Interstate Shellfish Dealer's Certificate

OMB No. 0910-0021

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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, FDA participates 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.” FDA uses this information to publish the “Interstate Certified Shellfish Shippers List,” a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program.

If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

FDA requests the extension of OMB approval for Form FDA 3038, Interstate Shellfish Dealer's Certificate.

2. Purpose and Use of the Information Collection

FDA uses this information 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 FDA and the states to assure 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 and local regulatory agencies and foreign nations. Respondents are "State, Local or Tribal Governments."

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.

FDA estimates that ninety percent (90%) of the respondents will use electronic means to submit the Form FDA 3038.

4. Efforts to Identify Duplication and Use of Similar Information

There is no other information available that can be used for these purposes. The FDA is the only Federal agency that collects this information. There are no similar data that can be used or modified for this use. This 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. Therefore, the information being submitted to the agency will be original for each submission.

5. Impact on Small Businesses or Other 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.

If the information was not collected the consequences to the program would be to nullify its effectiveness to control shellfish in interstate commerce. Without the collection and periodic dissemination of this list of certified shellfish dealers, the existing public health controls pertaining to molluscan shellfish in interstate commerce would be less effective. States that are in the program are not willing to receive shellfish from noncertified shippers.

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), FDA published a 60-day notice for public comment in the Federal Register of June 2, 2009 (74 FR 26407). FDA received one letter in response, which contained multiple comments. One comment was generally supportive of the Interstate Certified Shellfish Shippers List program and recommended maintaining the program as it currently exists. Another comment noted that it requires little effort to input information into the form and that the Interstate Certified Shellfish Shippers List is critically important to the National Shellfish Sanitation Program. FDA agrees with the comments.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gift to respondents.

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.

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

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information to be 228 hours.

There are 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 a 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. FDA estimates 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. FDA bases its estimate on its experience with similar certification programs.

ESTIMATED ANNUAL REPORTING BURDEN

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3038	40	57	2,280	6/60	228

12 b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $7,091.44. FDA estimates that this certification will be prepared by an employee making an average wage similar that of a Federal government employee at the GS-5/Step-1 rate for the year 2009, which is $14.74 per hour. To account for overhead, this cost is increased by 100 percent, which is $29.48 per hour. Thus, the annual wage cost for completion and submission of these certifications is approximately $6,721.44 (228 hours x $29.48 per hour). Administrative cost, i.e. printing and mailing are estimated at $370.00. Therefore, total costs are $7,091.44 ($6,721.44 + $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 information collection.

14. Annualized Cost to the Federal Government

FDA receives approximately 2,280 responses from 40 respondents annually which include the States and some international countries. FDA estimates that it expends $17,858.60 in processing the data received in these forms. Administrative expenses account for approximately $800 of this sum, and the remainder is a personnel cost. FDA bases its estimate on the salary of one full-time employee at GS-8, Step 1, in the Washington-Baltimore Locality Pay Area for the year 2009 who spends an estimated 780 hours on this program (780 hours x $21.87/hour = $17,058.60). Thus, the total estimated cost to the Federal government is approximately $17,858.60 ($17,058.60 + $800.00).

15. Explanation for Program Changes or Adjustments

The burden has decreased from 242 hours to 228 hours. This adjustment is a result of an increase in the estimated number of respondents and a reduction in the frequency per response from 62 to 57.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA publishes the “Interstate Certified Shellfish Shippers List” on the Internet on a monthly basis.

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

There are no reasons why display of the expiration date for OMB approval of the information

collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.