Chapter 1.1.8.

principles of veterinary   
vaccine production

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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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