of higher risk where CSF introduction is more likely to occur, and will continue control measures in those areas as a precaution to prevent CSF spread to other EU Member States during the period between introduction, should it occur, and subsequent detection.

APHIS finds that the EC's CSF framework is commensurate with the CSF epidemiological situation in the EU Member States reviewed. The EC maintains legislation making CSF a notifiable disease, outlining surveillance requirements to confirm CSF if it is suspected, and outlining measures to control CSF if it is detected. Given the five-year absence of CSF in the European CSF Region, APHIS concluded that the CSF regionalization legislation that prohibits or otherwise restricts intra-community movement of live animals and animal products from all or part of two EU Member States, is maintained as a precaution based on an assessment of the risk of introduction into and subsequent spread from those areas.

<sup>&</sup>lt;sup>7</sup> Portions of Croatia, which had been listed in the Annex to Decision 2013/764, were removed from the Annex on November 26, 2019 [13]. Portions of Latvia, which had been listed in the Annex to Decision 2013/764, were removed from the Annex on October 16, 2020 [14].

# EU Member State Implementation of EC CSF Measures

Successful implementation of the CSF prevention and control measures outlined in the EC framework for CSF is heavily dependent upon the central competent authority responsible for implementation in each EU Member State. In its review of the thirteen selected EU Member States, APHIS found that each country had a competent veterinary infrastructure implementing the EC's CSF prevention and control measures. APHIS found evidence of well-organized central competent authorities whose staff disseminated national swine health strategies to regional offices, including CSF prevention and control measures. These policies appeared to be successfully implemented at the local level by robust field veterinary services including local veterinarians either working directly for, or authorized to conduct work on behalf of, the central competent authority. With one exception, Greece, staffing levels and budgets appeared sufficient to effectively implement swine health programs, including CSF measures.

APHIS found that Greece's veterinary infrastructure has been constrained by resource limitations resulting in staffing shortages on the national, regional, and local levels. However, APHIS concluded that Greece leverages its available resources to ensure critical animal disease control activities remain functioning while the country moves towards filling critical vacancies in its veterinary services as it recovers from its recent financial crisis. It is also important to note that the EC stepped in and provided necessary financial resources to assist Greece during this time, especially to enhance Greece's capacity to respond to African swine fever (ASF). To that point, APHIS acknowledges that Greece was able to quickly detect an introduction of ASF into the country and to successfully contain and eliminate the disease in a relatively short period of time.<sup>8</sup>

Overall, APHIS observed knowledgeable swine producers, processors, and other swine industry officials effectively implementing Union-wide and country-specific requirements and standards for swine husbandry, production, and processing, including biosecurity measures and traceability components. Each country had a national registry and database to capture movements of live swine on to and off farms, including movements from farm to farm and from farm to slaughter. APHIS observed robust traceability practices for live breeding swine, pork, and pork products in accordance with EC standards. Lastly, APHIS observed knowledgeable forestry and hunting officials overseeing wild boar hunting and management programs, collaborating with animal health officials regarding swine health, including CSF sampling of hunter-harvested wild boar and wild boar found dead.

The information the thirteen EU Member States submitted, and information gathered by APHIS during the site visit to the seven EU Member States, confirmed that CSF is a notifiable disease in each country, and indicated that they are capable of detecting CSF via active and/or passive surveillance systems in domestic swine and/or wild boar. The type and level of CSF surveillance in each country varies and is based primarily on risk of introduction from adjacent regions and how animal subpopulations (e.g. feral swine vs. domestic pigs) and production types (e.g. backyard vs. commercial) may affect potential spread if CSF is reintroduced. Some of the countries APHIS reviewed conduct active surveillance for CSF only in domestic swine, while others include wild boar in their active surveillance plan. All of them conduct passive surveillance for CSF in domestic swine and wild boar, if only as a means of disease exclusion in suspected

<sup>&</sup>lt;sup>8</sup> Although no restricted areas remain in Greece due to ASF detection in domestic and wild swine, at the time of this report Greece continues to maintain an ASF surveillance zone as a precautionary measure (designated as a Part I zone in accordance with EU ASF zoning standards).

cases of swine disease. Greece has an active CSF surveillance plan for domestic swine but did not meet sampling targets. According to Greek authorities the staffing shortage contributed to falling short of collecting target sample numbers. While staffing shortages in Greece are a challenge, APHIS considered Greece's nationwide active CSF surveillance program to be ancillary to its passive CSF surveillance program, which APHIS concluded to be sufficient to ensure detection if CSF were to be introduced.

# APHIS Conclusions for the European CSF Region

APHIS found no evidence that CSF is present in the thirteen countries selected for review. Therefore, by extension, APHIS considers it unlikely that the disease is present in the European CSF Region.

The EC maintains legislation requiring competent EU Member State veterinary authorities be notified if CSF is detected and outlines the control measures to implement when CSF is detected. The EC legislation and affiliated requirements are transposed into national legislation and programs by all countries that are included in the European CSF Region. The EC implements a CSF regionalization strategy to address potential reintroduction of CSF into regions of the EU identified as being at higher risk. As a precaution, the EC imposes additional measures on these higher risk regions in order to mitigate against potential spread of CSF via intra-Union trade that might occur during the period between introduction and subsequent detection. Currently, these measures apply in the whole territory of Romania and Bulgaria.

APHIS found the countries selected for review effectively implement CSF prevention and control measures and maintain robust traceability practices for live breeding swine, pork, and pork products in accordance with EC standards. The thirteen countries reviewed have demonstrated a history of promptly reporting CSF detections and taking appropriate measures to prevent exportation of infected or contaminated commodities.

APHIS concluded that the thirteen EU Member States are capable of detecting CSF in both domestic swine and wild boar through their active and/or passive surveillance systems. Due to the adoption of the EC requirements by the non-EU Member States (United Kingdom, Lichtenstein, and Switzerland), this conclusion extends to the countries of the entire European CSF Region. APHIS further concluded that if CSF was introduced, the appropriate competent authorities could mount an effective emergency response against the disease and could safeguard against spreading CSF to third countries through the export of susceptible commodities.

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<sup>&</sup>lt;sup>9</sup> The European CSF Region is comprised of twenty-eight countries in Europe: twenty-five are the EU Member States of Austria, Belgium, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain and Sweden (APHIS does not include Bulgaria and Romania in the European CSF Region); and three are the non-EU countries of Lichtenstein, Switzerland, and the United Kingdom.

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