

Bovine Serum, BSE and Extraneous Agents

Updates on WOAHA Standards

A review of recent revisions to the WOAHA Terrestrial Code and Manual affecting the regulatory status, safety assessment and international sourcing of bovine serum.

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Talk Roadmap



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Why WOAH standards matter

The Terrestrial Code and Manual as the international reference framework for bovine-derived starting materials



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BSE — Terrestrial Code Chapter 11.4

The 2023 risk-based revision, and the new safe commodities list



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Extraneous agents — BVDV focus

Manual Chapter 3.4.7 update and the emerging Code Chapter 11.X



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Remaining technical challenges

Inactivation, testing variability and specification-setting



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Key takeaways for the sector

What these updates mean for bovine serum supply and safety

Why WOAH Standards Matter for Bovine Serum

WOAH sets the international reference standards that underpin national and regional regulation of bovine-derived biological starting materials

Terrestrial Animal Health Code

Sets trade standards

Country/zone BSE risk categories, safe-commodity lists, certification requirements for international movement of bovine commodities.

Chapter 11.4

Bovine spongiform encephalopathy (BSE)

Chapter 11.X (in development)

Infection with bovine pestiviruses (BVD)



Terrestrial Animal Health Manual

Sets diagnostic & vaccine standards

Validated test methods, sampling, and quality standards referenced by Code chapters and by national regulators (incl. the European Pharmacopoeia).

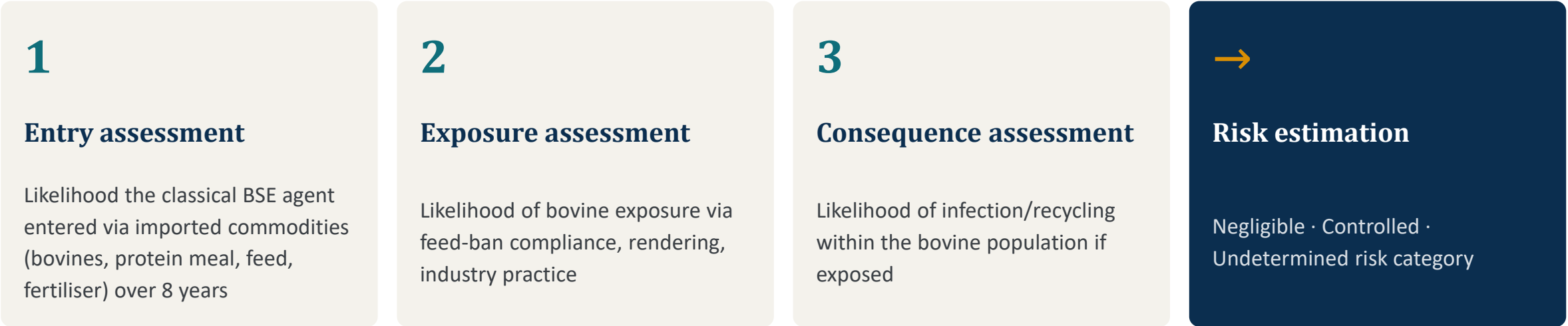
Chapter 3.4.7

Bovine viral diarrhoea — revised chapter, adopted May 2024 at the 91st General Session. Updates pestivirus taxonomy and validated diagnostic methods.

A Shift to a Fully Risk-Based Framework



Country/zone BSE risk is determined via a structured risk assessment (Art. 11.4.3):



Safe Commodities — What's New

Commodities Veterinary Authorities should trade without BSE-related conditions, regardless of exporting country risk status



Milk & milk products



Semen & in-vivo derived embryos



Hides & skins



Gelatine & collagen



Tallow ($\leq 0.15\%$ impurities) & derivatives



Dicalcium phosphate



NEW — Fetal blood

Added to the safe commodities list in the 2023 revision. Fetal blood — the source material for foetal bovine serum — can now be traded without BSE-related conditions, regardless of the exporting country's BSE risk status.

What This Means for Bovine Serum Supply

Most exporting nations

now hold WOAHP negligible BSE risk status

4 countries only

hold controlled risk status — none are major FBS exporters*

7 safe commodities

now listed under Article 11.4.2, incl. fetal blood

**Chinese Taipei, Ecuador, Greece and Russia hold controlled BSE risk status as of 2025.*



The historical picture

Manufacturers have long favoured serum sourced from Australia and New Zealand, on the basis of perceived lower purity risk and BSE-related restrictions elsewhere.



The emerging picture

With most exporting countries now at negligible risk, and fetal blood classified as a safe commodity, geographic sourcing constraints may ease — potentially widening the qualified supplier base.

Bovine Viral Diarrhoea Virus (BVDV)

The principal extraneous-agent risk in bovine serum production



What is BVDV?

Genus Pestivirus, family Flaviviridae — 3 recognised species/types:

- Pestivirus bovis (BVDV-1)
- Pestivirus tauri (BVDV-2)
- Pestivirus brasilense (BVDV-3)

Animals infected in-utero during early gestation typically become persistently infected (PI) — shedding virus for life without necessarily showing signs.

PI cattle in the source herd are the principal route by which BVDV contaminates bovine serum and blood-derived products.



Terrestrial Manual Chapter 3.4.7

Revised chapter adopted at the 91st General Session, May 2024.

Updates taxonomy of the pestivirus genus in line with ICTV classification.

Describes validated diagnostic methods for BVDV — antigen/RNA detection and MAb-based differentiation of pestivirus species.

Provides the diagnostic reference underpinning serum-donor herd screening and batch testing programmes.

New Code Chapter 11.X — Infection with Bovine Pestiviruses (BVD)

- **Sept 2022** Code Commission agrees to develop a new Chapter 11.X, defining occurrence of infection with bovine pestiviruses
- **May 2024** Underpinning Manual Chapter 3.4.7 revision adopted, enabling the Code Commission to resume its review
- **May 2025** Proposed for adoption at the 92nd General Session — not adopted; Members raised concerns on the case-definition criteria
- **Sept 2025 →** Terrestrial Animal Health Standards Commission continues review of the amended draft chapter



Current status: not yet part of the Terrestrial Code. Until adopted, BVDV/bovine pestivirus trade recommendations rely on the diagnostic standards in Manual Chapter 3.4.7 and on bilateral/national requirements.

Remaining Technical Challenges

WOAH standards set the reference framework — but implementation gaps persist across the supply chain



Gamma-irradiation limitations

Inactivation kinetics for BVDV and other extraneous agents are not uniform across viral targets, serum matrices and irradiation doses.



Testing method variability

Divergent diagnostic and validation approaches across regions and laboratories complicate consistent batch release decisions.



Specification-setting

No single harmonised global specification yet reconciles WOAH standards, Ph. Eur. (under revision), USDA-CVB and other regional requirements.



Supply & logistics pressure

Rising global demand for serum intersects with evolving regulatory requirements, adding complexity to sourcing and distribution.

Key Takeaways



BSE risk assessment is now fully risk-based (Chapter 11.4, 2023 revision) — geography alone no longer determines eligibility.



Fetal blood is now a WOAHL-listed safe commodity, potentially easing historical sourcing constraints tied to BSE.



BVDV remains the key extraneous-agent risk; the Manual diagnostic chapter has been updated, but a dedicated Code chapter is still pending adoption.



Inactivation and testing-method harmonisation remain open technical questions relevant to the EDQM monograph revision.



Supply, regulatory and technical factors are converging — reinforcing the need for the cross-stakeholder dialogue this meeting convenes.

Thank You

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KEY SOURCES

WOAH Terrestrial Animal Health Code, Chapter 11.4 — Bovine spongiform encephalopathy (2023 revision)

WOAH Terrestrial Animal Health Manual, Chapter 3.4.7 — Bovine viral diarrhoea (adopted May 2024)

WOAH Code Commission & Terrestrial Animal Health Standards Commission reports, 2024–2025 — draft Chapter 11.X

WOAH BSE risk status lists and ad hoc Group reports, 2024–2025

