PTA / PIA: FDA - AFRA - QTR4 - 2025 - FDA5059833

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General Information

PTA / PIA Name:	FDA - AFRA - QTR4 - 2025 - FDA5059833	**PTA / PIA ID:**	3978331
Component Name:	FDA - CVM Animal Food Risk Algorithm	**ATO Boundary Name:**	CVM Animal Food Risk Algorithm
Overall Status:	Complete	**# of Days - Open:**	29
Submitter:		**Submit Date:**	11/10/2025
Next Assessment Date:	12/08/2028	**Expiration Date:**	12/8/2028
Office:		**OpDiv:**	FDA
Security Categorization:	Moderate		
Make PIA available to Public?:	Yes	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	Yes
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
General 04:	ATO Date or Planned ATO Date.	11/3/2025
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Kelly Louviere
PTA 01A:	POC Title and Organization	POC Title: Consumer Safety Officer POC Organization: Center for Veterinary Medicine
PTA 01B:	POC Email Address	kelly.louviere@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-5815
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)

PTA 02A:	Describe in further detail any changes to the system that have occurred since the last PIA.	Since this Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) was last approved, FDA made the following changes to the system: updates to align CVM Animal Food Risk Algorithm (AFRA) with animal food inspectorate reorganization, updates to dashboard reports in the user interface, and implementation of a notification process when there is a system outage.
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA 04:	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	The Animal Food Risk Algorithm (AFRA) system is a comprehensive and dynamic application that will enable Center for Veterinary Medicine (CVM) and Office of Inspections and Investigations (OII) personnel to conduct risk assessments and rankings of all animal food facilities within the CVM inventory as mandated per Section 201 of the FDA Food Modernization and Safety Act (FSMA). Specifically, CVM animal food facilities will receive a designation as high risk or non-high risk based on risk assessment findings. Once assigned a risk ranking, CVM and OII will then use the AFRA to determine the inspection frequency for all CVM animal food facilities. The AFRA system will also be utilized by CVM and OII authorized personnel to identify animal food facilities which pose the highest risk to public health, both human and animal, and based on these findings, prioritize inspections at these facilities. The application will also be used for related work planning purposes, responding to Congressional inquiries, preparing Congressional reports, targeting segments of the animal food industry based on new, emerging issues, internal audits, and tracking and trending inspections and compliance. Users of the system include FDA permanent employees and Direct Contractors. System administrators and those serving in business related roles use AFRA to manage user roles and user access, create and maintain business rules, and initiate ad hoc business rule execution. Individuals with report viewer roles can use the AFRA website to view AFRA reports and frequently asked questions but do not have access to manage roles, users or business rules.
PTA 05:	List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.	The AFRA system will obtain animal food facility firm-specific information, including Point of Contact (POC) personally identifiable information (PII), from the OII Online Reporting Analysis and Decision Support System (ORADSS, the subject of a separate assessment) database. Information obtained from ORADSS consists of PII about POCs that includes name, business/personal email address, business mailing address, inspector/investigator responses to inspection protocol (IP) questionnaires (which include the name(s) of the person interviewed

		and/or the most responsible person at the firm, and information about firm operations), and firm name, FDA Establishment Number/Identifier (FEI), and firm address. Additionally, the system collects and maintains the name and FDA email address of FDA employees and Direct Contractors who use and maintain the AFRA system Additional data made available to the AFRA system as views in FDA's ORADSS database includes Judicial District Travel Area (JDTA) Codes, country codes, location data by longitude and latitude, district and division firm location data, establishment size, operational status, workload obligation, establishment type and industry code list, district use codes, dates and classifications from inspections, last inspection Program Assignment Code (PAC) list, District Use Code, dates and classifications of complaints, dates and classifications of recalls, dates and descriptions of lab class 3 samples and their analyses, food facility registration dates and types, program risk identifiers for the human and animal food program, risk category, and qualified facility attestation type. Import information (e.g., entry number and ID; line number; country of origin; product description, quantity, and value; disposition activity dates and descriptions; import alerts; and Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) data) is also made available for view. Private citizen PII is stored temporarily and is updated at least monthly based on the animal food inventory data in the ORADSS database. Animal food inventory data prior to the update is not retained. OII and Field Programs records and employee PII in the AFRA system is retained based on approved National Archives and Records Administration (NARA) record control schedules. Information will be used by the AFRA system to establish a high or non-high-risk ranking, as well as a cover-by date based on a series of business rules that the AFRA system will maintain (e.g., calculated risk scores, high risk or non-high program risk identifiers, and calculated cover-by-dates). The stored animal food facility information will be updated on at least a monthly schedule. The only individuals who can access the AFRA system are FDA employees and Direct Contractors approved as AFRA users. Once approved, AFRA users access the system via a single-sign-on (SSO) process using multi-factor authentication. The AFRA system does not require, use, or maintain system-specific user FDA logon credentials (e.g., username and password).
PTA 05A:	Are user credentials used to access the system?	Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system.
PTA 05C:	Please identify the system that maintains the user credentials or controls access to this system.	Active Directory

PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	PII is collected and/or temporarily maintained by the AFRA system. The PII contained in AFRA consists of the following POC information: name, business/personal email address, business mailing address; information derived from inspector/investigator responses to inspection protocol (IP) questionnaires (which include the name(s) of the person interviewed and/or the most responsible person at the firm, and information about firm operations). AFRA also collects and maintains farm owner name, FDA Establishment Numbers/Identifiers (FEI), and mailing address in the CVM animal food inventory when a firm has been designated as a farm/residence. Additionally, the system collects and maintains the name and FDA email address of FDA employees and Direct Contractors who use and maintain the AFRA system. CVM personnel (FDA permanent employees and Direct Contractors) use the AFRA system to create and maintain business rules that assign the level of risk (high or non-high) a facility poses to public health, both human and animal. Those rules are based on a firm's inspection history, history of complaints, recalls, lab class 3 samples, import alerts, and refusals, and risk associated with the type of firm or products. Additional business rules assign a "cover-by" date (the date which an inspection should be performed to meet the FDA FSMA inspection frequency mandate) to a firm based on the risk category and relative risk to the rest of the animal food inventory. The high or non-high-risk categorizations and cover-by dates are exported to the ORA Firm Management Service (FMS) within OII's Field Accomplishments and Compliance Tracking System (FACTS) to be used by OII for work planning. The AFRA system also temporarily stores and uses the following animal food facility firm-specific information provided by FDA's ORADSS database: Judicial District Travel Area (JDTA) Codes, country codes, location data by longitude and latitude, district and division firm location data, establishment size, operational status, workload obligation, establishment type and industry code list, district use codes, dates and classifications from inspections, last inspection Program Assignment Code (PAC) list, District Use Code, food facility registration dates and types, program risk identifiers for the human and animal food program, risk category, and qualified facility attestation type, and import information (e.g., entry number and ID; line number; country of origin; product description, quantity, and value; disposition activity dates and descriptions; import alerts; and Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) data). Additional data made available for view in the FDA ORADSS database includes inspection information (inspection dates, classifications, industry, and

		establishment codes, etc.), recalls (e.g., dates, recall classifications, responsible firm FEI), and complaints (e.g., date, adverse event type and description). The data made available in the ORADSS views are maintained in OII program databases, including FDA's Recall Enterprise System (RES), OII's Field Accomplishments and Compliance Tracking System (FACTS), and FDA's Unified Registration Listing System (FURLS) databases, all of which are the subject of separate assessments. The AFRA system also includes a dashboard to produce reports summarizing the output of the business rules (e.g., calculated AFRA risk scores, facilities identified as high risk or non-high risk, facility cover-by dates, and the number and percent of inspections completed relative to fiscal year work plan) used for work planning, Congressional inquiries, Congressional reports, targeting segments of the animal food industry based on new, emerging issues, internal audits, and tracking and trending inspections and compliance.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	https://afra.fda.gov/ords/afra_workspace/r/afra
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No
PTA 09:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	The AFRA website is an HHS internal site and is the user interface for the AFRA system. The only individuals who can access the AFRA system are FDA employees (primarily from FDA's Human Foods Program (HFP), CVM, and OII including Direct Contractors who have been approved as AFRA users. Access is restricted to individuals who have been granted permission to the system by AFRA Administrators (e.g., AFRA contractors and/or the AFRA system owner). Once approved, AFRA users access the system via a single-sign-on (SSO) process using multi-factor authentication. Role-based access restricts portions of the website to only those CVM employees and AFRA contractors who have administrative and AFRA business rule-related roles. The few individuals with administrative and business rule-related roles use the AFRA website to manage user roles and user access, create and maintain business rules, and initiate ad hoc business rule execution. Individuals with report viewer roles can use the AFRA website to view AFRA reports and frequently asked questions but do not have access to manage roles, users or business rules.
PTA 10:	Does the website have a posted privacy notice?	Yes
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	No

PTA 12:	Does the website use web measurement and customization technology?	No
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No
PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Biographical Information Name Contact Information Email Address (Personal) Email Address (Business) Mailing Address (Business) Other Other
PIA 22A:	Identify the "other" type(s) of personally identifiable information (PII) not mentioned in the above list.	Professional contact information includes firm name and address that may identify or be linkable to an individual (e.g., farm owner); Email address of FDA employees/Direct Contractors is work not personal. FEI numbers also collected/maintained.
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	PII about members of the public are used as animal food facility identification information (e.g., name and address). Inspector/investigator responses to inspection protocol (IP) questionnaires, which may include PII, are used in the calculation of level of risk (high or non-high) a facility poses to both human and animal health. PII about FDA employees is used for maintaining AFRA system access and user lists.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	Information in this system is collected, used, and disclosed pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301. Provisions of the FFDCA require the regulated animal food industry to register facilities and/or are subject to inspections for compliance with requirements in 21 CFR parts 558, 507, 225, and 589.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No

PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains In-person Online Government Sources Within the OPDIV
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	0910-0751 (FDA 3942b) exp.2/29/2028 0910-0337 (FDA 3448) exp.6/30/2028 0910-0502 (FDA 3537/3537a) exp.11/30/2025
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	Yes
PIA 32A:	Identify with whom the PII is shared or disclosed.	Within HHS
PIA 32B:	For each disclosure, name the organizations/systems the system shares PII with and the purpose(s) of the disclosure.	Employees from HFP, CVM, and OII will use and have access to the AFRA system for work planning and animal food inventory risk ranking reports.
PIA 32C:	List any agreements in place that authorize the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	None. Disclosures are within FDA and restricted to need-to-know for authorized agency activities.
PIA 32D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	FDA does not expect or plan to disclose records in the AFRA system to any individuals or entities outside of FDA. This is not a Privacy Act system of records, and the Act does not require that FDA/CVM maintain an accounting of disclosures.
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
PIA 34:	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	In the case of information for a public citizen, the information was collected during an FDA investigation or submitted as part of an animal food facility registration. For animal food facilities submitting information on an OMB approved form or online system, the FDA privacy policy is displayed or available via a hyperlink. For employees, there is not a notice/consent or opt-out process specific to the AFRA system. At the time of hire, CVM personnel are given notice of a consent to FDA's use of their personal information in relation to their work as a federal/FDA employee. They can update and correct the information at any time through existing procedures.

PIA 35:	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). If they cannot be notified or have their consent obtained, explain why.	If FDA changes its practices with regard to the collection or handling of PII related to the AFRA system, the Agency will employ measures to provide any required notice and obtain consent from individuals regarding the collection or use of this PII. This may include email to individuals, adding or updating online notices or forms, or other available means to contact the individuals.
PIA 36:	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	Individuals who suspect their PII has been inappropriately obtained, used, or disclosed in any FDA system have several options available to resolve the situation. These individuals may contact the office or division where they have determined their information is being held. Individuals may also seek assistance from the FDA Privacy Office. Employees with such concerns can additionally work with their supervisors, the Privacy Office, the Enterprise Resource and Information Center (ERIC a 24-hour technical assistance line), and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). Contact information for these offices and resources is available across FDA's internet and intranet pages. FDA personnel and contractors are required to rapidly report actual or suspected breaches to FDA's CIOCC.
PIA 37:	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	An individual's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Incorrect data is corrected in the course of FDA/CVM's use of the system/information, e.g., updating name of the entity point of contact. Accuracy is ensured by individual review at the time of submission. FDA personnel may correct/update their information themselves. External individuals (e.g., members of the public) may contact the FDA through phone or email to correct their PII. PII relevancy is ensured by the design of forms, web pages and other data collection methods to allow only for the submission of PII that is essential for necessary and authorized uses. Access to PII is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability are protected by privacy and security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on National Institute of Standards and Technology (NIST) guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. CVM performs annual reviews to evaluate user access.

PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	Users: Review the animal food firm inventory to assess the accuracy of the risk ranking and cover-by dates. Some of the users are Direct Contractors. Administrators: Monitor the system and manage user access. Contractors: “Contractors” refers to FDA Direct Contractors who monitor the system and manage user access.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to the AFRA system must obtain sign off from the system owners or administrators before access is granted. The AFRA system owner will confirm that system access is required in order for the user to complete his/her job and will confirm with the user's supervisor if necessary.
PIA 41:	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	All users of the system may require access to all PII in the system. While access requires authorization, all authorized users need and have access to all PII. The access list for the information system is reviewed on a semi-annual basis during which time users' access permissions are reviewed/adjusted, and unneeded accounts are purged from the system.
PIA 42:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.	All system users at FDA complete annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity, and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Information Management and Technology (OIMT) verifies that training has been successfully completed.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	No additional system-specific training is received by users; however, users are provided with user guides and manuals, and privacy guidance is available on the FDA intranet and from Privacy staff.

PIA 44:	Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	Records are maintained and disposed of according to NARA approved records schedule for Information Technology/Electronic Records: Data Administration Records-GRS 3.1 Item 051-Temporary, destroy 5 years after project/transaction completed or suspended, or associated system terminated, or data migrated to successor system. Records may be retained longer if business use exists.
PIA 45:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and user access report audits. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system severs are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the NIST') Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	11/10/2025
Privacy Analyst Review Comments:	The PIA is experiencing an Archer error with Question #3 of the general information " Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 11/3/2025.	**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	11/10/2025
SOP Review Comments:	The FDA’s Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls. 11/10/2025	**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	11/26/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 11/26/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	16

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	12/9/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	13

SAOP Signature

Date	User	Type	Name	Original Value	New Value
12/9/2025 2:14 PM	BAUR, VANESSA	Signature	SAOP (Email PIN)		Content Signed

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 01	BLAND, CRYSTAL	11/26/2025	11/26/2025 ATO expiration date has expire on 11/17/2025.	