



International Alliance for
Biological Standardization

**Maintaining the Quality of Vaccines through the Use of Standards:
Current Challenges and Future Opportunities**
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Abstract

**WOAH* Procedures for Development, Validation and Adoption
of Standards for Veterinary Vaccines and Reagents**

*Founded as OIE

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Abstract

Background: The World Organisation for Animal Health (WOAH, founded as OIE) is an intergovernmental standard-setting organisation that develops and implements animal health technical standards, including standards for vaccines and diagnostic tests, and capacity building programs, through a global network of Members and experts in Reference Laboratories and Collaborating Centres. WOAH standards are developed, validated, and adopted by Members in a science-based, transparent, democratic procedure. Once adopted, the standards are published in WOAH Codes and Manuals, which are applicable for all WOAH Members and become the internationally agreed basis for trade, under the World Trade Organization Sanitary & Phytosanitary (WTO SPS) Agreement.

Challenges: WOAH and the Food and Agriculture Organisation of the United Nations are jointly engaged in a comprehensive vaccination and testing program to control and globally eradicate a disease of sheep and goats, peste des petits ruminants (PPR), by 2030. The participating vaccine manufacturers, animal health workers and farmers in PPR infected regions of Africa, Middle East, Asia and Europe require timely access to safe and effective vaccines that conform to international quality standards, as published in the WOAH *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*. The PPR Global Eradication Program (PPR GEP) will require large scale production of conventional modified live PPR vaccines, as well as specialized vaccines, diagnostic tests, and reagents, such as: (1) vaccines with well characterized or enhanced thermotolerance properties for use in regions where the cold chain may be interrupted; (2) 'DIVA' vaccines and corresponding diagnostic tests for differentiating infected animals from vaccinated animals; and (3) clearly defined quality assurance standards for PPR vaccines to help ensure that manufacture consistently provide high quality vaccines while also conforming to the 3R principles for refining, reducing and replacing use of animals for laboratory testing and (4) PPR diagnostic tests and reference reagents for use in vaccine production and quality control.

Conclusions: To address animal health stakeholders' ongoing needs, including those of the PPR GEP, the WOAH continuously updates the relevant *Terrestrial Manual* standards for vaccines, diagnostic tests, and reagents. The slide presentation will review the key challenges and discuss some recent actions that have been undertaken to address them.