Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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Import Permits for Research and Evaluation or Transit Shipment Only

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Import Permits for Research and Evaluation or Transit Shipment Only

Mention of trademark or proprietary product does not constitute a guarantee or warranty of the product by USDA and does not imply its approval to the exclusion of other products that may be suitable.

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1. Purpose and Scope

This chapter covers requirements and activities for the issuance of Center for Veterinary Biologics (CVB) import permits. As indicated in title 9, *Code of Federal Regulations* (9 CFR), part 104.1, "No biological product shall be brought into the United States unless a permit has been issued for such product." The CVB issues 3 kinds of import permits for veterinary biologics. Only permits for Research and Evaluation or for Transit Shipment Only are discussed in this document. Permits for Distribution and Sale are covered in CVB-SOP-0084.

The Research and Evaluation (R&E) Permit is for importation and use of an unlicensed veterinary biologic in the United States. These requests are common, and the material is generally either a vaccine or a diagnostic kit. The material is typically limited to *in vitro* or contained *in vivo* use, although this permit can also be used for field use of an imported unlicensed product in special situations. This chapter covers jurisdiction determination, application review, and processing of R&E permit applications. Note that material imported on an R&E permit may still require further authorizations. This includes permission to move anything into a licensed production area, or permission to ship the biologic elsewhere in the United States as described in 9 CFR 103.3.

The Transit Only permit is for transport of unlicensed material that would normally be under CVB jurisdiction from one foreign country to another by way of the United States. These requests are rare and generally fall into two categories. First, the product may go through a US port on the way to another country. Second, the product may be imported for use in animals being shipped from the US, but not while in the US. For example, foot and mouth disease (FMD) vaccine has been imported under the control of a Veterinary Services veterinarian to vaccinate cattle on a ship headed to another country. Both cases are considered transit since the product is not unpackaged or used within the US.

2. Related Documents

Regulations:
Title 9, *Code of Federal Regulations* (9 CFR), parts 104.1 – 104.7

Policy:
- NCAH Portal: https://ncahappspub.aphis.usda.gov/NCAHPortal/public/
- Portal permit application user guides: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/sa_ncah_portal_guidance/ct_vb_ncah_portal_user_guides
- APHIS Form 2005: https://www.aphis.usda.gov/library/forms/pdf/APHIS2005.pdf
- SIF for Importation: https://www.aphis.usda.gov/animal_health/vet_biologics/publications/SIF_import.pdf
- LSRTIS User Guide

3. Regulatory Jurisdiction of Imports

The first step in the import permit process is often determining the appropriate jurisdiction. The CVB only provides permits for veterinary biologics as defined in 9 CFR part 102. Veterinary biologics include vaccines, bacterins, toxoids, antiserum, antitoxins, diagnostic kits, and immunomodulators for the prevention, diagnosis, or treatment of animal diseases. Conversely, Veterinary Services, Animal Product Import and Export (APIE) provides permits for bacteria, viruses, toxins, et al (Organisms and Vectors) and cells, serum, antibodies, et al (Animal Products) that do not meet the specific criteria of a biological product. The APIE is granted an overarching authority under the Animal Health Protection Act that is not afforded to the CVB under the Virus-Serum-Toxin Act. Therefore, APIE regulates the import and interstate movement of material unless it is clearly identified by the permit applicant as a veterinary biologic. The permittee is responsible for submitting accurate information and understanding the nature of the material that they want to import.

There may be gray areas between the CVB and APIE. The CVB only has the authority to regulate veterinary biological products and cannot regulate the components of veterinary biological products, which may include potential master seeds, potential master cell lines, reagents, or manufacturing components. Thus, the CVB typically draws the line at "complete" or "final form" products. For example, a vaccine in a bottle that is ready to give to an animal is a final product and under CVB jurisdiction, but an attenuated or recombinant virus that might someday be a vaccine is an organism/vector under APIE jurisdiction. A complete diagnostic kit is under CVB jurisdiction, but an antigen or antibody to be used in an in-house diagnostic assay is under APIE jurisdiction. Although a diagnostic proficiency panel is used to support diagnostic testing, it is ultimately a collection of organisms or antibodies and therefore regulated by APIE. In cases where a jurisdiction case can be made for either the CVB or APIE, the most important consideration is that ultimately one of the units reviews the application and determines whether a permit should be granted.

Appendix 7.1 contains an example letter of no jurisdiction; this same language is often used in response to email inquiries as well. APIE applicants must use VS Forms 16-3 and 16-7 and submit via the APHIS e-permit system. Contact information for APIE is (301) 851-3300 or APIE@usda.gov.

Examples of requested materials that have received no jurisdiction responses from CVB include: bacterial/viral cultures, pig serum, human Zika virus kit, sheep bones, skin biopsies, human antibodies, archeological materials, gel capsules, pregnancy tests, milk powder, lung samples, pancreatic islets, pet treats, food, proficiency panels, and PCR primers.

4. Evaluating Import Applications for Research and Evaluation Permits

Consider the following areas when reviewing the permit applications. This SOP, however, may not account for every situation or detail. Apply and weigh the principles on a case-by-case basis.

4.1 Applicant Eligibility

Each person making application to import veterinary biologics shall reside, or operate a business, in the United States. Under U.S. law, only domestically produced products may be issued a license; therefore, foreign-produced product must be imported under a permit. The holder of the permit is therefore a U.S. entity importing the foreign-produced biologic for research and evaluation and is legally responsible for regulatory compliance.

Consider the affiliation and location of the applicant as part of the review. Specifically, CVB will generally not issue a permit to a home address, a mobile address (e.g., a boat on Puget Sound), or to someone with no affiliation to an established veterinary clinic, academic institution, commercial manufacturer, animal producer, or diagnostic laboratory. If the applicant uses their home address or a warehouse address, is not forthcoming about the purpose of the import, and wants to import a large quantity of vaccines or diagnostic kits, then they may intend to market them. Some importers think that importing "for research purposes only" means that they can market or distribute products to research facilities.

It is acceptable for a broker or assistant to be involved in the import process but not as the permit applicant/ holder. The applicant must be the end user of the product since the entity named on the permit is responsible for adhering to the permit conditions. The only exception is if the permit scenario includes a 9 CFR 103.3 restriction that, once fulfilled, allows the product to be moved elsewhere. Sometimes the e-Authentication account associated with the application is different than the applicant name. This may be acceptable if it means an assistant submitted the permit on behalf of the applicant.

4.2 Reviewing Data Fields from APHIS Form 2005

Applicants for R & E and transit permits must use the NCAH Portal; do not accept paper applications. Level 1 e-authorization is required for applicants to submit these permit applications, which is less than the level-2 authorization required for other biologics submissions. Review each entry on the Mail Log entry screen; these align with APHIS Form 2005. If any information is too vague, ask the applicant for more details. Specific details for the reviewer to consider include:

- **Previous Permit #:** This information is only to aid the reviewer if similar applications have been made in the past. Permits are valid for one year and cannot be renewed. Applicants must re-apply yearly to receive a new permit.
- **Name and Address of Applicant:** See applicant eligibility criteria above.
- **Name and Address of Producer:** This field refers to the producer of the product being imported. The country of origin is the most important factor and will be further discussed below. The producer organization is often the next most important thing to consider; does it appear to be a legitimate institution versus someone's home address? Sometimes the applicant will identify the producer but indicate in another field of the application that the material is being shipped from another location, such as a distributor; this is acceptable.

- **Product Name:** There is no required convention; usually the applicant lists the Trade Name. Only one product per permit is allowed. If the applicant wants to import multiple different products, then they need to apply for multiple permits.
- **Product Type:** This interface is a picklist, currently limited to Vaccine, Diagnostic kit, or Other.
- **In Vitro/In Vivo:** Clarifies whether the product will be administered to animals (*in vivo*) or not (*in vitro*) or both.
- **Product Description:** A general description of the vaccine or kit. Ensure that the description and/or Product Name includes, at a minimum, the information equivalent to that included in the True Name of a USDA-regulated biologic such as which antigens are in the product, whether its live or killed, recombinant or conventional, etc.
- **Product Use or Evaluation:** A brief description of intended use. This field is often enough to support approval of a diagnostic kit, but vaccines require additional documentation discussed below.
- **Estimated Arrival Date:** This information is most significant for transit permits (to arrange pick up) and to coordinate any pre-use safety testing of products under R&E (see Section 4.5).
- **Estimated Quantity**: The NCAH Portal currently limits entries to mL (for vaccines) and tests (for diagnostics). Consider the potential for illicit marketing if volumes seem unreasonably high for single institution use. Note that the quantity is not included in the final permit and is not tracked in any way once the permit is issued.
- **Port of Entry:** This defaults to "Any US Port" and currently can only be changed by the CVB. The most common reasons to limit the port of entry are to allow safety testing at the Foreign Animal Disease Diagnostic Laboratory (FADDL), Diagnostic Virology Laboratory (DVL), or to control transit shipments. Note: Sometimes the applicant may list a specific port e.g. FedEx hub in Memphis) and an arrival date that is a few days away. This may mean that they shipped the product without a permit. Since part 104.1(a) indicates that the shipment must have a permit before it enters the US, the CVB is not obligated to cut corners with import requirements or "rush through" an application if it is placed on hold by U.S. Customs.
- **Institution Info:** This will often be "same as applicant." If another institution is involved in the evaluation, such as a contract research organization, ensure it is listed here. If the applicant intends to move the material to another institution, a 9 CFR 103.3 restriction likely applies as described in Section 4.6.

4.3 Supporting Documentation

Some or all of the following documents may be necessary to evaluate an application; consider them on a case-by-case basis. These documents may be attached to the initial application, but often the reviewer will need to request these via email and subsequently upload them to the application. (The NCAH Portal functionality for R&E and transit permits does not include the ability for submitters to upload their own supporting documents subsequent to the initial submission.)

4.3.1 Import Summary Information Format (SIF)

Depending on the product being imported and the country where it is manufactured, an applicant may need to submit a SIF for the Importation of Veterinary Biological Products into the United States from Countries where Foreign Animal Diseases Exist and Other Specified Countries prior to issuing a permit. This SIF identifies critical information regarding the manufacturing facilities, reagents included in diagnostic kits, ingredients used in production, production procedures, and testing procedures to be evaluated when assessing the risk of importation. Key portions of the SIF may be required to evaluate the application even when the foreign country is not known to have foreign animal diseases of concern to APHIS. Required information typically includes inactivation procedures, inactivation confirmation testing, origin of any ingredients of animal origin included in the product or used in the manufacturing process, and a list of other organisms maintained in the producer facility.

4.3.2 Product Labeling Insert

If available, a product insert should be submitted with every application. This is strongly enforced with vaccines, but has become flexible for diagnostic kits due to the volume and repeated requests for the same kits. If the insert is not provided because of repeated applications, be sure a previous permit number, citing the location where an insert can be found, is listed.

4.3.3 State Veterinarian Approval

This may be requested to support any permit request but is typically limited to unique situations. Always ensure the applicant requests approval when an unlicensed biologic will be used in client-owned animals or animals outside of containment. Common examples include imported anti-venin or when an importer plans to share product with another in the same local area (which may be reasonable in an outbreak scenario). From a practical standpoint, the CVB never wants a State Veterinarian to be caught unaware if a controversial event occurs from the use of an unlicensed veterinary biologic. For example, repeat importation of a diagnostic test kit for an endemic disease for use in a State Diagnostic laboratory may not need approval, but importation of a vaccine that has the potential to trigger a program disease traceback into the State would need approval. If a new State approval is not provided for a repeat application, ensure that the Mail Log record links to the prior permit application where a State Vet approval is attached.

4.3.4 Study Protocol

Ensure that applications for all biologics other than diagnostic kits contain at least a brief protocol describing the intended use. This should, at a minimum, include where product will be stored, a description of any animals receiving the product, the location of the study, biosafety level, waste handling, and disposal method of animals from the study. As applicable, ensure there is assurance the animals given imported biologic will not

enter the food chain. If there have been previous studies, reviewers may request a summary of those studies.

4.3.5 Experimental Labels

In some cases an experimental label should be submitted for the file. The label must include an accurate description of the product, any warnings, and the statement "Unlicensed veterinary biological product for experimental use only, not for sale."

4.3.6 Client Consent Forms

Applicants must provide a copy of the client consent form they will use when administering product imported under an R&E permit in client-owned animals. The consent form, at a minimum, must include information similar to an experimental label (section 4.3.5) and a place for the client to confirm an understanding of this information. In an outbreak situation, the form might also instruct the client to keep proof of vaccination, especially if treatment might impact diagnostic testing.

4.3.7 Risk Analysis

The primary concern for evaluating CVB permits is the risk of introducing a foreign animal disease (FAD) into the US. In general, the CVB has an extremely low risk tolerance related to FADs. This is especially true for any product that contains ingredients of animal origin or is proposed for use in animals. For vaccines, the following information is minimally required and assessed for each situation. A description of the product and ingredients of animal origin including source, a product insert, a study protocol describing any animals being used, a description of vaccine storage facilities and animal study facilities including biosafety level, proposed treatment of lab waste, and treatment of animal waste and carcasses.

Diagnostic kits are generally given more flexibility, primarily because most kits are utilized by trained laboratories and not in contact with animals. However, some kits are not considered zero risk, so scrutinize diagnostic kits applications in regard to use (e.g., pen-side), country of origin, live components, and ingredients of animal origin.

Other factors may be relevant to the risk review. Are there alternative products available in the US? Does the country of origin have a recognized competent regulatory authority with oversight of the product? Does the foreign producer have a CVB permit for distribution and sale for other products? What is the quantity being requested? Is there a history of approvals for this applicant/producer? Is the applicant at a University with an Institutional Biosafety Committee (IBC) approval of the project?

Some items may not be relevant. For example, a request to import a live vaccine for dogs from a country with an FAD of concern to APHIS is not exempt from any requirements just because the dog is not known to be susceptible to the FAD. Likewise, a State

Veterinarian approval does not by itself supersede any requirements and does not mean the application will be approved.

4.3.8 Country of Origin

Applications can generally be grouped into risk scenarios based on country of origin. Consult the following sources to evaluate the FAD status of a particular country:

- https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions
- https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information
- https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/apm.pdf
- VS International Health also sends out real-time notifications from the World Organization for Animal Health (OIE) on disease outbreaks.

4.3.8.1 Country of origin has foot and mouth disease (FMD) virus

By default, the CVB will not approve for import any kit or vaccine, whether live or killed, from an FMD-positive country. Any consideration of unique circumstances requires the items below for other FADs, and the proposed evaluation is typically restricted to BSL-3 facilities.

4.3.8.2 Country of origin has other FADs of interest to APHIS

Whether the product is live or inactivated, err toward the conservative side on import decisions. Use the full Import SIF and study protocol as the basis for the risk analysis. For vaccines, a safety test is typically required. State Vet approval and facility restrictions (e.g. BSL-3) also may be warranted.

4.3.8.3 Country of origin is low FAD risk with caveats

In some cases, the APHIS Disease Status notes that a country, while free of a particular FAD, is in proximity, or has trade practices, with countries that are affected. Many EU countries fall into this category. For a live product, treat the product the same as if it were from a country with FADs and request additional information. For an inactivated product, request and review detailed information about the inactivation method and confirmatory testing. If satisfactory, safety testing may not be required.

APHIS-level risk assessments are performed for the import of certain commodities, e.g. meat, live animals, semen/embryos. Since these risk assessments do not address vaccine safety, the CVB is justified in requiring, for example, a safety test for CSF and/or FMD for the import of a live swine vaccine from the EU. Even with a safety test, the CVB would likely restrict the vaccine to use in containment under laboratory conditions, not in commercial herds/flocks. It would set a difficult precedent if, with

our extensive licensing process, the CVB allowed an unlicensed live vaccine to be used under commercial/field conditions.

4.3.8.4 Country of origin is free of FAD of concern to APHIS

At a minimum, request a subset of information from the Import SIF, including ingredients of animal origin, sources and history of seeds/cells, and a list of other organisms maintained in the facility. If this information and a study protocol raise no undue concerns, safety testing is typically not necessary. For an inactivated product, request and review detailed information about the inactivation method and confirmatory testing.

4.4 Safety Testing

As indicated above, some applications can only be approved subject to satisfactory safety testing by the National Veterinary Services Laboratories (NVSL). This typically occurs at the Foreign Animal Disease Diagnostic Laboratory (FADDL) on Plum Island for non-poultry FAD and in the Diagnostic Virology Laboratory (DVL) in Ames for poultry diseases.

Use the following procedure for NVSL-FADDL:

- Notify the applicant that, due to the risk factors or failure to provide satisfactory information, safety testing by the USDA is required. Use the following language, or equivalent applicable wording, in correspondence to the applicant: "This product must be safety tested at the USDA's Foreign Animal Disease Diagnostic Lab (FADDL) as a condition of import. If you wish to proceed, the CVB will notify FADDL, and a permit will be issued to allow importation to FADDL via John F Kennedy International airport. The product will be released to you only after satisfactory testing at FADDL. In most cases, transport and testing will cost $500 to $1,000, depending on the number of samples and pathogens tested. The exact cost is subject to project details."
- If the applicant agrees to proceed: Notify FADDL (FADDL Director, or currently Dr. Ming Deng) via email of the need for safety testing. Include a completed copy of the '[redacted] form found at K:\CVB PEL Shared\Risk Manager\CVB Permits & Docs.
- Issue an R&E permit to the FADDL Director to import the product to FADDL only via JFK airport.
- FADDL provides and instructs the applicant to complete the "PIADC Risk Assessment Questionnaire."
- Once safety testing has been completed, FADDL is authorized by this permit to transfer the material to the permittee

Use the following procedure for NVSL-DVL:

- Imported material must be addressed and imported directly to the National Veterinary Services Laboratories, [redacted]
  The permittee should contact NVSL for packing and shipping instructions.
- Prior to shipment, provide [redacted] with the following information: flight number, waybill number, date and time of arrival, and a copy of this permit. This information should also be sent via email to [redacted]
- Once safety testing has been completed, DVL is authorized by this permit to transfer the material to the permittee

4.5 Specific Application Scenarios

4.5.1 Diagnostic Kits

This is the most common permit request, often associated with biologics firms or university/commercial diagnostic laboratories. Often the target diseases are endemic, and seemingly similar alternatives may be licensed in the US. To date, applications have not been denied based on possible alternatives. Although kits imported under an R&E permit are not to be sold or distributed, the CVB recognizes that some laboratories may use these kits in fee-for-service testing.

4.5.2 Master Seeds and Cells

A common jurisdiction issue is whether the organism is currently an approved master seed/cell (regulated by the CVB) or an unapproved "master seed/cell" (regulated by APIE). An organism/cell is not truly a master seed/cell until it has been approved as such by the CVB. APIE might not know if something described by the applicant as a master seed/cell is currently approved or if the applicant is using the term because they want to get it approved someday. APIE might check with the CVB whenever they see the "master" terminology. A firm must have the necessary APIE permits to import an unapproved seed/cell into the US for confirmatory testing. Even with an APIE permit, these items may not be moved into a biologics production area without CVB approval. The CVB may require additional information and testing for such movement.

4.5.3 Live Vaccines

The CVB typically limits live vaccines to facilities where biocontainment can be assured. Additional risk analysis and scrutiny are needed prior to allowing outside of biocontainment.

4.5.4 Recombinant Vaccines

Recombinant vaccines or Master Seeds are acceptable only for use in a proper biocontainment facility or as part of an *in vitro* diagnostic kit. Do not approve live recombinants for use outside of containment due to NEPA requirements.

4.5.5 Prelicense Serials

Applicants pursuing a permit for General Sale and Distribution (S&D) must import pre-licensing serials for confirmatory testing, but they may not always identify the shipment as part of the pre-licensing process on their R&E permit application. Contact the CVB reviewer assigned to the applicant firm if there are questions and to ensure the importation is not premature. Occasionally applicants want to import a large quantity of product as soon as they apply for the S&D permit, before they have submitted an Outline of Production or any other preliminary information. Unless there are extenuating circumstances, decline such requests and instruct the applicant to reapply for the R&E permit once the reviewer has accepted supporting information.

4.5.6 Disease Emergency or Outbreak

In the case of a state or federal disease outbreak for which no USDA-licensed product exists, an R&E permit may be used to import product for use in the field. This typically is limited to inactivated products, preferably licensed in a country with proper regulatory oversight, and is subject to a CVB risk analysis. State Veterinarian approval is required, as well as approval by any relevant USDA programs.

4.5.7 FAD or USDA Program Diseases

Do not allow importation of vaccines against FADs or USDA Program diseases unless there is USDA approval from the appropriate program. Kits for USDA Program diseases, such as tuberculosis and brucellosis, are usually imported by State veterinary diagnostic labs. Do not allow importation of FAD diagnostic kits unless explicitly approved by the Director of the National Animal Health Laboratory Network (NAHLN). Historically specific applications have been approved after consultation with the NAHLN, NVSL, and upper management. Research use by reputable institutions may be approved with specific restrictions. Obtain State Veterinarian approval for the initial permit for kits for USDA Program diseases or FADs.

4.5.8 Select Agents

Do not allow vaccines for protection against Select Agents without additional federal approval. Safety testing would likely be required. Some diagnostic kits, such as those for brucellosis, may be approved if they do not contain live organisms or toxins. If there are questions, consult Program staff.

4.5.9 Product Manufactured in the US, Exported, and Re-Imported

Requests to re-import finished product are subject to restrictions in 9 CFR 104.2(d) and 104.4(d). Re-imported product may not be used in animals in the US. Small quantities may be re-imported under an R&E permit for *in vitro* testing only.

Re-importation of approved master seeds or cells originally prepared in the US may happen when a global company shuts down a facility. This situation may be approved, subject to a thorough history of the materials and a risk review. Ideally the vials have not been opened or manipulated in any way.

4.5.10 Antivenin/Antivenom

These products are frequently requested by southern US states and imported from Mexico or South America, based on justifications of why US products are not sufficient. Ensure that applications include a product description, justification, plan of use, client consent form, and State Vet approval.

4.6 Permit Conditions (Restrictions)

Reviewers must select the appropriate conditions to print on the permit. One or more of the following conditions is required on each permit. **See LSRTIS LOV Report for APHIS 2005 Conditions to see full text of each currently used restriction.** Reviewers may modify the syntax of each condition as applicable. *The permit automatically includes, "A copy of this permit must be included with the shipment for port inspection."*

Condition Title in LSRTIS	Use on Permits For
Antivenom Product	Antivenins, antivenoms
Diagnostic Test Kits	All diagnostic kits
Disclaimer only	All biological products other than kits, approved seeds/cells
Experimental Label Required	For products requiring an experimental label, usually those used outside of containment.
FADDL Safety Test	For non-poultry products requiring APHIS safety testing prior to being shipped to the permit applicant
NVSL Safety Test	For poultry products requiring APHIS safety testing prior to being shipped to the permit applicant
Product Evaluation Under 103.3	For products for which a Permit for General Sale and Distribution is being pursued. To import such products for "pre-license" evaluation before issuing the S&D permit.
Product Under Veterinary-Client-Patient Relationship	For products to be used in client-owned animals
Vaccine 104.4(d) Restriction	For product originally manufactured in the US, which was exported and is now to be re-imported in small quantities for in vitro research & evaluation
Vaccine Import Under Specific Conditions	For in vivo use specified in application.

5. Evaluating Import Applications for Transit Only Permits

Requests for transit permits are uncommon. When requested, require a sound justification for why a product needs to go through the US even though it can't be used here. These permits typically have a short expiration period (a couple months) to cover the anticipated transit timeline. Common application scenarios include:

5.1 Shipped through a US port

This is the most common reason for a transit permit. Even though the product will not be unpackaged or used in the US, Customs needs this permit to move the product through the port.

5.2 Research in another country

Occasionally an applicant will try to use a transit permit to bring product into the US with an explanation that they intend to take the product with them to another country for use. The CVB prefers these products be sent directly to the country where they will be used.

5.3 Vaccination of animals in transit

A transit permit is appropriate since the product is not unpackaged or used on US soil. The product is administered on a shipping boat departing the US for another country. The shipper must be working with a USDA VMO for this scenario. The VMO is the permit applicant and holder. Place a restriction on the permit similar to the one titled "Transit Shipment Specific for Inactivated FMD".

6. Processing Permit Applications in the Mail Log

Process all permits through the NCAH Portal. Instruct applicants who attempt to submit hard copy to resubmit via the Portal. Applicants for R&E or transit permits need only a Level 1 e-Authentication, less than that required for other submissions to the CVB.

- R&E and Transit applications will go to the Permit Pool tab in the mail log. From here, anyone with access to the pool can self-assign the ML to their own Active queue.
- The application should be reviewed based on the criteria discussed elsewhere in this SOP.
- If additional information is needed to make a decision, the ML item can be child looped to "request info from submitter." However, a request can't actually be sent this way, the information will need to be requested via another route such as email and then added to the ML.
- All fields should be checked for accuracy, the fields below require action. Click Edit Mail Item to start processing the application.
- The submitter frequently leaves the "Brief Submission Description" box blank. To

benefit future internal searches, a few words describing the product should be inserted by the reviewer. These can often be copy and pasted from the Product Name box further down the page.

- Select and add the appropriate Agents.
- Choose the Final Disposition:
    - Approved: a permit will be granted
    - Canceled: application is a mistake, duplicate or per request from submitter
    - Denied: application is appropriate but request not approved
    - No Jurisdiction: product is not a biologic regulated by CVB
- If the permit is approved, one or more Conditions (restrictions) must be selected and added. Note these can be edited as needed.
- Click Update
- If the application is approved, scroll down and click "Generate Report" to create the permit.
    - Review the permit wording for accuracy.
    - Permits should be limited to one page. If longer, the text should be edited or condensed to make the permit one page only.
    - The default expiration date is one year, this can be edited on the permit as needed.
    - Electronically sign the permit and check the "lock document after signing" box
    - Save the permit PDF to K:\CVB PEL Shared\Risk Manager\CVB Permits & Docs. The file name should be the same as the Permit No.
    - In the ML, click the documents tab and upload the signed permit as outgoing correspondence.
    - After uploading, return to the documents tab and confirm the correct and signed permit was added. There are no other internal checks before the permit is pushed to the portal.
    - Move the ML forward and choose Workflow completed-no records management.
- If the application is canceled, denied, or no jurisdiction
    - The appropriate template letter should be used and modified as needed for the applications. These letters are composed outside of the ML.
    - Templates are found at K:\CVB PEL Shared\Risk Manager\CVB Permits & Docs
    - The final letter should be converted to a PDF, and electronically signed.
    - Save the letter PDF to K:\CVB PEL Shared\Risk Manager\CVB Permits & Docs. The file name should be the same as the ML No.
    - In the ML, click the documents tab and upload the signed letter as outgoing correspondence.
    - After uploading, return to the documents tab and confirm the correct and signed letter was added. There are no other internal checks before the letter is pushed to the portal.
- Move the ML forward and choose Workflow completed-no records management.

7. Appendices

7.1 APPENDIX I: Example No Jurisdiction Letter

<date>

<applicant address>

Dear <name of applicant>:

Importation of a mammalian cell line is not regulated by the Center for Veterinary Biologics because it is not a veterinary biological product. Veterinary biologics include vaccines, bacterins, antitoxins, and diagnostic kits for the prevention, diagnosis, or treatment of animal diseases.

Please review the Import Guidelines on the following web page to determine if your item fits in one of these categories and therefore would not need an import permit: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/no-import-permit-req

If these Guidelines are not applicable to your item, submit an import permit application using Veterinary Services (VS) Form 16-3, *Application for Permit to Import or Transport Controlled Material or Organisms or Vectors*, through the ePermits portal. https://www.aphis.usda.gov/aphis/resources/sa_epermits/eauth-epermits

Please contact Animal Product Import and Export at (301) 851-3300 or at APIE@usda.gov for more information.

Sincerely,

<reviewer name>
Risk Manager
Center for Veterinary Biologics

ML xxxxx

7.2 APPENDIX 2: Example R&E Permit

United States
Department of Agriculture

UNITED STATES VETERINARY BIOLOGICAL PRODUCT PERMIT
RESEARCH AND EVALUATION

NO. VB-178485

Issued at Washington, D.C. on 04/14/2019

Expires: 04/15/2020

This permit is issued pursuant to the terms of the Act of Congress approved March 4, 1913 (37 State. 832), governing the preparation, sale, barter, exchange, shipment, and importation of veterinary biological products. So far as the jurisdiction of the U.S. Department of Agriculture is concerned,

John Doe
Super Laboratory
1234 Street, Ames, IA 50010
is authorized to import
ABC Company Salmonella ELISA Plates

This product is a Diagnostic to be used In Vitro

Product is a diagnostic ELISA kit containing plates coated with Salmonella antigen and a positive control antiserum produced in goats. No other ingredients of animal origin are included. The kit will be used to screen sheep samples for experimental purposes. Samples and unused imported material will be autoclaved.

prepared by
ABC Company
Jane Doe
1234 Rue, Paris, France

into the United States through the port of Any US Port
Importation shall be made subject to the following special conditions:
This importation is authorized in accordance with Title 9, Code of Federal Regulations, Part 104 for evaluation at the research/containment facility or diagnostic laboratory specified in the application filed with the Animal and Plant Health Inspection Service. All unused portions of imported materials must be autoclaved or incinerated before disposal. Imported materials have not been approved by the USDA for sale and distribution. Therefore any claims regarding the prevention, diagnosis, management or cure of animal diseases have not been proven.

A COPY OF THIS PERMIT MUST BE INCLUDED WITH THE SHIPMENT FOR PORT INSPECTION.

This permit may be revoked if the permittee violates or fails to comply with said Act, the regulations made thereunder, or the conditions specified herein.

04/14/2019
Date

for Director, Center for Veterinary Biologics Animal and Plant Health Inspection Service

APHIS FORM 2006 (APR 2001)

Signature Manifest

Document Number: CVB-SOP-5109 **Revision:** 01
Title: Import Permits for Research and Evaluation or Transit Shipment Only
Effective Date: 20 Jul 2020

All dates and times are in Central Standard Time.

CVB-SOP-5109 01 Import Permits for Research and Evaluation or Transit Shipment Only

Review for Doc Format

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QM Program Asst	11 May 2020, 01:48:27 PM	Approved

Director Final Approval

Name/Signature	Title	Date	Meaning/Reason
PAUL HAUER (PHAUER)	CVB PEL DIRECTOR	09 Jun 2020, 01:15:06 PM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
MARK PAGALA (MPAGALA)	Assistant Director	20 Jul 2020, 03:27:24 PM	Approved