Summary Information Format for the Importation of Veterinary Biological Products into the United States

I. INTRODUCTION

The purpose of this Summary Information Format (SIF) is to provide the USDA-APHIS Center for Veterinary Biologics (CVB) with the necessary information to conduct a risk analysis for proposals to import unlicensed veterinary biological products into the United States, as described in 9 CFR 104. This includes proposals to import complete veterinary biological products licensed in other countries, experimental veterinary biologics in either final or bulk form, CVB-approved master seeds, CVB-approved master cells or diagnostic kits. Other forms of biologics will be considered, however cultures of microorganisms other than master seeds, cells other than master cells, recombinant material, animal products, human biologics, human diagnostic kits or other materials for research studies are typically not considered a veterinary biologic for importation purposes.

This SIF may be requested to support an import from any country, with special emphasis on imports from: 1) countries where foreign animal diseases or other diseases of concern exist, or 2) other specified countries that supplement their national meat supply by the importation of fresh, chilled, or frozen meat of ruminants or swine from, or 3) have common land borders with countries where foreign animal diseases exist, as provided in 9 CFR Part 94.

Completion of Section II is always required. Sections III and IV might be required based on the type of import request and guidance from CVB. Items that are not applicable should be marked as such.

II. PRIMARY INFORMATION

A. Characteristics of the imported biological material

1. Provide a thorough description of the product (product literature and publications should be attached as supplementary information):

2. If applicable, describe any live/viable components:

3. If applicable, describe any recombinant/genetically modified components:

4. If applicable, describe any inactivation methods and confirmatory testing:

5. If applicable, describe any extraneous agent or purity testing:

(a) If final product has not been tested, list testing conducted on all components:

(b) List any other testing or inactivation information relative to components in the product that should be considered when evaluating the risk of possible contamination of this product with extraneous micro-organisms or prions:

6. If applicable, indicate any product licensure in other countries:

B. Sources of materials

1. Country from which the biological product will be imported:
2. List other countries the biological product or components were developed in, originated from, or passed through:
3. List all ingredients of animal origin used in the development and production, and their sources:
4. List all other microorganisms in the production facility:

C. Describe the use of the material in the US

1. Location and biosafety level where the material will be stored and used:
2. Summary of the intended use (a detailed protocol should be attached as supplementary information for any products that will be used in animals, authorization from the State Veterinarian may also be required):
3. Handling and disposal of unused imported material, study waste, and carcasses (if applicable):

4. Are there similar/alternative products available in the US? If so, indicate why importation is still necessary. NOTE: Importation of unlicensed products with US sourced and licensed alternatives will require extensive justification.

III. SUPPLEMENTARY INFORMATION

This section is only required for permits for sale and distribution, **or** if requested by CVB after initial submission of the information above.

A. Production history of each biological component. This could include a vaccine microorganism, cell line, antibody, nucleic acid, diagnostic material, or other biological component. Provide this information for each component. Indicate if the component is a Master Cell or Master Seed as described in 9 CFR 101.6 and 101.7, respectively.

1. Identity and source of each microorganism or biological component:
2. Procedures used in the identification and purification of the biological component:
3. Procedures used to attenuate or genetically modify the biological component:
4. Procedures used for purity and extraneous agent testing, including the ability of testing procedures for detecting potential contaminating agents exotic to the U.S.:

B. Ingredients of animal origin (e.g. cells, serum, etc) used at any step of development or production. Provide the following information for each:

1. Indicate steps in which these ingredients were used:

2. Describe validation of testing procedures used to determine the absence of extraneous agents in each ingredient of animal origin prior to use:

3. Describe validation of treatment procedures to inactivate (or eliminate) extraneous agents in each ingredient of animal origin prior to use:

4. Methods used to verify accurate geographical origin of source materials:

C. Production media and any preservatives or additives used in production

1. Identity and source:

2. Quality control and/or sterilization procedures:

3. Purity testing:

D. Final product purity testing, including the sensitivity of testing procedures for potential contaminating agents exotic to the U.S.:

E. Packaging, labeling, and storage conditions for the final container samples:

F. Proposed shipping procedures and conditions:

IV. FACILITIES INFORMATION

This section is only required for permits for sale and distribution, **or** if requested by CVB after initial submission of the information above.

A. For each organism (master seed), cell (master cell), diagnostic kit material or other biological component:

1. Research/Development Facility: (if multiple components/locations, include the information for each)

(a) Location address:

(b) Description of activity:

(c) Biocontainment:

(i) Air-handling system:

(ii) Containment equipment (eg: biosafety cabinets):

(iii) Operational, validated procedures:

2. Production Step Facility: (if multiple components/locations, include the information for each)

(a) Location address:

(b) Description of activity:

(c) Facilities documents, one copy – see reference 9 CFR Part 108 and Veterinary Services Memorandum 800.78:

(d) List of functions performed in each area and validated cleaning procedures in place to protect against contamination:

(e) List validated biocontainment practices used to protect against cross-contamination:

(f) List of equipment used:

(i) Validated cleaning, sanitation and sterilization processes in place:

(ii) Calibration of equipment to determine if in proper working order: