

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 <u>Veterinary Services Memo 800.52</u> will still be followed.

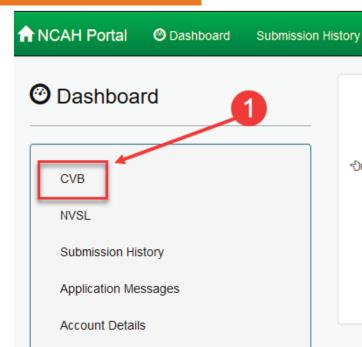
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Some fields may look differently than the screenshots in this user guide depending on the browser you are using. Basic functionality should not be affected.



Biologics Export Certification - APHIS Forms 2046 and 2046-S

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.

the 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
- View Draft Submissions (APHIS Form 2048) to CVB
- 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.



ENTERING INFORMATION TO BE SUBMITTED

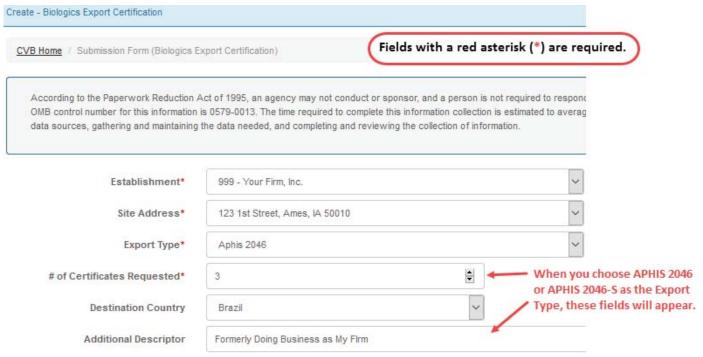
Click on 'Submission Form' in the Biologics Export Certification section of the CVB Dashboard to enter information for an APHIS 2046 or 2046-S.

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.



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.



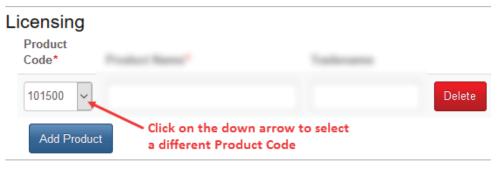
ENTERING INFORMATION TO BE SUBMITTED - LICENSING

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



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.



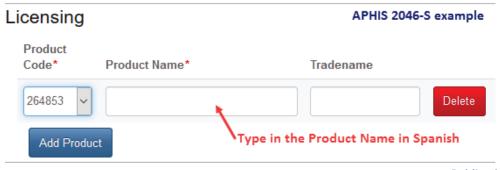
NOTE: The Product Name and Tradename fields will appear differently depending on if you selected APHIS 2046 or APHIS 2046-S in the 'Export Type' field.

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.



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





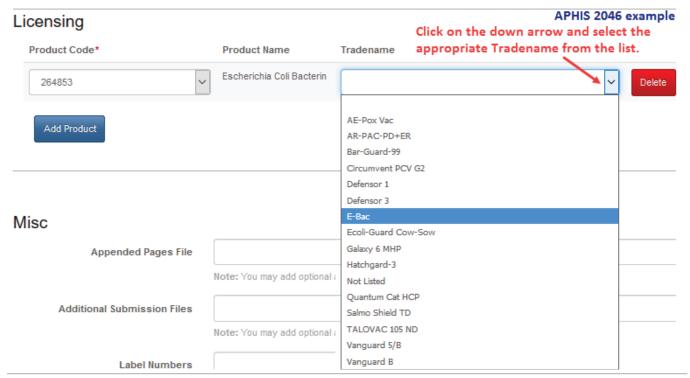
Biologics Export Certification - APHIS Forms 2046 and 2046-S



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:

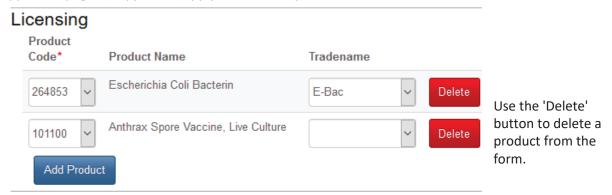
If you selected APHIS 2046 as the Export Type, then you will select the Tradename from a drop down list.



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



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 appicable) apply to the other products.





Biologics Export Certification - APHIS Forms 2046 and 2046-S

ENTERING INFORMATION TO BE SUBMITTED - MISC

Misc		
Appended Pages File		🗁 Browse
	Note: You may add optional attachment that contains pages to be appended to final result.	
Additional Submission Files		🚡 Browse
	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.



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."



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 - 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.

Submission History

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

Clone Submit To CVB Delete Submission

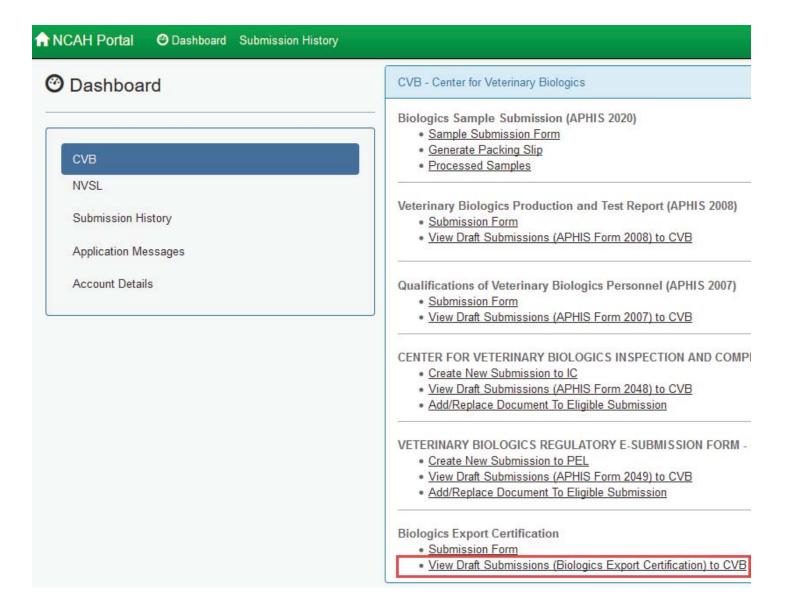
Return to Dashboard



Biologics Export Certification - APHIS Forms 2046 and 2046-S

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.





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	Туре	Product Code(s)	Destination Country	
\square	999	Aphis 2046	264853	Brazil	More Info
	999	Aphis 2046	264853	Brazil	More Info
	999	Aphis 2046	264853	Brazil	More Info



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.

extstyle ext



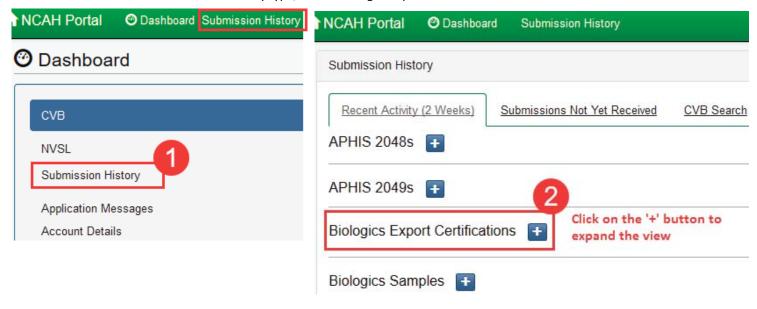
CHECKING YOUR SUBMISSION STATUS

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.

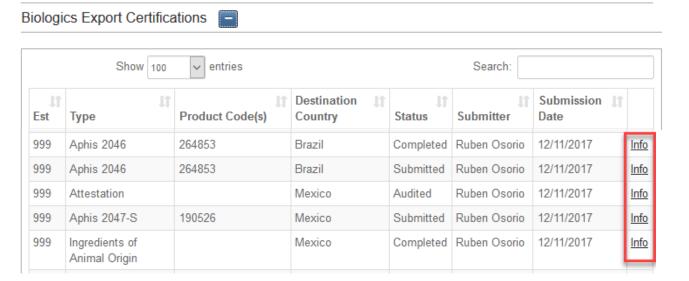
Recent Activity (2 weeks) - shows items that have had actions of them by you or the CVB in the last 2 weeks **Submissions Not Yet Received** - shows items that you have not yet submitted to the CVB

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



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.





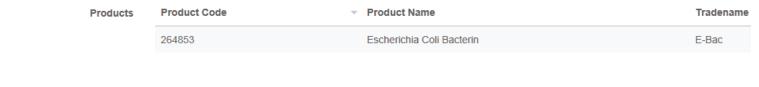
YOUR OFFICIAL CERTIFICATE

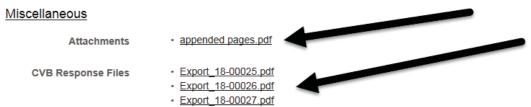
Within the record, scroll to the Miscellaneous section. Included in the files there will be an example of the certificate. This CVB Response file will not include the embossed seal or the wet signature.



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

Licensing





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	

