§ 113.29 Determination of moisture content in desiccated biological products.

The moisture content shall be determined for each serial of desiccated product. The maximum moisture content for each product shall be established and an acceptable method used to determine the moisture content shall be described in an Outline of Production approved for filing by APHIS.

§ 113.30 Detection of Salmonella contamination.

The test for detection of Salmonella contamination provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in the filed Outline of Production for the product.

(a) Samples shall be collected from the bulk suspension before bacteriostatic or bactericidal agents have been added. When tissue culture products are to be tested, 1 ml of tissue extract used as the source of cells or 1 ml of the minced tissue per se shall be tested.

(b) Five ml of the liquid vaccine suspension shall be used to inoculate each 100 ml of liquid broth medium (tryptose and either selenite F or tetrathionate). The inoculated media shall be incubated 18–24 hours at 35–37 °C.

(c) Transfers shall be made to either MacConkey agar or Salmonella-Shigella agar, incubated for 18–24 hours and examined.

(d) If no growth typical of Salmonella is noted, the plates shall be incubated an additional 18–24 hours and again examined.

(e) If suspicious colonies are observed, further subculture on suitable media shall be done. If the test is positive, the source of contamination shall be determined.
Animal and Plant Health Inspection Service, USDA § 113.32

Detection of Brucella contamination.

The test for detection of Brucella contamination provided in this section shall be conducted when a test is necessary to maintain viability and samples harvested from each passage shall be tested for group specific antigen.

(4) Biological products or primary cells which are found contaminated with lymphoid leukosis viruses are unsatisfactory. Source flocks from which contaminated material was obtained are also unsatisfactory.


§ 113.32 Detection of Brucella contamination.

The test for detection of Brucella contamination provided in this section shall be conducted when such a test is

media shall be made for positive identification. If Salmonella is found, the bulk suspension is unsatisfactory.

[38 FR 29888, Oct. 30, 1973]

§ 113.31 Detection of avian lymphoid leukemia.

The complement-fixation test for detection of avian lymphoid leukemia provided in this section shall be conducted on all biological products containing virus which has been propagated in substrates of chicken origin: Provided, An inactivated viral product shall be exempt from this requirement if the licensee can demonstrate to Animal and Plant Health Inspection Service that the agent used to inactivate the vaccine virus would also inactivate lymphoid leukemia virus.

(a) Propagation of contaminating lymphoid leukemia viruses, if present, shall be done in chick embryo cell cultures.

(1) Each vaccine virus, cytopathic to chick embryo fibroblast cells, shall be effectively neutralized, inactivated, or separated so that minimal amounts of lymphoid leukemia virus can be propagated on cell culture during the 21-day growth period. If a vaccine virus cannot be effectively neutralized, inactivated, or separated, a sample of another vaccine prepared from material harvested from each source flock shall be used in the test. Before use, each sample shall be thawed and frozen three times to disrupt intact cells and release the group specific antigen.

(2) The antiserum used in the microtiter complement-fixation test shall be a standard reagent supplied or approved by the Animal and Plant Health Inspection Service. Four units of antiserum shall be used for each test.

(3) Presence of complement-fixing activity in the harvested samples (from passages) at the 1:2 or higher dilution, in the absence of anticomplementary activity, shall be considered a positive test unless the activity can definitely be established to be caused by something other than lymphoid leukemia virus, subgroups A and/or B. Activity at the 1:2 dilution shall be considered suspicious and the sample further subcultured to determine presence or absence of the group specific antigen.

(4) Biological products or primary cells which are found contaminated with lymphoid leukemia viruses are unsatisfactory. Source flocks from which contaminated material was obtained are also unsatisfactory.