United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Export Certificates and Certificates of Licensing and Inspection

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Entered into CVB Quality Management System
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1. Purpose

The Center for Veterinary Biologics (CVB) program implements the Virus-Serum-Toxin Act to ensure that veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent and effective. In support of satisfying the global demand for agricultural products, the CVB program provides certification to assist in the trade of veterinary biologics manufactured by licensees and permittees.

Licensees, permittees, or distributors may submit requests for certification regarding the preparation of the veterinary biological product and the marketability of those products in accordance with the Virus-Serum-Toxin Act [VSTA] (37 Stat. 832-833, 21 U.S.C. 151-158) and its regulations. This request may be either an Official Export Certificate for Animal Biological Products (APHIS Form 2017) or a Certification of Licensing and Inspection (APHIS Forms 2046, 2046-S, 2047, or 2047-S), formerly known as a Certificate of Free Sale. APHIS does not require either document for the export of licensed/permitted veterinary biological products. The authority to issue export documentation is granted under title 9, *Code of Federal Regulations* (9 CFR), part 112.2(e), and is further described in Veterinary Services Memorandum No. 800.52.

2. Export Documents

2.1 The Certificate of Licensing and Inspection (CLI) certifies that the manufacturer listed has been licensed and inspected as required under the laws and regulations of the United States. In addition, the document allows certification that the product(s) listed are also licensed, inspected, and freely marketed. This is a product based certification. CLIs include:

2.1.1 APHIS Form 2046 – Certificate for use with unrestricted product licenses provided in English language

2.1.2 APHIS Form 2046-S – Certificate for use with unrestricted product licenses provided in Spanish language

2.1.3 APHIS Form 2047 – Certificate for use with restricted product licenses provided in English language

2.1.4 APHIS Form 2047-S – Certificate for use with restricted product licenses provided in Spanish language

2.1.5 A statement regarding good manufacturing practices (Attestation)

2.1.5.1 This statement may be an appended page to the CLI or may be submitted as a stand-alone document. Refer to **Section 5** of this document.

2.1.6 A statement of ingredients of animal origin specific to the risk for the transmission of bovine spongiform encephalopathy. Refer to **Section 5** of this document.

Note: These statements may be an appended page to the CLI or may be submitted as a stand-alone documents.

2.2 The Official Export Certificate for Animal Biological Products (APHIS Form 2017) certifies the serials (batches) of product prepared by the listed manufacturer:

2.2.1 Are intended for the use in treatment of animals;

2.2.2 Have been prepared under a Veterinary Biological Product License/Permit; and

2.2.3 Are suitable for use in the United States. The APHIS Form 2017 can be used for both restricted and unrestricted licensed product and is a serial based certification. Only product released for market by CVB can be reflected on this certification.

2.3 APHIS Form 16-4 and 16-4A – Export Certificate for Animal Products is a form routinely used by the National Import Export Services. The CVB certifies this form on rare occasions for statement of ingredients used in production and the disease status in the United States.

2.4 Electronic copies of APHIS forms can be downloaded from the CVB Website or may be submitted using the NCAH Portal.

2.5 Requirements of Importing Countries – CVB does not maintain current knowledge of importing requirements. Additional information regarding exports can be found in the current version of **ICWI0063**, *Export Information*.

2.6 For the remainder of this document and applicable work instructions, the phrase "export document" will include both the APHIS Form 2017 and the Certificates of Licensing and Inspection. If a section applies to only one type of export document, it will be noted.

3. Definitions, Roles, and Responsibilities

3.1 Licensing, Serial Release, and Testing Information Service (LSRTIS)

The information system, LSRTIS, is used to process all export certification at the CVB. It integrates the licensing actions, market actions, compliance actions with export

certification requests. Access to this information is only available through APHIS designated personnel and equipment.

3.2 Export Manager – Secondary review and authorization may be conducted by an employee acting for the Export Manager. The Program Coordinator may assist with the certification of APHIS Forms 2017.

3.2.1 Reviews processes for all aspects of export certification to ensure consistent application of policy

3.2.2 Conducts secondary review of export documents

3.2.3 Authorizes (via signature) export documents

3.3 Export Document Examiner – The Biologics Compliance Assistants provide back up for support activities.

3.3.1 Enters incoming export requests into LSRTIS

3.3.2 Conducts preliminary review of export documents

3.3.3 Finalizes export documents

3.4 NCAH Portal – System used for the electronic submission of export documents.

3.4.1 It is only used by firm employees with specific designated NCAH Portal roles. It is not for APHIS Forms 16-4, 16-4A, or certificates with request to use the date when the product or establishment was first licensed.

4. Requests for Attestations and Other Non-Standard Information

4.1 Certain importing countries may require United States exporters to provide governmental attestation about the manufacturer or product beyond that stated on the standard certificate. The exporting entity may submit additional export documents to CVB for signature that fulfill the specific requirements of the importing country.

4.2 Requests for the CVB to attest to non-standard information are handled on a case-by-case basis. All statements on non-standard forms must be fully supported by data on file at the CVB. Statements that are too general to be fully supported by data on file shall not be signed. If the request is supplied in Spanish, a direct English translation must be provided.

4.3 Documents containing non-standard information must be appended to a certificate. The statements allowed as a separate document with a signature box are the

manufacturer's attestations and the ingredients of animal origin statements specific to the negligible risk of transmitting Bovine Spongiform Encephalopathy (BSE) from product manufactured in the United States of America.

4.4 The attestations indicate that the licensed veterinary biologics manufacturer is authorized to manufacture, package, and sell immunological veterinary medicinal products in the United States of America under the United States Veterinary Biologics Establishment License Number XXX using principles and practices of good manufacturing as required by the Virus-Serum-Toxin Act (37 Stat. 832-833, 21 U.S.C. 151-159) and the regulations and standards issued pursuant to the Act (title 9, *Code of Federal Regulations*, parts 101.1 et. Seq.)

A template of attestations may be obtained from CVB on request to be submitted as a hard copy or may be requested through the NCAH Portal.

4.5. Ingredients of animal origin statement specific to the negligible risk to transmit

BSE from U.S. Licensed products indicates that the United States of America is recognized as having a negligible BSE risk according to the *World Organisation for Animal Health*, also known as Office International des Epizooties (OIE).

TSE/BSE Statement:
Ingredients of animal origin used in the preparation of licensed veterinary biological products will be procured from materials in compliance with the regulations for importation, from sources eligible for entry in the United States and in compliance with all USDA requirements. By meeting all USDA requirements for the use of ingredients of animal origin, Establishment License XXX will produce licensed veterinary biological products that present negligible risk for the transmission of transmissible spongiform encephalopathy (TSE's) specifically Bovine Spongiform Encephalopathy, and other animal diseases foreign to the United States.

A template TSE/BSE statement may be obtained from CVB on request to be submitted as a hard copy or may be requested through the NCAH Portal.

4.6 APHIS Forms 16-4 and 16-4A are used on rare instances and for exporters that have received specific requests from a receiving country to use this form. The information declared in this form will match information on file at the CVB. The CVB encourages the exporters to use the routine export documents used by CVB.

4.7 The United States State Department requests a current sample of signatures for export documents. CVB supplied a list of signatures in the Year 2011. Evidently, this government organization comes across with certain CVB documents and they proof the wet signature. Signatures from CVB-Inspection and Compliance (IC) personnel not

included in this list may be subjected to export delays from the State Department. CVB will routinely supply a list to the State Department. Follow work instructions **ICWI0065**, *Submitting Letter to the U.S. Department of State Office of Authentications*.

5. Procedure

5.1 Receipt and Entry of Export Documents from Licensees, Permittees, or Distributors

5.1.1 Export documents are generated by the vaccine manufacturer or exporter. The documents are received hard copy, via mail or through the NCAH Portal. The requestor must use the hard copy forms listed on the CVB Website or the NCAH Portal user guides for further guidance. Submitters must follow the directions provided in Veterinary Services Memorandum No. 800.52.

5.1.2 Export documents are received and information is entered into the LSRTIS Database. NCAH Portal submissions are received real-time. See the current version of **ICWI0068**, *Entry and Primary Review of Export Documents, (APHIS Form 2017 and Certificates of Licensing and Inspection),* for detailed processes.

5.2 Primary Review of Export Document

5.2.1 The primary review of an export document is to ensure the document is complete and matches the data on file with CVB.

5.2.2 If the forms are incomplete or do not match the data on file with CVB, the form may be audited back to the requestor for correction. See the current version of **ICWI0075**, *Audits and Reference Slips for IC Documents*, for more information on process.

5.2.3 The preliminary review is documented using tools, such as Product License Profile, Serial Status, SharePoint, Mail Log, or any other tool that can be confirmed against information on file. The primary review is recorded in the LSRTIS database. See the current version of **ICWI0068** for detailed process.

5.2.4 Export Certificate for Animal Products (16-4) – Information is reviewed case by case. The CVB may use Veterinary Services security paper to process these requests. The decision to process this form is made by the Export Manager.

5.2.5 Discrepancies – If a discrepancy is identified on the certificate during the primary review that is verified by the official hard copy documents in the CVB

File Room or on the SharePoint site, audit the certificate back. See current version of **ICWI0075**.

5.3 Secondary Review of Export Documents

5.3.1 The secondary review of an export document is to determine sufficiency and acceptability of the information to be certified. It is also validation that the product is freely marketed in the United States, and the serial has been prepared in accordance with the VSTA and ensuing regulations.

5.3.2 The signing of the certificate does not exempt firms from following all applicable regulations and/or restrictions.

5.4 Returning Certificates to the Licensee/Distributor Using an Audit Form or a Reference Slip

If a discrepancy is found during either the primary or secondary review, the discrepancy should be noted. Depending on the severity of the discrepancy, either a reference slip or an audit form may be used to document the discrepancy. A reference slip notes a discrepancy that is minor and would not preclude the certificate being signed. However, an audit form documents a discrepancy that is severe enough to warrant not signing the certificate. A reference slip might be used to document minor spacing or punctuation errors. An audit slip would be used when incorrect or missing information was found. See the current version of **ICWI0075** for more information.

5.5 Finalizing Certificate Requests

Export documents reviewed and found to be acceptable are assigned an unique certificate number and a seal is applied. See current version of **ICWI0070**, *Finalization and Mailing of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection)*, for information regarding the process.

6. Additional Work Instructions for Using LSRTIS for Processing Certificates

Refer to the current versions of **ICWI0068, ICWI0069**, *Secondary Review of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection)*; **ICWI0070** and **ICWI0075**.

7. Summary of Revisions

Version .02

- Addition of NCAH Portal submissions.