Section 5 Exemptions

1. Clinical or diagnostic labs that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the select agent provisions (other than Section 14, Transfer) provided that all of the following apply:

    a. Upon identification of a select agent or toxin as the result of diagnosis or verification, the Principal Investigator immediately either transfers according to §73.16 or destroys on-site by a recognized sterilization or inactivation process within seven calendar days, unless otherwise directed by the HHS Secretary, and

    b. The select agent or toxin is secured against theft, loss, or release during the period between identification or the select agent or toxin and transfer or destruction of such agent or toxin and any theft, loss, or release of such agent or toxin is reported and

    c. The Principal Investigator reports to appropriate authorities, as required under other Federal, State, or local law; and to the Responsible Official

    d. The identification of any of the following select agents or toxins must be immediately reported by the Principal Investigator to the HHS Secretary by telephone, facsimile, or e-mail any of the following:

        - Variola major virus (Smallpox virus),
        - Variola minor (Alastrim),
        - *Bacillus anthracis*
        - *Brucella melitensis*
        - *Francisella tularensis*
        - Hendra virus
        - Nipah virus
        - Rift valley fever virus
        - Venezuelan equine encephalitis virus,
        - *Yersinia pestis*,
        - Botulinum neurotoxins,
        - *Francisella tularensis,*
        - Ebola viruses,
        - Marburg virus,
        - Lassa fever virus,
        - South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito);

    d. This immediate report is followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

e. For all other overlap or HHS select agents or toxins APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

f. A copy of APHIS/CDC Form 4 must be maintained for three years.

g. The Principal Investigator transfers in accordance with §73.16 or destroys on-site by a recognized sterilization or inactivation process those select agents or toxins used for proficiency testing within 90 days after receipt; and

h. The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin and any theft, loss, or release of such agent or toxin is reported

i. The Principal Investigator reports to appropriate authorities, as required under other Federal, State, or local law; and to the Responsible Official.

j. For all other overlap or HHS select agents or toxins APHIS/CDC Form 4 must be submitted within 90 calendar days after identification during proficiency testing.

k. A copy of APHIS/CDC Form 4 must be maintained for three years.

2. Unless the HHS Secretary issues an order otherwise, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use is only for the approved purpose and meets the requirements of such laws:

   a. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

   b. Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262);

   c. The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

   d. The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq*).

3. The HHS Secretary may exempt from the requirements of this part on a case-by-case basis an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under a Federal Act referred to in paragraph (2) of this section and additional regulation under this part is not necessary to protect public health and safety.

   To apply for an exemption a Principal Investigator must submit a completed APHIS/CDC Form 5 through the Responsible Official to the HHS Secretary certifying that the product is being used in an investigation authorized under a Federal Act referred to in paragraph (2) of this section, and that additional regulation under

this part is not necessary to protect public health and safety. The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. The Principal Investigator must notify the Responsible Official when an authorization for an investigation no longer exists, and the Responsible Official will notify the HHS Secretary. This exemption automatically ceases when such authorization is no longer in effect.

4. The HHS Secretary may temporarily exempt an entity from the requirements of this part, in whole or in part, based on a determination that the exemption is necessary to provide for the timely participation of the entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 days, except that the HHS Secretary may grant one extension of an additional 30 days.

   To apply for an exemption or an extension of an exemption, the Responsible Official must submit to the HHS Secretary a completed APHIS/CDC Form 5 establishing the need to provide for the timely participation of the entity in a response to a domestic or foreign public health emergency. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.