CONCURRENCE WITH OIE RISK DESIGNATIONS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to concur with the World Organization for Animal Health’s (OIE) bovine spongiform encephalopathy (BSE) risk designations for 14 regions. The OIE recognizes these regions as being of negligible risk for BSE. We are taking this action based on our review of information supporting the OIE’s risk designations for these regions.

FOR FURTHER INFORMATION CONTACT: Dr. Roberta Morales, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7735.

SUPPLEMENTARY INFORMATION:

The regulations in 9 CFR part 92 subpart B, “Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard to Bovines” (referred to below as the regulations), set forth the process by which the Animal and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as
presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS Web site at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status. The list can also be obtained by writing to APHIS at National Import Export Services, 4700 River Road Unit 38, Riverdale, MD 20737.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for countries that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country by the OIE.

If the OIE has recognized a country as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support our concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that countries supply the same information given to the OIE. APHIS will announce in the Federal Register, subject to public comment, its intent to concur with an OIE classification.

In accordance with that process, we published a notice\(^1\) in the Federal Register on December 4, 2015 (80 FR 75849, Docket No. APHIS-2015-0055), in which we announced our intent to concur with the OIE risk designations for 16 regions. The OIE recognizes these regions as being of negligible risk for BSE. We solicited comments on the notice for 60 days ending on February 2, 2016. We received two comments by that date, from a private citizen and a representative of a foreign government.

\(^1\) To view the notice and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0055.
One commenter stated that if a product is being imported only for use in pet food, then the BSE risk status of the exporting region should not be an issue.

We disagree that bovine products imported for use in pet food do not pose a risk for introducing or spreading BSE in the United States. It is possible that pet foods could be used for cattle feed, either by accidental misfeeding of pet foods to cattle or by misusing salvage pet food for cattle. Farms that raise multiple species (e.g. dogs, swine, and cattle) present a particular risk for misfeeding.

The other commenter stated that the United States does not recognize all the OIE’s risk designations for BSE, noting that the United States still considers several countries as controlled risk regions though the OIE has classified them as negligible risk.

As we explained above, § 92.5 of the regulations provides two ways that APHIS may classify a region for BSE. One way is for countries that have not received a risk classification from the OIE to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country by the OIE. If the OIE has recognized a country as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support our concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that countries supply the same information given to the OIE.

The length of APHIS’s review of information in support of concurrence depends on a number of factors, including whether the information is publicly available, and, if it is not publicly available, how quickly a country responds to our request for information. This notice updates APHIS’ list of regions recognized as negligible risk for BSE to include all the regions for which we have been able to review information. We intend to announce concurrence with additional countries recognized by the OIE in a future notice.
One commenter noted that while the OIE guidelines call for removal of specified risk materials (SRMs) from animals older than 30 months of age, our regulations require the removal of SRMs from animals 30 months of age or older. The commenter stated that while this is not a significant difference from an epidemiological perspective, it creates a major problem for certification through the veterinary services of exporting countries and presents a barrier to trade.

APHIS notes that the wording “30 months of age or older” is consistent with Food Safety and Inspection Service (FSIS) and U.S. Food and Drug Administration (FDA) regulations as well as with Canadian regulations. We also note that anyone wishing to import bovine products into the United States must also meet FSIS or FDA requirements as well as APHIS requirements. We do not anticipate that this difference will have a significant impact on trade.

In the December 2015 notice, we mistakenly announced our intent to recognize Romania as a region of negligible risk for BSE. In December 2014, the OIE suspended Romania’s status as a negligible risk region because Romania reported a case of atypical BSE. Since then, the OIE has announced its intent to reinstate Romania’s status as a region of negligible risk for BSE. We will be seeking information to verify Romania’s status and will announce our intent to concur with the OIE’s designation in a future notice.

Also in the December 2015 notice, we announced our intent to recognize France as a region of negligible risk for BSE in concurrence with the OIE. Since then, France has confirmed a case of classical BSE in a 5-year-old cow. Accordingly, the OIE has suspended France’s status as a region of negligible risk for BSE and reinstated its status as a region of controlled risk effective March 25, 2016. For this reason we have removed France from the list of regions of negligible risk for BSE in this document. We will continue to recognize France as a region of controlled risk for BSE.
Therefore, in accordance with the regulations in § 92.5, we are announcing our decision to concur with the OIE risk classifications of the following countries:

- Regions of negligible risk for BSE: Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, India, Korea (Republic of), Latvia, Liechtenstein, Luxembourg, Malta, Portugal, Slovakia, and Switzerland.


Done in Washington, DC, this 4th day of August 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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