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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2022-0005]

Concurrence with World Organization for Animal Health's Risk Designation for Bovine Spongiform Encephalopathy for Ireland

AGENCY: Animal and Plant Health Inspection Service, Department of Agriculture (USDA).

ACTION: Notice.

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

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Gordon, Senior Staff Officer, Regionalization Evaluation Services, Veterinary Services, APHIS, 920 Main Campus Drive, Raleigh, NC, 27606; (919) 855-7741; email: AskRegionalization@usda.gov.

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 website at

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions. The list can also be obtained by writing to APHIS at Regionalization Evaluation Services, Veterinary Services, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1238.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for regions that have not received a risk classification from the World Organization for Animal Health (WOAH)[1] to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country or region by the WOAH.

If the WOAH has classified a region as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support concurrence with the WOAH classification. This information may be publicly available information, or APHIS may request that regions supply the same information given to the WOAH. APHIS will announce in the *Federal Register*, subject to public comment, its intent to concur with a WOAH classification.

In accordance with this process, we published a notice[2] in the *Federal Register* on April 14, 2022 (87 FR 22168- 22169, Docket No. APHIS-2022-0005), in which we announced our intent to concur with the WOAH risk classification of Ireland as being a region of negligible risk for BSE. We solicited comments on the notice for 60 days ending on June 13, 2022. We received one comment by that date, from a private citizen.

The commenter claimed that we provided no evidence to support that BSE levels in Ireland's cattle population approach zero.

Neither the notice nor the conclusions of the WOAH referenced in the notice claimed that BSE cases in Ireland approach zero. Rather, the WOAH classified Ireland as BSE negligible risk. While negligible risk indicates that the occurrence of BSE is very rare, it does not translate

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[1] On May 28, 2022, the World Organization for Animal Health announced a change to its acronym from OIE to WOAH to match its full name. See https://www.woah.org/en/the-world-organisation-for-animal-health-launches-its-refreshed-brand-identity/.

[2] To view the notice, go to www.regulations.gov and enter APHIS-2022-0005 in the Search field.

to zero risk, nor does it imply the expectation or assumption that the risk will become zero in the future. Atypical BSE may still be detected in countries or regions with a negligible risk status. The atypical BSE forms, L-type and H-type, occur spontaneously at very low levels in all cattle populations.

The commenter also stated that relying on slaughterhouses/abattoirs to find cases of BSE is an unreliable surveillance method.

Because there is currently no test to detect BSE in a live animal, sampling for BSE is often performed in the slaughterhouse/abattoir environment. It may also be performed at rendering or salvage facilities, on-farm, at veterinary clinics, or at veterinary diagnostic laboratories. Ireland provided documentation for the standard operating procedures for active surveillance for BSE in cattle and documented that the samples collected are representative of the cattle population in the country. Furthermore, Ireland provided documentation that BSE surveillance exceeded Type B surveillance minimum requirements in Chapter 11.4 of the WOAH *Terrestrial Animal Health Code*. As the commenter provided no information to support the claim that this surveillance is unreliable, we continue to concur with the WOAH risk classification of Ireland as being a region of negligible risk for BSE.

The commenter also claimed that laboratories in general lack the skills necessary to detect BSE.

All BSE confirmatory testing in Ireland is carried out in the Central Veterinary Research Laboratory in Backweston, which is the National Reference Laboratory (NRL) for transmissible spongiform encephalopathies in Ireland. The confirmatory tests used are histopathology, immunohistochemistry using antibody F89, and immunoblot (Biorad TeSeE). All confirmatory and discriminatory tests used are accredited to the international standard for laboratories (IS0-17025). All rapid screening for BSE is conducted with European Union-approved rapid tests at Rapid Test Laboratories that are approved and monitored by the NRL. Ireland provided documentation that BSE diagnostic procedures and the reference laboratory facilities (NRL and

Rapid Test Laboratories) meet the requirements in the WOAH *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. As the commenter provided no information to support the claim that these laboratories or tests are unable to accurately detect BSE, we continue to concur with the WOAH risk classification of Ireland as being a region of negligible risk for BSE.

Therefore, in accordance with the regulations in § 92.5, we are announcing our decision to concur with the WOAH risk classification for Ireland.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), the Office of Information and Regulatory Affairs designated this action as not a major rule, as defined by 5 U.S.C. 804(2).

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 30th day of September 2022.

Anthony Shea,

Administrator, Animal and Plant Health Inspection Service.

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