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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2010-0077]

Notice of Determination of the Foot-and-Mouth Disease Status of Japan

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination regarding the foot-and-mouth disease status of Japan. Based on an evaluation that we made available to the public for review and comment through a previous notice, the Administrator has determined that Japan is free of foot-and-mouth disease. As a result, the importation of whole cuts of boneless beef from Japan may resume. Other ruminant meat and meat byproducts, as well as fresh pork, live ruminants, and live swine, remain prohibited due to Japan's status for bovine spongiform encephalopathy, classical swine fever, and swine vesicular disease.

EFFECTIVE DATE: This determination is effective [Insert date 15 days after publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Kelly Rhodes, Senior Staff Veterinarian, Regionalization Evaluation Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 851-3300.

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 rinderpest and foot-and-mouth disease (FMD).

The regulations prohibit or restrict the importation of live ruminants and swine, and products from these animals, from regions where FMD is considered to exist. The regulations also restrict the importation of meat and other products of ruminants and swine from regions that are considered free of FMD but that supplement their national meat supply by importing fresh (chilled or frozen) meat of ruminants or swine from regions that are considered to be affected with FMD, or have a common land border with such regions, or import ruminants or swine from such regions under conditions less restrictive than would be acceptable for importation into the United States.

On April 20, 2010, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) of Japan reported an outbreak of FMD in that country to the World Organization for Animal Health (OIE). In response, the Animal and Plant Health Inspection Service (APHIS) administratively issued temporary restrictions on commodities from Japan that could harbor FMD virus.

Subsequently, in an interim rule¹ effective and published in the Federal Register on October 25, 2010 (75 FR 65431-65432, Docket No. APHIS-2010-0077), we amended the regulations in part 94 to remove Japan from the list of regions considered free of FMD, and from the list of regions considered free of FMD and rinderpest but from which the importation of meat and other products of ruminants and swine into the United States is restricted because of shared land

¹ To view the interim rule, the follow-up notice and evaluation, and the comments we received, go to

borders or trading practices with regions that have one or both of these diseases. The interim rule also clarified that, as a result of the change in Japan's FMD status, the importation of whole cuts of boneless beef from Japan, formerly allowed under § 94.27 of the regulations, was prohibited due to FMD. These actions were necessary to protect against the introduction of FMD into the United States. We solicited comments on the interim rule for 60 days ending December 27, 2010. We received one comment by that date, from the Government of Japan. The comment acknowledged the interim rule and encouraged APHIS to begin its reevaluation of Japan's FMD status as soon as was appropriate.

By July 4, 2010, when the last case was detected, Japan had reported FMD on a total of 292 premises in Miyazaki Prefecture of that country to the OIE. Although the source of the virus that caused the outbreak has not been definitively identified, MAFF suspects that it was introduced by people or personal goods entering Japan from a nearby country affected with FMD. Japan's official veterinary services addressed the FMD outbreak through a stamping-out policy that involved movement restrictions, culling, active surveillance, and ultimately vaccination. All vaccinated animals were subsequently culled. Intensive surveillance demonstrated that the virus did not spread outside Miyazaki Prefecture. On February 4, 2011, the OIE reinstated Japan to its list of countries that are free of FMD without vaccination.

We stated in our interim rule that, based on Japan's response to the detection of the disease, we intended to reassess the situation at a future date in accordance with OIE standards to determine whether we can restore Japan to the list of regions APHIS considers free of FMD.

On July 26, 2011 (76 FR 44503-44504, Docket No. APHIS-2010-0077), we published in the Federal Register a notice² announcing the availability for review and comment of a document titled “APHIS Evaluation of the Foot and Mouth Disease Status of Japan.” This evaluation examined the events that occurred during and after the outbreak and assessed the risk of live animals and animal products from Japan harboring the FMD virus. We stated that the evaluation would provide a basis for determining whether to reinstate Japan to the list of regions free of FMD and to the list of regions considered free of FMD and rinderpest but from which the importation of meat and other animal products of ruminants and swine into the United States is subject to additional restrictions.

We made the evaluation available for public comment for 60 days ending September 26, 2011. We received two comments by that date. They were from a State animal health board and an organization that represents cattle farmers and ranchers. The issues they raised are discussed below.

Comment: One commenter stated that APHIS’ evaluation of the FMD status of Japan is incomplete and inadequate for determining the risk of introduction and spread of FMD into the United States from Japan because it is qualitative, rather than quantitative, and because it does not include either an exposure assessment or a consequence assessment. The commenter said that APHIS’ 2004 Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking (Evaluation Process)³ explains that quantitative risk modeling is typically used when a foreign country requests to export a specific product to the United States,

² See footnote 1.

³ Process for Foreign Animal Disease Status Evaluations, Regionalization, Risk Analysis, and Rulemaking, USDA-APHIS, 2004.

which the commenter said is the case here where the only product subject to a resumption of exports is whole muscle cuts of boneless beef from Japan. The commenter said that APHIS' Evaluation Process also states, "The risk assessment may conclude if the release assessment demonstrates no significant risk. However, some form of exposure and consequence assessment is typically included for completeness."

Response: The 2004 document referenced by the commenter was intended as a description of general practices rather than as a statement of future policy. A decision on whether to prepare a qualitative or quantitative risk assessment for any action must be made on a case-by-case basis after considering all of the circumstances involved.

The OIE has established international standards for import risk analysis.⁴ Article 2.1.1 of the OIE guidelines on import risk analysis states, "No single method of risk assessment has proven appropriate in all situations, and different methods may be appropriate in different circumstances." Article 2.1.1 further states that risk assessments may be either qualitative or quantitative and that, particularly for diseases listed in the Terrestrial Animal Health Code, where there are international standards and broad agreement concerning likely risks, a qualitative assessment may be all that is required.

Most risk evaluations prepared by APHIS are qualitative. In particular, APHIS has historically used qualitative evaluations to assess requests from regions to be considered free of a particular disease, as is the case for Japan. These evaluations are based on science and conducted according to the factors identified in 9 CFR part 92, § 92.2, which include veterinary infrastructure, biosecurity measures, livestock demographics, marketing practices, disease surveillance, and diagnostic laboratory capabilities. Neither these regulations nor APHIS

guidance documents require a quantitative risk assessment or indicate that one is needed here.

The commenter did not specify how the results of our evaluation would be improved by a quantitative risk assessment.

Additionally, while reinstatement of FMD-free status for Japan would allow a resumption of exports of boneless beef from Japan to the United States, the evaluation prepared for this action was not designed to evaluate specific mitigation measures for boneless beef or any other commodity from Japan. Those mitigation measures were developed based on separate, previous risk assessments and through prior rulemakings.

Regarding the need for exposure and consequence assessments, Article 2.1.4 of the OIE guidelines on import risk analysis states that, if the release assessment demonstrates no significant risk, the risk assessment does not need to continue, meaning that no exposure assessment or consequence assessment is necessary. While APHIS has sometimes included exposure and consequence assessments when the release assessment has demonstrated no significant risk, they provide no additional value under the circumstances. Therefore, we did not include them in the evaluation for Japan's FMD status, and, as a general rule, will not include them in future evaluations when the release assessment demonstrates no significant risk.

Comment: One commenter said that APHIS does not provide a scientific basis for recommending the resumption of exports from Japan within only months following Japan's latest FMD outbreak. The commenter recommended that APHIS wait at least 3 years following the last case of FMD that occurs in a foreign country before considering the resumption of trade in FMD-susceptible products from that country. The commenter said that Japan's 3-year waiting

⁴The Terrestrial Animal Health Code, Chapter 2.1, Import risk analysis.
http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2010/en_titre_1.2.htm

period before its FMD burial sites can be disturbed supports this recommendation. He said that APHIS should explain the security measures in place to prevent wild boars, floods, earthquakes or other natural phenomenon from prematurely disturbing the burial sites within 3 years and what risks can be expected if those security measures fail.

Response: OIE guidelines for reinstatement of FMD freedom are set out in Article 8.5.9 of the Terrestrial Animal Health Code.⁵ When an FMD outbreak or FMD virus infection occurs in an FMD-free country or zone where vaccination is not routinely practiced, such as Japan before and after the 2010 outbreak, the OIE recommended waiting period to regain FMD-free status is 3 months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination, and serological surveillance are applied consistent with articles 8.5.42 to 8.5.47 and article 8.5.49. The last case of FMD in Japan was detected on July 4, 2010, and all affected animals on the farm were destroyed on July 5, 2010. No additional cases were found during extensive surveillance that included testing of wildlife and testing of sentinel cattle that were introduced onto previously affected and depopulated farms. It has now been well over a year since all affected farms were cleaned and disinfected. There is no scientific basis for a 3-year waiting period.

Japan's 3-year prohibition on disturbing FMD burial sites is required by Japan's Animal Infectious Disease Prevention Law (AIDPL) to prevent animals from being exposed to carcasses or materials. Disturbance by wild animals is unlikely, as buried carcasses are covered with thick layers of slaked lime and under at least 3 feet of soil. The sites cannot be used for farming or grazing during the 3-year period, which limits exposure of domestic animals. MAFF told APHIS that the sites were selected taking environmental factors, such as underground water and

⁵ Terrestrial Animal Health Code, Chapter 8.5, Foot and Mouth Disease.

water sources, into account, and that water quality surveys and regular disinfection are implemented to maintain the sites properly during the 3-year period. MAFF also said that soil on the sites would be supplemented or leveled if disturbed by natural causes during the restricted period. Barriers and standing sign boards have been placed around the disposal sites to restrict the entrance of people.

Comment: One commenter stated that APHIS' evaluation contains overly optimistic and unsupported assumptions regarding Japan's ongoing risk for FMD given that the source of the 2010 outbreak is not definitively known, Japan's import policies related to FMD are less stringent than those of the United States, and wildlife cannot be ruled out as a potential source of another FMD outbreak in Japan. Another commenter said that it is difficult to judge the risks associated with the introduction of FMD from Japan without knowing how the FMD virus came in contact with the index animal, and, thus, how Japan can prevent it from happening again.

Response: While the source of the 2010 outbreak and mode of introduction have not been definitively identified, the mechanisms and pathways by which FMD can be transmitted to livestock are well known. Japan's MAFF conducted an epidemiological investigation that identified the presumed index herd, the estimated date of introduction, and the most likely route of infection.

As noted in section 5.1.2 of the evaluation, it is likely that the virus was brought into Japan from another Asian country through the movement of people or goods. Japan has implemented additional biosecurity measures at airports for all persons arriving from international destinations, from aggressive public awareness campaigns, including

announcements on inbound flights, to floor mats soaked in disinfectant that travelers must cross.

MAFF has also increased biosecurity measures at the farm level. Additionally, public awareness of FMD has been heightened by both the outbreak and MAFF's educational outreach.

Regarding Japan's import policies, MAFF prohibits the importation of products derived from animals susceptible to FMD from countries with FMD unless the products are heat treated according to set protocols. Products are subject to inspection upon arrival, as discussed in section 9.2.3 of the evaluation. Live susceptible animals must be accompanied by a health document certified by the veterinary authority of the exporting region. The animals undergo inspection upon arrival, as well as quarantine, during which time the animals undergo clinical inspection and diagnostic testing. Prefectural veterinary officials for the farm of destination are responsible for follow-up inspections. Live animals denied entry may be reshipped or destroyed with pathological examination.

Although Japan allows the importation of live cloven-hoofed animals, genetic materials, and meat under lesser restrictions from several regions that APHIS does not recognize as free of FMD -- namely, Bosnia and Herzegovina, Croatia, Northern Mariana Islands, Romania, Singapore, and Vanuatu -- Japan has not received such imports from any of these countries for at least the past 5 years. Additionally, the last years that FMD was reported in any of these countries ranges from 1935 to 1978. APHIS evaluates and recognizes foreign regions as free of FMD only when a foreign government asks us to do so. None of these countries has requested that APHIS recognize them as FMD free.

Contaminated straw was implicated in the last previous outbreak of FMD in Japan (2000), and Japan currently allows importation of grain straw and hay for animal feed from regions that APHIS does not consider free of FMD. Most notably, Japan imports substantial

amounts of rice straw from China each year because there is not enough arable land to grow sufficient forage for livestock in Japan. However, Japan requires the straw to be produced, processed, and stored in an area that has been free from FMD, rinderpest, and African swine fever for at least 3 years, and strictly enforces requirements that the hay and straw be heat treated to inactivate the FMD virus and stored afterward in a manner that prevents recontamination. Rice straw from China is processed in dedicated plants with a Japanese inspector on site whose sole job is to check the core temperature of each lot. The straw is shipped to Japan in sealed containers and tested upon arrival. The failure rate for compliance in 2010 was 0.15 percent, due to a missing seal on one container, and 0.06 during the first three quarters of 2011, because Japanese officials could not confirm that the rice straw had been properly stored following treatment in order to prevent recontamination.

Regarding the potential for wildlife to be a source of another FMD epidemic, Japan collected and tested 159 samples from susceptible wildlife with negative results. The samples were taken from animals hunted as nuisance species, as well as from the carcasses of dead and injured wildlife. Of the 159 samples, 145 came from hunted nuisance species, including sika deer (46) and wild boar (99). The remaining 14 samples were taken from carcasses of dead and injured wildlife: 5 were from sika deer, 7 from wild boar, and 2 from Japanese serows. Japan estimates that there are about 70,000 deer and 65,000 wild pigs in Miyazaki Prefecture. The wildlife surveillance conducted by Japan during and after the 2010 outbreak was statistically sufficient to detect a 7 percent or higher prevalence level of FMD with 95 percent confidence. We consider Japan's surveillance to be adequate due to the highly contagious nature of FMD, which would normally produce much higher prevalence than 7 percent if it was present. To provide additional assurance of the absence of FMD in wildlife in Miyazaki Prefecture, Japan

initiated another round of wildlife sampling and testing during the 2011 hunting season that began in October.

Comment: One commenter, observing that the 2000 FMD outbreak in Japan was linked to contaminated straw/feedstuffs imported into that country, asked whether the recent reported low refusal rate for incoming shipments of straw was the result of good mitigation methods or just luck. He noted the refusal rate of 0.15 percent in 2010, due to rejection of one container because it did not have a seal. Estimating that this meant one container was rejected out of 667, he asked whether 667 was the number of containers imported per year.

Response: The low refusal rate is based on a high level of compliance with import requirements, as determined through inspections conducted prior to shipment and again upon arrival. Japan told APHIS that it does not record the number of containers imported, but said it imported 175,233,764 kilograms of straw in 2010 and 148,226,568 kilograms in the first three quarters of 2011. The rejection rate for January through September of 2011 was 0.06 percent (1 inspection testing case out of 1,550). In that instance, Japanese officials said that the straw had been heat treated as required, but they were unable to confirm that the treated straw had been properly protected after treatment to prevent recontamination.

Comment: One commenter asked, “Does the new path towards liberalization, in light of an unidentified source, of normalized trade practices allow for adequate opportunity to find disease if it were present in a species that would not normally show outward signs?” The commenter expressed concern about the rate at which depopulated farms were restocking. He suggested that a low concentration of animals provides fewer opportunities to determine whether the disease is still present and asked how effective the sentinel cow program could be with only a 3-month waiting period. He asked how long it is expected to take to repopulate the farms and

how that process might affect, or be affected by, the “post quarantine timeframe of active and passive surveillance.”

Response: APHIS disagrees with the notion that there is a new path towards liberalization of trade practices. We have not changed any of our criteria for determining whether a region can be reinstated as FMD free following an outbreak. We are satisfied that FMD has been eradicated in Japan. During the 2010 outbreak, veterinary officials in Japan conducted active surveillance for FMD, both in Miyazaki Prefecture and throughout the country to ensure detection of FMD. Investigators assumed an average incubation period of 10 days for swine and 7 days for cattle, with a maximum of 14 days for both species. However, each epidemiological investigation traced animal movements onto and off of the farm for 21 days prior to detection of infection. The last case of FMD in Japan was detected on July 4, 2010, and all susceptible animals on the farm were destroyed the next day. By August 26, 2010, all affected farms had completed cleaning and disinfection procedures. Japan conducted clinical and serological surveillance around previously affected farms prior to lifting movement restrictions and throughout Miyazaki Prefecture to reestablish freedom from FMD. Japan also introduced sentinel cattle onto 175 previously affected farms beginning on August 31, 2010, to assist in determining whether any FMD virus remained in the environment. Farmers were required to conduct daily clinical observations of the cattle, and local veterinary officers conducted clinical inspections 3 to 4 weeks after the cattle were introduced onto the premises. Serum samples were collected on the day of introduction and 3 to 4 weeks after, in accordance with international recommendations.⁶ The samples were subject to liquid-phase blocking

⁶ FAO Animal Health Manual No. 16: Preparation of Foot-and-Mouth Disease Contingency Plans. Food and Agriculture Organization of the United Nations, Rome, 2002. <http://www.fao.org/DOCREP/006/Y4382E/y4382e09.htm>.

enzyme-linked immunosorbent assay testing, with negative results. Finally, Japan collected and tested samples from susceptible wildlife species in Miyazaki Prefecture, also with negative results. Even if the disease were present in animals that did not show outward signs, those animals would have spread the disease long before now to susceptible species that show clinical signs.

Restocking of affected premises has proceeded slowly, in large part due to economic concerns related to the natural disasters Japan experienced in 2011. According to MAFF, 58 percent of depopulated cattle farms and 47 percent of depopulated swine farms—57 percent of the total number of depopulated farms—had restocked or started restocking as of the last day of August 2011. MAFF told APHIS that many farmers have delayed restocking because of a decline in livestock prices following the great earthquake of 2010 in eastern Japan.

The 3-month waiting period mentioned by the commenter appears to refer to MAFF's declaring Japan once again free of FMD on October 6, 2010, 3 months after the animals on the last affected farm were destroyed. A 3-month waiting period is in line with OIE recommendations for reinstatement of FMD-free status in a previously free country where a stamping-out policy is followed and all vaccinated animals are destroyed.

As discussed previously, while the specific source of this outbreak has not been identified, the mechanisms and pathways by which FMD can be transmitted to livestock are well known. Japan has identified the most likely route of infection and has implemented measures to prevent another introduction.

Comment: One commenter said that it would be helpful to get an idea of what biosecurity measures were in place prior to March 19, 2010, what measures are new since

the disease was identified, and what measures will continue to be in place after recognition of FMD freedom.

Response: Biosecurity measures prior to the outbreak varied from farm to farm, as is typical in many other countries, including the United States. Neighboring cattle farmers commonly visited each other's premises and shared farm equipment. Swine farms generally had better biosecurity with disinfecting footbaths in place and restricted access to areas where the animals were kept. Since the outbreak, many of the biosecurity measures employed during the emergency are now required by law. Standards of biosecurity for farming include defining areas of increased biosecurity on the farm where persons entering are required to wear particular clothing, requiring people and vehicles entering the biosecurity area to be disinfected, and preventing contact between domestic and wild animals.

Comment: One commenter asked how APHIS can be comfortable with Japan's process for dealing with the outbreak when the prefectural government's Livestock Hygiene Service Center was notified about the first animal on March 31, 2010, notified about a second farm with oral lesions on April 9, 2010, and no samples were submitted for FMD testing until April 16, 2010. The commenter stated that the lack of astuteness to the symptoms of the disease present illustrate that all aspects of disease prevention, detection, and mitigation must be fully understood and employed or response and recovery are all that is left.

Response: There is no question that delayed detection was a major cause of virus spread during the 2010 FMD outbreak in Japan. As discussed in section 7.1 of the evaluation, prior to confirmation of the first FMD case on April 20, 2010, Japan relied on passive surveillance for detection and reporting of suspect FMD cases. Passive surveillance depends on awareness of FMD, however, and local veterinarians who initially saw cattle with clinical signs compatible

with the disease apparently did not suspect FMD and, therefore, did not act quickly. As a result of the outbreak, the level of awareness among farmers and veterinarians throughout Japan is now quite high. Additionally, government officials and an independent committee established by the Japanese Government to look into the 2010 outbreak and make recommendations have noted the high cost of delays in detecting FMD, and the committee has made several recommendations for improving passive surveillance and emergency preparedness, as well as other aspects of FMD prevention, detection, and mitigation. APHIS is confident that veterinary officials would react far more promptly today should clinical signs compatible with FMD be observed in a susceptible animal.

Comment: One commenter stated that APHIS' evaluation deceives the public by falsely claiming that all FMD-exposed livestock in Japan have been depopulated. Evidence of this deception is the discussion in the evaluation concerning six bulls that were removed from a farm just 3 days before the farm experienced an outbreak. According to the evaluation, one of the bulls became infected with FMD, and the five other bulls were spared. Since the average incubation period for cattle is assumed to be 7 days, FMD was likely incubating on the farm before the bulls were removed.

Response: APHIS did not claim that all FMD-exposed livestock were depopulated. The evaluation stated that all FMD cases and susceptible animals kept in the same and epidemiologically related farms, as well as all susceptible animals on unaffected, vaccinated farms, were depopulated. Additionally, the evaluation included an extensive discussion of the disposition of the bulls referenced by the commenter. As described in section 5.3.3, six high-value bulls from the Miyazaki Livestock Improvement Association (MLIA), which supplies semen to Miyazaki producers of Wagyu beef, were removed from the MLIA during the outbreak

in Miyazaki Prefecture. FMD virus was subsequently detected at the MLIA and all remaining animals were depopulated.

APHIS agrees that FMD was likely incubating on the MLIA premises when the six bulls were removed. However, the six bulls tested negative for FMD on May 13, 2010, the day they were removed from the MLIA. As described in the evaluation, once on the new premises, the bulls were kept isolated from each other and underwent daily clinical inspections and repeated testing for FMD. One bull tested positive and was destroyed. For the next 14 days, the remaining bulls were each tested daily using reverse transcription polymerase chain reaction on nasal swabs with negative results, and serum samples taken on June 4, June 10, and August 27, 2010, were also negative. In light of these results, the statistical probability of a bull being infected but not detected approaches zero.

Comment: One commenter stated that section 5.3.2 of the evaluation mentions that six bulls were depopulated and buried on July 17, 2010, yet section 5.3.3 indicates that the bulls were serologically tested on September 4, 2010, with two subsequently moved to another location.

Response: Section 5.3.2 discusses six bulls belonging to a farmer in Takanabe-cho who refused to allow the bulls to be vaccinated and depopulated. All of those bulls were depopulated and buried on July 17, 2010. The six bulls discussed in section 5.3.3 are not the same bulls. These bulls belonged to the MLIA. Only one of those bulls was destroyed. The other five bulls remained isolated and underwent testing for FMD, with negative results.

Comment: One commenter said that many sources report the presence of wild boar in the area, but only seven wild boar were tested. When the average time to depopulate from time of

identification of virus on a farm was 9 days (range of 0-30), how does testing of only seven wild boar provide any assurance that no virus was or is circulating within the population?

Response: The commenter refers to section 7.2.4 of the evaluation, which indicates that Japanese officials tested seven samples from the carcasses of dead or injured wild boar for FMD, with negative results. However, that same section states that negative results were obtained on serologic testing of samples from 99 wild boar that were hunted as nuisance species (MAFF has since updated this number to 106). Sampling was sufficient to detect 10 percent prevalence with 95 percent confidence which, along with the fact that no clinical signs of FMD have been reported, provides assurance that the virus is not circulating within the wild boar population of Miyazaki Prefecture.

Comment: One commenter, noting that table 4.1 in the evaluation showed the number of dairy cattle, beef cattle, and swine in Miyazaki Prefecture, asked for the total population of each susceptible species in the prefecture, including “those species which tend to mask the virus,” and wildlife. He questioned whether dairy cattle meant Holstein-type cattle or water buffalo-type cattle. The commenter also asked for the population of animals within identified zones.

Response: Sheep and goats are not commercially produced in Miyazaki Prefecture, thus the numbers are quite low. Figures available from February 2010 show only 28 sheep and 74 goats. Water buffalo were not included in the count of cattle. At the time of the outbreak, there were 42 water buffalo in Miyazaki Prefecture. Japan estimates a wildlife population in Miyazaki Prefecture of approximately 70,000 deer and 65,000 wild pigs. Sheep and goats, and possibly deer, are the most likely species that could become infected without showing clinical signs. Clinical signs in water buffalo were apparent but not classic, according to reports from the one

affected farm with water buffalo. MAFF noted that there was a high incidence of clinical signs among infected cattle and swine with this particular strain of virus.

Comment: One commenter, noting the discussion of penalties for non-reporting in section 3.2 of the evaluation, asked about the relationship of the penalty to the range of values of animals involved. For example, how many slaughter-weight pigs does a 1 million yen fine buy? The commenter said that a producer making 20 percent profit will have a very different risk tolerance to being fined than will a producer making a 2 percent profit margin. He said the outlook for stability within the marketplace will have a large impact on the risk tolerance a producer is willing to take as well.

Response: The comment refers to penalties for violating Japan's AIDPL. The AIDPL requires animal owners, caretakers, and veterinarians to immediately report a suspect or confirmed case of a foreign animal disease, including FMD, to prefectural authorities, who must then notify MAFF and others. The AIDPL also provides for payment of compensation to owners of animals on affected farms up to 80 percent of market value; in this outbreak, the prefecture provided the remaining 20 percent. We do not have the data to determine whether the penalty is sufficient to induce reporting, or the extent to which economic considerations factor into reporting. Compensation tends to encourage reporting. Evidence suggests that the delay in detecting the first case of FMD in the 2010 outbreak was the result of a failure to suspect FMD rather than a failure to report a suspected case.

Comment: One commenter referred to section 3.3.1 of the evaluation, which contains information about the relative numbers of male and female graduates of veterinary medical schools in Japan who become licensed veterinarians each year. He asked what difference it

makes, when responding to FMD and protecting the food supply, whether the veterinarian is a male or female?

Response: None.

Comment: One commenter said that section 3.4 of the evaluation contains statements about confusion concerning the prefecture's roles and responsibilities, with obvious changes made during and after the response. He asked how enough time has passed to know whether the implemented changes are effective.

Response: Section 3.4 states that it appeared that the practical roles and responsibilities of MAFF and the prefectures were not clearly defined prior to the 2010 outbreak, which caused some confusion in the initial stages. Japanese officials say that roles were clarified, rather than changed, following the 2010 outbreak. Local veterinary officers in Japan participate in foreign animal disease simulations and training organized by MAFF and the National Institute of Animal Health, Japan's national reference laboratory. MAFF conducted quality control exercises with all prefectures in late 2010, after the FMD outbreak, and also in February 2011. The purpose was to verify details of the emergency response plans and address any weaknesses detected.

Comment: One commenter asked what the basis is for APHIS' last statement in section 3.4 of the evaluation, which the commenter said appears to be directly related to response, when prevention is more important.

Response: The last statement under section 3.4 of the evaluation is "APHIS concludes that the authority, organization, and infrastructure of Japan's veterinary services were sufficient to address the 2010 FMD outbreak, although opportunities for improvement exist."

APHIS evaluates veterinary authority, organization, and infrastructure to determine whether the veterinary services in a region have the capability and resources to effectively

investigate, diagnose, and report the disease under evaluation, if detected. The sentence referenced by the commenter is our finding in this area. We also evaluated other factors pertaining to FMD risk in Japan, including measures to prevent the introduction of the disease. These are described in section 9 of the evaluation.

Comment: One commenter, referring to a discussion of animal identification and traceability in section 4.4 of the evaluation, asked how effective the animal identification system was in Japan in helping to stop/prevent the spread of disease.

Response: We found that animal identification practices in Japan allowed officials to effectively trace animals to investigate the source and potential spread of infection. Once the location of affected and at-risk animals was known, they were targeted for destruction, and officials established movement restriction zones around the involved farms to prevent further spread of the disease. In this way, animal identification practices helped officials contain and eventually stamp out the disease.

Comment: One commenter stated that the word “sufficient” is used several times throughout the evaluation and asked: How is sufficient determined, by whom, and by what definition?

Response: APHIS used the term “sufficient” seven times in the evaluation. As used, the word has the standard dictionary meaning, i.e., enough to meet the needs of a situation or proposed end. In each case, the word was used in a context that identified the situation or proposed end. For example, “Active clinical and serological surveillance within the restricted zones proved sufficient for detection of additional case farms within Miyazaki Prefecture” (section 7.3). The context indicates how “sufficient” was determined. In this sentence, for example, the use of the word sufficient suggests that the surveillance found all of the remaining

cases in the Miyazaki Prefecture, and, in fact, no additional cases have been detected. The answer to the question “by whom” also depends on context. In the sentence just quoted, APHIS has made the determination.

Comment: One commenter asked, when the time to depopulate confirmed herds becomes delayed, what is the appropriate time lag whereby it becomes more beneficial to vaccinate than depopulate? The commenter stated that having knowingly positive animals potentially spreading virus through incubation and amplification while waiting to be depopulated cannot be good, especially with operations being separated by just over a quarter of a mile.

Response: The decision to vaccinate rather than depopulate is a difficult one that may have long-term effects on trade in susceptible animals and products from those animals. The determination of when that is the best course of action must be made on a case-by-case basis. That was not the question in Japan, however. Rather, the question in the 2010 outbreak was whether to vaccinate as part of the stamping-out program, when lack of burial grounds led to delays in depopulation. The government recognized that those delays increased the risk that the disease would spread. The difficulty with the decision to vaccinate or not was that the Japanese government did not have the authority at the time to kill apparently healthy, but vaccinated, animals. Japan would need to destroy the vaccinated animals in order to regain its status as FMD-free without vaccination. Recognizing that vaccination was the only way to keep the disease from spreading while additional burial sites were located, the government passed emergency legislation authorizing the precautionary depopulation of susceptible animals in areas designated by the MAFF Minister.

Comment: One commenter expressed concern that reestablishing trade with Japan would subject U.S. industry to greater risks than it can bear. As evidence, the commenter pointed to a

30 percent restocking rate in Japan 6 months after depopulation. The same commenter asked several questions about the number of veterinarians available to deal with livestock disease in both Japan and the United States: What is the per capita ratio of government (all levels) employed veterinarians to livestock in Japan, and how does that ratio compare to that of the United States? Is Japan's incident command structure too top heavy? Is the declining number of food animal veterinarians in Japan, as in the United States, due to declining economic incentive within the industry to sustain interest in the field? The commenter also said that without having a clear and distinct picture of what the APHIS response would be in the United States to FMD, it is impossible for the industry or the States to calculate the risk APHIS is requesting them to take.

Response: As discussed previously, Japanese producers continue to make progress in restocking of farms, which was slowed largely by a decline in livestock prices following the 2010 earthquake. Fifty-seven percent had restocked by the end August 2011.

Regarding the decline in the number of food animal veterinarians--and not just in the United States and Japan--a number of factors have contributed, including burdensome student loans, low starting salaries, the decline of family farms, and a preference among many professionals to live in areas with urban lifestyle choices. We do not have data on per capita ratio of government-employed veterinarians to livestock in the form requested by the commenter, but the World Animal Health Information Database (WAHID) on the OIE Web site⁷ provides information on the relative numbers of veterinarians and paraveterinarians by country. According to WAHID, Japan had 3,465 public sector veterinary personnel in 2010, an average of 0.0092 per square kilometer or 7.92 per livestock unit, for a country ranking of 6th. The

⁷ WAHID Interface, Veterinarians and paraveterinarians.
http://web.oie.int/wahis/public.php?selected_start_year=2010&display_class=ah_gov&page=country_personnel&sort=1

United States is ranked 98th, with 1,874 public sector veterinary personnel in 2010, an average of 0.0002 per square kilometer or 0.01 per livestock unit. Differences among countries in the organization of their veterinary infrastructures, additional resources in the event of an emergency, size and nature of geographical areas, population densities (human and livestock), and other factors would have to be explored to provide context for these numbers.

The commenter's questions about the numbers of livestock veterinarians and what the APHIS response would be to an outbreak of FMD in the United States are based on the commenter's concern that a decision to reinstate Japan's FMD-free status would result in an unacceptable risk of FMD being introduced into the United States. As discussed earlier, APHIS has not changed any of its criteria for determining whether a region can be reinstated as FMD free following an outbreak. For the reasons given in the evaluation and this document, we are satisfied that FMD has been eradicated in Japan and that products authorized by the regulations may be safely imported.

Therefore, based on the evaluation and the reasons given in this document in response to comments, we are reinstating Japan's status as FMD-free.

A final rule⁸ published in the Federal Register on January 10, 2012 (77 FR 1388-1396, Docket No. APHIS-2009-0035) and effective on February 9, 2012, removed lists of regions classified with respect to certain animal diseases and pests from our animal and animal product import regulations in 9 CFR parts 92, 93, 94, 96, and 98. The lists are now posted on APHIS' Web site, rather than published in the Code of Federal Regulations. Accordingly, we are adding Japan to the list of regions that APHIS has declared free of FMD (formerly in § 94.1) and to the list of FMD-free regions that are subject to additional restrictions because they supplement their

⁸ See <http://www.regulations.gov#!docketDetail;D=APHIS-2009-0035>.

national meat supply by the importation of fresh (chilled or frozen) meat of ruminants or swine from regions that APHIS considers to be affected with rinderpest or FMD, or have a common land border with such regions, or import ruminants or swine from such regions under conditions less restrictive than would be acceptable for importation into the United States (formerly in § 94.11). These lists are maintained on the APHIS Web site at http://www.aphis.usda.gov/import_export/animals/animal_disease_status.shtml. Copies of the lists are also be available via postal mail, fax, or email upon request to the Sanitary Trade Issues Team, National Center for Import and Export, Veterinary Services, Animal and Plant Health Inspection Service, 4700 River Road Unit 38, Riverdale, Maryland 20737.

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 27th day of July, 2012 .

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

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