


General Information

PTA / PIA Name:	FDA - SS - QTR2 - 2025 - FDA4918661	PTA / PIA ID:	3073937
Component Name:	FDA - HFP Shellfish Shippers	ATO Boundary Name:	CBER Office of Regulatory Operations
Overall Status:	Complete 	# of Days - Open:	29
Submitter:		Submit Date:	5/2/2025
Next Assessment Date:	05/21/2028	Expiration Date:	5/21/2028
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?		No
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.		10/17/2023
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	Wenmin Chen
PTA 01A:	POC Title and Organization	PM/ HFP FDA
PTA 01B:	POC Email Address	wenmin.chen@fda.gov
PTA 01C:	POC Phone Number	240-402-0730
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
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 Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) is responsible for providing information on retail food protection, milk safety and seafood safety.

The Shellfish Shippers (SS) falls under the National Shellfish Sanitation Program (NSSP), by where states, provinces or countries have the responsibility of certifying their firms. The state, province or country sends the FDA form 3038 information and the changes to the Shellfish Safety Team.

The purpose of CFSAN's Shellfish Shippers (SS) system, a subcomponent of the CFSAN's Food Safety & Nutrition Submission Applications (CFSNSA) system boundary, is an online electronic data submission system allowing the State Control Authority (SCA) SS inspectors or administrators to submit FDA form 3038 directly via Internet access. The information entered by the state user is stored in the centralized FDA/CFSAN database.

The key functional element of CFSAN Shellfish Shippers Administrator is to process the certificate data submitted by the state user through the CFSAN Intranet. The CFSAN SS administrator can either accept or refuse to accept the Shellfish Certificate data. If the information on the form is incorrect, it is not accepted. Once a certificate is approved, the approved Certificate information is available to the public through Internet access and listed monthly on the Interstate Certified Shellfish Shippers List. The SCA no longer needs to submit the hard copy FDA form 3038 to the FDA but still has the option to submit it. To access the system, state users must first establish an account through the request user account function on the SS System. All SS data is protected by the Privacy Act of 1974.5 (USC 552A as Amended, 5252a).

System users for SS consist of two user modules. Users of the external module include members of the public and non-HHS entities (e.g., industry users including but not limited to food control officials, seafood industry and other interested persons who require a user account (username and password as well as token factor authentication) to access the system. Users of the internal module is limited to a very small group of FDA employees (permanent and Direct Contractors) serving in the role of System Administrators (Admins) and investigators.

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.

Shellfish Shippers (SS) collects and maintains the following personally identifiable information (PII) about FDA employees (permanent and Direct Contractors): (a) first and last name; (b) job title; (c) center.

The Shellfish Shippers system collects certified shellfish business name, address, and its shellfish function (i.e., re-shipper, shucker-packer); list of FDA regional offices with contact names, address, phone and fax numbers, and e-mail; and State and country shellfish regulatory official contact information including the name of the official, title, address, phone and fax number, and e-mail address.

Non-PII collected and maintained in the system includes regulatory compliance and inspections and auditing data.

CFSAN SS also collects PII about external users of the system (members of the public; non-HHS entities; and individual users at third-party vendors (i.e., industry users including but not limited to food control officials, seafood industry and other interested persons)). PII may include: (a) first and last name; (b) work e-mail address; and (c) work telephone number. Non-PII data collected from external users include: (a) organization affiliation; (b) state/province; and (c) country.

The types of data that are maintained in and/or shared from the system is/are: The FDA system providing employee data is the Enterprise Administrative Support Environment (EASE) system (the subject of a separate assessment). Employee data is used to log on authorized users automatically and securely.

The amount of time the PII is stored in the system is: Once a certificate is approved, the approved Certificate information is available to the public through Internet access and listed monthly on the Interstate Certified Shellfish Shippers List.

PTA 05A:

Are user credentials used to access the system?

Yes

PTA 05B:

Please identify the type of user credentials used to access the system.

HHS User Credentials

HHS/OpDiv PIV Card

Non-HHS User Credentials

Username

Password

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.

The information about non-HHS entities (industry users, to include but not limited to restaurant owners, retail food and other service vendors) is collected and/or maintained in order to identify its certified shellfish processors to FDA and FDA uses this information to compile the Interstate Certified Shellfish Shippers List, a monthly publication that lists certified shellfish processors. This list is used to identify and exclude shellfish processed by

uncertified processors.

The information about administrators and investigators (FDA Employees) and developers (FDA Direct Contractors) is collected and/or maintained in order to submit and approve Shellfish Certificate data, CFSAN SS promotes compliance with FDA food safety requirements.

PII from the component is shared with in order to because The SS is an online electronic data submission system allowing the State Control Authority (SCA) SS inspectors or administrators to submit FDA form 3038 directly via Internet access. Designed to serve as a resource to submit and approve Shellfish Certificate data.

Note: The SS is an online electronic data submission system allowing the State Control Authority (SCA) SS inspectors or administrators to submit FDA form 3038 directly via Internet access. Designed to serve as a resource to submit and approve Shellfish Certificate data, CFSAN SS promotes compliance with FDA food safety requirements.

FDA and regulatory agencies for each state, foreign nations, and the molluscan shellfish industry participate in the National Shellfish Sanitation Program. Regulatory agencies are not FDA but rather part of another state agency. Each participant identifies its certified shellfish processors to FDA and FDA uses this information to compile the Interstate Certified Shellfish Shippers List, a monthly publication that lists certified shellfish processors. This list is used to identify and exclude shellfish processed by uncertified processors.

FDA employees and Direct Contractors who access or use these applications do not use any PII to retrieve records held in the SS application.

The SS system is Single Sign On (SSO) and PIV enabled for internal users. The system has implemented a multifactor authentication via alternate PIV cards for network access to privileged accounts. The FDA uniquely identifies and authenticates organizational users. For PIV authenticated system, PIV credentials are based on user's certification which are also unique. Users of the external module include members of the public and non-HHS entities (e.g., industry users including but not limited to Restaurant owners, Retail food and other service vendors) who only require a user account (email address only; no password) to access the system.

Users of the system include administrators and investigators (FDA Employees) and developers (FDA Direct Contractors). SS utilizes PIV cards and Single Sign On (SSO). The authenticator is managed by Active Directory and all access is managed and

		granted through PIV/SSO.
		Users of the external module include members of the public and non-HHS entities (e.g., industry users including but not limited to food control officials, seafood industry and other interested persons who require a user account (username and password as well as token factor authentication) to access the system.
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://www.cfsanappsexternal.fda.gov/scripts/shellfish/shadmin/ https://cfsanappsinternal.fda.gov/scripts/shellfish/ss
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes
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 purpose of the website is to allow the State Control Authority (SCA) SS inspectors or administrators to submit FDA form 3038 directly via Internet access. Shellfish Shippers is designed to serve as a resource to submit and approve Shellfish Certificate data, CFSAN SS promotes compliance with FDA food safety requirements. The following categories of individuals have access to the website: The SS system includes a website or online application that is accessible to the general public. Users access the website via public URL.
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?	Yes
PTA 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies- Does Not Collect PII Persistent Cookies- Does Not Collect PII
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 Employment Status/History Contact Information Email Address (Personal) Phone Numbers (Personal) Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Job Title Center
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies) Employees/HHS Direct Contractors Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors)
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	100 – 499
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purpose of managing user access and to allow users to submit and approve Shellfish Certificate data; CFSAN SS promotes compliance with FDA food safety requirements.
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.	Federal Information Processing Standards (FIPS) 199 and NIST SP 800-60 Rev. 1, Volumes I and II.
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 Hard Copy Mail/Fax Email Online Government Sources Within the OPDIV State/Local/Tribal Foreign Other Federal Entities Non-Government Sources Private Sector
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No

PIA 31B:	Explain why an OMB information collection approval number is not required.	This system/component does not collect information using an information collection request as defined by the Paperwork Reduction Act.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
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.	<p>There is no option to object to or opt-out of the information collection because there is no specific opt-out process. Individuals may decline to provide PII but will not be able to use the system.</p> <p>For SS although the submission of all information is "voluntary" as that term is used in the context of the Privacy Act, submission of PII is necessary to coordinate and conduct oversight for the functions enabled by SS.</p>
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 website, the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include email to individuals, adding or updating online notices or forms, or other available means to inform the individual.
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.	<p>The processes in place to resolve an individual's concerns when they PII has been inappropriately obtained, used or disclosed include:</p> <p>The processes in place to resolve an individual's concerns when they PII has been inappropriately obtained, used or disclosed include:</p> <p>Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource, and Information Center (ERIC-employees or Direct Contractors only), the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues (all listed on fda.gov and the FDA intranet).</p> <p>In the event of a suspected incident or data breach, FDA personnel must report without delay to FDA's Cybersecurity and Infrastructure Operations and Coordination Center (CIOCC).</p>

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.	<p>The agency reviews PII during the approval and certification process.</p> <p>Availability, relevancy, accuracy, and integrity of PII about FDA employees is addressed at the source system, EASE, where reviews and controls are applied pursuant to security and privacy assessments of that system as well as under organizational business practices.</p>
PIA 38:	Identify who will have access to the PII in the system.	<p>Administrators</p> <p>Developers</p> <p>Contractors</p>
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.	<p>The reason the following groups need access to PII is:</p> <p>Users: Users require access to submit Shellfish Certificate data.</p> <p>Administrators: For development, testing, and maintenance purposes. Some of the administrators are Direct Contractors.</p> <p>Developers: For development, testing, and maintenance purpose. Some of the developers are Direct Contractors.</p> <p>Contractors: Direct contractors who perform administrative, development, testing, and maintenance purpose.</p>
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	<p>The administrative procedures in place to determine which system users may access PII are:</p> <p>Users who require access to the PII in the system need to obtain supervisory approval before access is granted. There are two ways to request access to the applications: the user emails the business owner/IT Technical Lead or submits a request online through the 'Request Access' application option.</p>
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.	Role based security controls ensure that each user role is appropriately assigned at the individual level in accordance with an individual user's need-to-know and least-access-privileges in regard to official duties such that each user sees/accesses only that data that is essential to complete his/her job. The agency reviews the access list for the information system on a quarterly basis. During this process 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 users for CFSAN Food Safety & Nutrition Submission Applications (CFSNSA)/Shellfish Shippers (SS) are required to complete FDA annual security and privacy awareness training that provides information on protecting PII. The Office of Digital Transformation tracks completion.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	The SS application has a user manual which serves as system reference material and training.
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).	SS adheres to National Archives and Records Administration (NARA) approved GRS 5.2 Item 020 schedule for intermediary records. Therefore, PII records are reviewed during the periodic User Access Review process and retained or destroyed when no longer needed for business use.
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.	<p>FDA secures PII in the system using the following administrative controls:</p> <p>Administrative safeguards include user training on PII and implementation of Need to Know and Minimum Necessary principles when awarding access.</p> <p>FDA secures PII in the system using the following technical controls:</p> <p>Technical Safeguards include the use of two-factor access authentication, device disk encryption, firewalls, virtual private network (VPN) and network monitoring and intrusion detection tools.</p> <p>FDA secures PII in the system using the following physical controls:</p> <p>Physical controls include the location of all system servers located at FDA facilities protected by guards, locked facility doors, and climate controls.</p> <p>Note: Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.</p>

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	Privacy Analyst Review Date:	5/2/2025
Privacy Analyst Review Comments:		# of Days - PA Review:	0

SOP Review			
SOP Review Decision:	Approved	SOP Review Date:	5/13/2025
SOP Review Comments:		# of Days - SOP Review:	11

Agency Privacy Analyst Review			
Agency Privacy Analyst Review Decision:	Approved	Agency Privacy Analyst Review Date:	5/15/2025
Agency Privacy Analyst Review Comments:	<p>Reviewer: Crystal Bland</p> <p>5/15/2025 FDA addressed the comments regarding providing a POC contact information. However, they did not address comment PIA-22 "PTA-5 states the collection of work email and work phone number, please also select "email address (business) and phone number (business)." Email address (personal) and phone number (personal) is selected. Since the PII elements are still present, the SAOP can determine to approve/reject.</p> <p>4/24/2025 Please see comments and update accordingly.</p> <p>PTA-01: Must provide a POC Name for PIA and ATO approval.</p> <p>PTA-01A: Must provide a POC Organization and title for PIA and ATO approval.</p> <p>PTA-01B: Must provide a POC Email for PIA and ATO approval.</p> <p>PTA-01C: Must provide a POC Phone number for PIA and ATO approval.</p> <p>PIA-22: PTA-5 states the collection of work email and work phone number, please also select "email address (business) and phone number (business)."</p>	# of Days - APA Review:	2

SAOP Review					
SAOP Review Decision:	Approved	SAOP Review Date:	5/22/2025		
SAOP Review Comments:		# of Days - SAOP Review:	7		
SAOP Signature					
Date	User	Type	Name	Original Value	New Value
5/22/2025 11:44 AM	GUENTHER, BRIDGET	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	4/24/2025	<p>The PIA is experiencing an Archer error with Question #3 of the general information.</p> <p>Q-3 "Does the system have or is it covered by a Security Authorization to Operate (ATO)?"</p> <p>The FDA instance of Archer is automatically entering the answer "No," which is incorrect.</p> <p>The ATO date is 11/21/2022.</p> <p>At this time, we are unable to update Archer to reflect the correct answer "Yes."</p> <p>The FDA Archer Team is aware of this occurrence and is working on a solution.</p>	<p>RE_PIA in Queue HFP Shellfish Shippers.pdf</p> <p>HFP Shellfish Shippers PIA.pdf</p>
PIA 22	BLAND, CRYSTAL	4/24/2025	<p>PTA-5 states the collection of work email and work phone number, please also select "email address (business) and phone number (business)."</p>	
PTA 01	BLAND, CRYSTAL	4/24/2025	<p>Must provide a POC Name for PIA and ATO approval.</p>	
PTA 01A	BLAND, CRYSTAL	4/24/2025	<p>Must provide a POC Organization and title for PIA and ATO approval.</p>	
PTA 01C	BLAND, CRYSTAL	4/24/2025	<p>Must provide a POC Phone number for PIA and ATO approval.</p>	
PTA 01B	BLAND, CRYSTAL	4/24/2025	<p>Must provide a POC Email for PIA and ATO approval.</p>	
PTA 01	BLAND, CRYSTAL	5/15/2025	<p>5/15/2025 Resubmitted</p>	<p>HFP Shellfish Shippers.pdf</p>