UNITED STATES FOOD & DRUG ADMINISTRATION

Interstate Shellfish Dealer's Certificate

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, the agency, us or we) Interstate Shellfish Dealer's Certificate program. Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations, and is 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 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 nonmotile, 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, 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 processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, "*Interstate Shellfish Dealer's Certificate*." We use information from Form FDA 3038 to publish an "*Interstate Certified Shellfish Shippers List* (ICSSL)," a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program.

We are revising the information collection to also include certain NSSP compliance documentation. Having determined that the European Union (EU) food safety control system for raw bivalve molluscan shellfish intended for export into the United States, as administered by the European Commission (EC), provides at least the same level of sanitary protection as the United States' system, we are accepting the submission of information from NSSP-participating shellfish control who wish to seek recognition under the EC's equivalence determination. This documentation includes:

- 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 firm seeking to export shellfish to the EU.

For State NSSP participants that do not produce live/raw shellfish, required documentation is limited to the State's most recent Plant and Shipping Element Program Evaluation Report and the most recent inspection report for each shellfish processing firm to be listed for export to the EU. Collection of the information allows for an equivalence determination thereby permitting the importation of shellfish harvested from certain production areas and processed by establishments that have been listed by FDA on the ICSSL.

Accordingly, we request OMB approval of the information collection provisions of the Interstate Shellfish Dealer's Certificate program, including documentation associated with 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 molluscan shellfish processors certified under the cooperative program. State and local food control officials and the food industry use the list to determine certified sources of shellfish. 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 shellfish exports to the EU by demonstrating the compliance of NSSP-participating shellfish control programs with NSSP requirements determined equivalent by the EC. In addition, we use the information to identify U.S. shellfish processors eligible to obtain health certificates required for products to be shipped to the EU.

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 the 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 a FDA computer database program that allows the addition, deletion, down loading 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 the 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 processors 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 the EC'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, most 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 shellfish processed by uncertified processors in other States and foreign nations. As a result, the NSSP would be ineffective in controlling the distribution of uncertified and possibly unsafe shellfish in interstate commerce. Without the collection of NSSP compliance documentation, FDA would be unable to provide the EC the information it requires to determine that a NSSP participating shellfish control program is implementing NSSP requirements determined equivalent by the EC.

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 June 8, 2018 (83 FR 26699). No comments were received.

In the Federal Register of March 9, 2018 (83 FR 10487), we published a notice that described the European Commission's (EC's) determination that the United States' food safety control system for shellfish intended for export to the United States is equivalent to its own, and, that as a result of that determination, it intends to accept shellfish from certain growing areas in the United States. Comments received supported the equivalence determination. On November 6, 2018, the EC published Commission Implementing Decision (EU) 2018/1668 which added the United States (Massachusetts and Washington only) to the list of Third Countries from which molluscan shellfish imports are permitted. As part of the equivalence determination, the EC identified the need for FDA to provide NSSP compliance documentation collected from NSSP-participating shellfish control authorities seeking recognition under the EC's equivalence determination. Accordingly, and based on respondent interest, we have incorporated collection elements that will enable respondents to seek such a compliance determination.

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

All information collected is part of State government agencies' administrative files and is available to the public. The information collected is not confidential.

Privacy Act

This ICR request contains only state government agency administrative information and does not contain any personally identifiable information. It does contain a form, but the form does not require a Privacy Act Statement under 5 U.S.C. §552a(e)(3).

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 Costs

Description of Respondents: Respondents to this information collection are participating State and local regulatory agencies and foreign nations. Respondents are "State, Local or Tribal Governments."

12 a. Annualized Hour Burden Estimate

We estimate the burden for this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden[1]

Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. 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 Compliance Documentation	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.

There is a total of 40 respondents. In the past year the program received approximately 2,280 responses, or an average of 57 responses per respondent. The respondents complete the three-part Form FDA 3038, Interstate Shellfish Dealer's Certificate, using the information they have collected previously during state and international inspections. The original copy of this form is sent to FDA,

the other parts are retained for their files. The information is readily available from State and international records which must be kept to satisfy their own laws and regulations. We estimate that it takes a respondent an average of 6 minutes, or 0.1 hours, to complete each form. Therefore, 2,280 responses x 0.10 hours = 228 hours total response time. We base this estimate on our experience and the number of certificates received in the past 3 years.

In order to gain equivalence recognition by the EC, we estimate that respondents will make a one-time submission of documents demonstrating NSSP compliance. We estimate that 13 respondents will each submit 1 response, for a total of 13 responses. We estimate that each response will take 15 minutes, or 0.25 hour, for an annual total of 3.25 hours (13 responses × 0.25 hour).

12 b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be $8,782.88. We estimate that this certification will be prepared by an employee making an average wage similar to that of a Federal government employee at the GS-5/Step-1 rate, in the Washington-Baltimore Locality Pay Area for the year 2019, which is $18.19 per hour. To account for overhead, this cost is increased by 100 percent, which is $36.38 per hour. Thus, the annual wage cost for completion and submission of these certifications is approximately $8,294.64 (228 hours x $36.38 per hour). The annual wage cost for completion and submission of NSSP-compliance documentation is approximately $118.24 (3.25 hours x $36.38). Administrative cost, i.e. printing and mailing are estimated at $370.00. Therefore, total costs are $8,782.88 ($8,294.64 + $118.24 + $370.00).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 NSSP-compliance documentation from 13 respondents. We estimate that we expend $40,720 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 2019 who spends an estimated 800 hours on this program (800 hours x $24.95/hour = $19,960). Allowing for overhead, the figure will be doubled, for a total of $39,920. Thus, the total estimated cost to the Federal government is approximately $40,720 ($39,920 + $800).

15. Explanation for Program Changes or Adjustments

The information collection reflects a program change. We are revising the collection to include NSSP-compliance documentation, as discussed previously in Question 1, for which we gave notice

and an opportunity for public comment (see Question 8). This change results in an overall increase to the collection by 3.25 hours and 13 responses.

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 www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006753.htm.

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.