Notices

Federal Register
Vol. 79, No. 190
Wednesday, October 1, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2013–0064]

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 15 regions. The OIE recognizes these regions as being of either negligible risk for BSE or of controlled 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. Silvia Kreindel, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 851–3300.

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 *http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml*. 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, 2013 (78 FR 72859–72860, Docket No. APHIS–2013–0064), in which we announced our intent to concur with the OIE risk designations for 15 regions. In the notice we mistakenly stated that we intended to concur with the risk designations for 14 regions; the correct number is 15. The regions listed in the notice, however, were correct. The OIE recognizes these regions as being of either negligible risk for BSE or of controlled risk for BSE. We solicited comments on the notice for 60 days ending on February 3, 2014. We received three comments by that date, from two private citizens and a foreign industry association.

One commenter expressed general concern that the risk designations did not accurately reflect the actual risk of BSE, but the commenter did not address the specific details of the OIE process or of any region's designation. Another commenter expressed concern that the OIE process is not transparent and there is insufficient detail in the OIE summaries to make an adequate determination of BSE risk. This commenter stated that APHIS should undertake its own assessment of BSE status rather than accepting the OIE risk designation.

The summaries are the only information the OIE makes publicly available. Countries may make their BSE dossiers publicly available, in whole or in part, or they may share their dossiers with other countries upon request. For this reason, before announcing our intent to concur with the OIE classification, APHIS verifies that the information can be provided to us, or is publicly available, for review to support our concurrence with the OIE classification. APHIS' intention is to follow the OIE's BSE guidelines while ensuring that OIE-recognized countries apply adequate BSE risk mitigation measures assuring that bovines and bovine commodities destined for export pose a negligible risk for BSE, and that the country complies with OIE requirements for the specific BSE country recognition. If the information is not publicly available and the country does not provide the information, then we will not recognize the country's BSE status. APHIS thus has greater confidence in the outcomes of the evaluations and will have the necessary documentation to support or defend recognition decisions. The process we use is described in the regulations in § 92.5.

The information provided in the OIE dossier is more comprehensive than what appears in the summaries of the OIE Scientific Commission, and includes information about the likelihood that the disease could have been introduced into the country though the importation of bovine or bovine commodities in the last 7 years, the likelihood that the agent could have been recycled in as meat-and-bone meal or greaves for the last 8 years, the awareness, notification and laboratory capabilities of the region, BSE surveillance in the region, and the history of BSE in the region.

One commenter stated that, according to the OIE summary reports, the evaluation for Brazil was provided by the OIE in February 2012. The commenter also stated that in December

[1] To view the notice and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0064*.

2012, it was learned that a cow from Brazil that was sampled for testing in December 2010 tested positive for BSE. The commenter noted that immunohistochemistry (IHC) tests were not completed until June 2012, and it was another 6 months before a confirmatory test was completed at the Community Reference Laboratory in Weybridge, United Kingdom. The commenter stated that the lack of specific information regarding the OIE evaluation of the surveillance system made it difficult to determine if this was a one-time error or a failure of the system.

APHIS agrees that the delays in the testing and reporting of the atypical BSE case detected in Brazil were problematic. In response to these concerns, the OIE Scientific Commission requested that Brazil provide all relevant information for their meeting in February 2013. At that meeting, the OIE Scientific Commission affirmed that the identification of this single case of BSE did not put Brazil's or its trading partners' animal and public health at risk because the animal was destroyed and no parts of it had entered the food or feed chain. However, the OIE was also concerned about the delay before Brazil sent the clinical samples for a confirmatory diagnosis and requested more detailed information on the procedures for processing samples and the improvement of the surveillance system in the country, so that they could further monitor compliance by Brazil with international standards.[2] At a subsequent meeting in September 2013, the OIE assessed the additional information provided by Brazil.[3] The OIE was satisfied with the evidence submitted but also concluded that Brazil should submit the results of the proficiency tests conducted for 2013 to the OIE as soon as they became available.

In addition, representatives of APHIS and the United States Department of Agriculture's Food Safety and Inspection Service visited Brazil in February 2013 to evaluate the BSE laboratory infrastructure, emergency response, and BSE-related mitigations at the slaughter level. APHIS' review of the epidemiological and laboratory reports, including the report from the confirmatory tests conducted at Weybridge, shows that Brazil's first BSE case was most consistent with the atypical form of the disease. In addition, as a result of the delays in testing and reporting of this case, Brazil's Ministério da Agricultura, Pecuária e Abastecimento conducted audits of the laboratories to identify areas for change and improvement, and has implemented several new procedures to assure the timely testing of samples and reporting of results. Corrective actions include addition of a second lab to conduct IHC tests, expansion of testing capabilities to include Western Blot, and the development of an inter-laboratory data management system which will issue reports, record improper samples, and flag delays in sample receipt, completion, and notification of test results. Samples will be forwarded for IHC testing immediately after the immunofluorescence test for rabies is completed, rather than waiting for the animal inoculation tests to be completed.

We note that Brazil detected a suspected case of BSE in a 12-year-old cow in April 2014. The Brazilian authorities carried out the required epidemiological investigation in accordance with OIE guidelines. In May 2014, tests at the OIE reference laboratory in Weybridge confirmed that it was an atypical case of BSE.

Brazil still meets the criteria for a negligible risk region. In Article 11.5.3 of the Terrestrial Animal Health Code, the OIE requires, among other things, that if there has been an indigenous case of BSE in a region, every indigenous case was born more than 11 years ago. The cow in which BSE was detected was over 11 years of age. Therefore, this most recent case will not affect Brazil's negligible risk status.

One commenter stated that India should be included in the list of regions of negligible risk for BSE.

Our review of information in support of concurrence with the OIE designation for India is ongoing; we have requested the OIE dossier but have not yet received it. When our review is complete, if the findings support concurrence with the OIE designation, we will publish a notice in the **Federal Register** announcing our preliminary concurrence with the OIE's designation for India and provide the public with an opportunity to comment.

One commenter stated that the United States should be included on this list of regions of negligible risk for BSE because some raw material may be exported from the United States and then reimported after processing abroad.

When APHIS assesses the disease status of a region, it is to determine whether imports can be safely allowed from that region. For this reason we do not typically include the United States in the lists of regions recognized for any given disease status. In the event that raw material was exported for processing, we could allow it to be reimported under conditions that would be specified on the import permit.

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: Austria, Belgium, Brazil, Colombia, Israel, Italy, Japan, the Netherlands, Singapore, Slovenia.
- Regions of controlled risk for BSE: Bulgaria, Costa Rica, Croatia, Nicaragua, Taiwan.

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 26th day of September 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014–23407 Filed 9–30–14; 8:45 am]

BILLING CODE 3410–34–P

[2] The report of the OIE scientific commission meeting in February 2013 can be viewed at *http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2013.pdf*. The discussion of the BSE case in Brazil appears on pages 13–14.

[3] The report of the OIE scientific commission meeting in September 2013 can be viewed at *http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Sept2013.pdf*. The discussion of the BSE case in Brazil appears on page 7.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2014–0004]

Availability of an Environmental Assessment and Finding of No Significant Impact for a Biological Control Agent for Soybean Aphid in the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment and finding of no significant impact relative to the release of *Aphelinus rhamni* for the biological control of the soybean aphid, *Aphis glycines,* in the continental United States. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

FOR FURTHER INFORMATION CONTACT: Dr. Shirley A Wager-Pagé, Chief, Pest