National Pork Producers Council®

The Global Voice for the U.S. Pork Industry

November 2, 2026

Comments Regarding USDA Docket No. USDA-2026-0298
Modernization of Regulations Under 9 CFR Parts 101–118 and 123–124

United States Department of Agriculture
Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB)
Re: Docket No. USDA-2026-0298

The National Pork Producers Council (NPPC), which represents the interest of more than 60,000 U.S. pork producers, appreciates the opportunity to submit input regarding the modernization of regulations governing veterinary biologics under the Virus-Serum-Toxin Act (VSTA).

We support USDA's objectives of protecting animal health, preventing the distribution and use of contaminated or harmful biological products, and ensuring that veterinary biologics are safe and effective. However, we are concerned that an overly broad interpretation or expansion of the regulations could unintentionally restrict responsible, veterinarian-directed population health management practices that are important to modern swine production. In particular, we wish to emphasize the importance of preserving access to farm-specific natural planned and controlled exposure (NPE), commonly referred to as feedback. These practices are not intended to replace commercial vaccine manufacturing, establish a commercial distribution system for biological materials, or circumvent legitimate veterinary biologics oversight. Rather, they represent a practical, farm-specific disease management strategy used under veterinary guidance to address pathogens for which effective commercial vaccine options remain limited or not available. We strongly encourage USDA to recognize the distinction between commercial veterinary biologics and the responsible, limited use of farm-specific biological material under the direction of a licensed veterinarian.

1. The importance of natural planned exposure in swine virus management
The immunological rationale for NPE is that exposure to farm-relevant virus can stimulate mucosal and systemic immune responses in the breeding herd, contributing to protective antibodies delivered through colostrum and milk. This is particularly relevant for enteric viruses. Published immunological research has demonstrated the importance of mucosal IgA responses and the advantages of replicating oral exposure for generating intestinal immune responses. Swine are particularly dependent upon maternal immunity for protection during early life. Piglets depend heavily on colostrum and subsequent lactogenic immunity for protection against enteric pathogens. In practical swine production, natural planned exposure is an important component of the overall disease management program. Producers and veterinarians cannot simply substitute a commercially licensed or autogenous vaccine when an effective, appropriately matched product is not available. We are concerned that regulatory changes that inadvertently eliminate access to this NPE would remove an important disease management tool without necessarily providing a viable replacement.

2. AVMA policy supports appropriate veterinary discretion and access to exempt biologics
We strongly encourage USDA to consider the American Veterinary Medical Association's policy, *Use of Exempt Biologics*, when considering modernization of the veterinary biologics regulatory framework. The AVMA recognizes the importance of maintaining appropriate access to biological tools that are prepared and used within a veterinarian-client-patient relationship. We believe these principles are directly relevant to the situation facing

Iowa 10676 Justin Drive | Urbandale, IA 50322 | 515.278.8012
Washington, DC 122 C Street, NW, Suite 875 | Washington, DC 20001 | 202.347.3600 **nppc.org**

swine veterinarians managing enteric pathogens with NPE. The AVMA's policy reflects several important concepts:

- Veterinary oversight and professional judgment are essential when determining the appropriate use of farm-specific biological materials.
- Access to appropriate biological tools is particularly important when licensed commercial alternatives are unavailable or ineffective.
- Appropriate testing and safety procedures are necessary.
- Biological materials should be used within the appropriate veterinary-client-patient relationship and for their intended, limited purpose.
- Veterinary biologics regulation should protect animal health without unnecessarily restricting legitimate veterinary practice.

The herd veterinarian is uniquely positioned to evaluate the disease history of a swine (or live animal) production system, interpret diagnostic results, assess biosecurity risks, determine whether appropriate commercial alternatives exist, and establish whether NPE is warranted. This decision requires knowledge of the specific farm, its pathogens, its production flow, and its management practices. It could also create significant practical and economic burdens for producers without necessarily improving animal health outcomes. Again, it would be counterproductive if regulatory modernization unintentionally eliminated access to a legitimate veterinary disease management tool simply because the material does not fit neatly into a traditional commercial biologics framework. (AVMA policy reference: https://www.avma.org/resources-tools/avma-policies/use-of-exempt-biologics)

Conclusion

We encourage USDA to actively engage the swine industry professionals as it evaluates potential changes to the veterinary biologics regulatory framework. Veterinarians and producers have extensive practical experience with population-level disease management, maternal immunity, farm-specific pathogen challenges, and the limitations of currently available commercial biological products. Future regulatory action should not come at the expense of responsible veterinary/industry practices that are necessary to manage diseases for which effective commercial alternatives are not readily available. NPE for enteric pathogens represents an important population health management strategy in the swine industry. Its continued availability is particularly important given the biological limitations associated with vaccine development and approvals. We strongly oppose a regulatory approach that unnecessarily eliminates access to these practices or treats veterinarian-directed use of farm-specific biological materials as equivalent to commercial manufacture and distribution. The AVMA's policy on Use of Exempt Biologics provides an important professional framework for recognizing the value of veterinary discretion and maintaining access to appropriate biological tools when licensed alternatives are unavailable or ineffective.

Thank you for your consideration of our comments and we look forward to serving as a resource on this topic in the future.

Sincerely,



Bryan Humphreys, CEO, NPPC