

Privacy Impact Assessment

National Bio Agro-Defense Facility (NBAF)

AZURE Information Laboratory System

(NAILS)

Policy, E-Government and Fair Information Practices

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Owner Details	
Name	Dr. Elizabeth Lautner
Contact Number	(515) 708-2496
E-mail Address	Elizabeth.a.lautner@usda.gov

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Name	Title	Agency/Office	Contact Information
Dr. Elizabeth Lautner	System Owner	NBAF	elizabeth.a.lautner@usda.gov

Privacy Impact Assessment for the NBAF Azure Information and Laboratory System

1 December 2023

Contact Point

**Christopher Hall
Information Systems Security Manager
APHIS/NBAF
(785) 712-3335**

Reviewing Official

**Tonya Woods Privacy
Act Director
United States Department of Agriculture
(301) 851-4072**

System Owner

**Dr. Elizabeth Lautner
Associate Deputy Administrator
United States Department of Agriculture
(515) 708-2496**

Abstract

This Privacy Impact Assessment (PIA) is for the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Bio-Agro Defense Facility (NBAF) Azure Information Laboratory System (NAILS). NAILS is a collection of virtualized servers operating in Azure Cloud that are used to support daily operations for NBAF.

This PIA is focused specifically on the Environmental, Health, Safety and Quality (EHSQ) and the Laboratory Information Management System (LIMS) subsystems under NAILS, as these are the only services in NAILS that process Personally Identifiable Information (PII). The EHSQ allows for the tracking of work-related safety and health incidents in order to improve workplace safety. The LIMS tracks animals that are being tested or used for research in order to ensure compliance with animal welfare regulations and to track lab test results.

Overview

The primary mission of the NBAF is the protection of animal health for the livestock industry in the United States. Capabilities for the NBAF include laboratories designed, constructed, and equipped for Biosafety. NAILS aims to provide automation support to employees and contractors working to fulfill the mission of inspecting and protecting animal and plant materials within the United States.

NAILS consists of the following nonpublic facing sub-systems:

- Biological Inventory Management System: (BioIMS): Provides inventory management of biological inventory samples through their entire lifespan with end-to-end traceability.
- Laboratory Information Management System (LIMS): Tracks the status and test results for animals submitted for testing to the USDA by members of the public. Provides inventory management for samples, reagents, and other items in the laboratory.
- Electronic Lab Notebook (ELN, also referred to as SCINOTE): Captures, organizes, manages, and collaborates experiments and test execution workflows across the organization.
- Environmental, Health, Safety and Quality (EHSQ): Tracks workplace health and safety incidents and facilitates workplace safety initiatives in order to ensure a safe workplace and to meet compliance with all regulatory health and safety requirements, including ISO accreditation.
- Research Animal Management System (RAMS): Supports the tracking and management of USDA-owned research animals, their use histories, and veterinary care records as required by the Animal Welfare Act.



- Quality Management System (QMS): Supports document control, change management, training, and audits.

The only two subsystems under NAILS that process PII are the EHSQ system and LIMS. USDA APHIS ensures safe and healthy working conditions by setting and enforcing safety standards and providing awareness and education to all employees. The EHSQ program is dedicated to identifying, assessing, and controlling hazards at NBAF by training USDA personnel about the hazards and how to work in a safe and healthy manner. The end goal is to protect their safety and health, the safety and health of others in the workplace, and the safety, health, and environmental conditions in the larger community. In the event of a workplace injury, USDA is required to maintain documentation on employee work-related injuries and illnesses, as well as the remediation of the risks and injury. Tracking workplace incidents and health events within EHSQ also allows NBAF to be compliant with all regulatory health and safety requirements and achieve ISO accreditation.

LIMS tracks information about animals, including their veterinary histories, care, and test results. This processing involves PII for animal owners and includes their names, phone numbers, email addresses and the states where they reside. This information is used to update the animal owners on the status of their animals, their care, and their test results.

NBAF and its private cloud maintains the data and is responsible for the security of the stored data.

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?

EHSQ collects the following PII about employees in relation to workplace incidents:

- ☒ Names
- ☒ Date and/or place of birth.
- ☒ Address Information (street or email address).
- ☒ Personal identification number (e.g., unique employee identification number generated by the system).
- ☒ Health data (including height, weight, blood pressure, health conditions and incidents in the workplace, etc.).

LIMS collects the following PII about animal owners:

- ☒ Names
- ☒ Address Information (street or email address).

☒ State of Residence

☒ Phone Numbers

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

The sources of the information within EHSQ are the USDA employees, including occupational health nurses, who input information about workplace incidents directly into the system. Additionally, The EHSQ system receives PII from USDA's EIMS (Enterprise Information Management System), including name, birthdate, sex, employment dates, employment status, and employee ID number under a data sharing memorandum of understanding with ICAM.

The sources of the information within LIMS are the animal owners who provide their information to USDA employees verbally over the phone or via email.

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

The PII in EHSQ is used to track and manage workplace health and safety issues and events at NBAF facilities, including remediation and compensation efforts. It also allows NBAF to track information for workplace health and safety accreditation and compliance.

The PII in LIMS is used to track the state locations of animals and to provide updates and communication with the animal owners and USDA veterinarians about test results and care history.

1.4 How is the information collected?

For EHSQ, the information is collected by USDA occupational health nurses or by NBAF employees and entered directly into the system.

For LIMS, the information is provided verbally (telephone) or by email by the animal owners to their respective USDA liaisons who then input the information directly into the system. The animal owners do not have access to LIMS.

1.5 How will the information be checked for accuracy?

NBAF employees, including occupational health nurses (for EHSQ) and the animal owners' USDA liaisons (for LIMS) review the information for accuracy using scheduled reviewing procedures or upon notice of any errors or updates (ad-hoc basis). The system automatically adds the date-time stamp for when the entry is added, updated, or edited.

1.6 What specific legal authorities, arrangements, and/or

agreements defined the collection of information?

- Homeland Security Presidential Directive 9 (HSPD-9).
- Virus-Serum –Toxin Act (21 USC §151-159 et.seq.)
- 9 CFR 53 (Foot-And-Mouth Disease, Pleuropneumonia, Rinderpest, and Certain other communicable Diseases of Livestock or Poultry).
- 9 CFR 56 (Control of H5/H7 Low Pathogenic Avian Influenza)9 CFR 82 (Exotic Newcastle Diseases and Chlamydiosis).
- 9 CFR 94 (Rinderpest, Foot-and-Mouth Disease, Exotic Newcastle Disease, African Swine Fever, Classical Swine Fever, Swine Vesicular Disease, and Bovine Spongiform Encephalopathy: prohibited and restricted importations).
- 9 CFR 121 (Possession, Use, And Transfer of Select Agents And Toxins) Animal Health Protection Act (7 USC Chapter 109) Animal Welfare Act (7 USC 54).
- Homeland Security Presidential Directives (HSPD) 5 (Management of Domestic Incidents).
- HSPD 7 (Critical Infrastructure Identification, Prioritization, and Protection) HSPD 8 (National Preparedness).
- HSPD 9 (Defense of United States Agriculture and Food).
- HSPD 12 (Policies for a common Identification Standard for Federal Employees and Contractors).
- The Organic Act of 1862 (7 U.S.C. 2201 note)
- Agricultural Research Act of 1935 (7 U.S.C. 427)
- Research and Marketing Act of 1946 (Pub. L. 79-733), as amended (7 U.S.C. 427,1621 note)
- Food and Agriculture Act of 1977 (Pub. L. 95- 113), as amended (7 U.S.C. 1281note)
- Food Security Act of 1985 (Pub. L. 99-198) (7 U.S.C. 3101 note)
- Food, Agriculture, Conservation, and Trade Act of 1990 (Pub. L. 101-624) (7 U.S.C.1421 note)
- Federal Agriculture Improvement and Reform Act of 1996 (Pub. L. 104-127)
- Agricultural Research, Extension, and Education Reform Act of 1998 (Pub. L. 105-185)
- Farm Security and Rural Investment Act of 2002 (Pub.L. 107-171).
- The Animal Welfare Act (Laboratory Animal Welfare Act of 1966, Pub. L. 89–544)

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

NAILS EHSQ collects health information related to workplace incidents which is inherently sensitive. To minimize the associated privacy risks, all user access is granted in the start after the completion of Information

Security Awareness Training and Acknowledgement of Rules of Behavior (ROB) and re-verify annually. Access is limited to USDA employees only (USDA civilian and contractor), on a need-to-know basis. A non-disclosure agreement (NDA) is an additional requirement for NBAF contractors.

LIMS only collects names, phone numbers, emails, and states of residence for animal owners. This is the minimum amount of information needed to carry out its intended business purpose and is inherently less sensitive. Additionally, these systems do not combine or share data with each other or any other data sets.

Employee information for access is validated by the individual's supervisor through the use of an Animal and Plant Health Inspection Service (APHIS) 513 form, digitized in the User Management System (UMS).

In order to prevent unauthorized access to this data the system uses security and privacy capabilities common to the USDA and the commercial products used, including:

- System access control by USDA domain credentials
- Role-based User access
- Separation of duties
- Limiting web access
- Audit logging
- Standard Operating Procedures (SOPs)

Section 2.0 Uses of the Information

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

2.1 Describe all the uses of information.

The PII within the EHSQ is used by NBAF to track and manage workplace health and safety events, to manage subsequent remediation and compensation efforts and to comply with workplace safety requirements and ISO accreditation.

The PII within LIMS is used to update and communicate with animal owners and veterinarians about their animals, including their care histories and test results.

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

EHSQ is able to produce reports on workplace incidents including injuries, spills and safety concerns in order to identify workplace safety trends and

ensure workplace safety compliance. The EHSQ system produces data about employee incidents, but it does not combine data with other subsystem datasets.

LIMS produces basic data reports in order to track the status and progress of animal testing and care. It does not analyze or combine data sets involving PII, including that of animal owners.

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

Not applicable.

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.

Technical Controls:

- NAILS applications use Enterprise Active Directory (EAD) for authentication and authorization services for approved user and computer accounts. It provides identity management controls and enforces security policies within the MRP Animal and Plant Health Inspection Service (APHIS) Azure Cloud.
- The security of the information being passed on this two-way connection is protected using FIPS 140-2 approved encryption mechanisms.
- Employee information is validated by the individual's supervisor through the use of an APHIS 513 form, digitized in the User Management System (UMS).

Administrative Controls:

- Users have formal training on an annual basis on how to properly manage PII.
- Users have formal training on how to use the system.
- All access to the system is limited to authorized personnel only on a need-to-know basis.
- Access to the data in the system is controlled and documented by formal authorization.

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?

For occupational health and safety training records, referring to <https://www.archives.gov/files/records-mgmt/grs/grs02-7.pdf>, "Destroy 5 years after training participation or when superseded, whichever is

applicable, but longer retention is authorized if required for business use.”

For biologic inventory and laboratory notes, referring to <https://www.aphis.usda.gov/library/records/downloads/VEB.pdf>, <https://www.aphis.usda.gov/library/records/downloads/ADIS.pdf>, and <https://www.aphis.usda.gov/library/records/downloads/LAT.pdf> where “Destroy when 3 years old”

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

All component records are using general record schedules, referring to <https://www.archives.gov/files/records-mgmt/grs/grs03-1.pdf> “General Records Schedule 3.1: General Technology Management Records”.

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 include the possibility of the data being accessed by unauthorized personnel. Role-based security and access rights are implemented to protect the confidentiality of information. Role-based security includes the use of USDA e-Authentication services, which provides user authentication. The login interface reminds users of their responsibility every time they log in.

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 in EHSQ involving workplace incidents, including the date and description of incidents, may be used by components of USDA, including Agricultural Marketing Service (AMS), Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), Office of the General Counsel, Office of the Inspector General (OIG), and other USDA agencies in order to review and respond to workplace incidents. Employees may also consent to their PII and health data being shared internally to help facilitate compensation claims.

4.2 How is the information transmitted or disclosed?

EHSQ shares requested information only on the internal secure SharePoint through encrypted and private forms with limited access to assigned SHEMs personnel only.

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.

The privacy risks associated with internal sharing could be unintended or unauthorized sharing of information inside of USDA systems, data loss, or the possibility of disclosure. These risks are mitigated by the following measures in place:

- Information is not shared outside of USDA APHIS.
- All NAILS systems have administrative as well as technical security controls that address access to and security of information.
- Access to the data in the NAILS systems is controlled and documented by formal authorization.
- All access to the system is limited by account identification and eAuthentication. The eAuthentication makes use of Personal Identification Verification (PIV) cards using associated certificates.
- Users have formal training on the authorized use and prohibited forms of communications of the system. Users are also required to sign a Rules of Behavior/Acceptable Use of Policy before being granted an account.
- A warning banner is displayed and must be acknowledged at every login.

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?

EHSQ Information is not shared outside of the USDA.

For LIMS. The contact information for animal owners may be shared with federal and state animal health officials in cases of outbreaks or other public health emergencies to assist with containment or mitigation of harm to the public.

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.

All external sharing within LIMS is in accordance with the SORN.

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

LIMS information that is requested to be shared in accordance with the SORN are sent via email and must be encrypted.

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

The privacy risks for external sharing include the unintended or unauthorized sharing of information outside of USDA systems. For LIMS, any external sharing is carried out via private Microsoft Teams channels or via encrypted emails. Additionally, for both LIMS and EHSQ, the USDA/APHIS/NBAF provide safeguards against invasions of privacy that limit the risk of it being leaked outside of internal systems. The USDA limits the collection of personal data to authorized personnel only. The data collection must be relevant for the purposes for which it is collected and shall not be used for any other purpose. All contractors are required to sign a non-disclosure agreement (NDA) for NAILS access. In addition, all users are required to take the Information Security Awareness Training (ISAT) and sign the Rules of Behavior (ROB). PII training is conducted as part of the yearly AgLearn mandatory training. To gain NAILS application access, the individual's supervisor approval is required.

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 Does this system require a SORN and if so, please provide SORN name and URL.

Yes. The NAILS system requires a SORN and a copy currently resides in CSAM under System ID 2518. The following URLs also lists the web locations:

National Animal Health Laboratory Network

<https://www.govinfo.gov/content/pkg/FR-2010-08-18/pdf/2010-20360.pdf>

OPM/GOVT-10 Employee Medical File System Records

<https://www.opm.gov/information-management/privacy-policy/sorn/opm-sorn-govt-10-employee-medical-file-systems-records.pdf>

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

Yes.

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

For EHSQ if the USDA user does not consent to the use of all requested information, their account request will be disapproved. For LIMS, Animal owners will not be able to participate in the animal tracking and testing if they do not submit their information.

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

For EHSQ, employees' consent to their information being processed, including information about workplace incidents, during conditions of employment. In cases where a workplace incident results in compensation, users can consent specifically to having their information shared internally to facilitate the compensation efforts. Individuals can also file claims to have their personal information disclosed to other administrations in accordance with the SORN, Note 5: **"ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES"** of the SORN. For LIMS, all of the information about animal owners is necessary and required to participate in the program. Participation is not mandatory, and animal owners can choose not to participate.

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

The risk associated with individuals being unaware of the collection is very limited. For EHSQ, employees and new hires are provided notice through emails, provided privacy statements via pop-up window during initial system login, this PIA, and the associated SORNs and have the right to consent to the particular uses of their information, including information about workplace incidents, during conditions of employment, onboarding and offboarding. For LIMS, animal owners will receive a copy of the Privacy Act Statement from their USDA liaison via email.

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?

Individuals seeking access to their records may file a Privacy Act or Freedom of Information (FOIA) request. Only U.S. citizens and lawful permanent residents may file a Privacy Act request. Any person may file a FOIA request. USDA offers several avenues to request access to their records. Individuals may file a Privacy Act request to view their record by submitting a Privacy Act request online through USDA's Public Access Link (PAL), or through mail or fax.¹

USDA – Animal and Plant Health Inspection Service
Privacy Act Director
4700 River Road, Unit 50
Riverdale, MD 20737
Facsimile: 301-734-5941
Email: APHISPrivacy@usda.gov

Further information about Privacy Act and FOIA requests for APHIS records is available at <https://www.aphis.usda.gov/aphis/resources/foia>.

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

Individuals may address any inaccuracies or errors within the system of origin by submitting a request for correction to the Privacy Act Director described in Section 7.1.

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

Individuals are notified via automated emails sent from Master Control and administrators, UMS, or Maximo for procedures on how to correct their information.

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

APHIS offers a formal redress process to access and correct records from the

¹ <https://efoia-pal.usda.gov/>

source system.

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

There is an inherent risk that individuals not knowing or understanding the redress process may input and disclose sensitive or privacy information without the knowledge to correct or remove the information. USDA takes reasonable steps to ensure that the chain of custody is maintained and that the electronic information in NAILS is not altered or destroyed. USDA mitigates this risk by continuing to allow individuals with redress mechanisms to access and correct information from source systems.

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?

Initial requests for granting access to the system are routed in User Management System from the user through their supervisor to the system owner. Need-to-know determinations are made at both the supervisor and system owner level. If validated, the request is passed on to the system administrator. The user and system owner are notified via email that the request has been processed along with instructions for the initial login. User profile modification requests follow the same process as for an initial request. The procedures are located on the [User Management System \(UMS\) home site](#).

8.2 Will Department contractors have access to the system?

Yes, and subject to the same background, training, need-to-know and confidentiality requirements as employees.

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

All members are required to complete the annual IT Security Awareness Training and must sign the 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. This Privacy Impact Assessment will be used in support of the Authority to Operate (ATO) package granted in September 2023.

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

- All access to the system is limited to USDA APHIS employees/contractors and enforced via multi-factor log-in credentials, which requires the use of PIVs and pin numbers.
- The application limits access to relevant information through assigned user roles, which enforce need-to-know and least privilege concepts.
- Log collectors are in place to monitor and audit all activities on USDA systems for misuse of data.
- Technical firewalls and intrusion detection systems are in place to prevent unauthorized network access.

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?

The EHSQ system processes health data (in the context of workplace incidents) which is inherently sensitive. The privacy risks that may be associated with such information sharing are primarily the unauthorized sharing and mishandling of shared data. The following security controls are in place to mitigate these risks:

- All access to the system is limited to USDA employees/contractors and external users with eAuthentication accounts at the appropriate identity verification level for the environment being accessed. Multi-factor authentication is enforced for eAuthentication accounts per Departmental standards and policies.
- The application limits access to relevant information through assigned user roles, and group membership managed by the programs.

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?

The National Bio and Agro-Defense Facility (NBAF) Azure Information and

Laboratory System (NAILS) provides Commercial off the Shelf Software (COTS) to fulfill the mission of inspecting and protecting animal and plant materials, maintaining compliance, ISO accreditation and security. The platform stores and processes research data, employee health data and basic contact information for animal owners across the Marketing and Regulatory Programs (MRP) Animal and Plant Health Inspection Service (APHIS) Azure Cloud.

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

No. This is a cloud-based system. Inherent with this type of system is a risk that unauthorized intruders could gain access to privacy information. However, the Azure Cloud system is FedRAMP certified, and all security controls are in place according to their certification.

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”?

Yes.

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

Not Applicable.

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

Not Applicable.

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.

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.

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

Not Applicable.

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.

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.

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.

10.10 Does the system use web measurement and customization technology?

No.

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.

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.



Responsible Officials

Dr. Elizabeth Lautner
NBAF/NAILS System Owner
Marketing and Regulatory Programs
United States Department of Agriculture

Approval Signatures

Tonya Woods
Privacy Act Officer (PAO)
Marketing and Regulatory Programs
United States Department of Agriculture

Angela Cole
Chief Privacy Officer/Deputy Assistant Chief Information Security
Officer Marketing and Regulatory Programs
United States Department of Agriculture