Risk Analysis and Summary Information Formats for Veterinary Biologics

Last Modified:

The Center for Veterinary Biologics uses risk analysis procedures to evaluate: (i) license applications for new live conventionally derived and biotechnology-derived veterinary biologics, and (ii) proposals to import veterinary biologics into the United States. The following Summary Information Formats (SIFs) and Risk Assessment (RA) Outline identify the relevant information that should be evaluated in Veterinary Biologics risk analyses. See Veterinary Services Memorandum 800.205 (18.57 KB) for additional guidance.

Summary Information Format for Conventionally Derived Live Veterinary Biologics (13.26 KB)
This SIF is designed to identify the appropriate information that should be provided to properly characterize the vaccine microorganisms for conventionally derived live vaccines. The characterization of the vaccine microorganism is based on its microbiological and biological properties, and those of the parental microorganism from which the vaccine strain was derived. To be considered conventional and not derived by recombinant means under NEPA restrictions, the parental history and path to attenuation should be included.

SIF Category I Veterinary Biologics (163.51 KB)

Subcategories	
I-A-1	non-replicating recombinant antigens--therapeutic/prophylactic use
I-A-2	non-replicating recombinant antigens--diagnostics
I-B-1	monoclonal antibodies--therapeutic/prophylactic use
I-B-2	monoclonal antibodies--diagnostics
I-C-1	synthetic peptides --therapeutic/prophylactic use
I-C-2	synthetic peptides --diagnostics
I-D-1	nucleic acid-mediated--therapeutic/prophylactic use
I-D-2	nucleic acid-mediated--diagnostics

It is not anticipated that inactivated microorganisms will pose a threat to the environment. Accordingly, the risk analysis process is used to ensure that the biotechnology-derived microorganism is properly characterized and inactivated, rather than to evaluate proposed environmental releases of inactivated products.

SIF Category II Veterinary Biologics (166.1 KB)

Category II biologics include biotechnology-derived live vaccines containing gene deletions and\or heterologous marker genes.

SIF Category III Veterinary Biologics (165.7 KB)

Subcategories	
III-A	live vectored organisms
III-B-1	transgenic plant-based--therapeutic/prophylactic use
III-B-2	transgenic plant-based--diagnostics

As of December 2021, please utilize the revised Category I SIF (163.51 KB) in place of the Category IV SIF.

Risk Assessment Outline For Use in Preparing Risk Analyses For Biotechnology-Derived Products (56.78 KB) (July 9, 2015)
When submitting a Risk Analysis to the CVB for prelicense evaluation of a Category I, II, III, or IV biotechnology-derived product, the Risk Analysis should contain the most current version of the SIF and a Risk Assessment based on safety characteristics of

the vaccine.

Summary Information Format for Environmental Releases (15.17 KB)
Risk analyses for new live conventionally derived and biotechnology-derived veterinary biologics need to include environmental release assessments, which evaluate the safety characteristics of the vaccine microorganism within the context of the target environment. This SIF identifies the information that should be included in release assessments.

Summary Information Format for the Importation of Veterinary Biological Products into the United States (173.75 KB)
The Veterinary Biologics risk analysis model for importing veterinary biologics centers on the risk of introducing foreign animal disease into the United States through the importation of a contaminated veterinary biological product. This requires a thorough evaluation of all potential sources of contamination during the development and manufacture of the product. This SIF identifies the information regarding the facilities, reagents, production procedures, and testing procedures that should be evaluated.

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