# *TERRESTRIAL MANUAL* REVISION: ADVICE FOR MEMBER COUNTRY COMMENTS

Chapter Number and Title: Chapter 2.3.4. Minimum requirements for the production and quality control of vaccines

Country making the comments:

Date:

It would be appreciated if the following guidance is followed when making a reply:

1. Comments may be general or specific, but specific comments are more valuable. General comments should be such that some conclusion and action can be taken in response to them. For example, instead of stating “This test is no longer used in our laboratory”, indicate the reasons the test is no longer used and what test is used instead.

2. Specific comments should be identified by indicating the line number in the text, to facilitate the editorial process.

3. Highlighting typing or technical errors is welcome, but the correct word or figure should be indicated in its place. For example, instead of indicating simply “0.8 M is too high”, the preferred value should also be indicated.

4. Bear in mind that the introductory chapters (Part 1 of the *Terrestrial Manual*) set general standards for the management of veterinary diagnostic laboratories and vaccine facilities and are not intended to be exhaustive, and indeed none of the chapters can give a completely comprehensive cover of the subject, otherwise the *Terrestrial Manual* would be too long. However, assistance in indicating priorities is always helpful.

5. The *Terrestrial Manual* is intended for world-wide use. The chapters need to reflect the development of new technology, while maintaining the established methods, usually requiring less sophisticated apparatus. New technology should not be described in detail until it has gained wide acceptance as a reliable method.

6. We recommend that if you have no specific comments, please respond to the OIE to that effect.

7. Any comments, proposed changes or revisions should be supported by clear evidence (the scientific rationale) such that some conclusion and action can be taken in response to them.

*Your participation in the OIE Standard-setting process is valued. Thank you for your engagement in the process!*

*General Comments*

*Specific Comments* (*add continuation sheets if required*)

*line:*

Chapter 2.3.4.

Minimum REQUIREMENTS FOR   
THE production and   
QUALITY control OF VACCINES

. . .

2. Rules governing quality control

. . .

2.4. Batch tests for immunological products

. . .

2.4.1.2. Batch or serial safety test

i) Safety tests are not required by many regulatory authorities for the release of each batch or serial where the seed-lot system is used. Other regulatory authorities may allow waiving of target animal batch safety tests in line with VICH GL50 and 55 and waiving of laboratory animal batch safety tests in line with VICH GL59.