Chapter 2.3.4.

Minimum REQUIREMENTS FOR
THE production and
QUALITY control OF VACCINES

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2. Rules governing quality control

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2.4. Batch tests for immunological products

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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 where alternative methods exist.