



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 16-14

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron E. Rippke
Director

SUBJECT: Expansion of the National Centers for Animal Health (NCAH) Portal for the Center for Veterinary Biologics

I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) is expanding the functionality of the web-based NCAH Portal by adding to the type of submissions that can be processed. This expansion will include APHIS Form 2048, Center for Veterinary Biologics Inspection and Compliance E-Submission Form, and APHIS Form 2049, Veterinary Biologics Regulatory E-Submission Form Policy, Evaluation, and Licensing.

II. BACKGROUND

The NCAH Portal is external-facing and enables web-based electronic submissions and responses between biologics firms and the CVB. The first phase of implementation included submissions for APHIS Form 2007, Qualifications of Veterinary Biologics Personnel; APHIS Form 2008, Veterinary Biologics Production and Test Report; and APHIS Form 2020, Shipment and Receipt of Biologics Samples, from all licensees and permittees on June 6, 2016, as communicated to stakeholders in CVB Notice No. 16-05.

III. ACTION

- A. Beginning September 15, 2016, all licensees and permittees may also submit most remaining types of correspondence to the CVB through the NCAH Portal using APHIS Forms 2048 and 2049. The NCAH Portal replaces hard copy submissions and submissions on electronic media, as described in CVB Notice No. 13-13. This phase specifically excludes facility documents, export certification, Outlines of Production, and Special Outlines.
- B. Veterinary biologics establishments must complete the following to gain access to the NCAH Portal:

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1. Each **employee** using the NCAH Portal must have a USDA Level 2 eAuthentication username. Detailed instructions are found at <https://www.eauth.usda.gov>.
2. Each **employee** must also have an active APHIS Form 2007 on file with the CVB.
3. Refer to the “Description of Portal Roles” on the CVB Website, which explains the NCAH Portal access each role has at https://www.aphis.usda.gov/animal_health/vet_biologics/publications/PortalRoles.pdf
4. Prior to CVB enabling NCAH Portal access for a licensed firm or permittee, at a minimum, each **firm** must have employee(s) who serve in the following CVB-authorized roles to have full NCAH Portal functionality:
 - Liaison or Alternate Liaison
 - Government Sampler

There are **no** changes in the process of the CVB authorization of liaison, alternate liaison, or sampler. These CVB authorizations will be processed by the assigned Reviewer or Specialist for the firm.

Other employees from the firm may be added as NCAH Portal users as needed. Various roles, having different read/edit/submit privileges, are available.

5. Email CVB at CVB.PIMS@aphis.usda.gov and provide the employee’s name, USDA Level 2 eAuthentication username, and NCAH Portal role(s). Firm employees can have multiple NCAH Portal roles. CVB will then enter this information into the Licensing, Serial Release, and Testing Information System (LSRTIS) and reply to the firm when this is completed.
6. There is mandatory annual information security awareness training for each NCAH Portal User. Each user will have to complete this security training prior to using the NCAH Portal the first time, and once a year thereafter. Information security training is available on the homepage of the NCAH Portal. The security training completion date will be listed in the “Accounts Details” of the “User Info” in the NCAH Portal and includes a link for renewing security training as required.
7. Each time an authorized NCAH Portal User logs on to the Portal, they will be presented with a warning banner that displays the following information:
 - You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.
 - Unauthorized or improper use of this system may result in civil and criminal penalties.

By using this information system, you understand and consent to the following:

- You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, the Government may, for any lawful government purpose, monitor, intercept, search, and seize any communications or data transiting or stored on this information system.
- Any communications or data transiting or stored on this information system may be disclosed or used for any lawful government purpose.
- Your consent is final and irrevocable. You may not rely on any statements or informal policies purporting to provide you with any expectation of privacy regarding communications on this system, whether oral or written, by any other official except USDA's Chief Information Officer.

8. Rules of behavior specific for submitting information via the NCAH Portal include the following:

- You will accept **all** CVB electronic responses via the NCAH Portal and understand responses will only be available for **60 days** after the CVB response is completed.
- Hard copy responses will **not** be provided by CVB for submissions received from the NCAH Portal.
- You will promptly report any information security incidents involving the use of the NCAH Portal to the CVB.

C. Submission guidance may be found on the NCAH Portal Guidance page of the CVB Website. This page includes user guides, training videos, and other useful information regarding the NCAH Portal.

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/sa_ncah_portal_guidance/ct_cvb_portal_guidance

D. The NCAH Portal Website address is

<https://ncahappspub.aphis.usda.gov/NCAHPortal/public/>.

E. The CVB will notify users of any scheduled system maintenance or issues by posting messages on the home page of the NCAH Portal, as well as on the NCAH Portal Guidance page of the CVB Website.

F. If you experience any technical issues using the NCAH Portal for CVB submissions, please email us at CVB.PIMS@aphis.usda.gov. The CVB is willing to schedule webinars or conference calls to discuss any specific issues or problems with using the NCAH Portal. Teleconferences are highly recommended prior to submitting to CVB-Policy, Evaluation, and Licensing using APHIS Form 2049 for those users who have not been submitting on electronic media per CVB Notice No. 13-13.

IV. IMPLEMENTATION/APPLICABILITY

Implementation of the NCAH Portal for APHIS Forms 2048 and 2049 is scheduled to begin September 15, 2016. Electronic submission via the NCAH Portal is strongly encouraged, as those submissions will be processed by CVB prior to paper-based submissions.