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Docket No. APHIS-2010-0077
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

RE: Availability of a Risk Analysis Evaluating the Foot-and-Mouth Disease Status of Japan

To Whom It May Concern:

It is exceedingly difficult to make good judgments on risks associated with the introduction of disease from Japan without having a clear idea of how the Foot and Mouth Disease (FMD) virus came in contact with the index animal. Consequently, how does Japan do a good job of mitigating the risk of reintroduction, when it is not clear how the disease was introduced initially? The document is deficient in adequate detail regarding the risks of disease introduction and more specifically, what mitigation efforts have been put in place. The document appears to be less about assessing the risk from Japan and more about setting precedent in allowing imports from other, more risky, nations or areas within nations, which have a lesser tolerance of disease reintroduction and lower food safety tolerances than does Japan. This appears to be yet another attempt at making the world a flatter place, not by bringing up the standards of other nations, but by bringing the standards of the United States down to the developing world standards.

The most disturbing absence within the document is explanation of the processes enacted as a result of this latest disease outbreak. Often times the term biosecurity is dropped as being all encompassing without explaining what was and hopefully will be done in the future to ensure biosecurity. Furthermore, it would be helpful to get an idea of what biosecurity measures were in place prior to March 19, 2010 and what measures are new since the disease was identified and additionally, what measures will continue to be in place after recognition of FMD freedom.

As contagious as the FMD virus is, it is the hazard associated with the transference of the virus across physical and geopolitical boundaries that is of more importance. On the timeline provided with the document, it is assumed that the disease was introduced on March 19th, 2010. The farmer on the assumed index farm reported signs to the prefectural animal health center on March 31st, 2010. On April 9th, a private veterinarian again reports symptoms to the prefectural veterinarian whom also examined the animal, but no further action was taken. It is not until April 16th that samples are tested for FMD. 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. As Ben Franklin so astutely stated, circa the founding of our nation, "An ounce of prevention is worth a pound of cure." Ben's statement holds even more true now with expanded world trade than in did in the late 1700's.

According to Wikipedia and other sources, the concentration of sika deer and wild boar are at levels causing concerns of overabundance. The disease outbreak was bad enough that over 200,000 domestic stock were stamped out, but only 14 wild animals needed to be tested to ensure there was no disease in the wildlife. Is that statistically significant sample? I think not. If the Japanese fences are so good that they keep wild boar out, maybe the design could be adapted for use here in the states in areas where wild boar are such a problem.

There are a number of questions left unanswered by this assessment.

1. 211,608 animals were destroyed in the response effort in the Prefecture, what was the total population of animals in the Prefecture of each susceptible species (cattle and swine are listed, but what about those species which tend to mask the virus), including wildlife, and what was the population of animals within zones identified? Does dairy mean Holstein type cattle or water buffalo type cattle? Information under section 5.9 should be included in table 4.1.

2. How long is it expected to take to repopulate the farms? How is the repopulation process likely to be impacted by or impact the post quarantine timeframe of active and passive surveillance?

3. 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 premises that do restock and the corresponding rate of restocking plays as large a role as do the methods used in assuring freedom of disease.

4. How does APHIS feel comfortable with the process when the Prefectural government's Livestock Hygiene Service Center is notified about the first animal on March 31, 2010, a second farm with oral lesions on April 9, 2010 and no samples submitted for FMD testing until April 16, 2010?

5. Many sources report the presence of wild boar in the area, but only seven wild boar were tested. When there was an average time to depopulate from time of identification of virus on a farm being 9 days (range of 0-30), how does testing of only 7 wild boar provide any assurance that no virus was or is circulating within the population?

6. While the ICS-like system used within the response is not published, what is the per capita ratio of government (all levels) employed veterinarians to livestock? How does that compare to the system we have here? Is the ICS chart too top heavy?

7. In section 3.2, on page 11, there is a penalty matrix laid out. What is the relationship of the penalty to the range of values of animals involved? I.e. How many slaughter weight pigs does a one million yen fine buy? 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. The outlook for stability within the marketplace will have a large impact on the risk tolerance a producer is willing to take as well.

8. In section 3.3.1, references are made to declining numbers of food animal veterinarians, like here in the United States. Is that likely due to a declining economic incentive within the industry to sustain interest in the field?

9. Also under section 3.3.1, on page 13, what difference does it make, when responding to FMD and protecting the food supply, whether the veterinarian is a male or female?

10. Under section 3.4, statements are made about confusion within the Prefecture's roles and responsibilities, with obvious changes made during and after the response. How has enough time passed to understand that the implemented changes are effectual?

11. Again under section 3.4, the last statement, what basis does APHIS use to make the statement, which appears is directly related to response when prevention is more important to response?

12. Section 4.4 discusses the Animal Identification and traceability program in Japan. How effective was the identification system in helping to stop/prevent the spread of disease?

13. What biosecurity practices were installed/ required at the farm level to prevent the reintroduction of disease?

14. The word sufficient is used several times throughout the document. How is sufficient determined? By whom and by what definition?

15. On page 20 under section 5.3.2, the six bulls are referenced as depopulated and buried on July 17th, under provisions of the SLCFMD. Yet in section 5.3.3, on page 21, reference is made to serologically testing the animals negative on September 4, 2010 and two are moved to Takabaru-cho. How does one serologically test an animal that has been depopulated and buried for six weeks?

16. When the time to depopulate confirmed herds becomes delayed, what is the appropriate time lag whereby it becomes more beneficial to vaccinate than depopulate? Having knowingly positive animals potentially spreading virus thru incubation and amplification, while waiting to be depopulated cannot be good, especially with operations being separated by just over a quarter of a mile.

17. With the delay in repopulation of animals and the large percentage of animal removed, how effective is the sentinel cow program with only a three month waiting period? Very low concentration of animals with fewer opportunities for exposure.

18. Although the 2000 FMD outbreak was linked to contaminated straw/feedstuffs, failure rate of incoming shipments was 0.15% due to one container not having a seal on the container (math = 1/.0015=667 containers). No containers refused for insufficient heat treatment. Are 667 all of the containers of straw imported per year? Is the low refusal rate good mitigation of threat or just luck? Good luck does not equal adequate mitigation, only sufficient mitigation until the one time luck or statistics puts you on the wrong side of the coin.

The level of risk that an entity should be willing to accept should be directly related to what the entity has to risk, or what the cost to the nation would be for being wrong. A near miss in a war using muskets is very different than a near miss in an all out nuclear war. The tools available in the toolkit make all the difference in the risk tolerance of a nation. Even within a nation, the risk tolerances will be vastly different depending upon where the responsibilities are held, more importantly who bears the true costs of the response, and lastly who answers to which constituents. As we move ever closer to the Vision 2015, where we are asking the industry to bear more of the responsibility and cost, while moving to ever more liberalized trade practices. We are seeing risks greater than the industry will bear, as is evident in Japan with a measly 30% restocking rate six months after depopulation. Without having a clear and distinct picture of what the APHIS response would be in the United States (stamping out only, vaccinate to slaughter, vaccinate to depopulate, vaccinate to live, do nothing while tracking the spread, or a combination of one or more), it is impossible for the industry or the states to calculate the risk APHIS is requesting the states and the industries to take. The federal government's track record in asking the states and industry for trust has been drastically diminished during Midwestern flooding, southern droughts, and various wildfires as of late. For the above reasons and the precedent this assessment would establish, it is inconceivable to support re-establishment of trade at this time. Just because you can respond and treat leprosy and AIDS does not mean you should go and put yourself at risk of getting infected or exposed unnecessarily by either.

Sincerely,

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Assistant State Veterinarian

JLV:tlc

cc: State Board of Animal Health Members