A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

2 The importation and interstate movement of VS select agents or toxins listed in paragraphs (c)(1) through (c)(3) of this section may be subject to the permit requirements under part 122 of this subchapter.

3 However, the importation and interstate movement of nonviable select agents may be subject to the permit requirements under part 122 of this subchapter.
(e) An attenuated strain of a VS select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to animal health or to animal products.

(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification of the applicant. Exclusions will be published periodically in the notice section of the Federal Register and will be listed on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any VS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to APHIS or CDC.

(i) The seizure of any of the following VS select agents and toxins must be reported within 24 hours by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), bovine spongiform encephalopathy agent, classical swine fever virus, foot-and-mouth disease virus, Newcastle disease virus (velogenic), rinderpest virus, and swine vesicular disease virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the select agent or toxin.

(ii) For all other VS select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

§ 121.4 Overlap select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products.

(b) Overlap select agents and toxins:

- Bacillus anthracis;
- Brucella abortus;
- Brucella melitensis;
- Brucella suis;
- Burkholderia mallei;
- Burkholderia pseudomallei;
- Hendra virus;
- Nipah virus;
- Rift Valley fever virus;
- Venezuelan equine encephalitis virus.

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms: