

Biologics Export Certification - APHIS Forms 2046 and 2046-S

Page left intentionally blank. As this user guide is updated, the most recent changes will be listed here for ease of use.

Biologics Export Certification - APHIS Forms 2046 and 2046-S

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This guide is intended for use by firms using the NCAH Portal for handling APHIS Forms 2046 and 2046-S. It is expected that procedures described in [Veterinary Services Memo 800.52](#) will still be followed.

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 Some fields may look differently than the screenshots in this user guide depending on the browser you are using. Basic functionality should not be affected.

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ACCESS INFORMATION

For APHIS Form 2046 or 2046-S submissions, start by selecting the CVB section of the Portal and then navigating to the *Biologics Export Certification* section.

Please click any of the links on the left to navigate to the section you would like.

CVB - Center for Veterinary Biologics

Veterinary Biologics Production and Test Report (APHIS 2008)

- [Submission Form](#)
- [View Draft Submissions \(APHIS Form 2008\) to CVB](#)

Qualifications of Veterinary Biologics Personnel (APHIS 2007)

- [Submission Form](#)
- [View Draft Submissions \(APHIS Form 2007\) to CVB](#)

CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPL

- [Create New Submission to IC](#)
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- [Add/Replace Document To Eligible Submission](#)

VETERINARY BIOLOGICS REGULATORY E-SUBMISSION FORM - F

- [Create New Submission to PEL](#)
- [View Draft Submissions \(APHIS Form 2049\) to CVB](#)
- [Add/Replace Document To Eligible Submission](#)

Biologics Export Certification

- [Submission Form](#)
- [View Draft Submissions \(Biologics Export Certification\) to CVB](#)



IMPORTANT INFORMATION ABOUT ROLES

*Users with USDA eAuth Level 2 accounts and roles of **Export Contact, Liaison and/or Alternate Liaison** can enter and submit Export Certificate information.*

*Users with USDA eAuth Level 2 accounts and a roles of **Quality Review** can enter and view Export Certificate information, but cannot submit.*

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ENTERING INFORMATION TO BE SUBMITTED

Click on 'Submission Form' in the Biologics Export Certification section of the CVB Dashboard to enter information for an APHIS 2046 or 2046-S.

Biologics Export Certification

- [Submission Form](#)
- [View Draft Submissions \(Biologics Export Certification\) to CVB](#)

The 'Create- Biologics Export Certification' screen will be shown. Enter information as directed below. Additional fields may only appear for certain Export Types, so be sure that you have selected the correct form in the Export Type field.

NOTE: The certificate will be issued with the most current date the establishment license and the product license were issued. If the original establishment or product license date is requested, please submit this as a paper copy submission to the CVB. Alternatively, you may use this original license date detail in portal in an appended page of the certificate.

Create - Biologics Export Certification

[CVB Home](#) / Submission Form (Biologics Export Certification)

Fields with a red asterisk (*) are required.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number for this information is 0579-0013. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing the collection of information, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Establishment*	<input type="text" value="999 - Your Firm, Inc."/>
Site Address*	<input type="text" value="123 1st Street, Ames, IA 50010"/>
Export Type*	<input type="text" value="Aphis 2046"/>
# of Certificates Requested*	<input type="text" value="3"/>
Destination Country	<input type="text" value="Brazil"/>
Additional Descriptor	<input type="text" value="Formerly Doing Business as My Firm"/>

When you choose APHIS 2046 or APHIS 2046-S as the Export Type, these fields will appear.

Establishment - Users will only have the opportunity to enter information for the firm they are assigned to as users. *Establishment employees wanting to submit certificates on behalf of other companies may submit paper copies to the CVB.*

Site Address - The Establishment address on the certificate is chosen from the Site Address field. This field will only list the addresses in the Establishment License.

Export Type - Select the applicable export type from the list. *When 'Aphis 2046' or 'Aphis 2046-S' are selected, additional fields will show on the screen.

of Certificates Requested - Enter the number of certificates requested.

Destination Country - A destination country may be entered here by selecting from the drop down list.

Additional Descriptor - The additional descriptor field is used to facilitate the description of the establishment name as it was formerly known.

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ENTERING INFORMATION TO BE SUBMITTED - LICENSING

Click on the 'Add Product' button to start entering information in the Licensing section of the screen.

Licensing

Product Code* Product Name

Add Product

Click on the 'Add Product' button to start this section

After clicking on the 'Add Product' button, the Product Code and the Product Name fields will be shown.

Product Code - Click on the down arrow to select a different Product Code.

Licensing

Product Code* Product Name* Tradename

101500 Delete

Add Product

Click on the down arrow to select a different Product Code

NOTE: The Product Name and Tradename fields will appear differently depending on if you selected APHIS 2046 or APHIS 2046-S in the 'Export Type' field.

Product Name:

If you selected **APHIS 2046** as the Export Type, then the Product Name (true name) will be autopopulated dependent on the Product Code selected.

Licensing **APHIS 2046 example**

Product Code* Product Name Tradename

264853 Escherichia Coli Bacterin Delete

Add Product

Product Name autopopulated

If you selected **APHIS 2046-S** as the Export Type, then you will have to enter the Product Name in Spanish.

Licensing **APHIS 2046-S example**

Product Code* Product Name* Tradename

264853 Delete

Add Product

Type in the Product Name in Spanish

Biologics Export Certification - APHIS Forms 2046 and 2046-S

NOTE: The Product Name and Tradename fields will appear differently depending on if you selected APHIS 2046 or APHIS 2046-S in the 'Export Type' field.

Tradename:

If you selected **APHIS 2046** as the Export Type, then you will select the Tradename from a drop down list.

Licensing **APHIS 2046 example**

Click on the down arrow and select the appropriate Tradename from the list.

Product Code*	Product Name	Tradename	
264853	Escherichia Coli Bacterin	<input type="text" value="E-Bac"/>	<input type="button" value="Delete"/>

Misc

Appended Pages File

Note: You may add optional :

Additional Submission Files

Note: You may add optional :

Label Numbers

AE-Pox Vac

AR-PAC-PD+ER

Bar-Guard-99

Circumvent PCV G2

Defensor 1

Defensor 3

E-Bac

Ecoli-Guard Cow-Sow

Galaxy 6 MHP

Hatchgard-3

Not Listed

Quantum Cat HCP

Salmo Shield TD

TALOVAC 105 ND

Vanguard 5/B

Vanguard B

If you selected **APHIS 2046-S** as the Export Type, then you will have to enter the Tradename.

Licensing **APHIS 2046-S example**

Product Code*	Product Name*	Tradename	
264853	<input type="text"/>	<input type="text"/>	<input type="button" value="Delete"/>

Type in the Tradename

i You may add up to five "Non-Restricted" products to this form by clicking on the 'Add Product' button again, as long as the appended pages (if applicable) apply to the other products.

Licensing

Product Code*	Product Name	Tradename	
264853	Escherichia Coli Bacterin	E-Bac	<input type="button" value="Delete"/>
101100	Anthrax Spore Vaccine, Live Culture		<input type="button" value="Delete"/>

Use the 'Delete' button to delete a product from the form.

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ENTERING INFORMATION TO BE SUBMITTED - MISC

Misc

Appended Pages File

Note: You may add optional attachment that contains pages to be appended to final result.

Additional Submission Files

Note: You may add optional attachments if you would like to add a cover letter/shipping info/etc.

Appended Pages File - Use the 'Browse' button to attach a file here that contains pages to be appended to the final certificate as per VS Memo 800.52.

Additional Submission Files - Use the 'Browse' button to attach a file here that contains pages that provide other pertinent information, but will NOT be appended to the final certificate, i.e.a cover letter or air bill.

Label Numbers - Enter the 5-digit assigned APHIS label number. To add additional label numbers, click on the blue '+' button to show another row.

NOTE: This field is for CVB reference only; labels to used for the certificate must be included in the Appended file.


Label Numbers	43525				Click on the '+' button to add more label number fields; enter the appropriate label numbers. Use the '-' button to remove label number fields.
	80809				
	90005				

Remarks - Use this section to enter any additional details about this submission.

Checkbox - Checking this box indicates that the user agrees with this statement, "I agree that I've looked over this information and everything entered is true to my knowledge."

Remarks

I agree that I've looked over this information and everything entered is true to my knowledge.



Save button - Click on the 'Save' button. This saves the submission and places it in a pending status. It is considered a "Draft" at this stage and has NOT been submitted to the CVB. This provides an opportunity to quality check the information entered prior to submission.

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After you have clicked on the 'Save' button, you will see the Submission History section at the bottom with a list of actions for the submission. At this point, you have additional options such as; Edit, Clone, Submit to CVB (only for some roles), Delete Submission and Return to Dashboard.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-06-2018 09:20 AM CST	Peterson, Amber	

[Edit](#)
[Clone](#)
[Submit To CVB](#)
[Delete Submission](#)
[Return to Dashboard](#)


Edit - Use this button to go back and make changes to the information entered or the files attached for the submission.

Clone - Use this button to duplicate the submission, creating a new submission identical to this one.

Submit To CVB - Only available to users with the roles of Export Contact, Liaison and/or Alternate Liaison. This button submits the submission to the CVB.

Delete Submission - Use this button to delete the submission completely.

Return to Dashboard - Use this button to go back to the CVB Dashboard.

 If changes are made to a submission, that action is captured in the Submission History.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-06-2018 09:20 AM CST	Peterson, Amber	
Submission Updated	Mar-06-2018 09:53 AM CST	Peterson, Amber	

Example of what you see after editing a submission

[Edit](#)
[Clone](#)
[Submit To CVB](#)
[Delete Submission](#)
[Return to Dashboard](#)

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SUBMITTING - Export Contacts, Liaisons and/or Alternate Liaisons only

You may submit the certificate to the CVB immediately after saving it or through the CVB Dashboard. The Draft submissions (pending submission to the CVB) are visible in the CVB Dashboard for the employees with specific portal roles.

The screenshot shows the NCAH Portal interface. At the top, there is a green navigation bar with 'NCAH Portal', 'Dashboard', and 'Submission History'. Below this is a 'Dashboard' section with a sidebar menu containing 'CVB' (highlighted), 'NVSL', 'Submission History', 'Application Messages', and 'Account Details'. The main content area is titled 'CVB - Center for Veterinary Biologics' and lists several submission categories:

- Biologics Sample Submission (APHIS 2020)**
 - [Sample Submission Form](#)
 - [Generate Packing Slip](#)
 - [Processed Samples](#)
- Veterinary Biologics Production and Test Report (APHIS 2008)**
 - [Submission Form](#)
 - [View Draft Submissions \(APHIS Form 2008\) to CVB](#)
- Qualifications of Veterinary Biologics Personnel (APHIS 2007)**
 - [Submission Form](#)
 - [View Draft Submissions \(APHIS Form 2007\) to CVB](#)
- CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE**
 - [Create New Submission to IC](#)
 - [View Draft Submissions \(APHIS Form 2048\) to CVB](#)
 - [Add/Replace Document To Eligible Submission](#)
- VETERINARY BIOLOGICS REGULATORY E-SUBMISSION FORM -**
 - [Create New Submission to PEL](#)
 - [View Draft Submissions \(APHIS Form 2049\) to CVB](#)
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When the "View Draft Submissions (Biologics Export Certification) to CVB" screen is opened a list of any submissions in the draft status is shown. Submissions can be reviewed when you select the "More Info..." link in the row for that submission.

When you are ready to submit to the CVB, you may select an individual submission or multiple submissions by clicking in the checkboxes next to each submission and then clicking on the 'Submit To CVB' button.

In the example below, the top two submissions would be submitted to the CVB when the 'Submit To CVB' button is clicked.

Biologics Export Certification Open Submissions

[CVB Home](#) / [Open Submissions \(Biologics Export Certification\)](#)

Select Open Submissions (Biologics Export Certification) To Submit To CVB

	Establishment	Type	Product Code(s)	Destination Country	
<input checked="" type="checkbox"/>	999	Aphis 2046	264853	Brazil	More Info...
<input checked="" type="checkbox"/>	999	Aphis 2046	264853	Brazil	More Info...
<input type="checkbox"/>	999	Aphis 2046	264853	Brazil	More Info...

 Submit To CVB

WHAT TO EXPECT AFTER SUBMISSION

When the APHIS 2046 or 2046-S is received by the CVB, it is evaluated for certification eligibility. Notification of status changes will be shown on the NCAH Portal Updates email that is sent for all NCAH Portal activity for the firm.



NCAH Portal Updates!



The following Submissions have been updated by CVB in the NCAH Portal today:


Biologics Export Certification Submissions:

Export Type	Product Code(s)	Destination Country	Status
Aphis 2017	142120	Brazil	Completed
Aphis 2046	142120, 264853	Bosnia And Herzegovina	Completed
Aphis 2046-S	142120, 264853, 190526, 205100	Bosnia And Herzegovina	Completed
Aphis 2047	500400	Belgium	Completed
Aphis 2047-S	500400	Mexico	Completed
Ingredients of Animal Origin		Anguilla	Completed
Ingredients of Animal Origin		Belarus	Completed

[Click Here to view detailed information about these and other Submissions](#)



The blue bar will guide you to log in to the NCAH Portal.

 **NOTE:** The records will only be available in the NCAH Portal for 60 days after completion.

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CHECKING YOUR SUBMISSION STATUS

After you've submitted you can check the status of all your submission in the 'Submission History' section of the CVB Dashboard.

Pay attention to the tabs at the top of the Submission History screen.

Recent Activity (2 weeks) - shows items that have had actions of them by you or the CVB in the last 2 weeks

Submissions Not Yet Received - shows items that you have not yet submitted to the CVB

CVB Search - use this to search for all items by type, select "Biologics Export Certification" in the 'Form' field

i If you want to see the full submission, click on the 'Info' link in the row.

If your submission is Audited or Completed, you will see that as the status in the Submission History, as well as in the email.

Biologics Export Certifications

Show entries Search:

Est	Type	Product Code(s)	Destination Country	Status	Submitter	Submission Date	
999	Aphis 2046	264853	Brazil	Completed	Ruben Osorio	12/11/2017	Info
999	Aphis 2046	264853	Brazil	Submitted	Ruben Osorio	12/11/2017	Info
999	Attestation		Mexico	Audited	Ruben Osorio	12/11/2017	Info
999	Aphis 2047-S	190526	Mexico	Submitted	Ruben Osorio	12/11/2017	Info
999	Ingredients of Animal Origin		Mexico	Completed	Ruben Osorio	12/11/2017	Info

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YOUR OFFICIAL CERTIFICATE

Within the record, scroll to the Miscellaneous section. Included in the files there will be an example of the certificate. This CVB Response file will not include the embossed seal or the wet signature.

 **NOTE: The official certificate will be mailed to the submitter.**

Licensing

Products	Product Code	Product Name	Tradename
	264853	Escherichia Coli Bacterin	E-Bac

Miscellaneous

- Attachments
 - [appended pages.pdf](#) 
- CVB Response Files
 - [Export_18-00025.pdf](#)
 - [Export_18-00026.pdf](#) 
 - [Export_18-00027.pdf](#)

At the bottom of the record, the Submission History is shown.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-06-2018 09:20 AM CST	Peterson, Amber	
Submission Updated	Mar-06-2018 09:53 AM CST	Peterson, Amber	
Submitted To CVB	Mar-06-2018 01:08 PM CST	Peterson, Amber	

