Items to Consider for No Tests Regarding the Wet Chick Safety Test, 9 CFR 113.207(a)

Test summaries with an NT reported for title 9, *Code of Federal Regulations* (9 CFR), part 113.207(a), testing should be carefully considered for release as even a small number of live virus may cause encephalomyelitis in the horse.

If a NT is reported for 9 CFR 113.207(a), the firm should perform due diligence in determining that the unfavorable reaction reported was not attributable to the product and, in fact, the virus is inactivated. All clinical observations and assessments must be documented appropriately by personnel familiar with assessing the health of young birds. Such documents should be supplied to the CVB-Inspection and Compliance (CVB-IC). Below are some items for the Specialist to consider when making a decision on serial release:

1. Were there neurological signs observed? Neurological symptoms may be subtle and exhibited in chicks as dehydration or failure to thrive due to their inability to find or ingest water or food.

2. In the event of a bird death, the following should be done to determine if the death was attributable to the vaccine:

    a. A full necropsy of the affected bird should be performed with the gross pathological findings documented and supplied with the request for product release.

    b. Tissues for histopathology should be taken and assessed by a person qualified to do so:
    i. Tissues taken should be properly selected and handled until examined.

    ii. Tissues to be collected for histopathology ***must include the brain***. Other organs to consider sampling for histopathology include, but are not necessarily limited to, heart, liver, thymus, spleen, and bursa of Fabricius.

    iii. Tissues should not be taken from autolyzed organs. If the frequency of animal observations and animal housing conditions are appropriate, this should not be an issue.

    iv. Results from all histopathological examinations should be obtained prior to requesting release of product and submitted with such a request.

    c. Review of inactivation steps should be done to confirm there were no deviations from the validated process.

3. Virus isolation and/or virus detection testing should be considered.

If you have any doubts as to if the firm has adequately confirmed any unfavorable reactions are ***not*** product related, then discuss this with a CVB-IC Section Leader. It is also appropriate to include the appropriate CVB-Policy, Evaluation, and Licensing reviewer(s) in such discussions.

Author: William L. Huls
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