NATIONAL CHICKEN COUNCIL

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November 2, 2026

Submitted electronically via Regulations.gov

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

Dear Mr. Perry:

The National Chicken Council (NCC) appreciates the opportunity to comment on the Request for Information (RFI) titled "Modernization of Regulations under 9 CFR Parts 101-118 and 123-124 by the U.S. Department of Agriculture (USDA).[1] NCC is the national, non-profit trade association that represents vertically integrated broiler companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC also represents numerous allied companies that provide goods and services to the industry including vaccine manufacturers. NCC supports USDA Center for Veterinary Biologics (CVB) efforts to modernize the veterinary biologics regulatory framework contained in 9 CFR Parts 101-118 and 123-124. As one of the world's most efficient and integrated animal protein sectors, the broiler industry relies on timely access to safe, effective, and innovative veterinary biologics to protect flock health, maintain food safety and security, and strengthen U.S. agricultural competitiveness. Regulatory updates should be science-based, data-driven, and reflect current production practices. Modernization of the regulatory framework should maintain USDA's rigorous standards for safety, purity, potency, and efficacy while providing greater regulatory certainty, increased flexibility, and more efficient pathways for development, licensure, and deployment of products needed to address both current and emerging broiler health challenges. Updates should also capitalize on efficiencies and minimize redundancies within CVB.

According to USDA National Agricultural Statistics Service, in 2025, 9.4 billion broiler chickens were produced at a value of $44.6 billion.[2] The U.S. broiler chicken industry provides over 1.5 million jobs with a total economic impact of over $500 billion.[3] It is important that industry has the tools needed to address current and emerging disease threats, and we encourage the Agency to consider the following items as it works to modernize the regulatory process.

**Modernization of Testing Requirements and Reduction of Animal Use**

The broiler industry supports continued efforts to modernize testing requirements and reduce reliance on animal-based testing where scientifically justified. We believe the following changes would improve regulatory efficiency and reduce unnecessary animal use without compromising product safety or effectiveness:

[1] 91 Fed. Reg. 57828 (Sept. 11, 2026), 2026-18531.pdf.
[2] Poultry - Production and Value 2025 Summary 04/30/2026.
[3] Chicken Feeds America - www.chickenfeedsamerica.org.

- Eliminate routine Target Animal Batch Safety Testing (TABST) and Laboratory Animal Batch Safety Testing (LABST) as standard serial release requirements while maintaining authority to require additional testing when product-specific risks warrant.
- Incorporate validated analytical methods and emerging technologies as alternatives to animal-based testing where appropriate.
- Modernize testing requirements under 9 CFR Part 113, including serial release testing, extraneous agent testing, and other required assays.
- Promote implementation of the principles of replacement, reduction, and refinement (3Rs) while maintaining confidence in product safety and quality.

**Ingredient and Supply Chain Flexibility**

Reliable access to vaccine ingredients is critical to maintaining continuity of broiler health programs. We ask CVB to reevaluate requirements applicable to ingredients used in veterinary biologics to reduce unnecessary supply chain constraints. Greater clarity and flexibility would help manufacturers respond to supply chain disruptions while maintaining product quality and safety. Specifically, we request that CVB:

- Reassess requirements associated with ingredients of animal origin using a science- and risk-based framework.
- Streamline regulatory requirements associated with changes involving non-animal-origin ingredients.
- Clearly publish and maintain ingredient sourcing expectations and requirements to improve transparency, consistency, and regulatory predictability.

**Science-Based Withdrawal Periods for Veterinary Biologics**

The broiler industry supports modernization of withdrawal period requirements for veterinary biologics used in food-producing animals. We encourage USDA to amend 9 CFR 112.2(a)(8) to replace the current mandatory 21-day slaughter withdrawal period with a product-specific, science-based risk assessment approach that also considers the attributes of the various livestock sectors. Science-based withdrawal periods would improve regulatory predictability and provide greater flexibility for integrated broiler producers and processors. A modernized framework should:

- Provide a clear pathway for establishing withdrawal periods based on product-specific scientific data.
- Allow zero-day withdrawal periods when supported by appropriate evidence and risk assessment.
- Increase transparency regarding the criteria used to establish withdrawal periods.
- Reduce unnecessary barriers to adoption of innovative biologics while maintaining food safety and consumer confidence.

**Acceptance of High-Quality Foreign Data**

The broiler industry supports greater regulatory flexibility regarding acceptance of scientifically robust studies conducted outside the United States. Broader acceptance of qualified foreign data would reduce duplication, accelerate access to important biologics, reduce reliance on animal-based testing, and support efficient global product development. We encourage CVB to:

- Apply consistent expectations for study quality, data integrity, and scientific validity regardless of study location.
- Accept qualified foreign safety and efficacy studies when they meet U.S. regulatory standards.
- Evaluate data based on scientific merit and relevance rather than geographic location.

- Recognize that standardized laboratory studies are generally not influenced by geographic location when conducted under appropriate protocols and quality systems.

**Building on Successful Regulatory Flexibility**

USDA-CVB has demonstrated that science-based regulatory flexibility can effectively support innovation and disease response. Such approaches can improve preparedness and foster innovation without compromising regulatory standards or scientific validity. The broiler industry encourages CVB to build on these successes by:

- Promoting early and ongoing engagement between industry and regulators.
- Reducing uncertainty regarding development and licensure requirements.
- Allowing real-world evidence generated through field use and post-market experience to support regulatory decision-making when scientifically justified.
- Establishing clear pathways to transition products from conditional licensure to full licensure.
- Expand the use of import permits to promptly address disease threats affecting the broiler industry.

**Addressing Limited-Market and Emerging Broiler Health Needs**

The industry recognizes that certain broiler diseases and emerging health challenges may not support traditional product development models despite their importance to animal health and production. We believe the following approaches would help ensure producers have access to tools needed to address evolving disease challenges:

- Expand regulatory flexibility for products serving limited markets or addressing emerging disease threats.
- Establish predictable pathways for products addressing unmet broiler health needs.
- Consider regulatory reliance approaches that leverage assessments conducted by trusted foreign regulatory authorities.
- Encourage investment in innovative biologics through streamlined and risk-based regulatory pathways.

**Autogenous Vaccine Recommendations**

Industry supports modernization of the regulatory framework governing autogenous vaccines and biologics to better reflect current animal production systems, scientific advancements, and industry practices. NCC recommends CVB consider the following:

- Modernize autogenous vaccine distribution requirements to align with today's vertically integrated broiler production system. Updated regulations could improve vaccine access, clarify permissible locations of use, promote food safety, and enhance animal health outcomes while maintaining appropriate regulatory oversight.
- Reevaluate the five-year expiration period for autogenous isolates and consider a more science-based, risk-based approach. As autogenous vaccines are increasingly used for viral diseases, expiration of an established isolate may create challenges if disease reemerges and a new isolate cannot be readily obtained. These same challenges apply to autogenous *Salmonella* vaccines. Industry supports exploring mechanisms that would allow continued use of existing isolates when scientifically justified.
- Update autogenous biologics regulations more broadly, including requirements under 9 CFR 113.113 and related testing provisions in 9 CFR Part 113. Regulations should reflect advances in diagnostics, manufacturing, and testing technologies while streamlining regulatory processes to reduce administrative burden without compromising product quality, safety, effectiveness, availability, or regulatory oversight.

**Conclusion**

NCC and our members support the modernization of USDA-CVB regulations to create a more efficient, science-based, and predictable regulatory framework for veterinary biologics. Modernizing testing requirements, adopting risk-based approaches to withdrawal periods, improving acceptance of qualified foreign data, strengthening preparedness authorities, and enhancing regulatory flexibility for emerging disease threats will help ensure industry has timely access to innovative tools needed to protect flock health. Updates should also take into consideration modern production practices and species-specific differences. A modernized regulatory framework will strengthen U.S. food security and safety, improve animal health outcomes, enhance industry competitiveness, and maintain public confidence in the safety and effectiveness of veterinary biologics.

We appreciate the Agency's interest in modernizing and streamlining these existing regulations, and we are available to discuss these comments in more detail if it would be helpful to the Agency's efforts. If you have any questions, please do not hesitate to contact me.

Respectfully submitted,



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