

SECTION 3.7

RECOMMENDATIONS FOR THE MANUFACTURE OF VACCINES

INTRODUCTORY NOTE

The OIE has adopted a formal standard entitled Principles of Veterinary Vaccine Production. Its most recent version, adopted in May 2015, may be found in the Terrestrial Manual as chapter 1.1.8:

The online version may be found at:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.08_VACCINE_PRODUCTION.pdf

In addition, many of the general principles of laboratory management set out in Chapter 1.1.1 Management of Veterinary Laboratories are applicable to vaccine production, including such areas as accountability, executive management, infrastructure, human resources and compliance.

The online version may be found at:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.01_MANAGING_VET_LABS.pdf

Part 3 of the Terrestrial Manual includes general recommendations for laboratories and vaccine manufacturers. These recommendations supplement and give explanatory content in support of the standards included in Parts 1 and 2. The following section of OIE Recommendations for the Manufacture of Vaccines is such a supplement, providing more detailed information for vaccine manufacture in accordance with the principles set out in the standards.

All of the recommendations have been written by experts in the respective fields, and have been subjected to an extensive process of consultation in arriving at the final texts.

None of these recommendations should be used in isolation. Each is designed to complement and inform the application of the OIE Principles of Veterinary Vaccine Production in specific situations.

Chapter 3.7.1. Minimum requirements for the organisation and management of a vaccine manufacturing facility:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.7.01_MANU_SITES_VACCINE_ORG_MANAG_E_RQ-CCOIE.pdf

Chapter 3.7.2. Minimum requirements for the production and quality control of vaccines:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.7.02_MANU_SITES_VACCINE_PROD_CONT_ROL.pdf

Chapter 3.7.3. Minimum requirements for aseptic production in vaccine manufacture:

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/3.7.03_MANU_SITES_ASCEPTIC_PROD.pdf