R-CALF USA
PO Box 30715
Billings, MT 59107
Phone: 406-252-2516
Fax: 406-252-3176
Email: r-calfusa@r-calfusa.com
www.r-calfusa.com

Sent via regulations.gov

Re: R-CALF USA's Comments in Docket No. APHIS–2020–0054, Petition To Manufacture Foot-and-Mouth Disease Vaccine in the United States, Notice of Petition and Request for Action

Dear Sir or Madam:

The Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF USA) appreciates this opportunity to comment to the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regarding the above captioned Docket No. APHIS-2020-0054 (hereafter, "Petition"), available at 85 Fed. Reg., 42,346-347 (July 14, 2020).

R-CALF USA is the largest trade association that exclusively represents United States cattle farmers and ranchers within the multi-segmented beef supply chain. Its thousands of members reside in 44 states and include cow-calf operators, cattle backgrounders and stockers, and feedlot owners, as well as sheep producers.

I. INTRODUCTION

Zoetis, Inc. (Zoetis) petitioned the APHIS to approve the manufacture of a vaccine derived from an attenuated, leaderless strain of the live foot-and-mouth disease (FMD) virus. It appears that APHIS has already granted Zoetis a permit to bring attenuated live FMD virus onto the mainland of the United States for the purpose of developing a vaccine, *i.e.*, for research and study in accordance with 21 U.S.C. § 113a. Now, however, Zoetis seeks the APHIS' approval to begin commercial manufacture of FMD vaccine using the attenuated live FMD virus, and to do so on the mainland.

For the reasons stated below, R-CALF USA asserts that the APHIS has no authority to approve Zoetis' Petition and, therefore, must reject it until and unless Congress amends 21 U.S.C. § 113a.

II. R-CALF USA's ANALYSIS OF THE PETITION

A. U.S. Law Unequivocally Prohibits the Introduction of Any and All Live FMD Viruses into Any Part of the Mainland of the United States Except for Specific Purposes.

The governing statute unambiguously states:

> Provided, That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States [] unless the Secretary determines that it is necessary and in the public interest *for the conduct of research and study in the United States* [] and issues a permit under such rules as the Secretary

> shall promulgate to protect animal health, except that the Secretary of Agriculture *may transport said virus* in the original package across the mainland under adequate safeguards. . .

(Emphasis added.) 21 U.S.C. § 113a.

Congress, therefore, has unequivocally prohibited the APHIS from introducing or allowing to be introduced any and all live FMD viruses into the mainland. It did so by clearly stating that "no live virus" may be introduced except for the conduct of research and study, and transport *across* the mainland.

The Petition, as represented by the APHIS, specifically requests permission to use the live FMD virus that USDA had permitted into the mainland for the lawful purpose of research and study, which live virus was purportedly modified before entry into the mainland, to now begin manufacture of FMD vaccine.

If the APHIS were to extend the purpose for which the live FMD virus was introduced into the mainland beyond research and study or transport, to include manufacture, that action would constitute unlawful government overreach as Congress was clear: The live FMD virus is prohibited from being introduced into the mainland "for any purpose" other than for research, study and transport across the mainland.

The APHIS need not consider the Petition any further. What is requested is contrary to existing law. Neither the advent of new technology nor the likely omission by Zoetis to fully disclose the ultimate purpose for which it initially sought a permit to introduce the live FMD virus into the mainland, *i.e.*, to ultimately begin manufacture of a vaccine, does not change the law. The Petition must be denied.

If the APHIS and/or Zoetis desires to expand the purpose for which the live FMD virus may be introduced into the mainland, they must go to Congress and seek an amendment to 21 U.S.C. § 113a. Anything less will likely result in an invitation for litigation.

B. The Petition Lacks Citations to Any Research or Study that Substantiates Zoetis' Claim that the Manufacture of Its Proposed FMD Vaccine Is Safe.

While the resolution of this particular issue is completely unnecessary for the APHIS to properly dispose of the Petition in a lawful manner, it is noteworthy that the only supporting and related material accompanying Docket No. APHIS-2020-0054 is a three-paragraph self-serving position paper by Zoetis. Zoetis' position paper is purely conclusory. The Petition itself is likewise conclusory as it too lacks any citation of or reference to a single scientific study that supports either the Petition or Zoetis' position paper.

Thus, the APHIS is seeking public comment on an extremely important matter that could lead to a potentially catastrophic outcome for the U.S. live cattle industry without affording the public with a single shred of scientific information.

Consequently, the APHIS should voluntarily withdraw its Petition both because it seeks comments regarding an unlawful act and because it is fundamentally insufficient for purposes of analyzing the potential risk the Petition potentially harbors for the U.S. live cattle industry.

III. R-CALF USA's RESPONSE TO APHIS' REQUEST FOR INFORMATION

A. Are there possible risks to livestock associated with the commercial manufacture of FMD vaccine in the United States? If so, are these offset by possible benefits associated with such development, assuming appropriate safeguarding?

The conclusory Petition and Zoetis' conclusory position paper answers the first question in the affirmative. They do so by claiming, without any scientific support, that their particular manufacturing scheme: 1) Will not lead to the establishment of a productive infection in host animals and is incapable of generating clinical or subclinical FMD. Therefore, the risk of manufacture of FMD vaccine in the U.S. includes the potential to establish a productive infection in host animals and generating clinical and subclinical FMD. 2) Will not result in the transmittal of FMD between host animals. Therefore, the risk of manufacture of FMD vaccine in the U.S. includes the potential to transmit FMD between host animals. 3) Will not result in the re-acquiring of attenuating mutations, rendering them incapable of becoming infection, pathogenic, or contagious. Therefore, the risk of manufacture of FMD vaccine in the U.S. includes the potential of re-acquiring attenuated mutations, making them infectious, pathogenic, and contagious.

In its 2010 evaluation of the potential risks of researching and studying, let alone manufacturing, the FMD virus on the mainland in the heart of the beef cattle industry in Manhattan, Kansas, the National Academy of Sciences concluded that the U.S. Department of Homeland Security's site-specific biosafety and biosecurity risk assessment (SSRA) of the Manhattan, Kansas National Bio- and Agro-Defense Facility (NBAF) "indicated that an escape of a pathogen, such as FMD[] [virus], and an ensuing disease outbreak is more likely than not to occur within the 50-year life span of the NBAF. As previously mentioned, the SSRA's estimates indicate that a release of FMD[] [virus] resulting in infection outside the laboratory has a nearly 70% chance of occurring with an economic impact of $9-50 billion."[1] The academy further found that human error is the most likely cause of an accidental pathogen release.[2]

Thus, the risk of manufacture of FMD vaccine in the mainland of the U.S. includes the inadvertent release of FMD that will most likely be caused by human error and result in catastrophic harm to the U.S. live cattle industry. Indeed, the Government Accountability Office (GAO) reports that from 1971 to 2004 there have been six inadvertent internal releases of FMD at the Plum Island Animal Disease Center.[3] These inadvertent releases were attributable to human error, lack of proper maintenance, equipment failure, and deviation from standard operating procedures.[4] Fortunately, until recently, the live FMD virus was allowed only on Plum Island where an inadvertent release is not likely to cause FMD infections in either the wildlife or livestock populations due to its island location.

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[1] National Research Council. 2010. *Evaluation of a Site-Specific Risk Assessment for the Department of Homeland Security's Planned National Bio- and Agro-Defense Facility in Manhattan, Kansas*. Washington, DC: The National Academies Press. https://doi.org/10.17226/13031.
[2] *Ibid*.
[3] *See* High-Containment Biosafety Laboratories, DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland, U.S. Government Accountability Office, GAO-08-821T, May 22, 2008, at 16-17.
[4] *Id.*, at 17.

All of the above risks would be associated with the manufacture of FMD vaccine anywhere on the mainland and an unbiased, scientific risk analysis would be needed for any particular manufacturing proposal before an accurate determination could be made regarding a cost-benefit analysis.

B. If there are possible risks, do these risks differ depending on the location and method of development? If so, how?

The only known safe location for researching and studying FMD and for maintaining a national vaccine bank is on Plum Island. Thus, and consequently, the only acceptable location for using live FMD virus for manufacturing vaccine would be an island location at or similar to Plum Island, which is far removed from any susceptible wildlife or livestock populations.

C. What safeguards should surround the commercial manufacture of FMD vaccine, if authorized?

An unbiased, scientific risk analysis of any proposed commercial manufacture of FMD would first have to be conducted prior to answering this broad question. Lacking such an analysis, locating the manufacturing on an island location is currently the only known safeguard for preventing an inadvertent release into the wildlife and livestock populations. Indeed, the inadvertent release of FMD that occurred in August 2007 from the Pirbright site in Surrey, England, where a commercial vaccine production plant and a research and diagnostic laboratory are co-located, is testament to the foolishness of carrying out such activities in close proximity to wildlife and livestock populations.[5]

D. How should the overall language of 21 U.S.C. 113a be interpreted in light of significant technical developments in the field of virology since its enactment?

See Section II above for R-CALF USA's detailed answer to this question.

E. APHIS notes that "introduced" is not defined within 21 U.S.C. 113a. How should "introduced . . . into the mainland United States" be interpreted?

It is a generally accepted canon that the meaning of words used in congressionally passed statutes is the usual and customary meaning of such words. In the context of 21 U.S.C. § 113a, the meaning of "introduced" should have its usual and customary meaning as is defined by Merriam-Webster, which is:

> to lead or bring in especially for the first time… U.S. fishery managers have *introduced* exotic species into most waters in North America, largely to please sport fishermen.— Yvonne Baskin[6]

Thus, the statutory language that states: "That no live virus of foot-and-mouth disease may be introduced for any purpose into any part of the mainland of the United States . . ." means that no live FMD virus shall be brought into the mainland for any purpose.

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[5] *See* FMD Outbreak Investigation in the UK Completed, NASDA, September 17, 2007, available at https://www.nasda.org/news/fmd-outbreak-investigation-in-the-uk-completed.
[6] Merriam-Webster online dictionary, downloaded Sept. 9, 2020, available at https://www.merriam-webster.com/dictionary/introduce.

F. Based on the information supplied, should the modified virus (master seed) be considered a "live virus of foot-and-mouth disease"? Specifically, should its inability to express as FMD be considered to place it outside the scope of 21 U.S.C. 113a?

As stated in detail in Section II above, the statute limits the purpose of introducing the live FMD virus to only research, study and transport. There is no question that the genetically modified FMD virus that Zoetis has produced is a derivative of the live FMD virus. Indeed, the Petition states the permit to bring the virus into the mainland characterized the virus as "attenuated *live* FMD virus" (emphasis added).[7] The APHIS has no authority to expand the purposes for which Zoetis has introduced the attenuated live FMD virus into the mainland beyond research, study, and transport. Therefore, the attenuated live FMD virus remains within the scope of 21 U.S.C. § 113a, which prohibits the use of an introduced live FMD virus for manufacture in the mainland. Further, and as also explained in detail above, Docket No. APHIS-2020-0054 is totally lacking of any scientific evidence with which to determine the validity of Zoetis' claim that its derivative of the live FMD virus is anything but "live virus of foot-and-mouth disease."

It is also R-CALF USA's position that the APHIS should cease its high-risk practice of allowing imports of raw beef from countries where FMD is known to exist, such as Brazil, Argentina, Uruguay and Namibia. More than anything else, this will best protect the U.S. from the introduction of this dangerous disease, thus eliminating the perceived need for introducing live FMD into the mainland.

IV. CONCLUSION

For the foregoing reasons, R-CALF USA respectfully urges the APHIS to reject Zoetis' Petition and, instead, to take immediate steps to prevent the introduction of FMD into the mainland of the United States from countries where the disease is known to exist by prohibiting the importation of livestock and meat from all FMD affected countries.

Sincerely,

Bill Bullard, CEO

[7] 85 Fed. Reg., 42,346, col. 3.