USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-15

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Geetha Srinivas, DVM, PhD.
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Date: 2024.12.10 09:50:45 -06'00'

SUBJECT: Salmonella Vaccines and USDA Food Safety and Inspection Service's Framework to Reduce Salmonella Illnesses Attributable to Poultry

I. PURPOSE

The purpose of this document is for the Center for Veterinary Biologics (CVB) and the Food Safety and Inspection Service (FSIS) to inform veterinary biologics manufacturers regarding FSIS' interest in *Salmonella* vaccines for poultry. This collaborative announcement is for information only, is not a CVB solicitation, and does not include any new regulatory guidance from CVB.

II. BACKGROUND

CVB regulates the licensing of veterinary biologics, including products for animal pathogens, such as *Salmonella,* that are also considered food safety risks. CVB has specific requirements that domestic veterinary biologics manufacturers must meet for their products to be licensed, or for foreign manufactured products to be permitted for sale and distribution within the United States. In addition to standard licensure requirements, CVB has published previous notices describing the jurisdictional issues where food safety is an additional consideration beyond an animal health claim, including Notice 05-07 *Biologics for Reduction of Colonization and/or Shedding in Animals* and Notice 12-09 *Licensing of Vaccines as Preharvest Food Safety Interventions*.

FSIS ensures the safety of meat, poultry, and egg products. On August 7, 2024, FSIS published a proposed rule and proposed determination to more effectively reduce *Salmonella* contamination and illnesses associated with raw poultry products. The proposal would establish final product standards to prevent raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products that contain any type of *Salmonella* at or above 10 colony forming units (CFU) per gram/ml **and** any detectable level of at least one of the *Salmonella* serotypes of public health significance from entering commerce. The proposed *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, and

comminuted chicken are Enteritidis, Typhimurium, and I,4,[5],12:I:- ; and for raw comminuted turkey are Hadar, Typhimurium, and Muenchen.
FSIS also noted that *Salmonella* Infantis remains a serotype of considerable concern in terms of potential severity of illness and antimicrobial resistance and has requested comment on the possible inclusion of Infantis as a serotype of public health significance. The list of serotypes of public health significance is essential to FSIS' framework, as it determines whether products are adulterated as defined in the Poultry Products Inspection Act. FSIS recognizes that science constantly evolves and therefore our understanding of virulence and other factors will evolve over time. If FSIS completes the proposed final product standards, the agency intends to re-evaluate the serotypes of public health concern every 3-5 years at a minimum or whenever new information on *Salmonella* serotypes associated with human illness become available.

Vaccination is currently the only intervention that can target specific *Salmonella* serotypes, including the serotypes of public health significance, and thus is an important component of a comprehensive *Salmonella* control program. As stated in the proposed rule, FSIS will provide sampling data and technical support, as appropriate, to industry and regulatory bodies to advance these goals.

As part of this initiative, FSIS acted to remove barriers to the use of vaccination as an important pre-harvest intervention to control *Salmonella* in poultry. Since April 1, 2024, FSIS has excluded current commercial vaccine subtypes confirmed in FSIS raw poultry samples from the calculation used to categorize establishments under the raw poultry *Salmonella* performance standards. FSIS announced this change after examining data from pilot projects at nine establishments. A summary report of the data from these pilots is posted on the Pilot Projects: *Salmonella* Control Strategies page of the FSIS website at: https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot.

III. ACTION

FSIS is interested in learning about and engaging in discussions with veterinary biologics manufacturers on vaccination technologies, especially modified-live vaccines targeting FSIS' proposed serotypes of public health concern or their associated serogroups. Stakeholders with questions about FSIS' *Salmonella* framework should contact FSIS directly at Salmonella@usda.gov.

Stakeholders with questions regarding CVB licensure of new products, pursuit of new label claims for existing products, or evaluation of unlicensed products should contact their Reviewer, or if new to veterinary biologics, please contact CVB at CVB@usda.gov. CVB licensure of products does not guarantee use in any control program.