

UNITED STATES FOOD & DRUG ADMINISTRATION

Interstate Shellfish Dealer's Certificate and Participation in the
National Shellfish Sanitary Program

OMB Control No. 0910-0021 - Revision

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration's (FDA's) Interstate Shellfish Dealer's Certificate program. Under section 243 of the Public Health Service Act (PHS Act) (42 U.S.C. 243), we are required to cooperate with and aid State and local authorities in the enforcement of their health regulations and are authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, we participate with State regulatory agencies, some foreign nations, and the U.S. bivalve molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

Molluscan shellfish consumed fresh (raw) and fresh frozen poses unique public health concerns. The safety of molluscan shellfish directly reflects the cleanliness of the waters where they are grown. Molluscan shellfish are sessile, filter-feeding organisms that pump large quantities of water through their bodies during their normal feeding process. The relationship between shellfish harvesting waters that are contaminated with sewage and other forms of pollution and food safety concerns has been demonstrated often. Additionally, bivalve molluscan shellfish must be held, packed, and shipped under sanitary conditions to prevent contamination subsequent to harvest and prior to delivery to the consumer.

The NSSP is a voluntary cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish dealers. Each participating State and foreign nation monitor its molluscan shellfish production and issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provide a certificate of its certified shellfish dealers using **Form FDA 3038**, "*Interstate Shellfish Dealer's Certificate*" available for download at <https://www.fda.gov/media/72094/download>. We use this information to publish the "*Interstate Certified Shellfish Shippers List (ICSSL)*," a monthly comprehensive listing of all molluscan shellfish dealers certified under the cooperative program, which is available at <https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list>. We also provide information on our website at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/state-cooperative-programs/fda-national-shellfish-sanitation-program>, which may serve as a helpful resource to respondents.

Form FDA 3038 may be submitted on paper or submitted electronically by State or international officials. These officials securely log into a shellfish shippers account to fill out Form FDA 3038 electronically. The information obtained from the form has been entirely automated. The

forms transmitted by the States, after approval by an FDA official, are entered into an FDA computer database program that allows the addition, deletion, download, and generation of the ICSSL, published monthly in PDF format, and may be updated daily when new data is available.

Under the authority of section 243 of the PHS Act, we are revising this information collection to also collect from State regulatory agencies samples of shellfish, along with associated sample metadata (date collected, temperature, and location). If available, we are also collecting analytical results needed to classify growing area waters for existing and emerging food safety hazards and to ensure that shellfish products of dealers listed on the ICSSL are safe.

Respondents will have already independently collected samples at a given location/time (our request is for an additional sample to be collected and sent to FDA for analysis) and, in some cases (for requested existing analytical results), conducted tests associated with information submitted as part of samples and analytical results. Regarding the collection of samples, FDA will provide shipping materials for transport and will bear any shipping costs.

The information collection also includes respondents providing to FDA documents demonstrating compliance with the NSSP requirements. When a competent authority in another country conducts an evaluation to determine whether the U.S. food safety control measures for bivalve molluscan shellfish are equivalent to its own system of controls, the competent authority may require FDA to provide information and records demonstrating compliance with the provisions of the NSSP. Only those firms that comply with the NSSP would be permitted to export bivalve molluscan shellfish to a country whose competent authority determined that the U.S. system of controls is equivalent to their own controls. For example, to implement the European Commission's (EC) determination that the U.S. system of food safety controls for raw bivalve molluscan shellfish is equivalent to the European Union's (EU) system of controls, the EC requires FDA to provide documentation collected from NSSP-participating shellfish control authorities for firms seeking to export raw molluscan shellfish to the EU. This documentation includes, but is not limited to:

- a list of growing areas with an approved classification;
- the most recent sanitary survey for each growing area with an approved classification;
- and
- the most recent inspection report for each dealer seeking to export bivalve molluscan shellfish to the EU.

The examples above are illustrative. Some competent authorities may require additional information to conduct an equivalence assessment or to implement an equivalence determination, or both. We provide respondents with information about the specific documentation that is required for each equivalence assessment. For those competent authorities that recognize the U.S. system as equivalent, additional documentation may be needed to implement that determination.

We therefore request OMB approval of the information collections supporting our Interstate Shellfish Dealer's Certificate program, **Form FDA 3038**, and the collection of samples and sample metadata, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA uses collected information to facilitate the export of U.S. bivalve molluscan shellfish to countries whose competent authorities have determined the U.S. system of food safety controls to be equivalent to their own system of controls by demonstrating that the exporter complies with the U.S. system of controls specified in the NSSP. We also use information submitted by respondents to publish the “*Interstate Certified Shellfish Shippers List*,” a monthly comprehensive listing of all bivalve molluscan shellfish dealers certified under the cooperative program. In addition, we use the information to identify U.S. bivalve molluscan shellfish dealers eligible to obtain health certificates required for products to be shipped to certain countries or regions. This notice includes the additional activity of collecting bivalve molluscan shellfish samples with metadata and analytical results which helps to ensure that shellfish products of dealers listed on the ICSSL are safe.

State and local food control officials and the food industry may also utilize the list to determine certified sources of bivalve molluscan shellfish. Bivalve molluscan shellfish offered for sale that originate from non-listed dealers will be removed by State and local food control officials. This procedure assists both FDA and individual states in assuring that shellfish are produced, packed and shipped under proper sanitary controls to protect the health of consumers of molluscan shellfish.

Description of Respondents: Respondents to this information collection are participating State regulatory agencies and foreign nations.

3. Use of Improved Information Technology and Burden Reduction

The *Interstate Shellfish Dealer’s Certificate*, **Form FDA 3038**, may be submitted on paper or submitted electronically by state or international officials. These officials securely log into a shellfish shippers account to complete the form electronically. Information submitted is used to produce the Interstate Certified Shellfish Shippers List, published monthly in PDF format, and may be updated daily as new data becomes available. We estimate that one hundred percent (100%) of the respondents will use electronic means to submit Form FDA 3038 and the NSSP compliance documentation.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities. Respondents are State and local regulatory agencies and foreign nations.

6. Consequences of Collecting the Information Less Frequently

The information is collected in accordance with applicable statutory and regulatory submission schedules. Respondents submit requisite information for dealer’s certification annually, as determined by applicable State or foreign law. State certifications are issued independently and

expire annually; therefore we administer the collection monthly to allow for individual submission schedules by respondents.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice soliciting public comment in the *Federal Register* of December 19, 2024 (89 FR 103832). One

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3038 (Interstate Shellfish Dealer's Certificate) is name, telephone number, email address, mailing address, username, and password. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 (5 U.S.C. 552a) and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and/or webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public (see 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden¹

IC Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of Interstate Shellfish Dealer's Certificate	3038	40	57	2,280	0.10 (6 minutes)	228
Submission of NSSP Documentation	N/A	13	1	13	0.25 (15 minutes)	3
Submission of Samples and Analytical Results	N/A	35	2	70	0.50 (30 minutes)	35
TOTAL				0		0

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. *Annualized Cost Burden Estimate*

We estimate the annualized burden hour cost to respondents for this collection of information to be \$11,762.52. We assume that certification information is prepared by an employee earning wages commensurate to that of a Federal government employee at the GS-5/Step-1 rate, in the Washington-Baltimore Locality Pay Area for the year 2025 (\$22.11 per hour). To account for overhead, we doubled the rate to \$44.22 per hour resulting in costs of \$10,082.16 (228 hours x \$44.22 per hour). We estimate the cost for completion and submission of other records related to participation in the NSSP will be \$132.66 (3 hours x \$44.22). We also estimate the cost to respondents for submission of samples and analytical results to be \$1,547.70 (35 hours x \$44.22). Thus, the total cost to respondents is estimated to be \$11,762.52 (\$10,082.16 + \$132.66 + \$1,547.70).

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Preparation of Interstate Shellfish Dealer's Certificate	228	\$44.22	\$10,082.16
Submission of Other Records Related to Participation in the NSSP (NSSP Compliance Documents)	3	\$44.22	\$132.66
Submission of Samples and Analytical Results	35	\$44.22	\$1547.70
Total			\$11,762.52

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We receive approximately 2,280 responses from 40 respondents annually which include the States and some international countries. We also estimate that we will receive 13 one-time annualized responses regarding other records related to participation in the NSSP from 13 respondents and 70 responses related to submission of samples with their metadata and analytical results from 35 respondents. We estimate that we expend \$93,092.10 in processing the data received in the forms and records. Expenses for shipping samples and related materials account for approximately \$3,975, and processing samples account for approximately \$7,000. We base our estimate for personnel costs on the salary of one full-time employee at the GS-12, Step 1 rate, in the Washington-Baltimore Locality Pay Area for the year 2025 who spends an estimated 845 hours on this program (845 hours x \$48.59/hour = \$41,058.55). Allowing for overhead, the figure is doubled, for a total of \$82,117.10. Thus, the total estimated cost to the Federal government is **\$93,092.10** (\$82,117.10 + \$3,975 + \$7,000).

15. Explanation for Program Changes or Adjustments

The information collection reflects program changes. We have added the submission of samples and associated information as a third element to the information collection and have therefore increased our burden estimate by 35 hours and 70 responses annually. We have made no adjustments to the remaining to collection elements.

16. Plans for Tabulation and Publication and Project Time Schedule

We publish a monthly list entitled, “*Interstate Certified Shellfish Shippers List*,” which is available on our internet site at <https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list>.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.