

R-CALF United Stockgrowers of America

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Docket No. APHIS-2009-0073 Regulatory Analysis and Development, PPD U.S. Department of Agriculture Animal and Plant Health Inspection Service Station 3A-03.8 4700 River Road, Unit 118 Riverdale, MD 20737-1238

Via E-Mail: www.regulations.gov

Re: R-CALF USA Comments in Docket No. APHIS-2009-0073: Notice of Availability of a Bovine Tuberculosis Concept Paper

Dear Sir or Madam:

The Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA) appreciates this opportunity to submit comments to the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regarding the Notice of Availability of a Bovine Tuberculosis Concept Paper published at 74 Fed. Reg. 51116 (Oct. 5, 2009).

R-CALF USA is a non-profit association that represents thousands of U.S. cattle farmers and ranchers in 46 states across the nation. R-CALF USA works to sustain the profitability and viability of the U.S. cattle industry, a vital component of U.S. agriculture. R-CALF USA's membership consists primarily of cow-calf operators, cattle backgrounders and feedlot owners. Various main street businesses are associate members of R-CALF USA.

R-CALF USA believes that APHIS' concept paper, "A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan" (Concept Paper), contains several very positive, sorely needed improvements to the agency's current bovine tuberculosis (TB) strategy. In general, these very positive, sorely needed improvements include:

- Applying additional requirements to cattle imports from Mexico
- Enhancing efforts to mitigate risks from wildlife
- Accelerating diagnostic test development to support surveillance
- Conducting epidemiological investigations and assessing individual herd health
- Applying whole-herd depopulation judiciously and developing alternative control strategies

Unfortunately, the Concept Paper also contains several very negative, counterproductive and fundamentally flawed proposals that R-CALF USA believes should be summarily rejected by APHIS. In general, these unacceptable proposals include:

- Crafting a comprehensive national surveillance plan, which R-CALF USA believes would be detrimental because control would be transferred away from the States
- Applying animal identification (ID) standards to meet animal ID needs, which R-CALF USA believes is a back-door approach to implementing the National Animal Identification System (NAIS)
- Modernizing the regulatory framework to allow Veterinary Services (VS) to focus resources where the disease exists, which R-CALF USA believes would undermine the democratic rulemaking process
- Transitioning the TB program form a State classification system to a national zoning approach, which R-CALF USA believes would usurp States' rights and undermine State sovereignty

Below are R-CALF USA's more detailed comments regarding its support of several key proposals contained in the Concept Paper, along with its strong opposition to several other proposals:

I. APHIS' TUBERCULOSIS CONCEPT PAPER CONTAINS SEVERAL VERY POSITIVE, SORELY NEEDED IMPROVEMENTS TO THE AGENCY'S CURRENT BOVINE TUBERCULOSIS STRATEGY

A. The Concept Paper Correctly Identifies Mexican Cattle as a Chronic Source for TB Reintroduction.

APHIS correctly states that epidemiological investigations indicate that most TB-infected cattle detected at slaughter were imported, with most of the cases originating from Mexico. The USDA's Office of Inspector General (OIG) reported in 2006 that of the 272 bovine TB cases detected during the previous five years by U.S. slaughter surveillance, 75 percent (205) originated in Mexico, and these cases were detected in 12 U.S. states. The OIG explained that because Mexican cattle spend many months on U.S. farms and ranches prior to slaughter, each bovine TB case is potentially spreading the disease in the United States. In addition, the OIG stated, "Until additional controls are added, APHIS cannot reasonably expect to achieve its goal and eradicate TB when it is being imported into the United States each year.

¹ See A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan, U.S. Department of Agriculture, Animal and Plant Health Inspection Agency (hereafter "Concept Paper"), at 1.

²See Audit Report: Animal and Plant Health Inspection Service's Control Over the Bovine Tuberculosis Eradication Program, U.S. Department of Agriculture, Office of Inspector General, Midwest Region, Report No. 50601-0009-Ch, September 2006, at 19, 20.

³ See id., at iii.

⁴ *Id.*, at 19.

R-CALF USA supports APHIS's proposal to establish new standards regarding the importation of Mexican cattle to: 1) require additional testing of livestock prior to entry into the United States (including tests conducted at the port of entry); 2) require certain classes of imported cattle be sent to quarantined feedlots or terminal feedlots where animals are only destined for slaughter; 3) prohibiting the exposure of domestic cattle not destined for slaughter with high-risk imported cattle in feedlots; 4) require risk evaluations, herd plans, or additional testing requirements for herds exposed to imported animals; and, 5) conduct supplemental surveillance in geographic areas that have an increased risk for exposure to imported cattle. In fact, R-CALF USA's members have overwhelmingly voted on a policy that would provide even greater protection against the introduction of TB from Mexico.⁵ That policy states:

[D]ue to the increased prevalence of bovine tuberculosis in cattle of Mexican origin, R-CALF USA requests USDA-APHIS to require all cattle from Mexico be tested for bovine tuberculosis, and that all cattle entering the United States from Mexico shall go to designated feedlots and remain in such feedlots until time of slaughter.

Consistent with its member-developed policy, R-CALF USA urges APHIS to strengthen Item I, A(1) above by imposing a requirement that *all* cattle imported from Mexico be tested for TB. And, R-CALF USA urges APHIS to strengthen Item 2 above by imposing a requirement that all cattle entering the U.S. from Mexico be placed in designated feedlots and remain in such feedlots until the cattle are transported directly to slaughter.

In addition to Items I, A(1-5) above, APHIS proposes also to require annual TB testing for interstate movement of cattle used for rodeo events, regardless of origin. R-CALF USA does not have data regarding the incidence of TB in non-imported rodeo stock and requests that APHIS provide additional information that would provide more information concerning the TB risks associated with non-imported rodeo stock.

B. APHIS Should Include Canadian Cattle as a Known and Persistent Source of TB and Take Steps to Eliminate this Foreign Disease Threat.

Currently, only Canadian cattle originating from the Canadian Province of Manitoba and Elk Island National Park are subject to TB testing as a precondition to export to the United States. However, TB is known to be prevalent in Canadian cattle in provinces for which there are no TB testing requirements. In Nov. 2007, CBC News reported that TB was detected in a bull slaughtered in Quebec and 470 cattle in Alberta and British Columbia were subsequently

⁵ See Concept Paper, at 2, 3.

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⁶ See Veterinary Health Certificate: Export Cattle or Bison to the United States of America, Government of Canada, Canadian Food Inspection Agency; see also Veterinary Health Certificate: Export of Bison Originating From the Elk Island National Park to the United States of America, Government of Canada, Canadian Food Inspection Agency.

destroyed to prevent further spread of the disease. And, in 2008, the United States imported two TB-infected Canadian heifers that originated from British Colombia.

Given that TB is known to exist in Canada, and the fact that the U.S. has recently reintroduced the disease into the U.S. from Canada, APHIS must take steps to protect the people of the United States and U.S. livestock from the further reintroduction of Canadian TB. R-CALF USA strongly urges APHIS to significantly increase its TB testing requirements for imported Canadian cattle as U.S. livestock and the people of the United States are currently being exposed to an unnecessary and avoidable risk of TB reintroduction from Canada.

Although APHIS has failed to recognize the TB risk associated with Canadian cattle imports, the people of the United States and U.S. cattle producers at least are afforded some protection by virtue of those individual States that have exercised their sovereign rights to protect their respective citizens and cattle herds from the introduction and spread of such a dangerous disease. For example, the North Dakota State Board of Animal Health requires a negative TB test on all imported Canadian cattle 60 days of age or older within 60 days prior to import into North Dakota. Montana is another State that requires imported Canadian cattle to be tested for TB within 60 days of importation. To

Until and unless APHIS implements responsible restrictions to prevent the continued reintroduction of TB from imported Canadian cattle, APHIS' goal of eradicating TB in the U.S. will remain untenable and the U.S. cattle herd and the people of the U.S. will remain exposed to an unnecessary and avoidable risk of TB from Canada. R-CALF USA urges APHIS to immediately follow the example established by those States have already implemented such responsible restrictions.

C. The Concept Paper Correctly Identifies the Need to Mitigate TB Risks in Wildlife.

R-CALF USA strongly supports APHIS' proposal to establish measures to detect TB in wildlife, reduce the prevalence of TB in wildlife, and mitigate the risks of transmission of TB between livestock and wildlife. Specifically, we support the proposed alternatives to: 1) conduct supplemental surveillance in wildlife in geographic areas where TB has been identified in wildlife; and, 2) support research to identify tools and strategies to reduce the prevalence of TB in wildlife. 12

⁷ See Bovine TB Forces Cattle Cull in B.C., Alberta, CBC News, Nov. 11, 2007.

⁸ See Canadian Food Inspection Agency Still Mum on TB Reported Cases, 250 News, June 26, 2008 (the cases were confirmed via an e-mail from a U.S. state animal health official).

⁹ See Canadian Import Requirements for Cattle and Bison, North Dakota State Board of Animal Health, effective Nov. 19, 2007, available at

http://www.agdepartment.com/Programs/Livestock/BOAH/AnimalImportation.htm#canimport.

¹⁰ See Montana Department of Livestock, Animal Health Division, Official Order No. 08-01-I, effective Jan. 18, 2008, available at http://liv.mt.gov/liv/ah/orders/0801i.pdf.

¹¹ See Concept Paper, at 3.

¹² See Ibid.

In addition to the proposed alternatives listed in Items I, C(1 and 2) above, APHIS proposes also to consider the establishment of minimum requirements for targeted surveillance in wildlife as part of a comprehensive, national surveillance plan. 13 R-CALF USA urges APHIS to grant deference to the States when determining such minimal requirements for targeted surveillance in wildlife. Under no circumstances should minimal requirements be established that would be less stringent than those currently practiced and/or imposed by any State. In other words, APHIS should not establish standards that would encourage any State to reduce the level of surveillance it currently conducts in wildlife populations. This recommendation would apply until TB is eradicated from a given States' wildlife population.

Also, APHIS proposes the alternative to develop on-farm mitigations to control the risk of disease transmission between wildlife and livestock and evaluate the effectiveness of these mitigations. 14 Before APHIS develops such on-farm mitigations, it should provide early notice to livestock producers prior to issuing a proposed rule that would provide affected livestock producers with ample time to fully consider and then comment on APHIS' plan. This step is necessary because, e.g., additional costs associated with certain on-farm mitigations could render an independent livestock operation unprofitable.

D. The Concept Paper's Proposal to Accelerate Diagnostic Test Development to Support Surveillance Is Commendable.

R-CALF USA agrees that the current diagnostic test for live cattle is in need of improvement. The current test, which requires multiple handling of cattle, is resource intensive, increases the risk of death or injury to livestock, and adds considerable stress on livestock, particularly when such testing is conducted during extreme weather conditions, e.g., during the height of the summer heat season. For these reasons R-CALF USA supports APHIS' efforts to facilitate development of a more effective and efficient diagnostic testing tool for live cattle.

E. APHIS Is Correct that It Should Continue Epidemiological Investigations and Assess Individual Herd Risk.

R-CALF USA interprets the Concept Paper to mean that State animal health officials would be in charge of epidemiological investigations involving cattle herds within their respective States, responsible for – in coordination with affected producers – assessing individual herd risk, and that these responsibilities would be carried out in coordination with APHIS. 15 If this interpretation is correct, we agree.

APHIS indicates a desire to revise program definitions, such as those for "herd" and "feedlot," to reflect current industry practices. ¹⁶ The need for such revisions is not expressly stated. The current program definition for feedlot is: "A facility for congregating finished fed cattle prior to their being shipped to slaughter." (9 C.F.R. § 77.5). This definition would not

¹³ See Concept Paper, at 3.
14 See Ibid.
15 See Id., at 5.
16 See Ibid.

include a background facility, which may be why APHIS desires revision. It would be helpful if the agency would provide additional information to demonstrate the perceived need for revising its current definitions.

F. APHIS Should Proceed with Efforts to Establish Alternatives to Whole Herd Depopulation.

APHIS proposes to offer alternatives to whole herd depopulation that presumably would not impede the goal of eradicating TB from the United States. If this can be accomplished, it could mitigate the severe consequences associated with TB detection, including financial loss and loss of genetically superior cattle. APHIS' motive for recommending a reduction in the maximum amount of Federal indemnity paid per individual animal is unclear. If, e.g., a cattle producer's herd becomes infected due to the transmittal of TB from a wildlife population, it is a matter of public interest that the disease be eliminated. The cost of eliminating the disease would include the lost fair market value for each animal depopulated to achieve the publics' interest in disease elimination. Thus, the producer should be entitled to recover the fair market value for his/her role in eliminating the disease. The amount of indemnity paid per individual should be based on the fair market value of the depopulated animals and should not be arbitrarily limited by a cap that would be insufficient to indemnify the producer for the full fair market value.

Also, APHIS proposes to link Federal indemnity payments to the implementation of specific risk mitigation and biosecurity practices within a herd. ¹⁸ This is a dangerous proposition that harbors the potential for agency coercion and abuse, and could result in the inequitable and unjust treatment of individual cattle producers. For example, if APHIS were to recommend a specific practice, and the cost of implementing that practice would render a cattle producers operation unprofitable, it would be unjust for APHIS to deny indemnity payments to that producer, particularly if he/she practiced all other customary industry practices. Another example: If APHIS were to link Federal indemnity payments to participation in the agency's coveted National Animal Identification System (NAIS), and even if NAIS participation was otherwise voluntary, a cattle producer with a bona-fide religious objection to NAIS would be unjustly deprived of indemnity payments if he/she refused to voluntarily participate in NAIS. In addition, this type of *quid pro quo* would constitute abusive agency coercion. R-CALF USA urges APHIS to reject this proposal.

With the exception of the foregoing objections to changes in indemnity payments, R-CALF USA believes that APHIS' proposal to seek alternatives to whole herd depopulation should be pursued and encourages APHIS to provide more detailed information to the public through notice and subsequent rulemaking.

II. SEVERAL PROVISIONS CONTAINED IN APHIS' CONCEPT PAPER ARE VERY NEGATIVE, CONTERPRODUCTIVE, FUNDAMENTALLY FLAWED AND UNACCEPTABLE

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¹⁷ See Concept Paper, at 6.

¹⁸ Ibid.

A. The Motive Underpinning APHIS' Desire to Craft a Comprehensive National Surveillance Plan Is Misguided and the Outcome of APHIS' Plan Would Be a Surveillance Plan Incapable of Eradicating TB.

The overriding force underpinning APHIS' desire to craft a comprehensive national surveillance plan appears to be the agency's quest to "establish Federal surveillance standards necessary to support claims about the TB status of the United States, or zones within the United States, consistent with OIE [World Organization for Animal Health] guidelines." This is disconcerting for many reasons including: 1) APHIS has failed to provide even a scintilla of evidence to demonstrate that compliance with OIE surveillance standards would enable the U.S. to eradicate TB. APHIS asserts that the reduction in TB in the U.S. since 1917 is considered by many to be "one of the great animal and public health achievements in the United States." This suggests that the individual States that worked together as the United States to achieve this success possess considerable experience and expertise that likely is unequaled anywhere in the world. Rather than blindly grant servile deference to the OIE, APHIS should capture the expertise and ingenuity of the States and work collaboratively to develop a surveillance plan for the States and the United States that would have a design prevalence capable of eradicating TB from the United States. 2) This proposal constitutes a top-down, backwardworking approach to address the specific TB challenge in a political, geographical, regulatory and cultural environment that is unique to the United States. APHIS would abrogate its duty to mobilize the unique characteristics and unequaled expertise in disease management within the States, and collectively in the United States, if it allowed an international organization, with all its multinational corporate influences, to set the bar for measuring its success. This approach would, fundamentally and structurally, impede the United States from achieving excellence in disease eradication.

R-CALF USA strongly objects to the servile deference APHIS accords the OIE and urges the agency to model a surveillance program based on the highly successful and likely unequaled surveillance strategies implemented by those States that have demonstrated exemplary TB eradication over the past several decades. APHIS and the individual States must coordinate efforts to design a State-by-State surveillance system capable of the earliest possible detection of TB at a design prevalence that will ensure the eradication of the disease. Further, APHIS must share the States' goal to eradicate TB from the United States and if it remains focused on that goal, it will assist the States in restoring the United States' lost reputation of being the world's leader in producing the safest, healthiest cattle in the world.

B. It is both Inappropriate and Unnecessary for APHIS to Attempt to Implement Its Objectionable National Animal Identification System (NAIS) Under the Guise of Improving the Current TB Eradication Strategy.

The considerable success of the current TB program occurred while State animal health officials and cattle producers were afforded considerable flexibility in identifying cattle. For

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¹⁹ Concept Paper, at 4.

²⁰ *Id.*, at 1.

example, the bovine TB program specifically authorizes "a brand registered with an official brand registry" in lieu of a premises of origin identification. And, contrary to claims made by APHIS that a foundational component of NAIS – the registration of producers' private property with a "premises identification" – has been part and parcel to the United States' successful brucellosis and bovine tuberculosis programs for decades, there was *no* requirement for any specific geographical-based premises identification under either the brucellosis or tuberculosis programs. APHIS provides no evidence to support a need for any new form of animal identification other than those that have been used successfully for decades to control TB.

APHIS does assert, however, that the cattle industry has created limitations to APHIS' ability to conduct successful tacebacks and claims. "The lack of ID for a particular animal and incomplete documentation kept by owners, dealers, or brokers continues to hamper successful tracebacks and epidemiological investigations."²⁴ This attempt to fabricate a need for a new system by placing blame on the cattle industry is disingenuous at best. The OIG conducted an audit of USDA's control over its bovine TB eradication program in September 2006. According to the audit, the OIG found that a lack of identification on individual animals was not the sole source of USDA's problem in conducting its bovine TB investigations. In fact, the OIG found that over half of the investigations that were closed with an outcome of "untraceable" were animals that were identified with eartags, but the eartags either were not collected at the time of slaughter, had been removed by the feedlot prior to slaughter, or were unable to be traced because there was no requirement to maintain records.²⁵ Equally important, the OIG found that USDA's disease eradication efforts were hampered because the agency was not using its oversight tools in a timely manner, i.e., not timely reviewing and responding to the annual and monthly summaries of program results submitted by States nor was it properly reviewing States for program compliance. 26 The OIG also found that USDA was not following Federal regulations for declaring affected bovine TB herds, which weakened the agency's ability to contain and eradicate the disease and resulted in no additional controls being put in place for the majority of bovine TB cases detected in the past 5 years.²⁷ The agency was also cited for not timely downgrading the TB status of States after the agency knew that the disease was not isolated in one herd;²⁸ not having adequate controls to restrict the introduction of bovine TB in

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²¹ See 9 CFR § 77.2.

²² Veterinary Services Memorandum No. 575.19, USDA-APHIS, Veterinary Services, Dec. 22, 2008, at 2 ("VS [Veterinary Services] animal health programs have used premises identification for many years. For example, premises information was used in the early 1980s to support the eradication of brucellosis and tuberculosis in cattle.").

cattle.").

²³ See 69 Federal Register, at 64646, col. 3 ("The new definition of premises identification number (PIN) differs from the definition it is replacing not only in recognizing the new numbering system but also in recognizing a premises based on a State or Federal animal health authority's determination that it is a geographically, rather than epidemiologically, distinct animal production unit.").

²⁴ Concept Paper, at 6.

²⁵ See Exhibit F – Reasons for Closing FY 2004 Investigations as "Untraceable," Audit Report: Animal and Plant Health Inspection Service's Control Over the Bovine Tuberculosis Eradication Program, September 2006, at 38. ²⁶ See Audit Report: Animal and Plant Health Inspection Service's Control Over the Bovine Tuberculosis Eradication Program, Report No. 50601-0009-Ch, September 2006, at 5-9.

²⁷ See id., at 11-14.

²⁸ See id., at 16-17.

Mexican cattle;²⁹ not requiring slaughtering facilities to conduct surveillance at the recommended rate;³⁰ not monitoring high-risk herds and the corresponding on-farm testing that is required;³¹ and not providing sufficient training to investigators so investigations could be completed in a timely manner.³²

APHIS must correct the systemic management problems described above that impede disease control and eradication as well as disease investigations. These internal management problems would not be solved by implementing NAIS or some other new form of animal ID. Nor would these internal management problems be solved by APHIS' proposal to centralize Federal control over disease surveillance. Further, APHIS provides no cogent explanation as to why an entirely new system of livestock disease control and eradication is needed rather than the more conservative and reasoned approach of continuing to build on the time-proven successes of preexisting systems, e.g., by taking steps to increase the use of preexisting animal identification devices within each of the 50 States to increase the numbers of identifiable livestock. APHIS should reject this Concept Paper's intention to establish a new animal ID system and a centralized, Federal surveillance program on the grounds that these changes are both inappropriate and unnecessary to eradicate TB from the United States.

The Concept Paper proposes that "official animal ID and electronic movement certificates be used" under its new program.³³ These requirements also are inappropriate and unnecessary. The use of an official animal identification device, i.e., the metal ear tag that identifies the breeding animal's state of origin with a numeric state code, registered brands, backtags, and a host of other identification methods were instrumental in reducing the prevalence of TB to what it is today. APHIS does not explain why these simple, low cost, efficient and State-referenced systems should not continue to be used for animals leaving affected herds or areas where the disease is known to exist. APHIS should not impose upon the States a requirement to use any form of animal identification device other than the time-proven, metal ear tag with a State identifier, brands, or other forms already authorized. Nor should APHIS require States to use electronic movement certificates. The States should decide, based on their available resources, experiences and preferences, what medium to use for movement certificates. The success of the current TB program was not predicated on a centralized, Federally controlled program and surveillance plan and APHIS provides no valid reason why a continued, decentralized and State-vested program would not be far superior in achieving early detection of emerging TB outbreaks (both where the disease might or might not be expected to occur) and in responding quickly and appropriately following detection.

²⁹ See Audit Report: Animal and Plant Health Inspection Service's Control Over the Bovine Tuberculosis Eradication Program, Report No. 50601-0009-Ch, September 2006, at 19-21.

³⁰ See id., at 22-24

³¹ See Audit Report: Animal and Plant Health Inspection Service's Control Over the Bovine Tuberculosis Eradication Program, Report No. 50601-0009-Ch, September 2006, at 28-29.

³² See id., at 22, 25, 28.

³³ Concept Paper, at 6.

C. The Concept Paper Improperly Attempts to Undermine the Democratic Rulemaking Process Designed to Ensure that Federal Agencies Do Not Take Actions Without First Considering Fully the Concerns of Affected Individuals.

The Concept Paper seeks greater discretionary authority to allow APHIS to change requirements imposed on States and individuals without adhering to the agency's rulemaking procedures.³⁴ APHIS argues that the rulemaking process is too lengthy and results in rules that are too prescriptive and rigid to afford APHIS the flexibility it needs to adapt to changing program needs. Weighed against the intrinsic value of the democratic rulemaking process that provides citizens an opportunity to express their concerns before a Federal agency takes action that might harm their interests, APHIS' request must be denied. This proposal is particularly disconcerting given that APHIS has recently demonstrated its propensity to abuse its authority that arises from existing statutes, rules and regulations. For example, on July 3, 2008, a Federal District Court remanded to the agency the APHIS rule that allows the importation of over-30month (OTM) cattle and beef from Canada because the agency failed to initiate a new rulemaking as required by the Administrative Procedure Act before allowing importation of beef from Canadian cattle of any age into the United States.³⁵ It is obvious that in this instance APHIS desired the flexibility and discretion to take action without having to provide notice and consider comments from affected individuals. However, the exercise of APHIS' desire to be unencumbered by the public rulemaking process countermands our nation's core democratic principles.

More recently, on Sept. 22, 2008, APHIS issued its Veterinary Services Memorandum No. 575.19 (Memo 575.19) that declared, without affording the public notice or opportunity to comment, that the Premises Identification Number (PIN) established under the agency's National Animal Identification System (NAIS) "is to be the sole and standard location identifier for all VS program activities" and that premises "will be registered in the NAIS." The effect of APHIS' edict was to immediately transform NAIS into a mandatory system for persons engaged in interstate commerce and who participate in any one of the dozen or more regulated disease programs, despite APHIS' emphatic statement that, "In keeping with the objectives of the NAIS, the use of the new numbering system is voluntary. It was not until Dec. 22, 2008, well after R-CALF USA and perhaps others complained strenuously to Congress about APHIS' inappropriate and unlawful action did APHIS finally cancel its Memo 575.19.

The foregoing examples provide empirical evidence that APHIS has already abused its regulatory authority and has trampled over the rights and privileges vested in the citizens of the

³⁵ See R-CALF USA et al., v. USDA et al., Memorandum Opinion and Order on Motion for Preliminary Injunction, United States District Court, District of South Dakota, Northern Division, at 16.

³⁴ See Concept Paper, at 7.

³⁶ Veterinary Services Memorandum No. 575.19, John R. Clifford, Deputy Administrator, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Sept. 22, 2008. ³⁷ 69 Fed. Reg., 64645, col. 2.

³⁸ See Veterinary Services Memorandum No. 575.19, John R. Clifford, Deputy Administrator, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Dec. 22, 2008.

United States. It is incomprehensible that APHIS should now be granted any additional flexibility beyond that expressly granted by statute and the Federal rulemaking process.

D. The Concept Paper Erroneously Assumes that the OIE's Regionalization (or Zoning) Strategy is Suitable for the United States and an Effective Means of Disease Containment.

The Concept Paper proposes to adopt the OIE's regionalization (or zoning) strategy by dispensing with State geopolitical boundaries for disease control purposes and replacing them with what would essentially be a Federal disease management zone.³⁹ Not only would this approach infringe upon the sovereign rights of each State, but also, the OIE's regionalization concept is fundamentally flawed. The U.S. has recent, first-hand experience regarding the failure of the OIE's regionalization strategy to ensure that disease prevalence and spread can be contained in a specified zone or region within a geopolitical-defined area. For example, in Dec. 2000 APHIS proposed to regionalize Uruguay following that country's detection of foot-andmouth disease (FMD). APHIS proposed to remove only Artigas, a department in Uruguay, from the list of regions considered by the U.S. to be free of FMD as APHIS had determined that Artigas (a region or zone) qualified as a distinct subpopulation for disease control and international trade purposes. 40 However, within about four months, beginning April 2001, widespread FMD outbreaks were confirmed in numerous Uruguayan departments. 41 By June 22, 2001, there were 1,596 new cases of FMD confirmed in 18 separate departments in Uruguay. 42 This example empirically demonstrates that the ideological concept of regionalization is fundamentally flawed, inherently risky, and incapable of ensuring disease containment. Cattle producers in the U.S. are indeed fortunate that APHIS' attempt to relax essential import restrictions on Uruguayan imports via regionalization (or zoning) did not result in the introduction of FMD into the United States, an outcome that could have resulted in substantial financial losses to their industry.

APHIS should abandon its misguided effort to regionalize the U.S. and, instead, should continue to respect the geopolitical boundaries of the States and the sovereignty of each State. In coordination with each States' animal health agency, APHIS should consider the appropriateness of establishing a containment and surveillance area around those areas where TB is detected and that are within each State's geopolitical boundaries, and work in coordination with multiple States to establish complimentary containment and surveillance areas within each State as needed. The usurpation of State's rights that would result from APHIS' regionalization plan was not necessary to attain the enviable level of TB control achieved today and is not necessary to continue the process of eradicating TB from the United States.

There is no reason that AHPIS should not be able to promulgate regulations to change the way that individual States are classified to accommodate the current low level of known TB prevalence. There also is no reason that APHIS and the States should not be able to amend

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³⁹ See Concept Paper, at 8.

⁴⁰ See 65 Fed. Reg., at 77772.

⁴¹ See 66 Fed. Reg., at 36695.

⁴² *Ibid*.

current regulations to shorten the time needed for States to modify the geographic areas within their respective State that no longer meet the criteria that governed the original geographic area. Under no circumstances should APHIS impose the weaker, ineffective OIE regionalization (or zoning) concept that would not only infringe upon States' rights, but also, would completely ignore and usurp the intrinsic synergies created when States individually and collectively seek excellence in protecting their respective boundaries from the introduction and spread of disease.

III. CONCLUSION

R-CALF USA appreciates this opportunity to respond to APHIS' Concept Paper and urges the agency to proceed with the specific proposals discussed above in Sect. I, A-F. However, R-CALF USA urges APHIS to reject the proposals discussed above in Sect. II, A-D. R-CALF USA would be pleased to answer any questions that these comments may inspire.

R. M. Hisinsley DVM

R.M. (Max) Thornsberry, D.V.M.

R-CALF USA President of the Board