Supporting Statement
for
Interstate Shellfish Dealer's Certificate

OMB No. 0910-0021

Justification

1. Circumstances Necessitating Information Collection

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 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.

Under 42 U.S.C. 243 (Attachment A), 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).

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 OMB approval for Form FDA 3038, Interstate Shellfish Dealer's Certificate (Attachment B).

2. How, by Whom, and for What Purpose Information Used

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.

3. Consideration of Information Technology

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 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.

4. Identification of Duplication and Similar Information Already Available

There is no other information available that can be used for these purposes.

5. Small Businesses

Small businesses and small entities are not involved. Participating States and nations provide certificates of certified shellfish processors to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate."

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles

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

The frequency of collection is governed by State laws and regulations. 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. Consequently, the Federal program cannot dictate the frequency of collection unless newly enacted federal law would supersede State law. Because of the long historical nature of this State-Federal program changes are difficult to make unilaterally.

8. Outside Consultation

In accordance with 5 CFR 1320.8(d), onTuesday, April 11, 2006 (71 FR 18339), a 60-day notice for public comment was published in the Federal Register (Attachment C). No comments were received from the public.

9. Payments or gifts to Respondents

FDA does not provide any payment or gift to respondents.

10. Confidentiality of Information

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

11. **Sensitive Questions**

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

12. **Burden Hours and Explanation**

FDA estimates the burden of this collection of information to be 242 hours.

There are a total of 39 respondents. In the past year the program received approximately 2,418 responses, or an average of 62 responses per respondent. The respondents complete a three part Form FDA 3038, Interstate Shellfish Dealer's Certificate, using the information they have collected 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. This procedure takes an average of 6 minutes or 0.1 hours for a respondent to complete each form. Therefore, 2,418 responses x 6 minutes per response = 14,508 minutes divided by 60 = 242 hours total response time.

Cost to Respondent

There are 39 respondents that each submit approximately 62 certifications and cancellations annually. It is estimated that they spend 6 minutes to complete; 6 minutes x 62 responses = 372 minutes or 6.2 hours per respondent year. FDA estimates the hourly wage of a clerk in industry to be approximately $13.00 per hour or $13.00 x 6.2 hours = $80.60 per respondent. Administrative cost, i.e. printing and mailing are estimated at $370.00. Therefore, $80.60 x 39 respondents =$3,143.40 + $370.00 administrative costs = $3,513.40 total.

TABLE 1--ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
39	62	2418	.10	242

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

13. **Annual Cost to Respondents**

FDA estimates that there are no significant capital costs associated with this collection.

14. Annual Cost to Government

FDA receives approximately 2,418 responses from 39 respondents annually which include the States and some international countries. FDA estimates that it expends $13,280 in processing the data received in these forms. Administrative expenses account for approximately $800 of this sum, and the remainder is a personnel cost for a GS-8 clerk who spends a total of approximately 780 hours in servicing this program at approximately $ 19.46 per hour, (780 x $19.46) + $800 = $15,978.80.-

15. Explanation of Change in Items 13 and 14

The burden for this information collection is slightly greater than that estimated for the previous clearance request. This increase in burden of 31 hours is related to an increase in the number of shellfish firms certified. -

16. Statistical Reporting

Statistical reports were not part of this submission.

17. Expiration Date on Form

Approval not to display expiration date is not requested.

18. Exception to Certification Statement

No exceptions for this Certification Statement submission.