USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Germany

APHIS report on the review of classical swine fever, foot-and-mouth disease, and swine vesicular disease statuses, including information on preparedness activities for African swine fever

Veterinary Services

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1. Executive summary

The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) with the collaboration of the Canadian Food Inspection Agency (CFIA) conducted a review of the European Union (EU) animal health statuses for four transboundary animal diseases that affect swine: foot-and-mouth disease (FMD), swine vesicular disease (SVD), classical swine fever (CSF), and African swine fever (ASF). APHIS currently recognizes the Federal Republic of Germany (Germany) as free of FMD and SVD, and as low risk for CSF as part of the APHIS-defined European CSF region. Regarding ASF, APHIS recognizes EU zoning decisions for ASF rather than the ASF status of individual EU Member States, including Germany. APHIS concurrently reviewed the status of the EU ASF zoning and reported its findings in a separate EU-wide report. APHIS gathered information on Germany's ASF preparedness and monitoring activities which are described in this report and are also considered in the EU ASF zoning report. While APHIS considers ASF to exist in parts of the EU, at the time of this report it does not consider ASF to be present in Germany.

The objective of this review is to determine whether or not conditions in Germany justify maintaining its animal health statuses for the above diseases. The review consisted of a document review and a site visit in Germany conducted from September 9 to 13, 2019 to verify and complement information relevant to the factors APHIS considers when recognizing the animal health status of a region.

For this review, APHIS analyzed the information provided by Germany's Federal Ministry of Food and Agriculture (BMEL), Federal Office of Consumer Protection and Food Safety (BVL), and the competent authorities of Germany's 16 federal states (*Länder*); as well as on the observations made by the APHIS/CFIA team on the site visit; information available on the websites of the European Commission (EC) and the World Organization for Animal Health (OIE); and other publicly available information.

Based on the above, APHIS found no evidence that ASF, CSF, FMD, and SVD are present in Germany at the time of this report. We conclude that Germany conducts sufficient control measures to prevent their entry, and, in the event of a hazard incursion, is capable of detecting the hazard and containing its spread. In addition, Germany has demonstrated a history of promptly reporting disease events and taking appropriate measures to prevent their export to third countries. Furthermore, APHIS found Germany's ASF preparedness and monitoring to be sufficient to ensure prompt detection of incursion of ASF into the country.

In consideration of the favorable review of Germany's animal health statuses, APHIS concludes that current conferred statuses and import mitigations for CSF, FMD, and SVD are appropriate. APHIS recommends that recognition of these statuses be maintained until the next APHIS review or until a change in Germany's animal health status is reported.

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3. Abbreviations

ADNS	Animal Disease Notification System of the European Union
APHIS	Animal and Plant Health Inspection Service
ASF	African swine fever
BfR	Federal Institute for Risk Assessment
BIP	Border Inspection Post
BMEL	Federal Ministry of Food and Agriculture
BVL	Federal Office of Consumer Protection and Food Safety
CFIA	Canadian Food Inspection Agency
CSF	classical swine fever
CVED	Common Veterinary Entry Document
DG SANTE	Directorate General for Health and Food Safety
ELISA	enzyme-linked immunosorbent assay
EC	European Commission
EU	European Union
FLI	Federal Research Institute for Animal Health (Friedrich-Loeffler Institute)
FMD	foot and mouth disease
HIT	National database for animal identification, registration and traceability system (*Herkunftssicherungs und Informationssytem für Tiere*)
NRL	National Reference Laboratory
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
SVD	swine vesicular disease
TSN	German Animal Disease Notification System (*Tierseuchennachrichtensystem*)
TRACES	Trade Control and Expert System
USDA	United States Department of Agriculture
WAHIS	OIE's World Animal Health Information System

4. Introduction

The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products into the United States to guard against the introduction and spread of transboundary animal diseases. In support of this goal, APHIS prohibits or otherwise restricts the importation of animals and animal products from regions that APHIS either does not recognize as free of classical swine fever (CSF), foot-and-mouth disease (FMD), and swine vesicular disease (SVD), among other diseases, or recognizes as affected with African swine fever (ASF). These four highly contagious viral diseases are exotic to the United States, and CSF, FMD and ASF are among the OIE listed diseases of concern for international trade [1-4]. Currently, APHIS recognizes the Federal Republic of Germany (Germany) as low risk for CSF as part of the APHIS-defined European CSF region, and as free of FMD and SVD [5]. While APHIS considers ASF to exist in parts of the EU, at the time of this report it does not consider ASF to be present in Germany [5]. Furthermore, during the period of this review, Germany did not establish restricted zones due to detection of ASF [6].

Periodically, APHIS reviews the APHIS-recognized animal health statuses of foreign regions to determine whether the conditions in the region support the continuation of APHIS' recognition of those statuses [7]. Consistent with regulations in Title 9 of the Code of Federal Regulations Part 92 (9 CFR 92) [8], APHIS conducted a review of the EU's animal health statuses for four transboundary animal diseases that affect swine, FMD, CSF, SVD, and ASF. APHIS conducted this review with the collaboration of the Canadian Food Inspection Agency (CFIA). As part of this EU review, APHIS selected Germany as one of 13 representative Member States included in the review. This document is the report of findings and conclusions specific to Germany; findings and conclusions specific to the other 12 Member States are provided in individual reports and overall findings and conclusions regarding recognition of the APHIS-defined European CSF region and EU zoning decisions for ASF are provided in separate APHIS review reports for those two animal health statuses.

In order to evaluate whether conditions in Germany continue to support its recognitions by APHIS of its FMD, CSF and SVD statuses, and APHIS recognition of EU zoning for ASF, APHIS collected and analyzed information relevant to the factors used to conduct evaluations to establish initial animal health statuses as described in 9 CFR Section 92.2 [9]. These factors allow APHIS to establish a comprehensive representation of Germany's veterinary infrastructure, livestock demographics, livestock movement, surveillance programs, disease control capabilities, and emergency response systems for the specified hazards. APHIS evaluated the information in order to determine that Germany meets the following overarching standards:

- The hazards were not present in Germany at the time of this review;
- The hazards are unlikely to infect or contaminate the commodity being exported to the United States due to countermeasures taken by the German veterinary authorities; and,
- If Germany has an incursion, it will be rapidly detected, the United States and/or the OIE will be promptly notified, and all necessary actions will be taken to prevent the introduction of the hazards into the United States through exportation of commodities infected with or contaminated by the hazards.

During the period of this review, APHIS does not consider Germany to be affected with ASF, and at the time this report was written, ASF has never been reported in Germany. However, ASF

virus has been recently detected in domestic swine and wild boar in other parts of the EU, including neighboring Member States of Belgium, Czech Republic and Poland. APHIS gathered information on Germany's ASF preparedness and monitoring activities which are described in this report and are considered in a separate report on APHIS' review of its recognition of EU zoning decisions for ASF.

The review consisted of a document review and a site visit in Germany from September 9 to 13, 2019 to verify and complement all information APHIS collected and analyzed relevant to the factors used to conduct evaluations to establish initial animal health statuses. APHIS collected information from Germany through use of a standardized questionnaire developed for APHIS animal health status reviews. All information was collected from records of Germany's Federal Ministry of Food and Agriculture (BMEL), Federal Office of Consumer Protection and Food Safety (BVL), veterinary authorities of Germany's 16 federal states (*Länder*), the European Commission (EC), the OIE, and other publicly available information. All information and data gathered during the site visit, along with observations by the APHIS/CFIA site visit team are incorporated into this review report.

The results of this review are expected to inform APHIS management decisions regarding the status of CSF, FMD, and SVD in Germany; the status of EU zoning for ASF; and whether to amend restrictions on the importation of relevant commodities from Germany.

5. Scope of the review

The scope of this review of Germany covers CSF, FMD, and SVD status and ASF zoning. All four diseases affect swine. Acknowledging that FMD affects other cloven-hoofed mammals such as cattle, sheep, and goats; this review is focused on swine, as part of a larger APHIS evaluation of the swine health statuses of EU Member States. As of the conclusion of this review, Germany has never detected ASF in the country and had not established any restricted zones within the country because of detection of ASF. The hazards under consideration in this review are the viruses that cause ASF, CSF, FMD, and SVD.

6. Status of hazards under review in Germany

APHIS maintains a list of animal health statuses of regions on the APHIS website. APHIS considers Germany to be free of FMD and SVD. APHIS considers Germany to be low risk for CSF as part of the APHIS-defined European CSF region.[1] At the time of this report, Germany had never reported an occurrence of ASF, and therefore, had not established restricted zones because of detection of ASF [1, 6]. During the site visit, APHIS reviewed Germany's ASF zoning requirements, which were considered in the APHIS' overarching review of EU ASF zoning. The last outbreak of FMD in Germany occurred in 1988; CSF last occurred in 2006 in

[1] APHIS-defined European CSF region includes: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Ireland, Slovakia, Slovenia, Spain, Sweden, Switzerland, and United Kingdom. The importation of pork, pork products, and swine from the APHIS-defined European CSF region is subject to restrictions specified in 9 CFR 94.31. In addition, swine semen imported from the APHIS-defined European CSF region is subject to restrictions specified in 9 CFR 98.38.

domestic swine and 2009 in wild boar; and SVD last occurred in 1985 [10]. The OIE recognizes Germany as CSF free and FMD free where vaccination is not practiced [1].

Routine vaccination for CSF, FMD and SVD is prohibited in Germany and no vaccine is available for ASF [10]. Emergency vaccination for FMD and CSF is permitted only under exceptional circumstances to prevent disease spread and only in accordance with established official disease eradication regulations.

7. Likelihood of hazard entry into Germany

Germany is centrally located in Europe, bordering the Baltic Sea and the North Sea. It shares land borders with eight other EU Member States: Austria, Belgium, Czech Republic, Denmark, France, Luxembourg, the Netherlands, and Poland. It also shares a land border with Switzerland, a non-EU Member State which trades within the European single market.

Although Germany does not have land borders with third countries that are not part of the European single market, it does have significant international trade through its airports and seaports. Germany has a total of 17 border inspection posts (BIPs) approved by the EU (9 airports and 8 seaports) [10].

As other third countries and EU Member States, Germany is exposed to potential entry of transboundary animal disease agents through international trade of animals and animal products through both legal and illegal pathways and international movement of passengers. In addition, there is potential entry exposure though intra-Community movement of commodities, passengers and wildlife whenever disease agents are present in other EU Member States. Thus, APHIS collected information on Germany's veterinary infrastructure, including legal authority for the animal health activities and organizational structure of the veterinary services; livestock demographics and traceability; and movement controls for animals and animal products to determine the effectiveness of measures to prevent incursions of the hazards under evaluation.

7.1 Veterinary authority and infrastructure

Legal authority for animal health activities

The main legal authority for the animal health activities of the official veterinary services in Germany resides in the Animal Health Act (the Act) and more detailed regulations are provided in implementing statutory instruments (Ordinances) adopted pursuant to the Act [10, 11]. The Act represents the legal basis for public animal disease control. It provides the basis for preventing the introduction of animal diseases from other countries; specifies surveillance measures for FMD, CSF, SVD and ASF; and provides for emergency control countermeasures for the eradication of highly contagious diseases, including depopulation and compensation. It also comprises regulations with regard to intra-Community movement, import, transit, and export of animals, animal products and raw materials. The Act provides authority for imposing fines and criminal penalties for violation of animal health laws and regulations. The authority for on-farm inspection is provided by the General Administrative Regulation which provides authority for the verification of compliance with animal health law. These laws and regulations prohibit the vaccination for FMD, CSF, and SVD except as an emergency countermeasure in the event of disease outbreaks. Furthermore, they include requirements for obligatory notification of certain animal disease suspicion; animal identification and holding registration; and on-farm

biosecurity. The EC minimum standards for FMD, CSF, SVD and ASF prevention, preparedness and control countermeasures if disease occurs are implemented into German law through a series of specific Ordinances addressing those diseases.

The primary EC legislation pertaining to control of FMD, CSF, SVD, and ASF are listed in Table 1 with the corresponding transposition into German legislation.

Table 1: EC and German legislation pertaining to control of FMD, CSF, SVD and ASF [10]

Disease	EC legislation	German legislation
CSF	Council Directive 2001/89/EC on Community measures for CSF control (last amended)	German Ordinance on Protection against Swine Fever and African Swine Fever in the version promulgated on Dec. 16, 2018
	Commission Decision 2002/106/EC Diagnostic Manual for CSF testing and confirmation (as last amended)	Directly applicable to Member States
SVD	Council Directive 92/119/EEC on control of certain animal diseases and specific SVD measures (as last amended)	German Ordinance on Protection against Swine Fever and African Swine Fever in the version promulgated on Apr. 11, 2001 (as last amended)
	Commission Decision 2000/428/EC diagnostic procedures for SVD testing, confirmation & differential diagnosis	Directly applicable to Member States
FMD	Council Directive 2003/85/EC on Community measures for the control of FMD	German Ordinance on the Protection against Foot-and-mouth disease in the version promulgated on Dec. 20, 2005
	Commission Decision 91/42/EEC criteria applied for drafting FMD contingency plans	Directly applicable to Member States
ASF	Council Directive 2002/60/EC on specific provisions for the control of ASF	German Ordinance on Protection against Swine Fever and African Swine Fever in the version promulgated on Dec. 16, 2018
	Commission Decision 2014/709/EU concerning ASF control measures in certain Member States (as latest amended)	Directly applicable to Member States

Organizational structure of the veterinary services

The BMEL is the central competent animal health authority responsible for the regulatory structure for animal health programs and activities, including transposition of EU animal health law into German national law [10]. BMEL is also responsible for food safety, animal feed safety, animal welfare, plant protection, and laws governing the veterinary profession. BMEL coordinates but does not have administrative authority to enforce national law as it is the responsibility of the 16 Federal states (*Länder*) to implement and enforce national law. BMEL is responsible for external representation regarding animal health issues with the EU, OIE and third countries, including all agreements related to the import, export and intra-Community trade of animals and animal products and the notification of animal disease outbreaks. BMEL also negotiates bilateral agreements for non-harmonized commodities. BMEL works closely with

other departments within the federal government which share responsibilities pertaining to animal health, food safety, environmental protection, and industry.

The Federal Office of Consumer Protection and Food Safety (BVL) is an independent federal authority affiliated with BMEL. BVL coordinates the national food inspection system, playing a significant role coordinating the cooperative functions between the federal government and the *Länder*. It provides logistical and organization support, as well as facilitates information and data exchange, especially in regard to food safety, feed monitoring and consumer protection. BVL is the national contact point for third country and EU auditing of food safety and serves as advisor and coordinator for the export of animals, animal products and feed to third countries.

The Federal Research Institute for Animal Health (Friedrich-Loeffler Institute, FLI) is a research agency regarding issues related to health and welfare of farm animals and zoonotic diseases. It conducts research in the fields of animal diseases, animal welfare, animal husbandry, animal nutrition, and farm animal genetics. It is responsible for conducting risk assessments related to animal disease control and animal disease risk through importation of animals and animal products. The Federal Institute for Risk Assessment (BfR) is the scientific institution which prepares expert reports and statements on food safety and consumer protection issues.

Germany is comprised of 16 Federal states (*Länder*) each with their own parliament, their own government and their own administration. The *Länder* are responsible for implementation and enforcement of official controls to comply with the EC and German legislation in the relevant areas. The Federal Government has no authority to instruct the *Länder* in these areas. *Länder* are responsible for issuing certifications for the export of animals and animal products, as well as implementing animal identification, farm registration, and animal and animal product movement controls. The Federal states also implement control measures in the event of animal disease outbreaks.

Within each *Länd*, there are districts and independent municipal authorities which operate as the local food and veterinary authority. In Germany there are a total of 431 local and veterinary authorities in 401 districts and municipalities. The local food and veterinary authorities monitor compliance with veterinary requirements at the farm level and are responsible for facility approvals, under direction from the *Länd*.

Resources for the veterinary services

The total budget for Germany in 2019 is 356.4 billion Euro. The budget is set by the German parliament. The budget allocation for BMEL in 2019 is 6.32 billion Euro, which is 1.77% of the total federal budget. This is an increase of 304 million Euro in comparison to the 2018 budget [10].

Table 2: Total Federal and BMEL Budgets for 2017-2019 [10]

Fiscal year	Total budget of Germany	BMEL allocation
2017	329.1 billion Euro	6 billion Euro
2018	343.6 billion Euro	6.01 billion Euro
2019	356.4 billion Euro	6.32 billion Euro

Table 3: Budgets of Federal research laboratories & institutes funded by BMEL in 2017-2019 [10]

Federal bodies/institutes	2017	2018	2019
BVL	51.9 million Euro	62.2 million Euro	62.0 million Euro
FLI	106.7 million Euro	111.9 million Euro	103.8 million Euro
BfR	91.7 million Euro	95.5 million Euro	107.8 million Euro

The funds required to finance the official veterinary services in the *Länder* are included in the annual budget acts as adopted by each *Länd* parliament. The annual budget for animal disease control at the *Länd* level averages 300,000 – 900,000 Euro. In the event of an animal disease outbreak, additional appropriations will be made available from municipal budgets as stipulated by German law and implemented by the *Länd*. In addition, Germany has established a system of Animal Disease Funds in each *Länd*. These Funds are implemented and administered by each *Länd* and primarily provide the source of indemnity funding in the event of culling of animals as a countermeasure for an animal disease outbreak.

7.2 Livestock demographics and traceability

Livestock demographics

Germany has a swine population of over 26 million pigs, ranking second in Europe after Spain. It is the third largest pork meat producing nation after China and the United States and ranks first in Europe, as Germany not only slaughters pigs reared in Germany, but from other EU Member States as well. Germany's domestic swine population is concentrated mainly in the northwest part of the country in Lower Saxony and North Rhine-Westphalia, followed by Bavaria (*see* Figures 1 and 2 on next page). In 2017, almost 58 million pigs were slaughtered in Germany to produce 5.5 million tons of pork. Germany exports more than 2.9 million tons of pork to over 100 countries [12].

Increasingly swine production is becoming vertically integrated in Germany with slaughterhouses sourcing pigs through their own farming operations or through contracts with producers [10]. Around 60% of all swine are raised in Germany on holdings with greater than 1,000 animals [12]. In Germany, for the commercial animal market for swine, cattle, sheep and goat, animals move almost exclusively direct from farm to slaughterhouse. Collection centers are of secondary importance for livestock marketing used primarily for exchange of breeding animals for hobby farmers [10]. During the site visit, the APHIS/CFIA team was informed by German authorities that very small holdings, such as single pig holdings that raised pigs for personal consumption, have become rare in Germany.

The APHIS/CFIA team visited both large- and small-sized swine farms, a swine assembly center, a large (exporting) slaughterhouse/processing plant, and a processing plant which produced products for the domestic market. In general, the team observed good biosecurity and record keeping practices that were compliant with applicable EU and German regulations.

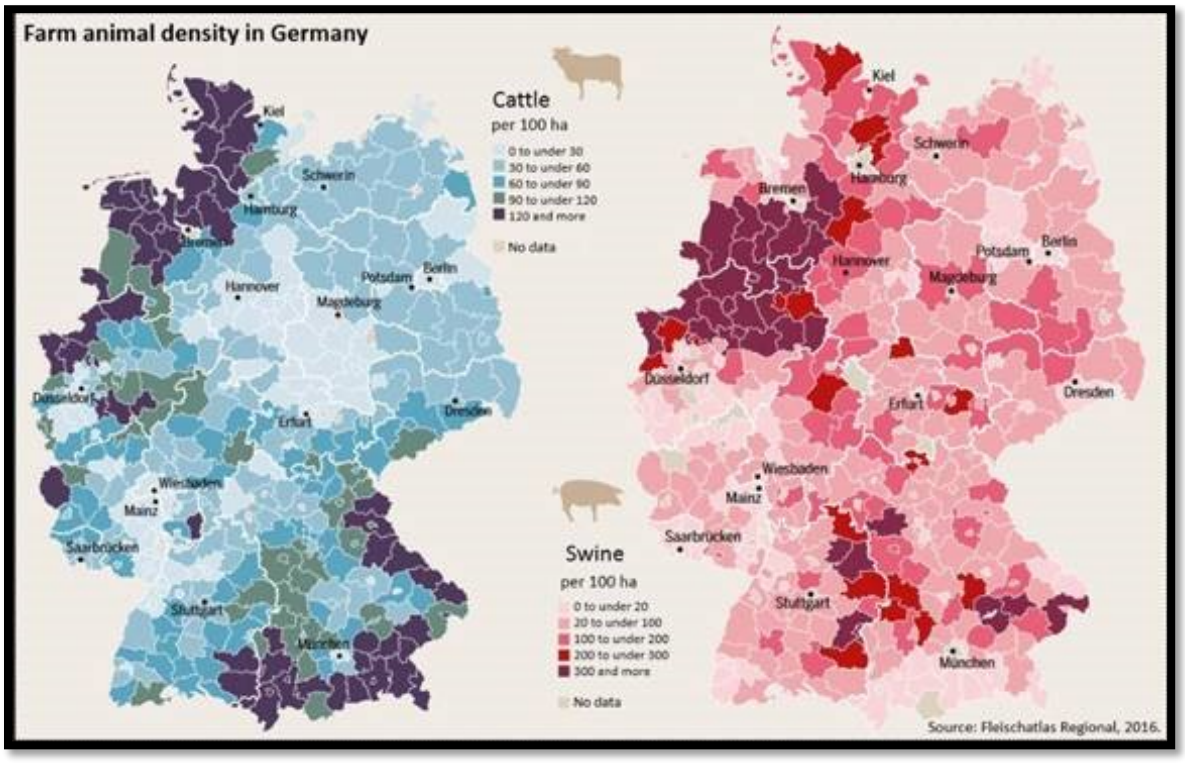

Figure 1: Farm animal density in Germany, 2016 [13]

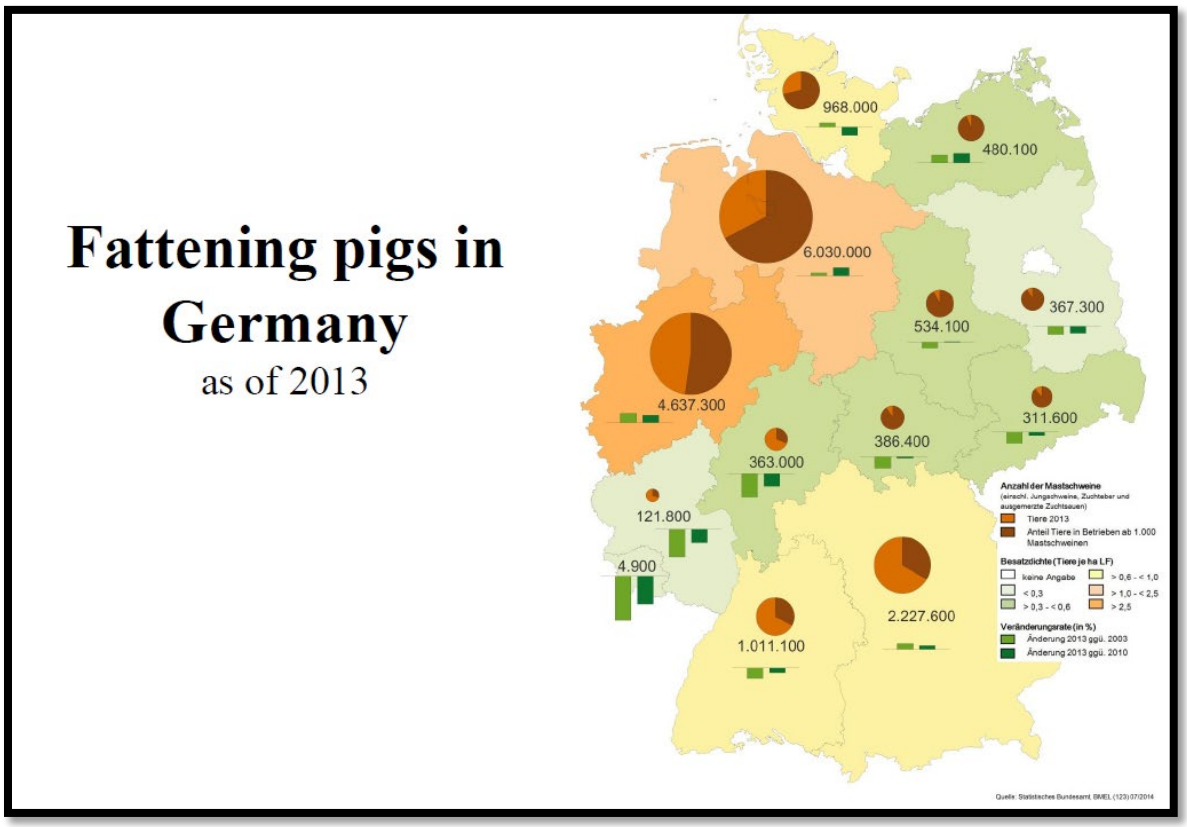

Figure 2: Fattening swine population and distribution in Germany, 2013 [13]

Holding registration and animal identification

The system for the identification and registration of groups of pigs includes ear tags or tattoos with holding number; maintaining a holding register on-site, which includes an inventory accounting for animals kept on the holding (applies to any place in which animals are held, kept or handled), and records all entry and exits of animals within the last 3 years; and a register of pig holdings in a national database [10]. *Länder* conduct inspections annually on a representative sample to account for 1% of holdings to verify compliance.

Any keeper of swine must notify the *Länd* veterinary authority before starting to keep swine and provide their name, address, intended yearly average number of swine, kind of swine production (e.g. sows, fattening pigs, piglets, etc.), location, and update this information as it changes. This requirement applies to both commercial and non-commercial holdings regardless of the number of animals being kept. The veterinary authority issues the holding a unique 12-digit registration number. During the site visit, the APHIS/CFIA team inquired about previous derogations for holdings with only a single pig (raised for personal consumption). German officials confirmed that such derogations were never granted in Germany, even though it was a practice used in other Member States until November 2018.

Each keeper is required to notify veterinary authorities of the number of breeding sows, boars and fattening pigs over 30 kg, and piglets under 30 kg, on the holding as of January 1 of each year. In addition, the keeper must notify veterinary authorities of all transfers of animals onto or off the holding within 7 days of the movement. This information is usually filed electronically, and data is maintained in a national database referred to as HIT (German animal identification, registration and traceability system, *Herkunftssicherungs und Informationssytem für Tiere*).

Piglets receive an ear tag or tattoo usually in the first days of their lives but no later than weaning. Ear tags are uniquely numbered and may only be used once. The place of birth can be traced with the ear tag/tattoo number.

Pigs entering the slaughterhouse are marked with a stamp (slap tattoo) indicating the holding registration number. The carcasses of slaughtered pigs are marked with stamps with a number that indicates the day of the week that the animal was slaughtered and the consecutive number on the processing line. The carcass stamps are linked back to the holding registration number in order to provide traceability of the product back to the holding of origin.

The APHIS/CFIA site visit team visited two large commercial swine holdings, a small swine holding, a swine assembly center, and a large (exporting) slaughterhouse/processing plant to verify the integrity of the traceability system in operation. The team observed that traceability processes, including animal identification and holding registries, were sufficient to support exportation to third countries.

7.3 Movement of animals and animal products

Controls on domestic and intra-Community trade

Information on movement of pigs within Germany are recorded in the holding registers for all movements to and from the holding. As mentioned previously, this information must also be entered into the HIT database system within 7-days of the movement which serves as the means to notify veterinary authorities of the movement. Approval and veterinary inspection certificates

issued by a *Länd* are required for movements to and from holdings that are under official control for animal disease (as well as for intra-Community trade and international import and export). Veterinary certificates must be issued within 10 days prior to the movement. These procedures also apply if the holding has received a disease status recognition by a *Länd* in regard to diseases for which Germany has an official control program (such as tuberculosis, brucellosis, etc.) [10].

Germany has been a member of the EU since 1958 [14]. A key policy of the EU is the establishment and functioning of an internal (intra-Community) market that provides for, among other things, the free movement of persons and goods, including agricultural products, among Member States [15]. As part of the European single market, intra-Community movement of animals and products are not subject to document or physical inspection at land border checkpoints, ports of entry, seaports or airports when shipments move between two Member States.

In general, movement of animals and animal products among EU Member States cannot be limited or prohibited except when such restrictions have been imposed by the EU on animal or public health grounds [16, 17]. However, movement of animals and animal products is only authorized when animals or their products come from holdings that are in compliance with pertinent legislative requirements (both EU and Member State) and are authorized and registered by the competent authorities from the Member State of origin. Swine, cattle, sheep, and goats for intra-Community trade must be identified in accordance with applicable legislation, be accompanied by a health certificate, not show clinical signs of disease, and not originate from a holding that is subject to animal disease-related restrictions [17-20].

To decrease the likelihood of spread of highly contagious animal diseases among EU Member States to other Member States, the EU has developed measures that are disease specific and specific to affected Member States [21, 22]. In general, these measures apply in addition to the animal health control measures applicable to all EU Member States. The measures, and the Member States or regions of Member States to which they apply, are specified in EC Decisions that are updated regularly as the disease situation in the EU changes. Among the measures are additional restrictions on movement of swine both to other Member States, and within affected Member States; additional requirements for serological testing and clinical examination for disease; and additional animal health certification requirements.

EC requirements for intra-Community trade of pigs (e.g. Directive 64/432/EEC, Directive 2008/73/EC, and Regulation (EU) 2017/625) have been incorporated into German law by the *Ordinance on Intra-Community Movement, Import and Transit of Live Animals and Products – Ordinance on Disease Control in the Internal Market* [10, 23]. These laws stipulate the following for intra-Community trade in bovine and swine: an identity check and clinical examination of animals be completed within 24 hours before transport; requires certification that origin is free of certain diseases; prohibits transport of animals from zones restricted due to animal disease to outside of these zones; and prohibits commingling with animals with a lower animal health status during transportation.

Intra-Community movements of animals and animal products must be accompanied and certified by the Trade Control and Expert System or TRACES document issued by an official veterinarian of the holding of origin. TRACES is the EC's online management tool to record the movements of animals, products of animal and non-animal origin, feed and plants transiting EU countries or imported from outside the EU, in order to ensure the safety of food, animal and public health.

Commodities, in most cases, are accompanied by health certificates or commercial documents and the competent authorities may issue these documents online through TRACES. Through this system, the EU aims to facilitate trade, speed up administrative procedures and improve the management of health threat risks, as well as combat fraud and improve the safety of the food chain and animal health [24].

The intra-Community trade of animals and products to and from Member States, as well as the import and export with non-EU countries, is summarized in the TRACES annual reports.

Import controls

Germany imports animals and animal products susceptible for the diseases under review primarily from other EU Member States and more limited quantities from certain third countries. Germany prohibits imports of animals and animal products from regions affected with the diseases under evaluation [10]. According to data published by the World Trade Organization, International Trade Center for the period 2016-2018, Germany primarily imported live swine from other EU Member States and countries in the EU single market (predominantly breeding swine from Denmark and slaughter pigs from the France, Poland, Czech Republic, Netherlands and Denmark) [25]. Germany imported a small number of live swine from third countries, Canada and the United States, during this period.

For meat and meat products during this same time period, Germany imported:

- Swine meat, fresh, chilled or frozen – primarily from other EU Member States and countries that trade in the EU single market, with the top three markets being Belgium, Denmark, and the Netherlands; and small amounts from third countries, with Chile, the United States, and Australia as the top three.
- Edible offal (large animals) – again primarily from the EU single market, primarily from the Netherlands, Austria, and Denmark; third country imports were primarily from New Zealand.
- Meat and offal, salted, in brine, etc. – the top markets were Italy and Spain, with significant amounts from Thailand and Brazil.

For importation of animals and animal products from third countries, Germany follows EU Directive 2004/68/EC as well as Commission Regulation (EU) No. 206/2010, which establishes a list of third countries or parts of third countries where sanitary certification conditions are approved for imports into the EU of live animals and their products [10]. To be authorized as an approved third country for imports, the interested third country must send an official request form and the required information to the EC's Directorate General for Health and Food Safety (DG SANTE) – Directorate F (formally known as the Food and Veterinary Office, FVO). DG SANTE reviews the information and performs an audit inspection visit to the country. If the evaluation is satisfactory, the country will be listed as an approved third country partner for importation of the specified commodity.

The animal health requirements for importing animals and animal products are set out in specific EU legislation and regulations. Commission Decision 2007/275/EC lists the animals and products to be subject to controls at BIPs under the main legislative import controls of Regulation (EU) 2017/625. These pieces of legislation set out the veterinary legislative requirements for consignments of live animals and animal-origin products to import into or

transit through the EU Member States. For live pigs, additional requirements can be found HERE. Import requirements for bovines and sheep/goats from third-countries are also laid out. For meat products, additional requirements can be found HERE.

In general, imports of animals and animal products must be accompanied by the following documentation:

- Common Veterinary Entry Document (CVED)
- Export health certificate
- Other documents, such as the commercial invoice, bill of lading or air waybill, and diagnostic laboratory reports

The requirement for the official veterinary service to provide a certificate confirming that veterinary checks have been carried out are described in Regulation (EU) 2017/625. This certificate is known as a Common Veterinary Entry Document or CVED. The certificate is produced via the TRACES system. The certificates must only be signed by the official veterinary service - it is not acceptable for the certificate to be signed by other officers. Each certificate will be assigned a serial number by TRACES. The official veterinary service must retain copies of the CVEDs and original third country health certificates or health documents accompanying consignments for 3 years. The export health certificate must be signed by an official veterinarian of the competent authority of the exporting third country guaranteeing that the conditions for import into the EU have been met.

Upon arrival and entry to the European single market, animals and animal products with their accompanying certificates are verified and checked by official veterinarians at an EU border inspection post (BIP). Although Germany does not have land borders with third countries that are not part of the European single market, it does have significant international trade through its airports and seaports.[2] Germany has a total of 17 border inspection posts (BIPs) approved by the EU (9 airports and 8 seaports). The list of approved BIPs in Germany and the types of commodities approved for entry can be found in Commission Decision 2009/821/EC.

At designated BIPs, an official veterinarian performs an inspection consisting of the following:

- **Document checks** are performed on 100% of consignments by the official veterinarian. The official veterinarian verifies information on the export health certificate, including verifying the goods come from an authorized country and establishment, and other documentation per Commission Regulation (EU) No. 206/2010.
- **Identity checks** for cloven-hoofed animals and horses, the official veterinarian confirms the individual identification of at least 10% of the animals or at least 10 animals representative of the shipment. For products, the official veterinarian verifies proper identification of the transport vehicle (e.g., seal on shipping container) as well as visually inspecting labeling and number of packages and/or containers. The identity check confirms the mechanism for traceability to the exporting country and the holding of origin.
- **Physical checks** are performed on a percentage of consignments per national sampling plans, Regulation (EU) 2017/625, suspicion/non-conformities/animal health or welfare

[2] Switzerland harmonizes its animal health laws with the EU and participates in the European single market, animals and animal products move freely between Switzerland and EU Member States without inspection at a BIP [26].

concerns, or notifications via TRACES. For products, the official veterinarian verifies the integrity of goods via sensory examination, labeling, testing of temperature or pH, and other laboratory diagnostic tests for residues, pathogenic agents, and contaminants. Laboratory examinations of products are conducted based on risk analysis of previous diagnostic testing results, product type, volume and frequency imported at the BIP, and any relevant EU legislation. Live animals are examined for clinical signs of disease, animal welfare compliance, and, for a certain percentage, blood sampling for diagnostic testing.

Animals and animal products are refused if the shipment does not pass the above inspection or is not in compliance with Commission Regulation (EU) No. 206/2010. After a positive laboratory result for animal products, in accordance with Regulation (EU) 2017/625, the next 10 consignments from the establishment are subject to 100% mandatory examination and testing; this continues until 10 consecutive negative laboratory results are confirmed. Refused products are destroyed, treated/transformed or re-exported to the country of origin. Refused consignments are classified and treated as Category I animal by-products in accordance with the EU animal product and by products (ABP) legislation (EC) 1069/2009 and its implementing regulation (EC) 142/2011. Destruction or treatment of such products must be carried out at approved animal by-product establishments and arrive under sealed containment accompanied by the CVED and commercial import documentation. Live animals may be quarantined, destroyed or re-exported to the country of origin. If refused, the CVED and other import documents are invalidated in TRACES. Notifications of refused shipments are recorded in TRACES to prevent attempts to re-enter at other BIPs in the EU. If considered necessary, an import ban against the country or importer could be issued.

A complete description of EU legislation and transposed German legislation regarding veterinary border control can be found HERE.

Upon clearance through the BIP, imported commodities circulate throughout the EU usually without additional mandatory controls or inspections by the official veterinary services of other EU Member States. Member States may conduct official controls and checks are conducted randomly anywhere within their territory. In Germany, inspections at the place of destination, particularly at slaughterhouses, occur on a regular basis [10].

Transit controls

Transit across EU Member States of products moving between third countries is allowed under EC legislation, provided that there are no import restrictions on the source country and meet the EU animal health requirements. The conveyances are sealed at the point of origin in the third country, although officials at the point of departure from that country can break and replace the seal for inspection purposes. Customs officers, from the EU Member State where the BIP is located, record the seal number and break the seal upon arrival at the BIP point of entry. While Germany does not have land borders with third countries that are not part of the European single market, products intended for transit through the EU to a third country may enter the EU through one of Germany's airport or seaport BIPs. The products in transit undergo the same checks as imported consignments, but no further unloading or alteration of the cargo is allowed while in the EU. A veterinary inspection seal and customs seal are applied at the entry BIP for transit, a route plan is approved, and a specific exit point is designated. The BIP at the point of exit is

notified of the transit shipment, records the exit, and sends confirmation back to the BIP at the point of entry when the vehicle leaves the country [10, 17].

Live-haul trucks, personal vehicles and baggage, swill feeding and international catering waste

In addition to the movement of animals and animal products, other vulnerable entry pathways for the diseases under review include contaminated livestock vehicles, animal-origin commodities carried into the country via personal vehicles and passenger baggage, feeding improperly cooked food waste to swine, and improper disposal of international catering waste. The EU and Germany have prevention mechanisms in place for these entry pathways.

As mentioned previously, Germany does not operate BIPs for land border crossings as it is completely surrounded by other EU Member States and Switzerland which participates in the EU single market. As such, Germany benefits from the implementation and enforcement by other EU Member States of vehicle cleaning and disinfection (C&D) control measures.

The EU has established legislation on the cleaning and disinfection (C&D) of empty livestock transport vehicles returning from third countries and regions of third countries with ASF. The requirements are described in Commission Implementing Decision 2013/426/EU (and subsequent amendments). All the returning empty livestock transporting vehicles from ASF-affected regions in Annex I of the Decision are checked at the BIP by the official competent authority.[3] Member States must require that drivers of livestock vehicles from third countries provide verification to the official competent authority of the Member State at the BIP that the interior of the vehicle and any equipment in contact with animals as well as the driver's protective clothes/boots used during unloading have been cleaned and disinfected after the last unloading of animals. If the cleaning and disinfection is deemed satisfactory by the official authority at the BIP, the official issues a C&D certificate and the vehicle may proceed to customs control and clearance. If deemed unsatisfactory, the official authority may refuse entry of the livestock vehicle and/or send the vehicle to a place designated by the official authority to undergo C&D.

For empty livestock transporting vehicles returning from regions that are not ASF-affected, there are general EU standards for C&D but currently no EU-level requirements for C&D certification for livestock vehicles entering the EU from third countries. Livestock vehicles from third countries must be cleaned and disinfected prior to loading animals in an EU Member State. In lieu of an official certification system, trucks must arrive cleaned and disinfected and, if requested, the truck driver must produce the C&D invoice from the washing station to the producer and/or regional official veterinarian to confirm C&D was performed. The disinfectant is typically noted on the invoice as well as date and location of the washing station. Although truck drivers are registered and receive required training about livestock hauling, including proper C&D procedures, this is a self-regulatory system with no official certification or regulatory oversight.

For in-country movement of livestock vehicles, transport vehicles, including feed delivery trucks, are expected to be cleaned and disinfected immediately after every transport of animals or of any product which could affect animal health [10]. Again, there is no official certification

[3] At the time of this status review, Annex I of Commission Implementing Decision 2013/426/EU listed the following third country regions: Belarus, Moldova, Russia, Serbia and Ukraine. None of these regions border the territory of Germany.

system; however, the transporter must ensure that for each vehicle used for the transport of animals has a register containing information about the date and place of C&D. This register must be kept for a minimum period of three years. If the truck does not appear clean, the producer or the official veterinarian can refuse entry and require the truck to be cleaned and disinfected before returning for loading. Prior to entering, many holdings enforce biosecurity measures for vehicles. Trucks must drive through spray stations and/or tire baths before entering the clean zone of the holding. Trucks enter and exit through specified gates; drivers wear appropriate personal protective equipment; and direct contact with the animals is limited or prohibited. On some holdings, the producer does not allow livestock vehicles to enter the holding; rather, the producer uses his own truck to transport animals from the holding to the livestock vehicle parked at the main road.

For non-commercial goods from third countries carried in personal vehicles and passenger baggage, the official veterinary services follow procedures in Commission Regulation (EC) 206/2009. This regulation lays down rules concerning the introduction of personal consignments of animal-origin products in personal luggage, personal vehicles, or items sent to private persons ordered via mail, telephone or internet. Personal consignments of meat, meat products, milk and milk products are not permitted from outside the EU other than Andorra, the Faeroe Islands, Greenland, Iceland, Liechtenstein, Norway, San Marino and Switzerland. Thus, personal consignments of animal-origin products are subject to inspection and seizure by the official veterinary services or other enforcement officials of the BIP. Veterinary officials of the *Länder* are in a close collaboration with German customs authorities who are responsible for the inspection of personal luggage. Transport officials at airports, seaports, travel agencies and postal services make travelers and customers aware of the prohibited materials in the Regulation by providing the information (posters) in Annexes III and IV of Commission Regulation (EC) 206/2009 [10].

To further prevent introduction and spread of animal diseases, the ban on feeding food waste to swine in the EU and disposal of international catering waste from cruise ships, airports, etc. is regulated by the Commission Regulation (EC) No. 1069/2009 and Commission Regulation (EU) 142/2011. Swill feeding or garbage feeding to swine is prohibited in Germany. International catering waste from cruise ships and airports is destroyed as Category I materials [27]. The regulation of international catering waste is the responsibility of the veterinary authorities of the *Länder*. International catering waste is stored in dedicated, covered, leak-proof containers and prominently labeled as “Category I – for disposal only”. Waste is disposed of by burial in authorized landfills or by incineration in approved plants. Typically, private companies are contracted to handle the waste and seized goods in accordance to Commission Regulation (EC) No. 1069/2009 and Commission Regulation (EU) 142/2011. It is the responsibility of *Länd* veterinary authorities to audit and inspect disposal documentation, incineration plants, and waste handling procedures of the private companies that handle the waste [27].

Collectively, the measures described in this section are in place to control and prevent incursions and spread of animal diseases that can be transmitted through animal-origin products.

8. Hazard detection, response, and notification

8.1 Disease detection and diagnostic laboratory support

For all diseases under review, passive surveillance is the strategy Germany primarily uses for early disease detection in domestic swine. Germany does not conduct active surveillance programs for FMD or SVD because those diseases have been absent from the country for many years [10, 27]. In November 2016, Germany established a monitoring program for ASF and CSF in both wild boar and domestic pig populations [10, 28].

Passive surveillance

Compulsory reporting to competent veterinary authorities for the diseases under review is mandatory in Germany in accordance with EU Directive 82/894/EEC, transposed into German law by the Animal Health Act which establishes the rules for the national animal disease notification system and the Ordinance on Notifiable Animal Diseases [10].

The Act stipulates that in the event of an outbreak of FMD, CSF, SVD, or ASF (notifiable animal diseases), or if there are symptoms suggesting the outbreak of any of these diseases, the owners, keepers, handlers, or transporters of the affected animals shall immediately notify the competent authority, stating their name and address, the location and farming method of the animals concerned, and any other animals kept which are susceptible to the disease in question, specifying the number of animals in each case. The animal keeper shall take measures to prevent the spread of the disease, in particular to keep diseased animals and animals suspected of being infected away from places where other animals are at risk of infection.

All veterinarians, including those in private practice, official government service, public or private research facilities, as well as those involved with animal production activities, are also obliged to notify the authorities without delay. The same applies to animal health supervisors, animal health inspectors, veterinary assistants, veterinary engineers, veterinary technicians, veterinary hygiene inspectors, official auxiliaries, food inspectors, feed inspectors, bee experts, wildlife wardens, farriers and claw trimmers, as well as persons who slaughter commercially and those engaged in the commercial handling, processing or disposal of slaughtered, culled or dead animals, or ingredients of animal origin. They must notify authorities if they become suspicious of a notifiable animal disease prior to the response by veterinary authorities.

After an infectious notifiable animal disease is identified by diagnostic investigations, the district competent authority must immediately (within 24 hours) notify the official veterinary authority of the *Länd*, who then notifies BMEL. This information must also be recorded into the German Animal Disease Notification System (*Tierseuchennachrichtensystem*, TSN), a national electronic database operated by the FLI to ensure information is shared between the district, *Länd* and Federal official veterinary authorities [29]. Within 24 hours of confirmation of a primary disease outbreak (i.e. not epidemiologically linked to another disease outbreak in Germany), BMEL notifies the EC and the other EU Member States (in accordance with EU Directive 82/894/EEC).[4] After receiving the disease notification, the EC posts the disease outbreak notification to the EU-wide Animal Disease Notification System (ADNS).

[4] Secondary disease outbreaks (i.e. epidemiologically linked to a primary outbreak in Germany) must be reported no later than the first working day of the week following confirmation, in accordance to EU Directive 82/894/EEC.

During the period 2016-2018, there were no suspect cases of the diseases under review reported to Federal or the *Länder* veterinary authorities. Furthermore, no samples tested positive for FMD or CSF during routine laboratory testing and no samples were tested for SVD (either suspect samples or samples collected for commercial or trade purposes). However, discriminatory tests to rule out other diseases for FMD and CSF with negative results were conducted in the federal states of Schleswig-Holstein and Thuringia during this time period [10].

CSF and ASF monitoring

Germany has established an annual monitoring program in wild boar and domestic swine to detect introduction of ASF and CSF. The Swine Fever Monitoring Ordinance (*Ordinance on Implementing the Monitoring of the Viruses of Classical and African Swine Fever in Wild Boar and Domestic Pigs of 9 November 2016*) require that wild boar carcasses found dead and hunted wild boar that show signs of illness be sampled for virological testing for ASF and CSF. A representative number of hunted wild boar that show no clinical signs of disease are randomly sampled for serological testing for ASF and CSF. In addition to the passive surveillance described above, a random sample of domestic swine are serologically tested only for CSF [28, 30, 31]. Target numbers for sample size are established by the BMEL and the *Länder* assign sample target goals to local authorities based on number and distribution of holdings and wild boar. During site visits, presentations from local veterinary officials indicate that the actual number of samples collected and tested exceeded the target number.

In 2017, 735 wild boar were found dead and 252 wild boar showing signs of illness were sampled and all tested negative for CSF and ASF. In 2018, negative test results for CSF and ASF were obtained from 2,833 wild boar that were found dead, 701 hunted wild boar that showed signs of illness, and 40,937 hunted wild boar that appeared healthy (a total of 44,471 wild boar tested negative for CSF and ASF) [28].

Diagnostic laboratory support

Germany has 23 accredited official laboratories conducting chemical and veterinary testing under the supervision of the *Länder*. The diagnostic laboratory tests on samples of animal origin must be carried out using approved diagnostic methods and materials (in accordance with the Animal Health Act). The FLI, Germany's National Reference Laboratory (NRL), publishes guidance for official sampling and diagnostic procedures for notifiable animal diseases. All laboratories required to perform tests for official animal health controls are accredited according to the International Organization for Standardization (ISO) standard EN ISO/IEC 17025.[5] In the official laboratories of the *Länder* that are approved for FMD, CSF, SVD and ASF testing, only rapid (screening) tests are used that comply with relevant EU and national legislation. All samples from suspect case investigations, inconclusive or positive results on screening tests, and samples for trade/export purposes are forwarded to the NRL (located on Isle of Riems). Confirmation and further analysis (typing, epidemiology) are the responsibility of the NRL and are conducted using at least one of the methods and protocols laid down in the latest edition OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals [10, 32].

[5] ISO/IEC 17025 is a company level accreditation based on a standard published by the International Organization for Standardization (ISO) titled "General requirements for the competence of testing and calibration laboratories". ISO/IEC 17025 is a general umbrella term used to refer to the specific standard.

If diagnostic investigations are positive and the test results are confirmed by the NRL, the *Länd* diagnostic laboratory is obligated to report the test results immediately to the local competent veterinary authority, who immediately reports the outbreak to the veterinary authority of the *Länd*. The local veterinary authority also transmits this information electronically via the TSN animal disease notification system which is immediately accessible to the BMEL.

In general, in a suspicious case of an animal disease outbreak the first diagnostic test results are obtained within 1-3 days, with completion of all test results within 7 days by the official laboratories of the *Länder*. Positive or reactive samples are transported directly by means of a courier service within 6-12 hours to the NRL. First results of confirmatory tests are usually reported by the NRL within 1-3 days after receiving the samples. Special diagnostic investigations for further characterization and clarification may take longer. In the most cases, confirmatory testing is not conducted outside of Germany, however, in rare cases the European Reference Laboratory or the FAO Reference Center (for CSF) may be involved [10].

8.2 Disease response

Germany's response strategy for controlling and eradicating notifiable diseases, including FMD, CSF, SVD and ASF, is provided in the Contingency Plan (Animal Disease Control Manual, *Tierseuchenbekämpfungshandbuch*) which is prepared by BMEL, the *Länder*, and the FLI. It is hosted and technically supervised by the FLI. The Contingency Plan is available on the TSN animal disease notification system website and is accessible to all Federal, *Länd* and local veterinary authorities. The Contingency Plan is intended to constitute a nationally standardized framework for measures to combat highly contagious animal diseases and diseases which could give rise to significant economic losses. It does not contain any legislative provisions, but rather lists the necessary facilities (crisis centers) and the measures required in accordance to German national regulations. During the site visit, the APHIS/CFIA team observed a mobile control center for animal diseases in Lower Saxony. Control centers such as this are ready to be deployed in the event of a disease outbreak. The *Länder* are responsible for implementation of emergency measures described in the Contingency Plan [10, 33].

The legal basis for Germany's emergency response to outbreaks of the diseases under review is provided in the Animal Health Act and these related ordinances, which comply with applicable EU regulations:

- Ordinance on the Protection against Foot-and-Mouth Disease;
- Ordinance on the Protection against Swine Fever and African Swine Fever;
- Ordinance on Protection against Vesicular Swine Disease; and
- Ordinance on Serums, Vaccines and Antigens in accordance with the Animal Health Act.

During the site visit, German officials at the national, *Länd* and local level provided the APHIS/CFIA team with details regarding their contingency plans for responding to ASF, in both wild boar and domestic swine, should the disease be detected in Germany. These plans comply with applicable EU ASF regulations. Also discussed was Germany's implementation of countermeasures addressing the risk of ASF introduction [23, 34, 35]. These countermeasures include the following:

- Information campaigns for the general public, as well as targeting farmers, hunters, long-haul truck drivers, and military staff;
- Biosecurity measures for hunting;

- Transposition of EU ASF regulations into German national law;
- Wild boar management to reduce population density; and
- Biosecurity requirements for pig holdings (Pig Husbandry Hygiene Ordinance of 2 April 2014).

German officials also provided information on recent education and training activities conducted by several *Länder*, which included CSF and ASF simulation exercises; ASF manuals such as the *Model Crisis Handbook ASF for Slaughterhouses*, verified by the APHIS/CFIA team during the slaughterhouse visit; ASF trainings and education campaigns [27, 31, 36, 37]. In general, the APHIS/CFIA team observed a high level of awareness and preparation for CSF and ASF throughout Germany.

In November 2019, Poland detected ASF in wild boar close to its border with Germany. As a result, Poland, in consultation with the EU, established Part I and II areas in this region in accordance with Implementing Decision 2017/709/EU. Subsequently in March 2020, Poland detected ASF outbreaks in two domestic swine holdings in these areas, so two Part III areas were established and the Part I and II areas were expanded [38].

In response to these nearby detections in Poland, Germany immediately enhanced its ongoing ASF awareness campaign, continuing to focus on hunters, farmers, long-haul truck drivers, tourists and foreign workers, adapting as necessary to the current COVID-19 situation. By order of *Länd* authorities, hunting was intensified in the area near the German-Polish border, including extension of the season for driven hunts. The requirement for the reporting of found wild boar carcasses to local authorities was imposed, as Germany tests all wild boar carcasses for ASF. At the time of this review, all samples have tested negative for ASF. Local authorities enhanced their focus on biosecurity requirements for all pig holdings, commercial and backyard, and emphasized passive surveillance reporting [38].

Beginning in January 2020, *Länder Brandenburg* and *Saxony* installed approximately 200 kms of mobile electric fencing as a barrier for wild boar movement close to the German-Polish border. A permanent chain-link fence is planned to be installed in Germany parallel to the infected area of Poland. Germany intends these actions will create a zone of intensified wild boar management, with intensified carcass search and reduction in wild boar density. Germany and Poland are working cooperatively to minimize the potential for ASF spread by migrating wild boar [38].

8.3 Reporting history

Compulsory reporting to competent veterinary authorities for the diseases under review is mandatory in Germany, as previously described. Disease reporting is the responsibility of veterinarians, paraprofessionals, producers, livestock and poultry owners, and the general public in Germany. Within 24 hours of confirmation of a primary disease outbreak, BMEL notifies the EC and the other EU Member States (in accordance with EU Directive 82/894/EEC). After receiving the disease notification, the EC posts the disease outbreak notification to the ADNS.

Germany is an active member of the OIE and immediately reports notifiable disease outbreaks to the OIE (in accordance with the OIE Terrestrial Animal Health Code). OIE immediately posts information about the outbreak event in its World Animal Health System (WAHIS) which is publicly available. In addition to the immediate notifications, Germany has a consistent history

of submitting biannual reporting of hazards. Information in OIE's WAHIS indicates Germany has promptly reported the animal health status of the country to OIE since at least 1996, the earliest available online reporting information [1].

8.4 Export controls

Per Commission Decision 93/444/EC, the export of live animals, animal products and by-products to third countries requires an export health certificate. The shipment is accompanied by a certificate conforming to the requirements of the third country of destination with data verified by the competent veterinary authority in the Member State. In Germany, export health certificates are issued by an official veterinarian of the local veterinary authority. BIPs' involvement in the export process include: randomly checking on the welfare of live animal consignments; verifying documents for consignments from other EU Member States or from Germany if there is suspicion of non-compliance; and as required to meet the import regulations of third countries. Approved or private veterinarians are not authorized to issue export certificates [10, 39].

The EC stipulates in Regulation (EU) 2017/625 the required procedures for EU Member States to issue veterinary certificates for the exportation of live animals and animal products to third countries (e.g. for swine commodities, including swine, swine semen, pig meat, which are intended for the exportation to the United States) [10]. The competent authority of the Member State shall ensure that certifying officers (veterinary officers) have a satisfactory knowledge of the specific veterinary legislation regarding animals or products being certified, including any required tests or examinations. They must also be knowledgeable of the general rules to be followed for preparing and issuing certificates. Certifying officers must not certify data of which they have no personal knowledge, or which cannot be ascertained by them.

Certifying officers must not sign blank or incomplete certificates, or certificates relating to animals or products which they have not inspected, or which have passed out of their control. Where a certificate is signed on the basis of another certificate or attestation, the certifying officer shall be in possession of that document before signing.

The Member State competent authorities shall also take all necessary steps to ensure the integrity of certification. In particular, they shall ensure that certifying officers designated by them have a status which ensures their impartiality and have no direct commercial interest in the animals or products being certified or in the holdings or establishments in which they originate; and are fully aware of the significance of the contents of each certificate they sign.

In Germany, the BMEL is responsible for coordinating with DG SANTE to negotiate with third countries to agree upon the certificate model and language, and then advises and coordinates with the *Länd* and local veterinary authorities on the certification requirements. In some cases, export certificates harmonized among the Member States may be issued through TRACES.

Veterinary certificates are issued only by an official veterinarian of the local competent veterinary authority. To this end, the meat processing establishments/food business operators have to present all documents to the certifying officer that are required for the issuing of the export veterinary certificate. Certifications are made on tamper-proof security paper with a specific consecutive numbering which is documented by the local competent veterinary authority. Printing on security paper is only on the front side that shows the consecutive numbering. The veterinary certificate must, at least, be drawn up in German and in the official

language of the importing third country. Only one original certificate may be issued per consignment. A duplicate copy which is also signed and sealed is retained by the competent authority for a ten-year period. It must be possible to clearly assign veterinary certificates to the certifying officer and the respective consignment. This is ensured by samples of signatures, lists of official stamps and an individual numbering of veterinary certificates. If a veterinary certificate consists of several pages, these should be stapled and sealed in such a way that individual sheets cannot be detached unnoticed.

In the EU, the professional qualifications and education requirements for official veterinarians are stipulated in Regulation (EU) 2017/625 and apply to both full-time and part-time officials.[6] This regulation further stipulates that official veterinarians must be free of conflicts of interest. In Germany, these requirements apply for certifying veterinary officers as they must be official veterinarians [10]. Candidates may acquire the required knowledge as part of their basic university veterinary education, through training undertaken, or professional experience acquired after qualifying as veterinarians. Each official veterinarian undergoes practical training for a probationary period of at least 200 hours before starting to work independently. During this period the probationer works under the supervision of existing official veterinarians in the competent authority of the Member State. The training covers auditing procedures for food safety, with particular attention to certification requirements. The official veterinarian must maintain up-to-date knowledge and be aware of new developments through regular continuing education activities and professional literature. German officials at the *Länd* and local level verify and document compliance with training requirements.

The official veterinarian is, wherever possible, to undertake annual continuing training activities. Veterinarians already appointed as official veterinarians must have adequate knowledge in the subjects concerned, such as veterinary and public health matters. Where necessary, they are to acquire this knowledge through continuing education activities which is made available by the Member State competent authority.

9. Conclusions and recommendations

In this review, APHIS found no evidence that CSF, FMD, and SVD are present in Germany. We conclude that Germany conducts sufficient control measures to prevent their entry, and, in the event of a hazard incursion, is capable of detecting the hazard and containing its spread. In addition, Germany has demonstrated a history of promptly reporting disease events and taking appropriate measures to prevent their export to third countries. Furthermore, APHIS found Germany's ASF preparedness and monitoring to be sufficient to ensure prompt detection of potential incursion of ASF into the country.

In consideration of the favorable review of Germany's animal health statuses, APHIS concludes that current conferred statuses and import mitigations for CSF, FMD, and SVD are appropriate. APHIS recommends that recognition of these statuses be maintained until the next APHIS review or until a change in Germany's animal health status is reported. APHIS' conclusions about EU ASF zoning are discussed in a separate report.

[6] During the site visit it was explained to the APHIS/CFIA team that part-time official veterinarians are primarily hired to assist full-time official veterinarians with inspection activities in slaughterhouses.

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