



## **Bovine Serum Meeting: Challenges and opportunities in the research and development and manufacture of vaccines and other biological products**

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Virtual Meeting**

### **Bovine Serum, BSE and Extraneous Agents: Updates on WOH Standards**

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The WOH Terrestrial Code and Manual constitute the principal international reference framework governing the safety assessment and regulatory status of bovine-derived starting materials used in vaccine and biological product manufacture. This presentation reviews recent revisions to both instruments and their implications for the serum sector.

The 2023 revision of Terrestrial Code Chapter 11.4 replaced prior country-based classification with a fully risk-based BSE assessment framework. Critically, fetal blood was added to the safe commodities list under Article 11.4.2, permitting trade without BSE-related conditions regardless of the exporting country's risk status — potentially widening the qualified supplier base beyond historically preferred sources.

On extraneous agents, the revised Manual Chapter 3.4.7, adopted in May 2024, updates bovine pestivirus taxonomy and validated diagnostic methods underpinning donor-herd screening and batch release. A dedicated Code Chapter 11.X on bovine pestivirus infection remains pending adoption following unresolved concerns on case-definition criteria.

Key technical challenges persist: non-uniform BVDV inactivation kinetics under gamma-irradiation, divergent testing approaches across regions, and the absence of a harmonised global specification reconciling WOH, European Pharmacopoeia and USDA-CVB requirements — all directly relevant to the ongoing EDQM monograph revision.

