A New Approach for Managing Swine Brucellosis and Swine Pseudorabies Virus: Veterinary Services' Proposed Action Plan

United States Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

Executive Summary

The swine industry within the United States contains three distinct segments. Most domestic swine are produced in biosecure operations. Such swine have minimal, if any, contact with wildlife, and usually commingle only with other swine moving in the same market channels. (Occasionally, these swine may commingle with other swine at fairs, events, exhibitions, and markets.) We refer to such swine as *commercial production swine*.

Other domestic swine are produced under less secure conditions that may allow a greater degree of exposure to wildlife. We refer to such swine as *transitional production swine*. In addition, in certain States, *captive feral swine* are captured and moved interstate.

The number of commercial production swine that are moved interstate yearly dwarfs the aggregate number of transitional production swine and captive feral swine moved interstate. However, because wildlife, in general, and feral swine, in particular, are known to be reservoirs of several diseases of swine, including swine brucellosis (SB) and pseudorabies virus (PRV), the interstate movement of transitional production swine and feral swine is considered a higher risk pathway for the spread of diseases of swine than that of commercial production swine.

SB and PRV are serious diseases of swine that can infect other species. These diseases can have adverse consequences for animal health, public health (for SB), interstate movement, and trade. Through initiatives involving Federal, State, Tribal, and industry cooperation, both PRV and SB have been eradicated from commercial production swine herds. However, the diseases still exist in feral swine and are often found in transitional production swine.

This document presents the current thinking of the Animal and Plant Health Inspection Service's Veterinary Services (VS) about possible changes to the SB and PRV programs. While U.S. commercial production swine herds were recognized as PRV-free in 2004 and all States have been considered free of SB since early 2011, both diseases still exist in wildlife reservoirs, which are neither monitored nor managed under current regulations. Federal, State, Tribal, and industry representatives have a vested interest in keeping these diseases out of commercial swine, and in reducing the number of infected swine discovered in transitional production herds. To achieve these goals, a new approach is necessary.

This new approach would enable VS, States, and Tribes to address current disease challenges by doing the following:

- Combining the PRV and SB programs into a single streamlined program
- Creating a comprehensive, risk-based, flexible regulatory framework for PRV and SB

- Enhancing SB and PRV surveillance
- Transitioning away from the current State classification system
- Revising requirements for laboratories conducting official testing
- Modernizing the indemnity regulations for the two diseases

To succeed, this new approach will require VS' continued partnership with State animal health and wildlife officials, other Federal agencies, Tribal officials, industry, international partners, academia, and other stakeholders. Successful partnerships will allow us to use available resources efficiently to achieve program objectives, minimize disease transmission risks, and protect the nation's swine herd.

The proposed approach offers several benefits. States and Tribes will be able to concentrate resources on minimizing the risk of disease introduction and spread and will have a variety of options for responding to outbreaks. The new approach will also reduce current confusion about the interaction between the SB and PRV regulatory programs. Stakeholders and regulators will have the flexibility to use up-to-date science to fit changing situations. Lastly, the approach is consistent with revisions to VS' bovine brucellosis and tuberculosis programs, and is in keeping with VS' intent to make its domestic animal health programs more performance based, less prescriptive, and more flexible.[1]

Introduction: The Need for Change

PRV and SB are serious swine diseases. Their spread through the U.S. commercial herd (all swine that move in commerce, but particularly commercial production swine) could significantly harm the U.S. swine industry. Federal, State, Tribal, and industry partners have successfully eliminated these diseases from commercial production swine herds, but, because of the existence of these diseases in feral swine and, to a lesser extent, transitional production swine, the risk of disease spread throughout the U.S. commercial swine herd remains. The regulatory framework needs to be updated to address the following aspects of swine health and marketing.

Risk from feral swine. Although commercial production swine in the United States are free of SB and PRV, both diseases are sometimes detected in transitional production swine and are known to be endemic in feral swine.

Feral swine pose the greatest disease threat to commercial swine herds within the United States. At least 38 States[2] have feral swine populations, and the overall feral swine population keeps expanding. Feral swine that are infected with SB or PRV present a direct risk of transmitting these diseases to any transitional production swine allowed contact with them. In addition, because transitional production swine sometimes commingle with commercial production swine at fairs, exhibitions, and markets, among other locations, feral swine present an attenuated risk of introducing SB and PRV into commercial production swine herds.

[1] See "Proposed Bovine Tuberculosis and Brucellosis Draft Regulatory Framework. Available at http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0044-0001.

[2] Wyckoff, C.A., Henke, S.E, Campbell, T.A., Hewitt, D.G., VerCauteren, K.C. 2009. Feral swine contact with domestic swine: a serologic survey and assessment of potential for disease transmission. Journal of Wildlife Diseases 45: 422–429

The current system, however, was not constructed with an eye towards the substantive risk that feral swine can present of introducing SB and PRV into commercial herds, but rather towards responding to SB and PRV in commercial production swine herds whenever the diseases are detected. Accordingly, the current system needs substantive revision to allow Federal, State, Tribal, and industry partners to move beyond eradicating the diseases in commercial production swine towards a program that focuses on mitigating the risk of disease introduction.

Interstate movement. Under current VS regulations, swine may move interstate under a protocol that was developed before PRV and SB were eradicated from commercial production swine herds. For example, current Federal regulations for interstate movement of swine include provisions based on widespread vaccine use. Such provisions need to be updated.

On a related point, under the current regulations and program standards, a State is considered free of SB and PRV if its commercial production swine herds are free of the diseases. Yet, when a State has disease-free status, all swine, including transitional production swine and even captive feral swine, within the State are considered free of the diseases and are eligible for interstate movement without restriction. Therefore, a State's status may not truly represent the risk posed by all types of swine when these animals move interstate.

Regulatory flexibility. The lack of flexibility of current regulations does not allow States to respond to State-specific PRV and SB risks. Prescriptive regulations also do not encourage States to use new surveillance tools to monitor reservoirs and reduce the risk of disease transmission.

The process to develop new regulations or modify existing ones is lengthy. The rigid requirements for PRV and SB currently in the regulations thus cannot adapt easily to changes in science and technology, disease risk, industry practices, and animal movement. Developing a flexible, results-based regulatory framework will make program changes easier to implement while still allowing for review and comment by stakeholders.

Program consistency. Indemnity regulations for SB, found in title 9 of the *Code of Federal Regulations* (9 CFR) part 51, differ in several substantive ways from the regulations for indemnity for PRV, found in 9 CFR part 52. The SB indemnity regulations prescribe a set value for the animals, whereas the PRV indemnity regulations allow payment of fair market value. In addition, the PRV indemnity regulations also allow for the payment of costs associated with destroying the animals, while the SB indemnity regulations do not. The swine disease indemnification process needs to be made simpler and more consistent to ensure swift herd depopulation if it is needed to control disease.

It is time to address these diseases through a combined, consistent approach.

The Proposed Framework: A New Approach

This document describes a proposed framework for a combined PRV and SB regulatory program that will do the following:

1. Streamline swine regulatory programs

2. Enhance surveillance activities
3. Transition the PRV and SB program from a prevalence-based State status classification system to a science-based approach that addresses disease risk
4. Outline the proposed conditions for interstate movement of swine
5. Modernize indemnity provisions
6. Improve laboratory methods

1. Streamline swine regulatory programs

Combining the PRV and SB Programs into One Program

VS wants to work with stakeholders to streamline the SB and PRV programs and address the risk that feral swine pose to all swine destined to move interstate. Merging the SB and PRV programs into a single swine health program will create consistency in dealing with these two diseases. The regulations for the new program would be found in 9 CFR part 85 and would supplant the existing SB regulations in 9 CFR part 78 and the existing PRV regulations in 9 CFR part 85.

VS believes that this combined program could be structured around an approach similar to the one being considered for a combined cattle tuberculosis and brucellosis program, which focuses on disease risk. Each State and, if they so choose, Tribe would assess the risk of PRV and SB introduction in swine destined for interstate movement and determine a method to reduce the risk of shipping diseased animals interstate. These risks will vary, depending in large part on the existence or size of the feral swine population in that State or Tribe. The regulations would be predicated on the fact that PRV and SB could be introduced from feral swine into commercial swine populations, either directly (for transitional production swine) or indirectly (for commercial production swine).

This risk-based approach aligns with VS' vision for its regulatory programs and parallels the approach currently being considered for the bovine tuberculosis and brucellosis regulations. It also provides regulatory flexibility to keep pace with changing science and the speed of business.

Swine Health Plans

Under a risk-based approach, States would have to develop and implement a Swine Health Plan (SHP) to address and minimize the risk that swine from their State may spread PRV and SB when moving interstate. Out of recognition of Tribal sovereignty, we would also allow Tribes to submit Tribal SHPs for activities conducted on their lands; however, Tribes would not be required to submit such plans. If a Tribe does not submit a plan, the Tribe would fall under the regulatory purview of the State in which the Tribal lands reside. All State and Tribal plans would be submitted to VS for review and approval.

We propose that State and Tribal plans contain the following:

- A description of the State or Tribal swine industry. This description would cover the types of swine industries in the State or Tribe, the markets for swine, and the types of other operations (such as hunt clubs or corporate farming).

- An outline or description of the possible sources for PRV or SB being introduced into the State's or Tribe's commercial herds, which we would define as all swine destined to move interstate from the State for any purpose, including movements to exhibitions, fairs, or hunting grounds. (Thus, within their SHPs, States would have to address any sources of possible disease introduction into transitional production swine or captive feral swine destined to move interstate.)
- The surveillance and recordkeeping methods the State or Tribe plans to use to reasonably ensure that swine that move interstate from the State or Tribe will not transmit PRV or SB. At a minimum, States and Tribes would have to adopt the surveillance and reporting procedures and standards in VS' Comprehensive National Surveillance Plan. (This plan, which we discuss at greater length later in this document, contains information for surveillance activities that are necessary for all States, as well as any Tribes that submit SHPs.) States and Tribes would also be free to conduct additional surveillance activities beyond those required by VS if they consider those surveillance activities necessary to ensure animals moving interstate will not spread the diseases.
- The measures the State or Tribe would take to control or manage a disease outbreak within commercial herds to prevent disease spread. This response should include the epidemiological investigation process as well as the quarantine and zoning procedures.
- A signed agreement by a responsible person for the State or Tribe to allow VS to make the plan publicly available, and to reevaluate and amend the SHP if adverse consequences occur such as a disease outbreak.

VS would review each plan to ensure it contains the information listed above. This review could include dialog with the State or Tribe, and guidance in helping the State or Tribe revise the plan to address deficiencies or clarify its provisions. Once VS considers the plan to be complete and adequate, VS would publish a notice in the *Federal Register* letting the public know that the State or Tribe's plan is available online for review and public comment. If no comments are received on the plan or if the comments do not affect the initial determination that the plan is complete and adequate, VS would approve the plan and consider the State or Tribe a consistent State or Tribe. (We discuss State and Tribal statuses at greater length on page 7.) Notification of this approval would be published in the *Federal Register*.

VS envisions that States and Tribes may consider it necessary to amend their plan as circumstances warrant. We also consider it possible that VS will identify deficiencies in the plan after it is implemented. For example, an outbreak of PRV or SB in a commercial herd could reveal that a State has failed to consider a potential source of disease risk. In such instances, APHIS would require the State or Tribe to amend its plan to retain consistent status. Conversely, any amendments to a plan initiated by a State or Tribe would need VS approval.

States and Tribes would not need to resubmit plans annually, but VS believes there should be a process to ensure that States and Tribes have implemented their plans. Accordingly, VS could audit a State or Tribe's implementation or maintenance of a plan. Similarly, there would be a mechanism for removing approval of a plan and redesignating the State or Tribe to a lower State or Tribal classification. Any of the following could be grounds to rescind approval of a State or Tribal plan and redesignate the State or Tribe:

- Allowing diseased animals to be moved interstate for purposes other than slaughter.

- Failing to implement or maintain the surveillance activities described in the plan.
- Failing to respond to an outbreak of PRV or SB in commercial herds in the manner specified in the plan.
- Refusing to amend the plan in response to a VS request.

Communication to Stakeholders

Stakeholders would be notified if a State or Tribe loses approval of its SHP through a *Federal Register* notice. This notice would list the reasons for the removal and allow for public comment. This notice would also redesignate the State or Tribe to inconsistent status (see below).

2. Enhance Surveillance Activities

Crafting a Comprehensive National Surveillance Plan

Currently, there is a national surveillance plan for PRV. This plan specifies that States should conduct surveillance of swine that have exhibited clinical symptoms of infection, surveillance of transitional production swine herds, and slaughter surveillance. (VS refers to these different types of surveillance as surveillance streams.) National surveillance for SB currently consists primarily of slaughter surveillance, which is conducted by VS in conjunction with the Food Safety and Inspection Service (FSIS) and State and Tribal animal health officials; however, VS is preparing a national surveillance plan that incorporates additional surveillance streams that must be monitored.

VS proposes to consolidate the national surveillance plans for both diseases into a Comprehensive National Surveillance Plan for swine. The goals of this comprehensive plan would be to rapidly detect disease and to demonstrate disease freedom to facilitate interstate and international trade of commercial production swine. The plan would specify the surveillance streams that will be monitored at the Federal level, the surveillance streams that all States and any Tribes that submit an SHP must monitor at the State and Tribal level, and the minimum required annual level of surveillance necessary for each of these latter streams.

In addition, in drafting their plans, States and Tribes may incorporate additional surveillance streams specific to the State or Tribe as part of their mitigation strategy to address the risk of transmission of PRV or SB from sources of these diseases to commercial swine. For example, a State with seasonal events in which there is high-density commingling of swine from multiple premises throughout the State, such as a State fair or expo, may specify that monitoring these events is part of their mitigation strategy for SB and PRV.

In turn, whenever VS approves an SHP that contains such additional surveillance streams, VS will incorporate these State- or Tribe-specific surveillance streams into the Comprehensive National Surveillance Plan. (Among other benefits, this will allow the comprehensive plan to more accurately demonstrate the full range of domestic surveillance activities to international trading partners.) Conversely, VS would monitor and give States and Tribes surveillance information from the VS- and FSIS-supported surveillance activities specified in the Comprehensive Surveillance Plan to aid in their surveillance efforts.

This approach stands in contrast to historical practices within VS' SB and PRV programs. While these programs were focused on eradicating the disease, surveillance efforts focused primarily, and sometimes exclusively, on slaughter surveillance. Such efforts serve well to remove diseased commercial production swine from market channels, but are not aimed at rapid disease detection, which would entail surveillance at earlier stages in the production cycle of commercial production swine and targeted surveillance of at-risk production swine populations.

Reducing the Reporting Burden on States

For PRV, States currently must report yearly that they have met the surveillance requirements specified in the Pseudorabies Program Standards and must draft a plan describing how the State will preclude feral swine from introducing PRV into commercial swine herds within the State. Additionally, States considered validated SB-free must submit triennial (once every 3 years) reports describing SB surveillance activities per requirements specified in 9 CFR part 78.1.

VS proposes to simplify this process. VS would originally review each State or Tribe's SHP to ensure completeness. Subsequently, VS would review the plan if requested by the State or Tribe or as part of an audit. States and Tribes with SHPs would be required to report on a regular basis on any surveillance efforts specified within their SHP that exceed the minimum required as part of the Comprehensive National Surveillance Plan, on any occurrences of PRV or SB within commercial herds in the State or Tribe, and as specified during an audit.

Therefore, in most instances, after development and approval of a State or Tribe's plan, only additional State or Tribal surveillance activities specified by the State or Tribe within its plan and any occurrences of PRV or SB in commercial herds would need to be reported.

3. Transition Away from Prevalence-based State Status

Under the current State status system, all producers in a State are affected when a State loses free status, even if the producers are hundreds of miles from any outbreak. Under our proposal, this would no longer be the case. Conversely, disease risks may exist even if the State is labeled free, as evidenced by occasional findings of PRV and SB in transitional production swine. The new approach would emphasize how a State or Tribe addresses this risk.

Instead of having status based on the prevalence of disease within a State or tribe, States and Tribes would be classified by whether they have an approved SHP in place. A State or Tribe with a VS-approved SHP would be classified as *consistent*.

A State or Tribe that fails to implement or maintain certain provisions of its SHP that are not mitigation measures in and of themselves (for example, a State or Tribe that conducts proactive surveillance of transitional production swine but fails to meet the surveillance levels specified in its SHP) would be redesignated as *provisionally consistent.* We would also redesignate States and Tribes as provisionally consistent if they failed to turn in reports regarding additional surveillance or disease outbreaks within a specified time period.

Provisionally consistent States or Tribes would be given a time period specified by VS to take appropriate remedial measures or turn in outstanding reports. If the State or Tribe takes these measures or turns in these reports within the specified time period, they would regain consistent status. If not, they would be redesignated as inconsistent.

A State without a VS-approved SHP would also be classified as *inconsistent.* In addition, a State or Tribe that loses APHIS approval for its plan, or that has repeatedly failed to turn in required reports, would be redesignated as inconsistent.

All designations and redesignations would be announced through notices in the *Federal Register*.

4. Interstate Movement

Implementation of the SHP approach will necessitate substantive changes to the current requirements for interstate movement of swine. We envision conditions for movement for three classes of swine.

Infected swine. Swine infected with PRV or SB could be moved interstate only if they are moved directly to a recognized slaughter establishment in an officially sealed conveyance, accompanied by a permit, and individually identified in accordance with the official identification standards prescribed for swine in 9 CFR 71.19. These provisions would allow for the slaughter of infected animals in establishments that choose to take them. These conditions for movement exist in the regulations today and would remain unchanged.

Exposed swine. The second set of conditions would set parameters for movement of exposed swine. Exposed swine could move directly to slaughter under the conditions described in the previous paragraph for infected swine. Alternatively, exposed swine could move to quarantined feedlots. Even though quarantined feedlots are not currently used, the concept already exists in 9 CFR 85.5. VS would modify the existing requirements to provide that swine intended for interstate movement would have to be tested for PRV and SB. Exposed swine that test negative would have to move interstate within the time specified by State, Tribal, or Federal officials and be accompanied by a permit that contains the quarantine status of the farm of origin, the date of the official tests, and approval from the State or Tribal animal health official of the State or Tribe receiving the swine. The swine would also have to be identified in accordance with 9 CFR 71.19 and move directly to their final destinations.

Should an outbreak of PRV or SB occur, exposed swine may need to be moved interstate to a feedlot to ensure their safety and well-being, or for other reasons. VS proposes, however, that individual State and Tribal animal health officials make the final decision whether to allow official quarantine feedlots in their State or Tribe. Additionally, those animal health officials would have the authority to make a science- and risk-based determination for their State or Tribe regarding whether exposed swine may be moved into their jurisdiction. States or Tribes would

not, however, be authorized to prohibit the transit of exposed swine through their State or Tribe to a quarantine feedlot in another State or Tribe.

In the unlikely event of a PRV or SB outbreak, this approach, which is modeled after the approach VS currently employs with regard to captive cervids exposed to chronic wasting disease, gives States and Tribes authority over movement of exposed swine into their State or Tribe for feeding purposes, while not interfering with commerce between other States or Tribes.

Swine not infected or exposed. The third set of movement conditions would be for all other swine: swine that are neither infected with nor exposed to PRV or SB. These conditions would be based on whether the State or Tribe has an approved SHP and, if not, whether the herd is eligible for movement (Appendix 1). Swine from consistent States and Tribes could move interstate if accompanied by a certificate of veterinary inspection and identified in accordance with 9 CFR 71.19.

These conditions would pertain to all swine moved interstate from a consistent State or Tribe, whether they are commercial production swine, transitional production swine, or captive feral swine. This is because, if APHIS approves a State or Tribe's animal health plan, this approval will be based on a determination that the State or Tribe has specified surveillance activities in the plan that provide adequate assurances that any swine moved from the State or Tribe, regardless of herd of origin, will not contribute to the spread of SB or PRV.

Swine from provisionally consistent States and Tribes could be subject to certain movement restrictions while the State or Tribe is still within the time period specified by VS to take remedial measures.

Swine from inconsistent States and Tribes that are not from a movement-eligible or qualified-negative herd would need to be tested for both PRV and SB with negative results before movement. Swine from inconsistent States and Tribes but originating from movement-eligible or qualified-negative herds would require a certificate of veterinary inspection and official identification or would have to be moved within a swine production system in accordance with 9 CFR 71.19, but could be moved interstate without testing before movement. VS would retain the concepts outlined in the 2003 PRV program standards for considering a herd to be qualified negative. We outline requirements for both movement-eligible herds and qualified-negative herds in Appendix 2 of this document.

5. Modernize Indemnity

Current indemnity regulations for SB and PRV are inconsistent and often lead to confusion. Such confusion is understandable, since indemnity paid for swine infected with SB may vary significantly from indemnity paid for swine infected with PRV.

To remove differences between the programs that are no longer warranted, and to ensure that our indemnity policies for SB and PRV (and any other indemnifiable disease of swine) are consistent and up to date, VS proposes to consolidate the SB and PRV indemnity regulations into one part

of 9 CFR. The provisions in this revised part would apply not only to SB and PRV, but to any swine disease approved by the Administrator for indemnity and listed on VS' Web site. To ensure all stakeholders are notified, VS will publish a notice in the *Federal Register* any time a disease is added or removed from the list, which will initially contain only SB and PRV.

Instead of listing prescriptive values for swine, as currently specified in the SB indemnity regulations, the regulations would be updated to allow for payment of up to fair market value, as currently specified in the PRV regulations and calculated by an indemnity calculator. Moreover, producers would be able to receive up to 100 percent of the costs of destroying and disposing of swine infected with SB, PRV, or any other indemnifiable disease of swine approved by the Administrator. This is currently true only for swine infected with PRV.

6. Improve Laboratory Methods

VS understands that a successful disease program must use the best available science and technology. The laboratories that test for the diseases must be proficient to ensure confidence in the results. VS also understands that testing methods change as technology advances and that regulations describing testing techniques, methods, and procedures become obsolete faster than the regulatory process can keep up with changes. Therefore, to make the regulations flexible enough to keep pace with technology, VS proposes to modify the basic requirements for laboratories testing for PRV and SB.

VS proposes that laboratories testing for PRV and SB use official tests. VS would post on the VS Web site all official tests approved by the Administrator. This would allow VS to update those tests, including additions and removal, without changing the CFR.

VS would require that tests for PRV and SB be performed in approved laboratories. Procedures for becoming an approved laboratory and standards for those laboratories would be posted on the VS Web site and may include those required for National Animal Health Laboratory Network laboratories. For example, any laboratory testing for PRV and SB may need to do the following:

- Comply with VS quality control requirements
- Have personnel qualified to conduct testing
- Follow VS testing protocols
- Pass proficiency requirements for laboratory personnel
- Report testing results to State and Federal authorities
- Send all presumptive positive tests to NVSL for analysis

Roles and Responsibilities

The success of this new approach will depend on cooperation among Federal, State, and Tribal animal health officials, the regulated industries, producers, and all other stakeholders.

Federal animal health officials will need to:

- Develop and revise regulations pertaining to the interstate movement of swine
- Develop the program standards and other policy documents, including guidelines, to assist States and Tribes with understanding the new requirements and regulatory standards
- Continue implementing the PRV National Surveillance Plan in States and Tribes
- Develop and implement an SB National Surveillance Plan (short-term)
- Draft and implement a Comprehensive National Surveillance Plan (long-term)
- Provide surveillance activity information to States and Tribes
- Monitor, analyze, and report national surveillance data
- Give States, Tribes, and other stakeholders feedback and recommendations based on these data
- Review the SHPs of States and Tribes, perform audits, and assess the actions of States and Tribes in implementing and maintaining those plans

State and Tribal animal health officials will need to:

- Develop State- and Tribe-specific SHPs
- Implement approved SHPs
- Oversee State- and Tribe-specific monitoring and surveillance activities
- Investigate, control, mitigate, and contain regulated diseases when they are identified
- Analyze the surveillance data received from VS to ensure premises moving swine interstate are low risk for disease
- Serve as liaisons with individual producers

Producers, industry, and other stakeholders will need to:

- Advance their knowledge about PRV and SB and the risk factors that could result in the introduction of disease into commercial swine herds
- Evaluate management practices to minimize risks
- Continue to engage in discussions with State officials concerning PRV and SB programs
- Develop and implement biosecurity plans intended to prevent the introduction of these two diseases

Potential Obstacles to Implementing a New Approach

VS recognizes that some partners, stakeholders, and regulated industries may have concerns and reservations about the concepts contained in this paper. As we stated above, this paper represents VS' current thinking about possible changes to the PRV and SB programs. VS thus envisions this paper as a discussion document.

That being said, in formulating this approach, we discovered that several concerns were shared among stakeholders. We address these below.

Concern 1: Some States have expressed concerns regarding the administrative burden of drafting a plan.

We agree that there will be certain administrative costs associated with drafting an SHP. However, once a State has an SHP that has been approved by VS, the State would likely experience a decrease in paperwork burden in comparison to the status quo.

Currently, States must report yearly that they have met the surveillance requirements specified in the National Surveillance Plan for PRV and must draft a plan describing how the State will preclude feral swine from introducing PRV into commercial swine herds within the State. Additionally, States considered validated SB-free must submit triennial (once every 3 years) reports describing SB surveillance activities.

In contrast, under the VS proposal, a State with an approved SHP would have to file a yearly report detailing surveillance efforts in the State during that previous year only if these surveillance efforts extended beyond the minimum surveillance required under the Comprehensive National Surveillance Plan. This report would provide assurances to VS that a State has successfully implemented and maintained the provisions of its SHP that pertain to surveillance. The only other reporting requirements under this new approach would occur when a State detects an occurrence of PRV or SB in the State, or when VS requests reporting as part of a compliance audit.

Concern 2: Moving away from State status may affect consumer confidence, regardless of the surveillance measures a State or Tribe may have in place to identify PRV- and SB-infected swine and to prevent disease spread.

Although, under the current program, all States and Tribes are considered free with regard to SB and PRV, State status is not necessarily indicative of the absence of SB and PRV in swine within the State. Since transitional production swine and captive feral swine within a PRV- or SB-free State do not have to be tested for the diseases prior to interstate movement, the current system allows for the potential unrestricted interstate movement of affected swine.

VS believes that, by requiring States and Tribes to identify and assess potential sources of disease introduction within their SHPs, our approach will provide stakeholders with a more accurate indication of the actual prevalence of PRV and SB within the United States, and will ultimately provide greater assurances that swine moving interstate from a State or Tribe do not present a risk of spreading PRV or SB.

Additionally, VS will utilize data supplied through the Comprehensive National Surveillance Plan to address any concerns raised by trading partners.

Concern 3: While VS approval of their State or Tribe's plan is pending, it appears that producers will have to shoulder costs for testing each animal moved interstate for purposes other than slaughter.

If VS finalizes the approach in this document, there would be a substantial "phase-in" period to allow States and Tribes ample time to draft and seek VS approval for their SHPs. In the intervening period, the existing regulations would remain in effect.

Concern 4: The current system provides a clear and unambiguous standard for State classification by basing them on prevalence levels. In the revised system, it seems as though States with disparate prevalence levels of PRV or SB could have the same consistent status.

The current standards for PRV and SB status are unambiguous, but only reflect prevalence rates within commercial production swine herds in the State. As such, they do not necessarily reflect the degree to which the diseases are present in States, particularly those with feral swine or transitional production swine populations.

State and Tribal SHPs will have to specify the potential sources of PRV and SB within the State or Tribe, the risk of introduction of PRV and SB into swine within the State or Tribe, and the measures that the State or Tribe intends to take to address this risk. VS will approve an SHP only if we consider the measures sufficient to address this risk. State classification, then, will be based on our determination that a State has described measures in its SHP that adequately address the risk of disease introduction into swine.

VS will make all SHPs publicly available. Thus, all stakeholders will be presented with the opportunity to evaluate the efficacy of these measures in light of the risk of disease introduction.

Conclusion

VS believes a combined program is needed for SB and PRV. Because all States are SB- and PRV-free in their biosecure commercial herds, it is time to move away from an eradication program. We need a program that is flexible enough to allow States and Tribes to manage and set safeguards necessary to protect their swine populations, yet rigorous enough to ensure that swine moved interstate do not present a risk of spreading PRV or SB.

Our proposed regulatory concept will:

1. Streamline swine regulatory programs
2. Enhance surveillance activities
3. Transition the PRV and SB program from a State status classification system to a science-based approach that addresses disease risk
4. Outline the proposed conditions for interstate movement of swine
5. Modernize indemnity provisions
6. Improve laboratory methods

To succeed, VS will require continued partnership from all stakeholders including State and Tribal animal health agencies, wildlife agencies, industry, international partners, academia, and other stakeholders. Successful partnerships allow VS to use available resources efficiently and as necessary to safeguard animal health.

Appendix 1: Proposed Requirements for Interstate Movement of Swine Not Infected With or Exposed to PRV or SB

State or Tribe has approved Swine Health Plan?	Swine originate from movement eligible herds within the State or Tribe?	Movement Requirements
Yes	N/A	• *Issuance of a certificate of veterinary inspection* • *Identification in accordance with 9 CFR 71.19*
No	No	• *Testing of all swine destined for movement for PRV and SB, with negative results from an official laboratory* • *Issuance of a certificate of veterinary inspection* • *Identification in accordance with 9 CFR 71.19*
No	Yes	• *Issuance of a certificate of veterinary inspection* • *Identification in accordance with 9 CFR 71.19*

Appendix 2: Certified Swine Herds

Movement-Eligible Herds

VS is proposing that herds electing to participate as a movement-eligible herd will need to comply with the following proposed requirements. These proposed requirements vary depending on a State's or Tribe's status.

Consistent and Provisionally Consistent States or Tribes

All swine in a consistent or provisionally consistent State or Tribe that are not under quarantine are considered movement eligible without restriction. Swine being moved would need to comply with all traceability and movement requirements.

Inconsistent States or Tribes

If a producer's State or Tribe is inconsistent, the producer may elect to test his or her swine herds to receive movement-eligible certification. If a producer's herd is movement eligible, the producer may move swine from that herd interstate without testing each swine individually.

To obtain movement eligibility, VS proposes that serological statistical tests equivalent to providing a 95 percent confidence level of detecting a 5 percent PRV or SB infection rate in a herd would need to be performed on a routine basis but no more than semiannually (two times a year). Testing that the producer has done to meet State requirements or for marketing purposes could count towards this VS testing requirement, if the producer provides adequate documentation of this testing to VS. To assist producers with testing, VS proposes to post guidance documents on the VS website.

Producers who receive swine from multiple sources may obtain movement-eligible status for their herds if all swine are from consistent or provisionally consistent States or Tribes and the producer semiannually tests a sufficient number of swine that have been randomly selected from the entire herd sufficient to obtain a 95 confidence level of detecting a 5 percent SB or PRV infection rate within the herd. If the producer receives swine from an inconsistent State or Tribe, the producer may still obtain movement eligible status for the herd if he or she performs testing sufficient to provide a 95 percent confidence level of detecting a 5 percent SB or PRV infection rate in each group within 30 days of receiving the swine, as well as performing the semiannual herd test described above.

Qualified-Negative Herds

Occasionally producers might add value to their animals by obtaining additional herd certifications. For example, the producer may seek to export swine to a country requiring herds to be qualified negative. A producer may voluntarily obtain qualified-negative herd status for both PRV and SB if the producer complies with requirements that are similar to those currently outlined and described in the 2003 PRV Program Standards. Like movement eligibility, if the

producer resides within an inconsistent State or Tribe, and he or she receives a qualified-negative certification for the herd, the producer would not have to individually test each animal before moving them interstate. The producer would, however, need to comply with all other movement requirements of the regulations.