US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/24/2013

OPDIV:

FDA

Name:

Seafood HACCP

PIA Unique Identifier:

P-4393794-810413

The subject of this PIA is which of the following?

Major Application

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

Yes

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

Agency

Is this a new or existing system?

Existing

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

PIA Validation

Describe in further detail any changes to the system that have occurred since the last PIA.

None.

Describe the purpose of the system.

Commercial seafood processors develop their plans of food safety controls to identify and prevent potential health hazards with their products. These controls comprise the processor's Hazard Analysis and Critical Control Point (HACCP) program. CFSAN's Seafood HACCP application provides the means both to capture the controls and to evaluate each processor's performance with respect to its HACCP program. FDA field inspectors enter data directly into the Seafood HACCP application through the CFSAN Intranet. Then CFSAN's Office of Food Safety (OFS) evaluates each processor's performance in complying with its controls and generates a series of summarized reports. This evaluation process enables OFS management to evaluate the performance of individual processors as well as determine industry trends with respect to compliance and regulatory activities. The Seafood HACCP application also allows OFS to meet the Center's post-market, scientific, and business process goals in the area of seafood safety.

Describe the type of information the system will collect, maintain (store), or share.

The system captures firm data regarding seafood processors and their HACCP programs. This information enables FDA to evaluate each processing firm's performance in complying with its HACCP program.

The Agency performs HACCP compliance inspections of domestic and foreign fish and fishery products processing facilities. These inspections ensure that these processors implement a system of preventive controls, in addition to ensuring compliance with more traditional regulatory requirements, such as the Current Good Manufacturing Practice Regulation. The Seafood HACCP system tracks the implementation of seafood HACCP plans and sanitation controls needed as part of the inspection of the processor's entire HACCP system.

The personally identifiable information (PII) in this system is limited to the names of FDA and State inspectors that are included as standard elements of the report forms submitted in the evaluation and approval process. Submission of the inspector names is not mandated by statute but is required in order to administer inspections.

Provide an overview of the system and describe the information it will collect, maintain (store), or share,

Commercial seafood processors develop their plans of food safety controls to identify and prevent potential health hazards with their products. These controls comprise the processing firm's HACCP program. CFSAN's Seafood HACCP application provides the means both to capture the controls and to evaluate each processing firm's performance with respect to its HACCP program. FDA field inspectors enter data directly into the Seafood HACCP application through the CFSAN Intranet. Then CFSAN OFS evaluates each processing firm's performance in complying with its controls and generates a series of summarized reports. This evaluation process enables OFS management to evaluate the performance of processing firms as well as determine industry trends with respect to compliance and regulatory activities. The Seafood HACCP application also allows OFS to meet the Center's post-market, scientific, and business process goals in the area of seafood safety.

Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Name

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Employees

Business Partner/Contacts (Federal/state/local agencies)

How many individuals' PII is in the system?

500-4,999

For what primary purpose is the PII used?

The names of FDA or the State inspectors who are responsible of the site inspection are collected for workflow management purposes and to enable CFSAN to evaluate each processing firm's performance in complying with its HACCP program.

Describe the secondary uses for which the PII will be used.

None.

Identify legal authorities governing information use and disclosure specific to the system and program.

Seafood HACCP includes data and reports that support post market food safety through inspection, analyses, and control of biological, chemical, and physical hazards from production to product consumption, in accordance with 21 CFR Part 123 as authorized under provisions of Title 21 of the U.S. Code including 21 U.S.C. 321 and 350g.

Are records on the system retrieved by one or more PII data elements?

No

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

Government Sources

Within OpDiv

State/Local/Tribal

Non-Governmental Sources

Identify the OMB information collection approval number and expiration date

OMB No. 0910-0466; January 31, 2014.

Is the PII shared with other organizations?

No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

PII in this system is limited to the names of FDA and State inspectors that are included as standard elements of the report forms (FDA forms 3501 and 3502) submitted during the evaluation and approval process.

FDA employees and contractors are notified at the time of hire that as a condition of employment they must consent to the government's use of their information in relation to their work. State inspection officials receive notice via the context of the forms submitted and the FDA privacy policies available via link provided on all of the FDA.gov pages.

Is the submission of PII by individuals voluntary or mandatory?

Mandatory

Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.

Although submission of the forms is voluntary, FDA employees and state inspection officials must provide their names on the FDA forms 3501 and 3502.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

If FDA changes its practices with regard to the collection or handling of PII related to the HACCP system, 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 e-mail to individuals, adding or updating online notices, or other available means to inform the individual.

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.

There is not a complaint/notification process specific to this system. The only PII collected is the name of the relevant inspector and FDA personnel. Individuals who are concerned with the use of their information may contact FDA or CFSAN by phone, mail or e-mail using the contact information provided on fda.gov.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

The limited amount of PII involved is reviewed during the approval and certification process conducted for all submitted Seafood HACCP forms.

Identify who will have access to the PII in the system and the reason why they require access.

Users:

Update and review submissions.

Administrators:

Monitor the system, manage users and control system access.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Users who require access to the information system need to have supervisor approval and sign off before access is granted.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

The user's supervisor will indicate on the account creation form the minimum information system access that is required in order for the user to complete his/her job. The agency reviews the information system access list semi-annually. In the course of this review the agency reviews/adjusts users' access permissions and removes unneeded accounts from the system.

Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.

All FDA system users complete annual FDA information security and privacy awareness training.

Describe training system users receive (above and beyond general security and privacy awareness training).

FDA employees and state inspectors receive generalized Seafood HACCP training, and may obtain privacy guidance through FDA's privacy office.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

Parts F5080 (titled Hazard Analysis and Critical Control Point (HACCP) System), F5081 (titled Seafood HACCP: Input Records; General Records Schedule [GRS] 20, items 2a4, 2b, 2c), and F5082 (titled Seafood HACCP: Data Files) of the The CFSAN Program Records Control Schedule apply to this system. Such data can be deleted/destroyed when they are no longer needed for business or regulatory purposes, or 20 years after cutoff, whichever is latest.

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

The information is protected by administrative, physical, and technical controls in accordance with policies and regulations of the FDA, NIST, and OMB. The agency reviews security controls on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system. Controls include user identification, passwords, firewalls, Virtual Private Network (VPN), encryption, Intrusion Detection System (IDS), guards, identification badges, key cards, cipher locks, and Closed Circuit television.