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

Chapter Number and Title: Chapter 1.1.8 Principles of veterinary vaccine production

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 1.1.8.

principles of veterinary   
vaccine production

. . .

quality controls in Vaccine Production

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2. Batch/serial release for distribution

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2.2. Batch/serial safety test

VICH Guidelines 50 (inactivated vaccines) and 55 (live vaccines) provide for a waiver of the target animal batch/serial safety tests ~~(TABST)~~ in recognition of the 3R principles. VICH Guideline 59 also provides for a waiver of the laboratory animal batch/serial safety tests (LABST) in recognition of the 3R principles. As stated in VICH Guidelines 50, ~~and~~ 55 and 59 (<http://www.vichsec.org/guidelines/biologicals/bio-safety/target-animal-safety.html>), these ~~TABST~~ batch safety tests may be waived by the regulatory authority when a sufficient number of production batches have been produced under the control of a seed lot system and found to comply with the test, thus demonstrating consistency of the manufacturing process. Some regulatory authorities still require safety tests for the release of each batch/serial and typical tests are described in CFR Title 9 part 113, in this *Terrestrial* *Manual* and elsewhere. Standard procedures are given for safety tests in mice, guinea-pigs, cats, dogs, horses, pigs, and sheep and are generally conducted using fewer animals than are used in the safety tests required for regulatory approval. Batches/serials are considered satisfactory if local and systemic reactions to vaccination with the batch/serial to be released are in line with those described in the regulatory approval dossier and product literature. Some authorities do not permit batch/serial safety testing in laboratory animals, requiring a test in one of the target species for the product. The European Pharmacopoeia no longer requires a batch safety test in target animal species for the release of vaccine batches/serials nor ~~and for many years has not required~~ a general safety test (abnormal toxicity test) in mice or guinea pigs.

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