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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0102]

Notice of Determination of the Classical Swine Fever, Swine Vesicular Disease, African Swine Fever, Foot-and-Mouth Disease, and Rinderpest Status of Malta

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are adding the Republic of Malta to the lists of regions considered to be free of swine vesicular disease (SVD), African swine fever (ASF), foot-and-mouth disease (FMD), and rinderpest, and to the list of regions considered free or low risk for classical swine fever (CSF), subject to conditions in the regulations governing the importation of certain animals and animal products into the United States. Based on our evaluation of the animal health status of Malta, which we made available to the public for review and comment through a previous notice, the Administrator has determined that Malta is free of SVD, ASF, FMD, and rinderpest, and is low risk for CSF. This action establishes the disease status of Malta with regard to SVD, ASF, FMD, rinderpest, and CSF while continuing to protect the United States from introduction of those diseases.

DATES: This change in disease status will be recognized on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

FOR FURTHER INFORMATION CONTACT: Dr. Chip Wells, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, USDA, 4700 River Road Unit 38, Riverdale, MD 20737-1231; Chip.J.Wells@aphis.usda.gov; (301) 851-3317.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including classical swine fever (CSF), foot-and-mouth disease (FMD), rinderpest, African swine fever (ASF), and swine vesicular disease (SVD). The regulations prohibit or restrict the importation of live ruminants and swine, and products from these animals, from regions where these diseases are considered to exist.

The regulations in 9 CFR 92.2 contain requirements for requesting the recognition of the animal health status of a region (as well as for the approval of the export of a particular type of animal or animal product to the United States from a foreign region). If, after review and evaluation of the information submitted in support of the request, the Animal and Plant Health Inspection Service (APHIS) believes the request can be safely granted, APHIS will make its evaluation available for public comment through a document published in the *Federal Register*.

In accordance with that process, on May 13, 2016, we published in the *Federal Register* (81 FR 29834-29836, Docket No. APHIS-2015-0102) a notice¹ announcing the availability for review and comment of our risk evaluation of the FMD, rinderpest, ASF, CSF, and SVD status of the Republic of Malta. Based on this evaluation, we determined that that the animal disease surveillance, prevention, and control measures implemented by Malta are sufficient to minimize

¹ To view the notice of availability, risk evaluation, environmental assessment, and the comment we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0102>.

the likelihood of introducing FMD, rinderpest, ASF, CSF, and SVD into the United States via imports of species or products susceptible to these diseases.

We also determined in our evaluation that Malta is low risk for CSF and therefore eligible to be added to the APHIS-defined European CSF region. This region is subject to the conditions in § 94.31 for pork, pork products, and swine and § 98.38 for swine semen. We also determined that the provisions of § 94.11 for import conditions for meat or meat products from ruminants or swine from FMD-free regions, and of § 94.13 for import conditions for pork or pork products from SVD-free regions, are applicable to Malta. With respect to rinderpest, the global distribution of the disease has diminished significantly. In May 2011, the World Organization for Animal Health (OIE) announced its recognition of global rinderpest freedom.

We solicited comments on the notice of availability for 60 days ending on July 12, 2016, and received one comment by that date. The commenter, representing a national pork industry association, expressed concern over the risk of allowing imports into the United States of live swine, pork and pork products from Malta. The commenter stated that any incursion of FMD, CSF, ASF, or SVD into the United States resulting from such imports would precipitate an immediate and costly loss of export markets for these commodities. The comment is discussed below.

Disease Surveillance

The commenter disagreed with our determination that passive disease surveillance conducted by the veterinary authority of Malta is sufficient to mitigate the risk to the United States from importations of swine, pork, and pork products.

The commenter noted that in the risk analysis, we cited Malta's "lack of capacity or intention for developing exports" to support our conclusion that passive disease surveillance

would be sufficient to detect any cases of CSF, SVD, ASF, FMD, or rinderpest. In challenging our conclusion, the commenter cited two articles. One article noted Malta's efforts to improve the health and management of its pigs in order to compete with European Union (EU) pork production standards, and reported that surplus swine are exported from Malta to Sicily for finishing and producing Parma ham.² The other article stated that Malta was engaged in discussions with other EU Member States about exporting pork.³ The commenter asked if the information contained in these articles is significant enough for APHIS to reconsider its risk evaluation and require Malta to undertake active disease surveillance of its swine before recognizing Malta as being free of SVD, ASF, and FMD and adding Malta to the APHIS-defined European CSF region.

We acknowledge the commenter's concerns but do not consider the information presented in the articles to be sufficient to reconsider the findings of our risk evaluation. APHIS considers both active and passive surveillance activities when evaluating the animal health system of a region.⁴ In the case of Malta, APHIS noted its long history of disease freedom (over 33 years) based on the results of both periodic active (most recently in 2007 and 2010) and passive surveillance; its geographic isolation and lack of land borders; movement controls based on EU Member State standards; requirements for farmers and private veterinarians to file notice of any suspected cases of diseases of concern; frequent farm visits by official veterinarians (about every 2 weeks); as well as its small livestock population and limited capacity to enlarge the scope or size of its animal and animal product export market. These factors lead APHIS to

² ACMC Ltd., April 18, 2011.

³ *Malta Independent*, March 19, 2014: <http://www.independent.com.mt/articles/2014-03-19/news/plans-to-export-pork-put-on-the-back-burner-4309385218/>.

⁴ APHIS did cite in its risk assessment that it concludes that Malta might benefit from an active CSF surveillance program in order to limit any spread of disease within the island's swine population, but noted that this benefit might be limited if Malta's emergency response would be to completely depopulate its swine herd.

conclude that the constraints upon enlargement of the Maltese swine industry have not changed, and that a primarily passive surveillance program will be sufficient to detect incursions of these diseases early enough to avoid introduction into the United States.

The commenter also expressed concern about diseases of swine in Malta that present symptoms similar to those caused by FMD, CSF, ASF, and SVD. The commenter noted that Malta vaccinates swine for Circo Virus, Pig Wasting Disease, Atrophic Rhinitis, Enzootic Pneumonia, and Porcine Reproductive and Respiratory Syndrome, and that these diseases are therefore likely to be present in Malta's pig populations. For this reason, the commenter stated that FMD, SVD, CSF, and ASF should be considered as differential diagnoses whenever case-compatible lesions and other signs of disease are observed and reported in pigs. The commenter further noted that, since 2002, the Veterinary Regulation Directorate of Malta has reported no suspicious cases with such case-compatible signs. The commenter concluded that the lack of such reports suggests that passive surveillance may not be adequate for early disease detection, as producers and veterinarians in Malta are likely seeing case-compatible lesions and other signs of disease but are not reporting them. The commenter asked APHIS if this lack of reporting warrants requiring an active surveillance program to detect FMD, SVD, rinderpest, CSF, and ASF in Malta before APHIS recognizes Malta as free of these diseases and adds it to the APHIS-defined European CSF region.

We acknowledge that an active surveillance program provides some benefits for early detection of these diseases but have determined that passive surveillance is sufficient to ensure early disease detection in Maltese swine, particularly in combination with other factors. For instance, Maltese regulations prohibit the movement of swine that are not considered healthy regardless of whether any specific disease has been diagnosed. Furthermore, APHIS concludes

that Malta has the capacity to handle initial serology screening and has a plan to obtain confirmatory testing at EU community laboratories for diseases under evaluation.

APHIS does agree with the commenter that FMD, SVD, CSF, and ASF should be considered during passive surveillance program investigations of cases where case-compatible lesions or other signs are present. We also agree that a review of more frequent suspicious case investigations would increase confidence in the quality of Malta's passive surveillance program. However, we found no indications of failure through passive surveillance to detect FMD, SVD, CSF, and ASF.

The commenter also raised questions about our statement in the risk analysis that we “consider the conditions in Malta to be equivalent to the conditions of other EU Member States for which APHIS imposes additional special restrictions on the importation of susceptible animals and their products.” The commenter cited a version of the OIE Terrestrial Animal Health Code,⁵ which states that for domestic pigs, appropriate surveillance, capable of detecting the presence of infection even in the absence of clinical signs, is required for determining CSF status. The commenter suggested that APHIS' decision not to require an active surveillance program in recognizing Malta's CSF status is inconsistent with surveillance requirements for other countries in the APHIS-defined European CSF region. Based on this information, the commenter asked APHIS to consider requiring Malta to implement active surveillance to detect FMD, SVD, CSF, and ASF as a condition of recognizing its disease status.

We disagree with the commenter's point that APHIS' disease surveillance requirements for Malta are inconsistent with those required of other EU Member States. The commenter has cited surveillance requirements from an outdated version of the OIE Terrestrial Animal Health

⁵Chapter 15.2, Article 15.2.2, “General criteria for the determination of the CSF status of a country, zone or compartment.”

Code. Chapter 15.2.2 of the current version⁶ of the OIE manual recommends appropriate surveillance in accordance with Article 15.2.26, which states that “surveillance strategies employed for demonstrating freedom from CSF at an acceptable level of confidence should be adapted to the local situation.” We have determined that the local conditions in Malta are equivalent to those of EU Member States where APHIS imposes additional special restrictions on the importation of susceptible livestock. The application of the requirements of § 94.11 for FMD and rinderpest, § 94.13 for SVD, and §§ 94.31 and 98.38 for CSF will mitigate risk for these diseases in Malta at a level consistent with that of other EU Member States authorized to export swine, pork, and pork products to the United States.

APHIS evaluated multiple factors regarding Malta’s animal health system and determined that the country’s reliance primarily on passive surveillance is adequate for Malta to detect incursions of CSF. For this reason, we determined that the likelihood is low of CSF being introduced into the United States through movement of infected animals or contaminated animal products from Malta. We consider our evaluation of Malta to be consistent with the current OIE recommendation to determine that an acceptable level of confidence be adapted to the local situation.

Waste Feeding

The commenter also raised concerns about the risk of disease transmission from the practice of feeding garbage and other waste to swine raised for export. The commenter noted that in the risk evaluation, APHIS stated that “waste feeding, specifically, feeding FMD-contaminated meat products to swine, is regarded as the most likely pathway for exposure of susceptible livestock to imported contaminated meat products.” The commenter added that

⁶OIE Terrestrial Animal Health Code, 25th Edition, 2016:
http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_csf.htm.

APHIS affirmed this determination again in a 2001 pathways assessment.⁷ The commenter asked what level of confidence does APHIS have that the assessments adequately reflect the current risk to the U.S. pork industry, and suggested that the 1995 work be repeated using more current data. The commenter also asked whether APHIS is confident that swine diseases will be detected in licensed and unlicensed garbage-feeding operations and what the estimated time is for detection in each of these operations.

We remain confident that the risk evaluations cited by the commenter provide an accurate account of risks to the current U.S. pork industry. If contaminated meat products were imported from Malta and managed to make it into plate waste, U.S. garbage feeding regulations are sufficient to mitigate that risk. Treatment of food waste fed to swine is covered under the Swine Health Protection Act⁸ (SHPA) regulations in 9 CFR part 166 and supported by APHIS' Veterinary Service (VS) Swine Health Program. Under the regulations, waste feeder operations must be licensed and regularly inspected by APHIS inspectors. In addition to other safeguards, the licensing process requires that producers adequately cook the waste fed to swine using methods designed to destroy foreign animal disease agents.

In the 1995 study cited by the commenter, we conducted a pathway analysis to estimate the likelihood of exposing domestic swine to infected waste. With 95 percent confidence, we estimated that 0.023 percent or less of plate and manufacturing waste would be inadequately processed prior to feeding to swine. Based on this percentage, less than 1 part in 4,300 of imported beef fed to swine as plate or manufacturing waste is likely to be inadequately cooked.

⁷ USDA-APHIS-VS, Pathway assessment of foot-and-mouth disease (FMD) risk to the United States: an evaluation in response to international FMD outbreaks in 2001. United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Centers for Epidemiology and Animal Health. 2001. A copy of the document can be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

⁸ 7 U.S.C. 3801.

Furthermore, the findings of the 2001 APHIS survey the commenter cited, which showed a substantial reduction in waste-feeding operations, indicated that the risk of FMD exposure via feeding of contaminated waste to swine was continuing to decline.

We acknowledge that waste feeding continues to be a potential pathway for transmission of swine diseases and that interstate trade patterns are subject to change. We maintain, however, that the 1995 and 2001 risk findings, combined with existing SHPA requirements, indicate to us a low likelihood of exposure of domestic swine to CSF, FMD, SVD, and rinderpest from food waste originating from Malta.

Environmental Assessment

The commenter noted that in the supporting documents provided for this notice, the environmental assessment (EA) we used to support this notice was a May 2011 EA for the importation of swine and swine commodities from Slovakia. The commenter also noted that we used an amended finding of no significant impact (FONSI) from importation of swine and swine commodities from Slovakia as the basis for the amended finding related to Malta. The commenter asked us to explain how it is justifiable to use an EA conducted for another country to amend the finding to Malta.

Since 2006, we have recognized the CSF, FMD, SVD, and rinderpest status for EU Member States Latvia, Lithuania, Poland, the Czech Republic, Slovakia, Slovenia, Estonia, and Hungary.

Given that the EU applies and ensures enforcement of the same disease mitigation requirements across all of its Member States, we recognized that the single-state EAs we were conducting were redundant and thus unnecessary with respect to meeting the requirements of the National Environmental Policy Act (NEPA). After consulting with Agency specialists on NEPA

compliance, we conducted an environmental impact analysis comparison of the Slovakia EA and similar proposed actions for other EU Member States. We determined that the environmental analysis of the Slovakia EA is sufficiently similar to cover the proposed action for Malta. The 2011 Slovakia EA stated that for any like or similar future regionalization actions proposed for EU Member States, APHIS would incorporate the Slovakia EA by reference in a new FONSI issued for a proposed new action for an EU Member State. That is what we have done for this action regarding Malta.

Additionally, we determined that future proposed actions of this nature pose negligible environmental impacts to each EU Member State or country that has entered into an agricultural equivalency agreement with the EU, provided that a disease assessment finds them to be free of or a low risk for relevant diseases. As Malta is an EU Member State and because we have determined that Malta is free of SVD, FMD, and rinderpest, and at low risk for CSF, we conclude that the “like or similar action” environmental analyses approach as presented in the 2011 Slovakia EA and FONSI is appropriate to use with respect to Malta.

Based on the evaluation and the reasons given in this document in response to comments, we are recognizing Malta as free of FMD, rinderpest, ASF, and SVD, and low risk for CSF. The lists of regions free of or at low risk of these diseases or where these diseases currently exist are available on the APHIS website at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

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

Done in Washington, DC, this 4th day of August 2017.

Michael C. Gregoire,

Acting Administrator,

Animal and Plant Health Inspection Service.

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