Privacy Impact Assessment for CVB Licensing, Serial Release & Testing (LSRTIS)

Technology, Planning, Architecture, & E-Government

- Version: 1.6
- Date: July 24, 2014
- Prepared for: USDA OCIO TPA&E

United States Department of Agriculture

Privacy Impact Assessment for the

CVB Licensing, Serial Release & Testing (LSRTIS) Application

July 24, 2014

Contact Point
Rod Chitty
APHIS Veterinary Services
United States Department of Agriculture
(515) 337-7816

Reviewing Officials
Tonya Woods
Director, Freedom of Information and Privacy Act Staff
United States Department of Agriculture
(301) 734-8296

Danna Mingo
APHIS Information Security Branch
United States Department of Agriculture
(301) 851-2487

Abstract

- This Privacy Impact Assessment (PIA) is for the USDA, APHIS, Veterinary Services (VS), Center for Veterinary Biologics (CVB) Licensing, Serial Release & Testing (LSRTIS).
- The Licensing Serial Release and Testing System (LSRTIS) allows the Center for Veterinary Biologics (CVB) to manage information related to licensing programs and processes. LSRTIS supports the following USDA-APHIS-VS-STAS CVB processes and associated data and services:
    - Veterinary Biologics Establishments and Products – Licensing
    - Veterinary Biologics Products Serial Release
    - Veterinary Biologics Products Testing
    - Veterinary Biologics Products Compliance
    - Veterinary Biologics Establishments and Products - Inspection
    - Veterinary Biologics Product Export Certification

- This PIA was conducted because the system collects personally identifiable information.

Overview

The overview is the most important section of the PIA. A thorough and clear overview gives the reader the appropriate context to understand the responses in the PIA. The overview should contain the following elements:

- The CVB-LSRTIS system is owned by USDA-APHIS-VS-STAS CVB.
- The system will allow APHIS-VS-STAS CVB to receive and process electronic submissions from Veterinary Biologics Firms related to licensing and releasing serials of Veterinary Biologics Products. The system allows CVB to capture detailed information about firms, establishment licenses, product licenses, product serials, product sample test results to enable decisions relating to new product licensing, serial release and inspection and compliance of Veterinary Biologics firms.
- CVB-LSRTIS contains information about Veterinary Biologics firms (e.g. name, contact information, etc) and information about a firm's products and production sites.
- Information entered into CVB-LSRTIS is received from various firm submission forms and APHIS Forms (i.e. 2001, 2003, 2005, 2007, 2008, 2015, 2017, 2046, 2047, and 2020) via fax (printed copy) or mail (hard copy).
- CVB-LSRTIS currently has an Authority to Operate (ATO) which was issued on March 11, 2011.

Section 1.0 Characterization of the Information

The following questions are intended to define the scope of the information requested and/or collected as well as reasons for its collection as part of the program, system, rule, or technology being developed.

1.1 What information is collected, used, disseminated, or maintained in the system?

The system collects the following types of information:

Customer:

- Veterinary Biologics Firm Name
- Subsidiary/Division Names
- Firm Address (Multiple Administrative & Production Sites)
- Firm Contact Name
- Firm Contact Phone No.
- Firm Contact e-mail
- Firm Contact Educational Credentials
- Firm Contact Position at Firm and no. of years at Firm

APHIS-VS-CVB Employee:

- Employee Name
- Employee Job Title
- Employee Business Phone no.
- Employee E-mail
- Employee Supervisor
- Employee Organizational Group within NVSL and CVB

Other:

- Information about firm products and firm production sites to support licensing and monitoring of Veterinary Biologics Products

1.2 What are the sources of the information in the system?

The sources of information in the system are from multiple firm and product licensing request submissions from firms and APHIS Forms 2001, 2003, 2005, 2007, 2008, 2015, 2017, 2046, 2047, and 2020.

1.3 Why is the information being collected, used, disseminated, or maintained?

Under the 1913 Virus–Serum–Toxin Act, further amended by the 1985 Food Security Act, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring that all veterinary biologics produced in or imported into the United States are pure, safe, potent, and effective. This regulatory activity is accomplished by Title 9, Code of Federal Regulations, Parts 101 to 123 by the Center for Veterinary Biologics (CVB) in Ames, IA.

1.4 How is the information collected?

Information is collected from firm submission forms (multiple firm and product licensing request submissions) and APHIS Forms 2001, 2003, 2005, 2007, 2008, 2015, 2017, 2046, 2047, and 2020. Biologic firms submit information via fax (printed copy) or mail (hard copy) which is then entered into the system by APHIS-VS-STAS CVB staff.

1.5 How will the information be checked for accuracy?

CVB-LSRTIS maintains a data schema to validate the type of information that is entered into the system (e.g. only certain types of characters can be entered into specific fields, etc). All data entered is also validated by APHIS-VS-STAS CVB staff for accuracy.

1.6 What specific legal authorities, arrangements, and/or agreements defined the collection of information?

1913 Virus–Serum–Toxin Act, further amended by the 1985 Food Security Act. Specific regulations are located in Title 9, Code of Federal Regulations, Parts 101 to 123.

1.7 Privacy Impact Analysis: Given the amount and type of data collected, discuss the privacy risks identified and how they were mitigated.

Privacy rights of the employees and external parties/persons will be protected by USDA, APHIS and VS management by the following means:

- All access to the system is limited by username/password.
- Application limits access to relevant information by assigned application functions to roles. This prevents access to unauthorized information.
- Access to CVB LSRTIS is internal to USDA APHIS staff.
- The USDA warning banner must be acknowledged at application login.

Section 2.0 Uses of the Information

The following questions are intended to delineate clearly the use of information and the accuracy of the data being used.

2.1 Describe all the uses of information.

The information is used to ensure that distributed veterinary biologics are in compliance with the Virus-Serum-Toxin-Act. Data in the system will be used to track information regarding the biological establishment's location, master seed and cells produced, product label submissions, employee qualifications, and product licenses. This information will enable decisions relating to new product licensing, serial release, product and manufacturing site inspections, and compliance of veterinary biologics firms.

2.2 What types of tools are used to analyze data and what type of data may be produced?

CVB-LSRTIS is a system with a graphical interface to enter and retrieve information from a database. The system can generate reports based on specific fields (e.g. date, firm establishment, product labels, licenses, etc) which are then manually analyzed by APHIS-VS-STAS CVB staff.

2.3 If the system uses commercial or publicly available data please explain why and how it is used.

CVB-LSRTIS does not use commercial or publicly available data.

2.4 Privacy Impact Analysis: Describe any types of controls that may be in place to ensure that information is handled in accordance with the above described uses.

Privacy rights of the customer and employees will be protected by USDA-APHIS-VS-CVB management. The following security controls are in place for the CVB-LSRTIS system:

- All access to the system is controlled by formal authorization. Each individual's supervisor must identify (authorize) what functional roles the individual needs in the CVB-LSRTIS system.

- All access to the system is limited by a username and password.

- CVB-LSRTIS limits access to information in the system using role-based access to individuals (i.e. individuals can only access information in the system if their role has been designated access to the specific information).

- Users are trained and are required to formally confirm that they understand value and sensitivity of data in the system. (Veterinary Services Memorandum #800.2)

- All users receive formal system training being given access to the system in accordance with the APHIS Directive 3575 – User Account Management Policy.

- Warning banner must be acknowledged before logging in.

- All general user access is recertified annually and administrative access is recertified quarterly as required by APHIS account management policy.

Section 3.0 Retention

The following questions are intended to outline how long information will be retained after the initial collection.

3.1 How long is information retained?

All electronic and paper records are retained per APHIS Record Management guidance:

http://inside.aphis.usda.gov/mrpbs/records/downloads/VEB.pdf
http://inside.aphis.usda.gov/mrpbs/records/downloads/PIV.pdf
http://inside.aphis.usda.gov/mrpbs/records/downloads/LAT.pdf

Paper records are retained for a minimum of 3 years. The specific retention period for data in the system depends on the type of record. Certain records must be maintained for the life of the licensed product, which could be over 30 years.

Electronic records will be maintained permanently until the NARA records retention schedule is approved according to the above information.

3.2 Has the retention period been approved by the component records officer and the National Archives and Records Administration (NARA)?

The retention period conforms to APHIS' "VS Record Retention Guidelines" document citing disposal authorities NCI 310-77-2 and NCI 463-85-2. APHIS VS

management authors the aforementioned document and CVB implements the directives within their environment.

The electronic records approval is pending.

3.3 Privacy Impact Analysis: Please discuss the risks associated with the length of time data is retained and how those risks are mitigated.

Risks associated with data retention are minimal including the possibility of the data being accessed by unauthorized personnel. CVB LSRTIS uses role based access to mitigate this risk. The Login interface reminds users of their responsibility every time they log in. Very little, if any, of the data stored are of a sensitive nature. Personally Identifiable Information (PII) would be limited to names, addresses, email and phone numbers of submitters; data that are usually easily accessible by other public means.

Section 4.0 Internal Sharing and Disclosure

The following questions are intended to define the scope of sharing within the United States Department of Agriculture.

4.1 With which internal organization(s) is the information shared, what information is shared and for what purpose?

Information is shared with APHIS-VS-STAS CVB staff for reporting and firm inspection purposes. Refer to Section 1.1 for the information that is shared internally with CVB staff.

4.2 How is the information transmitted or disclosed?

Reports and information are transmitted verbally, in print and electronic postings.

4.3 Privacy Impact Analysis: Considering the extent of internal information sharing, discuss the privacy risks associated with the sharing and how they were mitigated.

It is the intent of CVB LSRTIS that the uses of information remain in accordance with the stated purpose and use of the original collection at all times. Steps will be taken to ensure that access to the information system is provided only to authorized users.

All access to the data in the system is controlled by formal authorization.

All access to the system is limited by username/password.

The application limits access to relevant information and prevents access to unauthorized information.

Users are trained and required to formally confirm that they understand value and sensitivity of data in the system.

Warning banner must be acknowledged before logging in.

All information disseminated out of the VS control is stripped of all possible PII information.

Section 5.0 External Sharing and Disclosure

The following questions are intended to define the content, scope, and authority for information sharing external to USDA which includes Federal, state and local government, and the private sector.

5.1 With which external organization(s) is the information shared, what information is shared, and for what purpose?

The CVB-LSRTIS system does not share information with external organizations which are outside of USDA.

5.2 Is the sharing of personally identifiable information outside the Department compatible with the original collection? If so, is it covered by an appropriate routine use in a SORN? If so, please describe. If not, please describe under what legal mechanism the program or system is allowed to share the personally identifiable information outside of USDA.

The CVB-LSRTIS system does not share information with external organizations which are outside of USDA.

5.3 How is the information shared outside the Department and what security measures safeguard its transmission?

The CVB-LSRTIS system does not share information with external organizations which are outside of USDA.

5.4 Privacy Impact Analysis: Given the external sharing, explain the privacy risks identified and describe how they were mitigated.

The CVB-LSRTIS system does not share information with external organizations which are outside of USDA.

Section 6.0 Notice

The following questions are directed at notice to the individual of the scope of information collected, the right to consent to uses of said information, and the right to decline to provide information.

6.1 Was notice provided to the individual prior to collection of information?

Notice is provided prior to collection of information. Specifically, notice is provided referencing Title 9, Code of Federal Regulations Parts 102.3(a) & (b), 113.5 and 116. Additional guidance is provided in Veterinary Services Memoranda 800.50 and 800.53.

6.2 Do individuals have the opportunity and/or right to decline to provide information?

Licensed manufacturers of veterinary biologicals must comply with the 1913 Virus–Serum–Toxin Act and the subsequent regulations in Title 9 Code of Regulations Parts 101 to 123 in order to legally prepare and distribute veterinary biologics in the Unites States.

6.3 Do individuals have the right to consent to particular uses of the information? If so, how does the individual exercise the right?

Requests for this information that is not available on the public website for the Center for Veterinary Biologics must request information through the Freedom of Information Act process.

6.4 Privacy Impact Analysis: Describe how notice is provided to individuals, and how the risks associated with individuals being unaware of the collection are mitigated.

APHIS Form 2001, Application for United States Veterinary Biologics Establishment License and APHIS Form 2003, Application for United States Veterinary Biological Product License contain the following certification statement:
In accordance with the Act of Congress approved March 4, 1913 (37 Stat. 832-833; 21 U.S.C. 151-158), application is hereby made for a license to maintain an establishment for the preparation of animal biological products for the use in the treatment of domestic animals. If a license is issued by the United States Department of Agriculture under this application, the licensee expressly agrees to comply with the provision of the said Act, and all rules, regulations, and orders of the Department issued pursuant thereto relating to the operation of such establishment and the preparation, testing, and distribution of animal biological products prepared therein, and that the animal

biological products will not be labeled or advertised so as to mislead or deceive the purchaser in any particular.

Section 7.0 Access, Redress and Correction

The following questions are directed at an individual's ability to ensure the accuracy of the information collected about them.

7.1 What are the procedures that allow individuals to gain access to their information?

All information maintained in LSRTIS is proprietary to the licensed manufacturer and may contain confidential business information. The licensed entity can request information for their respective licensed veterinary biologics from the Center for Veterinary Biologics (CVB). Information requested for other licensed manufacturers or products must be requested through the Freedom of Information Act (FOIA) request.

7.2 What are the procedures for correcting inaccurate or erroneous information?

Information maintained in LSRTIS is provided to licensed manufacturers as reports during inspections of the licensed facility and they are requested to provide updates and corrections to the information to the CVB.

7.3 How are individuals notified of the procedures for correcting their information?

Licensed manufacturers are provided guidance in memorandums and notices that are available publicly on the CVB website.

7.4 If no formal redress is provided, what alternatives are available to the individual?

A formal process is available to correct any data inaccuracies. See section 7.3 for more information.

7.5 Privacy Impact Analysis: Please discuss the privacy risks associated with the redress available to individuals and how those risks are mitigated.

Data in the system is of limited sensitivity. Any data used or furnished to others would need to be cleared through the Freedom of Information Act process. Any data obtained illegally by unauthorized personnel would be of limited use and could

potentially be obtained easily by other means (e.g. names, addresses, and telephone numbers). Additionally, the following controls are in place:

All access to the data in the system is controlled by formal authorization.

All access to the system is limited by username/password.

The application limits access to relevant information and prevents access to unauthorized information.

Users are trained and required to formally confirm that they understand value and sensitivity of data in the system.

Warning banner must be acknowledged before logging in.

All information disseminated out of the VS control is stripped of all possible confidential business information.

Section 8.0 Technical Access and Security

The following questions are intended to describe technical safeguards and security measures.

8.1 What procedures are in place to determine which users may access the system and are they documented?

Access to CVB-LSRTIS is based on the need to do business and determined by APHIS-VS-STAS-CVB management. All access to CVB LSRTIS is authorized and documented by an APHIS 513 Form.

8.2 Will Department contractors have access to the system?

Access is based on need and limited to USDA, APHIS, VS, STAS, CVB employees. Department contractors do not have access to the system.

8.3 Describe what privacy training is provided to users either generally or specifically relevant to the program or system?

All individuals, prior to being provided access to the application, are briefed in accordance with Veterinary Services Memorandum #800.2. Currently, all individuals provided access to CVB LSRTIS are required to complete annual Information Technology (IT) Security Awareness Training and must sign APHIS Rules of Behavior form prior to receiving access to the information system. The standard USDA warning banner must also be acknowledged and accepted before logging in to the system.

8.4 Has Certification & Accreditation been completed for the system or systems supporting the program?

Yes, the certification & accreditation of this system is complete and an authority to operate (ATO) was issued on 3/15/2011.

8.5 What auditing measures and technical safeguards are in place to prevent misuse of data?

Technical safeguards and auditing measures are in accordance with FIP 199/200 Moderate baseline security controls. Technical safeguards for CVB LSRTIS include a security model that enables auditing, role-based access views (i.e. access only to authorized information), field-level security, and division of security (i.e. least privilege). This means all events, such as create, modify, soft deletion, and user login activity are audited at the field level. Every change to every field of the case data can be logged in the audit trail table.
- All access to the data in the system is controlled by formal authorization.

- All access to the system is limited by username/password.

- Application limits access to relevant information and prevents access to unauthorized information.

- Users are trained and are required to formally confirm that they understand value and sensitivity of data in the system.

- All users receive formal system training and are required to pass a proficiency test before being given access to the system.

- Warning banner must be acknowledged before logging in.

- Auditing is enabled both at the application and database level.

- Every change to every field of data can be logged in the audit trail table. The audit trail is activated automatically as soon as information is entered into the system, modified, or deleted.

The audit trail itself is fully compliant with the regulatory requirement, containing:

- the data change (old and new values)
- the name of the user making the change
- the date and time of the change (taken from the network server's clock)
- the reason for the change (either selected from a look-up table of pre-defined reasons or entered as free text).

8.6 Privacy Impact Analysis: Given the sensitivity and scope of the information collected, as well as any information sharing conducted

on the system, what privacy risks were identified and how do the security controls mitigate them?

Very little, if any, of the data stored are of a sensitive nature. **Personally Identifiable Information (PII)** would be limited to names, addresses, and phone numbers of submitters; data that are usually easily accessible by other means.

Section 9.0 Technology

The following questions are directed at critically analyzing the selection process for any technologies utilized by the system, including system hardware and other technology.

9.1 What type of project is the program or system?

CVB-LSRTIS is an information system that allows APHIS-VS-STAS CVB to manage information related to licensing programs and processes for the following:

- Veterinary Biologics Establishments and Products – Licensing
- Veterinary Biologics Products Serial Release
- Veterinary Biologics Products Testing
- Veterinary Biologics Products Compliance
- Veterinary Biologics Establishments and Products - Inspection
- Veterinary Biologics Product Export Certification

The system allows APHIS-VS-STAS CVB to receive and process submissions (i.e. via fax or mail) from veterinary biologics firms related to licensing and releasing serials of veterinary biologics products.

9.2 Does the project employ technology which may raise privacy concerns? If so please discuss their implementation.

This application does not employ technology which may raise privacy concerns.

Section 10.0 Third Party Websites/Applications

The following questions are directed at critically analyzing the privacy impact of using third party websites and/or applications.

10.1 Has the System Owner (SO) and/or Information Systems Security Program Manager (ISSPM) reviewed Office of Management and Budget (OMB) memorandums M-10-22 "Guidance for Online Use of Web Measurement and Customization Technology" and M-10-23 "Guidance for Agency Use of Third-Party Websites and Applications"?

The ISSPM and system owner have reviewed the OMB memorandums listed above.

10.2 What is the specific purpose of the agency's use of 3rd party websites and/or applications?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.3 What personally identifiable information (PII) will become available through the agency's use of 3rd party websites and/or applications.

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.4 How will the PII that becomes available through the agency's use of 3rd party websites and/or applications be used?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.5 How will the PII that becomes available through the agency's use of 3rd party websites and/or applications be maintained and secured?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.6 Is the PII that becomes available through the agency's use of 3rd party websites and/or applications purged periodically?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.7 Who will have access to PII that becomes available through the agency's use of 3rd party websites and/or applications?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.8 With whom will the PII that becomes available through the agency's use of 3rd party websites and/or applications be shared - either internally or externally?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.9 Will the activities involving the PII that becomes available through the agency's use of 3rd party websites and/or applications require either the creation or modification of a system of records notice (SORN)?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.10 Does the system use web measurement and customization technology?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.11 Does the system allow users to either decline to opt-in or decide to opt-out of all uses of web measurement and customization technology?

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

10.12 Privacy Impact Analysis: Given the amount and type of PII that becomes available through the agency's use of 3rd party websites and/or applications, discuss the privacy risks identified and how they were mitigated.

Not applicable. CVB-LSRTIS does not use Third-Party Websites.

Please note that records within the LSRTIS system may be retrieved by a personal identifier such as a name however, it is only for administrative purposes. There is no evidence that the names of contact persons will be used to obtain information about that person. The agency has determined that the risk impact and privacy impact of this data retrieval is very low therefore a SORN is not required. This decision is supported by the Henke vs US Department of Commerce 83 F.3d 1453 (D.C. Circuit 1996) page 24 of the Overview of The Privacy Act 2010 Edition.

Responsible Officials

Bonnie M. Coyle, System Owner, Center for Veterinary Biologics
United States Department of Agriculture

Rajiv Sharma, APHIS Information Systems Security Program Manager
United States Department of Agriculture

Tonya Woods, APHIS Privacy Officer
United States Department of Agriculture

Approval Signature

BONNIE COYLE Digitally signed by BONNIE COYLE
DN: c=US, o=U.S. Government, ou=Department of Agriculture, cn=BONNIE COYLE, 0.9.2342.19200300.100.1.1=12001000004077
Date: 2014.07.28 09:49:47 -05'00'

Bonnie M. Coyle
System Owner, Center for Veterinary Biologics
United States Department of Agriculture

Date

rajiv.sharma@usda.gov Digitally signed by rajiv.sharma@usda.gov
DN: cn=rajiv.sharma@usda.gov
Date: 2014.07.28 11:11:29 -04'00'

Rajiv Sharma
APHIS ISSPM
Animal Plant Inspection and Service (APHIS)

Date

tonya.g.woods@usda.gov Digitally signed by tonya.g.woods@usda.gov
DN: cn=tonya.g.woods@usda.gov
Date: 2014.07.30 10:58:34 -04'00'

Tonya Woods
APHIS Privacy Officer
Animal Plant Inspection and Service (APHIS)

Date