

**Supporting Statement
for
Interstate Shellfish Dealer's Certification
0910-0021**

Justification

1. **Circumstances Necessitating Information Collection**

The Food and Drug Administration (FDA) enforces the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 342, the Fair Packaging and Labeling Act, 15 U.S.C. 1451 et. seq., and certain portions of the Public Health Services Act, including 42 U.S.C. 242, 243, and 264. FDA issued the Hazard Analysis Critical Control Point (HACCP) (Attachment A) regulations for seafood under various sections of the Federal Food, Drug and Cosmetic Act. Besides the general HACCP provisions in subpart A of Part 123, the Raw Molluscan shellfish subpart C of part 123 set forth specific requirements for the processing of fresh or frozen molluscan shellfish. These laws require that all foods shipped in interstate commerce, including shellfish, be prepared, packed and held always under sanitary conditions; that they are honestly and informatively labeled; and that the foods themselves are safe, clean and sanitary. FDA is authorized to accept assistance from State and local authorities in the enforcement of laws to prevent and to suppress the spread of communicable disease, 42 U.S.C. 243. This information assists FDA to assure that shellfish originate from safe and sanitary sources and that controls are uniformly applied.

Molluscan shellfish consumed raw or partially cooked 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.

To assist themselves in the development and enforcement of shellfish safety laws, the states have formed the Interstate Sanitation Conference (ISSC). The ISSC is an organization of state officials, representatives of federal agencies, and representatives of the shellfish industry. The ISSC provides a forum to discuss problems and develop controls to assure the sanitary handling and production of molluscan shellfish.

Many, if not all, states require that molluscan shellfish offered for sale within their jurisdictions be tagged (or labeled). Tagging is required to assure that the shellfish came from properly classified waters and are harvested, packed, and shipped under sanitary conditions. In order to assist the states in their efforts to promote the safety of molluscan shellfish, the Food and Drug Administration has entered into a Memorandum of Understanding (Attachment B) with the Interstate Shellfish Sanitation Conference (ISSC). One of the major provisions of this agreement is that FDA publishes and distributes a current listing of all state-certified shellfish shippers. The 1992 ISSC adopted new procedures requiring that all interstate shellfish shippers, after January 1, 1994, must be inspected by a standardized state inspector. Therefore, the form 3038 requires the submission of the full name of the standardized state inspector and must bear the full name and signature of a responsible state official. These provisions were added, by the states, to add credibility and enhance state certified shellfish shipper inspection programs. The date of the certification inspection and the expiration date of the inspector's standardization were added to assure timely renewal and that qualifications of each inspector participating in the program. The States added this item of information to enhance the standardization program and assure accurate and uniform certification of all shellfish shippers.

The form also requests the full address and telephone number of the certified firm to assist epidemiological investigations in the event of an outbreak of shellfish related food-borne illness. Therefore the revised form has a check-off to indicate if the requested action pertains to a new, cancellation, change or renewal certification. FDA use only, a box indicating the receiving and date of publication.

We request OMB approval for Form FDA 3038, Interstate Shellfish Dealer's Certificate

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

The information collected is used to compile, publish and distribute a list of certified shellfish shippers. Food control officials and the food industry use the list to determine certified sources of shellfish. This procedure assists FDA and the states to assure that shellfish are produced, packed and shipped under proper sanitary controls. Shellfish offered for sale that originate from non-listed dealers will be removed by State and local food control officials. This public health control is necessary to protect the health of consumers of molluscan shellfish.

3. Consideration of Information Technology

The Interstate Shellfish Dealers Certificate Form FDA 3038 used for submitting information, has been developed for electronic form filling that will be displayed, filled, printed and faxed from states with computer capability. FDA has not received any

electronic submissions of the form at this time. The FDA 3038 has been printed on NCR paper to facilitate making duplicate copies for states without computer capabilities. The information obtained from the form has been entirely automated. This information is entered into a FDA computer database program that allows the addition, deletion, down loading and generating the Interstate Certified Shellfish Shippers List, published monthly.

4. **Identification of Duplication and Similar Information Already Available**

The NSSP program has operated since 1925 and there is no knowledge that it is duplicative. There is no other information available that can be used for these purposes.

5. **Small Businesses**

Small businesses and small entities are not involved.

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. The collection and publication of certified shellfish dealers list is a positive step toward strengthening source controls as part of HACCP, and thereby to support the cooperative program.

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), on Tuesday March 7, 2000, (65 FR 12013), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public.

FDA entered into a Memorandum of Understanding with the Interstate Shellfish Sanitation Conference (ISSC) to improve the sanitation of molluscan shellfish shipped in interstate commerce. The ISSC is composed of state officials from shellfish producing and receiving States; and representatives from the shellfish industry; and the National Marine Fisheries Service.

Annual meetings are held to discuss problems and methods to improve sanitary controls for shellfish. Information is exchanged between all participating parties within the ISSC.

In addition, to the ISSC, regional meetings are held annually to address issues that are relevant to the sanitary control of shellfish harvesting areas and the certification of shellfish handlers and packers.

Additional information in the ISSC and its activities can be obtained from the following officials responsible for operations of the Conference and their annual meetings:

Mr. Ken Moore, Executive Director
Interstate Shellfish Sanitation Conference
115 Atrium Way, Suite 117, Columbia, SC 29223
Telephone 803-788-7559

Mr. Mr. James Michael Hickey, Chairman
Interstate Shellfish Sanitation Conference
c/o Mass Department Fish Wildlife
and Environmental Enforcement
50-A Portside Drive
Pocasset, MA 02559
Telephone 508-563-1779

9. **Payments or gifts to Respondents**

FDA has not provided and has no intention to provide any payment or gift to respondents under the proposed requirements.

10. **Confidentiality of Information**

The information collected is all part of State government agencies administrative files and is available to the public. No jurisdiction for protecting the confidentiality of the information collected is required.

11. **Sensitive Questions**

The data collected relate to business that produce products for interstate commerce and no questions on form 3038 are considered sensitive.

12. **Burden Hours and Explanation**

The total burden for the information collection requirements in the Shellfish Program is 204 hours.

There are a total of 35 respondents: 30 states and 5 foreign country shellfish produces/processors. In the past year the program received approximately 2,036 responses, or an average of 58 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 if 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 .1 hours for a respondent to complete each form. Therefore, 2,036 responses x 6 minutes per response = 12,216 minutes divided by 60 = 204 hours total response time.

Cost to Respondent

There are 35 respondents that each submit approximately 58 certifications and cancellations annually. It is estimated that they spend 6 minutes to complete; 6 minutes x 58 responses = 348 minutes or 5.8 hours per respondent year. The hourly wage of a clerk in industry is approximately \$10.60 per hour or \$10.60 x 5.8 hours = \$61.48 per respondent. Administrative cost, i.e. printing and mailing are estimated at 315.00. Therefore, \$61.48 x respondents = \$2,151.80 + 315 administrative costs = \$2,467 total.

TABLE 1--ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
35	58	2,036	.10	204

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

13. **Annual Cost to Respondents**

There are no capital and start-up, and operation, maintenance and purchase costs associated with the information collection.

14. **Annual Cost to Government**

Federal Government Costs:

FDA receives approximately 2036 responses from 35 respondents annually which include the States and some international countries. FDA estimates that it expends \$10,549 in processing the data received in these forms. Administrative expenses account for approximately \$700 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. ($\$10,549 \div 780 = \13.52 or approximately \$14.00 per hour for a government clerk.)

15. **Explanation of Change in Items 13 and 14**

The burden for this submission is slightly less than that estimated for the previous clearance request. This slight decrease in a burden of - 27 (231 hours on previous submission opposed to 204 hours on current submission) is related to decrease of participant state/international and the FDA Form 3038 developed for electronic submission.

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.