



**PUBLIC CONSULTATION AT STEP 4 OF THE VICH
PROCEDURE
OVERVIEW OF COMMENTS RECEIVED**

**VICH draft Guideline GL55 on Harmonization of criteria to waive
target animal batch safety testing for live vaccines for veterinary use**

VICH EWG: BIOLOGICALS QUALITY MONITORING

Name & Country of individual, organisation, or VICH delegation that commented

| Comment n° | Name - Country |
|-----------------------|---|
| 1 | International Council on Animal Protection in Pharmaceutical Programmes (ICAPPP, USA) |
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Discussion of comments

| GENERAL COMMENTS – OVERVIEW | | |
|------------------------------------|---|---|
| Comment N° | Comment received | Outcome of consideration |
| 1 | <p>The ICAPPP warmly welcomes the creation of this guideline, which provides both internationally harmonised recommendations for criteria to waive target animal batch safety testing (TABST) of live veterinary vaccines to encourages global implementation to reduce the use of animals.</p> <p>The proposed text of the guideline does not make clear the extent to which further harmonisation between the VICH regions has been achieved. It appears that the US and Japan will consider waiving if 10 (or 5 over 3 years) consecutive batches have been tested successfully. However, the table does not suggest this. We request that this is clarified and encourage the US and Japan to work towards harmonisation with Europe as much as possible, with the global deletion of the TABST being the ultimate objective.</p> <p>The proposed text specifies that the guideline’s aim is to harmonize TABST waiver policies in VICH-participating regions, but omits information that would assist OIE member countries – which are encouraged by OIE to use VICH guidelines – in adopting harmonized policies.</p> | <p>The VICH EWG BQM acknowledged these general comments. The table has been updated in the light of the specific comments 1-3, see below.</p> <p>The guideline does not address the degree to which harmonisation has already been achieved as this is not its aim. Rather, it summarises the current requirements and describes a harmonised approach for future waiving of the TABST. Gathering information on TABST requirements for all OIE member countries would be a major undertaking, would greatly delay implementation of the guideline and is not necessary to allow its use in OIE member countries. Furthermore, opportunities (in particular through the VICH Outreach Forum) exist through which non-VICH countries can seek clarification on any issues relating to VICH guidelines.</p> <p>VICH secretariat to advice on acceptability of proposed reply.</p> |

SPECIFIC COMMENTS ON THE TEXT OF THE GUIDELINE

SECTION 2

| Paragraph | Comment N° | Comment received and rationale; proposed change | Outcome of consideration |
|--|------------|---|--|
| 2.2.1 Table 1 – Row Europe | 1 | <p>According to the guideline, Table 1 is supposed to contain a list of testing procedures that are “required for batch safety testing of live veterinary vaccines”. It therefore seems inappropriate to continue to include reference to the TABST in the ‘requirements’ or ‘remarks’ section of the table for Europe. Since the test has been deleted, it is no longer a requirement in Europe and this must be made clear. If the historical/background information surrounding the deletion of the test must be included in the guideline, it should instead be moved to a footnote so as not to allow for any confusion or misinterpretation.</p> <p>Proposed change (if any): We suggest that the text in both the ‘requirements’ and ‘remarks’ sections of Table 1 for Europe be deleted or moved to a footnote.</p> | Row "Europe" now only includes a sentence on deletion of the TABST in 2013. Information of waiving possibility is now moved to a footnote. |
| 2.2.1 Table 1 – Rows USA and Japan | 2 | <p>2.2 Table 1: USA and Japan It is not clear why there appears to be extra animal tests required for live vaccines in both the USA and Japan (tests in mice in addition to the target animal- USA; abnormal toxicity test, limit test in addition to the target animal- Japan). We encourage US and Japanese authorities to remove these surplus tests and reduce the requirements to either the TABST or the mouse test. At the very least, a justification should be included to explain why these tests are necessary, especially considering the fact that in Europe they have been deleted from the testing requirements.</p> <p>Proposed change (if any): Reduce the testing requirements in Table 1 for both the USA and Japan</p> | The guideline no longer lists the requirements for the safety tests in laboratory animals. Note that VICH is working on a guideline on harmonisation of criteria to waive the laboratory animal batch safety test for veterinary vaccines. |
| 2.2.1 Table 1 – row USA and Japan | 3 | <p>We are disappointed that the testing requirements in Table 1 for the US and Japan appear to suggest that waiving is not an option. Based on the text (section 2.3. Data Requirements for Waiving of Target Animal Batch Safety Tests) it does in fact appear that waiving is possible. We understand that this is both US policy (see https://ntp.niehs.nih.gov/iccvam/suppdocs/feddocs/usda/vsmemo-800-116-508.pdf) and Japanese policy (see JMAFF presentation at http://slideplayer.com/slide/10232852/).</p> <p>Both the text and the table need to be clear about what the requirements and waiving options are.</p> <p>Proposed change (if any):</p> | Table 1 now includes information on the update of Veterinary Services Memorandum 800.116 (row USA). |

SECTION 2

| Paragrap h | Comment N° | Comment received and rationale; proposed change | Outcome of consideration |
|-----------------------|-----------------------|--|---------------------------------|
| | | Include the following text in the 'remarks' section for each region: "Can be waived provided that at least 10 consecutive batches from separate final bulks had been tested and product complies with test". | |