

UNITED STATES FOOD & DRUG ADMINISTRATION

Interstate Shellfish Dealer's Certificate

OMB Control No. 0910-0021

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

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration's (FDA, the agency, us or we) Interstate Shellfish Dealer's Certificate program. Under section 243 of the Public Health Service 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 bivalve 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 to FDA on Form FDA 3038, "*Interstate Shellfish Dealer's Certificate*" available 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 bivalve 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>.

The information collection also includes providing certain documents demonstrating compliance with the NSSP. 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. FDA uses the information collection to support 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.

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 is requiring FDA to provide documentation collected from NSSP-participating shellfish control authorities for firms seeking to export raw bivalve 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 plan to 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 extension of OMB approval of the information collection provisions of the Interstate Shellfish Dealer's Certificate program, including other records related to participation in the NSSP compliance equivalence program, and approval of Form FDA 3038, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We 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. State and local food control officials and the food industry use 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. We also use the information to support bivalve molluscan shellfish exports to certain countries or regions by demonstrating the compliance of NSSP-participating shellfish control programs with NSSP requirements determined equivalent by the subject country's competent authority. 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.

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 Dealers 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 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, downloading, and generating of the *Interstate Certified Shellfish Shippers List*, published monthly in PDF format, and may be updated daily when new data is 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

The information collection schedule is determined by respondents. Also, we are unaware of duplicative information collection. The Interstate Shellfish Dealer's Certificate information is only provided to FDA when a State or foreign nation issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. The NSSP-compliance documentation is only provided when an NSSP-participating shellfish control authority seeks recognition under a foreign nation's shellfish control authority's equivalence determination.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities. Respondents are State and local regulatory agencies and foreign nations, not businesses. No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Respondents submit the required information on a yearly basis, as determined by applicable State or foreign law. Each State has a different expiration date for its certifications; therefore, there is a need for year-round collection of data. However, States certify for a one-year period or the applicable shellfish season within that State's jurisdiction.

Without collection of the information, participating States would be unable to identify and help prevent the introduction of bivalve molluscan shellfish

distributed by uncertified dealers in other States and foreign nations. As a result, the NSSP would be ineffective in controlling the distribution of uncertified and possibly unsafe bivalve molluscan shellfish in interstate commerce. Without the collection of NSSP-compliance documentation, FDA would be unable to provide certain foreign nations the information it requires to determine that a NSSP-participating shellfish control program is implementing NSSP requirements determined equivalent by that subject country's competent authority.

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 November 4, 2021 (86 FR 60840). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally identifiable information (PII), it is collected in the context of the individuals' professional capacity and the FDA-related work performed for the 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, username and password. FDA determined that although PII is collected, it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected.

Under the Freedom of Information Act (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, 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

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden¹

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 Other Records Related to Participation in the NSSP	N/A	13	1	13	0.25 (15 minutes)	3.25
Total						231.25

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 \$9,430.38. First, we assume that certification information is prepared by an employee making an average wage similar 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 2022 (\$19.59 per hour). To account for overhead, we double the rate to \$39.18 per hour resulting in costs of \$8,933.04 (228 hours x \$39.18 per hour). To account for completion and submission of other records related to participation in the NSSP, we assume costs of \$127.34 (3.25 hours x \$39.18). Administrative cost, i.e. printing and mailing are estimated at \$370.00 for a total costs of \$9,430.38 (\$8,933.04 + \$127.34 + \$370.00).

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Preparation of Interstate Shellfish Dealer's Certificate	228	\$39.18	\$8,933.04
Preparation of Other Records Related to Participation in the NSSP	3.25	\$39.18	\$127.34
Printing and Mailing			\$370.00
Total			\$9,430.38

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 also receive 13 one-time annualized responses regarding other records related to participation in the NSSP from 13 respondents. We estimate that we expend \$42,992 in processing the data received in these forms. Administrative expenses account for approximately \$800 of this sum, and the remainder is personnel cost. We base our estimate on the salary of one full-time employee at the GS-8, Step 1 rate, in the Washington-Baltimore Locality Pay Area for the year 2022 who spends an estimated 800 hours on this program (800 hours x \$26.87/hour = \$21,496). Allowing for overhead, the figure is doubled, for a total of \$42,992. Thus, the total estimated cost to the Federal government is \$43,792 (\$42,992 + \$800).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to the currently approved estimate.

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.