



Animal and Plant
Health Inspection
Service

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**Serial Release - Processing APHIS Form 2008s for Tests
Completed - UNSATISFACTORY and IF the Manufacturer
challenge of the CVB Laboratory Results**

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Section/Area: CVB-WI-IC

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Notes:

Serial Release - Processing APHIS Form 2008s for “Tests Completed – UNSATISFACTORY” [REDACTED]

Source Document: [CVB-SOP-0032](#), *Processing Serial Records* and title 9, *Code of Federal Regulations*, parts 113 and 116

Background

CVB-PEL laboratory can conduct confirmatory testing on all serials submitted for market release. When CVB tests a serial and the results are unsatisfactory, the Specialist considers these results when processing the APHIS Form 2008. The Specialist usually will base an APHIS Disposition on the CVB Laboratory testing; however, it is under the Delegation of Authority for Inspection and Compliance (IC) to assign an APHIS Disposition to a serial after evaluation of all testing.

If the APHIS Form 2008 is processed as Test Completed – UNSATISFACTORY, the serial may not be marketed and destruction of that serial must be observed by CVB during an on-site inspection and documented on APHIS Form 2045.

[REDACTED]

Note: If the firm is not NCAH portal enabled or if the APHIS Form 2008 for the serial in question was a hardcopy submission, the APHIS Dispositions and Release Requirements listed for NCAH portal submissions will be typed onto hardcopy APHIS Form 2008s, the routing will remain the same.

[REDACTED] CVB-L Tests a Serial - the Results are UNSATISFACTORY

1. BCA: BCA Ready for Approval Tab – APHIS Form 2008s with a Test Report and APHIS Disposition of Tests Completed UNSATISFACTORY should be moved to Specialist Review. The Reason should be “Other” and the note should indicate UNSAT CVB-L results.

2. Specialist: Specialist Review Tab (should be done within 24 hours of receipt, either by Specialist or Program Coordinator)

- a. Review CVB-L Test Report
 - i. Confirm validity results
 - ii. Confirm release requirement
- b. Request CVB-L bench records for review to confirm the storage, processes, validity, and results compliant with the regulations, OP/SO, and internal processes. The Specialist may also discuss results with the VMO/Microbiologist who validated the test report. An email with the bench records from the CVB-L to the Specialist is sufficient.
- c. Review the test data submitted by the firm for the serial tested.

- d. If no issues with CVB-L test report, mark the following in Specialist Review
 - i. APHIS Disposition = Tests Completed UNSATISFACTORY
For bulk testing, File For Information Tested UNSATISFACTORY
 - ii. Check the box under Mock Check
 - iii. Review Comments – CVB bench records reviewed
 - iv. Click on Release Criteria Required
 - v. Release Criteria = Unsatisfactory Results – NOT TO BE RELEASED. Disposition to be made under supervision of APHIS
 - vi. SAVE
 - e. If there are issues with the CVB-L test report, use Specialist Check Out to hold the serial in Specialist Review until resolved.
3. BCA: BCA Ready for Approval: continue processing for Signature.

██████████ If Manufacturer Contests CVB Lab Results.

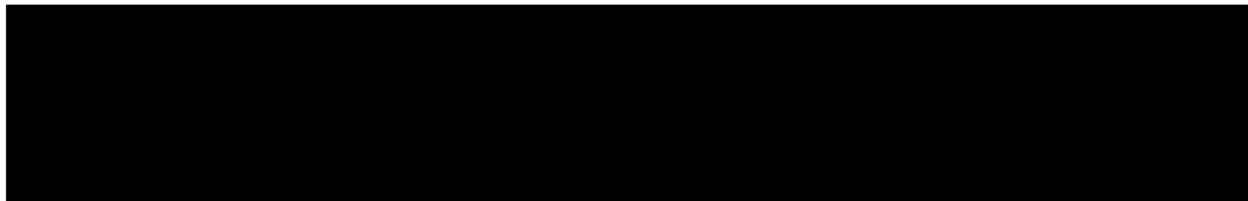
1. Specialist communicates expectations for reconsideration of a market release – this can be done verbally or by email. This communication is not official but simply providing customer service regarding the appeal process.
 - a. The phone log should include the product and serial number by clicking on +Add Product/Serial.
 - b. Emails should be converted to pdf and attached to the 2008. Click on Attachments and then click on Add Attachment to Aphis 2008 to upload email.
2. Specialist confirms that the serial and testing in question were prepared and tested in accordance with the filed Outline of Production. This can be a statement by the manufacturer or records could be submitted to CVB-IC and the evaluation is performed by the Specialist.
3. The manufacturer must perform a double independent re-test. Submit the results (satisfactory or unsatisfactory) to CVB on an APHIS Form 2008 and include test bench records. The double retest should be conducted before CVB provides the CVB-Laboratory testing records to the firm.
 - a. The APHIS Form 2008 results and bench records are reviewed by Specialist
 - b. Bench records may route to the Laboratory VMO/Micro for concurrence

██████████ Retest Outcome

1. Manufacturer Retest Confirm CVB-L UNSATISFACTORY results.
The firm may or may not resubmit an APHIS Form 2008; but the communication must be documented. If a 2008 is submitted:
 - a. The original APHIS Disposition is unchanged

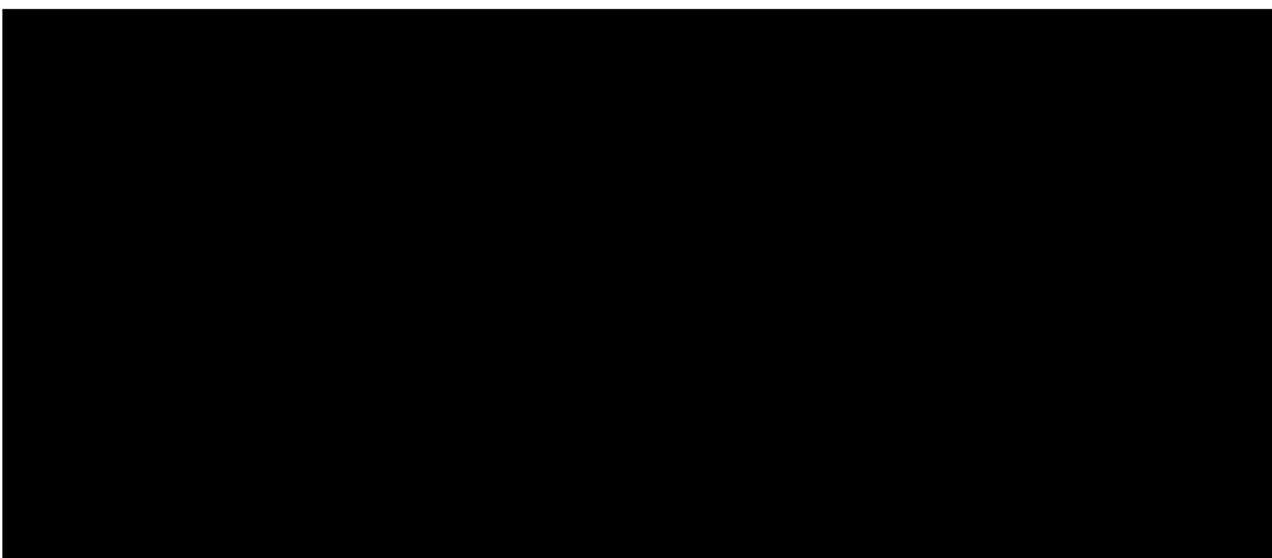
b. Under Specialist Review for the APHIS Form 2008s, the APHIS Disposition will be marked, "Other - File for Information Tested UNSATISFACTORY"

c. The manufacturer must inform CVB of the intended disposition for the serial, preferably a letter attached to the APHIS Form 2008 retest submission. The disposition should be supervised by CVB (When there is a difference between the initial disposition of the manufacturer and CVB disposition, CVB needs to witness destruction). Flexibility may be granted on a case-by-case basis.



2. Manufacturer Retest is still SATISFACTORY and no issues noted by Specialist during review of records. The Specialist may choose one of the following actions:

a. Follow [CVB-SOP-0047](#), *LSRTIS Special Test Request Procedures for Inspection and Compliance*, to request a double independent retest for the test in question.



ii. If the CVB test results are satisfactory after retest, the APHIS Form 2008 will be sent to Specialist Review.

1. APHIS Disposition = Other – Serial Released for Market
2. Check the box under Mock Check
3. Click on Release Criterial Required
4. Release Criteria = This rescinds the UNSATISFACTORY ACTION previously reported. Serial may be released.
5. SAVE

iii If the CVB test results are still unsatisfactory, follow the review of CVB-L records as outlined in Step 1, 2a. and 2b. The APHIS Form 2008 will be sent to Specialist Review.

If no issues are noted do the following:

1. APHIS Disposition = Tests Completed UNSATISFACTORY
2. Check the box under Mock Check
3. Click on Release Criterial Required
4. Release Criteria = This confirms the UNSATISFACTORY ACTION previously reported. Disposition to be made under supervision of APHIS.
5. SAVE

b. Determine the market release based on the data from the manufacturer's retest, no CVB retest. This is normally done only after a discussion with CVB-L regarding time, resources, [REDACTED] It should also be based on data and records reviewed and requires concurrence from an IC Section Leader.

i. If the serial is deemed marketable by the Specialist, the APHIS Form 2008 will be sent to Specialist review and processed as follows:

1. APHIS Disposition = Other – Serial Released for Market
2. Check the box under Mock Check
3. Click on Release Criterial Required
4. Release Criteria = This rescinds the UNSATISFACTORY ACTION previously reported. Serial may be released.
5. SAVE

ii. If the serial is NOT deemed marketable by the Specialist, the APHIS Form 2008 will be sent to Specialist review and processed as follows:

1. APHIS Disposition = Other – Serial NOT RELEASED FOR MARKET
2. Check the box under Mock Check
3. Click on Release Criterial Required
4. Release Criteria = Unsatisfactory Results – NOT TO BE RELEASED.
Disposition to be made under supervision of APHIS
5. SAVE

