# NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Date 02/06/2009

Department of Commerce
National Oceanic and Atmospheric Administration
FOR CERTIFYING OFFICIAL: Barry West
FOR CLEARANCE OFFICER: Diana Hynek

In accordance with the Paperwork Reduction Act, OMB has taken action on your request received 07/18/2008

ACTION REQUESTED: Extension without change of a currently approved collection
TYPE OF REVIEW REQUESTED: Regular
ICR REFERENCE NUMBER: 200807-0648-003
AGENCY ICR TRACKING NUMBER:
TITLE: Seafood Inspection and Certification Requirements
LIST OF INFORMATION COLLECTIONS: See next page

OMB ACTION: Approved without change
OMB CONTROL NUMBER: 0648-0266
The agency is required to display the OMB Control Number and inform respondents of its legal significance in accordance with 5 CFR 1320.5(b).

EXPIRATION DATE: 02/29/2012 DISCONTINUE DATE:

| BURDEN: | RESPONSES | HOURS | COSTS |
|---|---|---|---|
| Previous | 9,996 | 13,065 | 4,000 |
| New | 10,883 | 8,139 | 5,999 |
| Difference | | | |
| Change due to New Statute | 0 | 0 | 0 |
| Change due to Agency Discretion | 0 | 0 | 0 |
| Change due to Agency Adjustment | 887 | -4,926 | 1,999 |
| Change Due to Potential Violation of the PRA | 0 | 0 | 0 |

TERMS OF CLEARANCE:

OMB Authorizing Official: Kevin F. Neyland
Deputy Administrator,
Office Of Information And Regulatory Affairs

| List of ICs | | | |
|---|---|---|---|
| IC Title | Form No. | Form Name | CFR Citation |
| Application for Inspection Services | 89-14 | Request for inspection services | |
| Application for Appeal | | | 50 CFR 260.36 |
| Contract completion/amendment | 89-800 | Contract completion/amendment | |
| Label and specification submission | 89-819 | Specification and label submittal action request | |
| HACCP participant application - new respondents | | | |
| HACCP Participant Applicant - current respondents | | | |

# PAPERWORK REDUCTION ACT SUBMISSION

**Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.**

1. Agency/Subagency originating request
DOC/NOAA/NMFS

2. OMB control number b. [ ] None
a. 0648 - 0266

3. Type of information collection (*check one*)
a. [ ] New Collection
b. [ ] Revision of a currently approved collection
c. [✔] Extension of a currently approved collection
d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired
e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired
f. [ ] Existing collection in use without an OMB control number
For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [✔] Regular submission
b. [ ] Emergency - Approval requested by / /
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [✔] No

6. Requested expiration date
a. [✔] Three years from approval date b. [ ] Other Specify: /

7. Title
Seafood Inspection and Certification Requirements

8. Agency form number(s) (*if applicable*)
NOAA Forms 89-800, 89-814, 89-819

9. Keywords
"Fish," "Food Grades and Standards," "Seafood"

10. Abstract

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program (Program) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and Reorganization Plan No. 4 of 1970. The regulations for the Program are contained in 50 CFR Part 260. The program offers inspection grading, and certification services, including the use of official quality grade marks which indicate that specific products have been Federally inspected. Those wishing to participate in the program must request the services and submit specific compliance information.

11. Affected public (*Mark primary with "P" and all others that apply with "x"*)
a. ___ Individuals or households d. ___ Farms
b. P Business or other for-profit e. ___ Federal Government
c. ___ Not-for-profit institutions f. X State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [ ] Voluntary
b. [✔] Required to obtain or retain benefits
c. [ ] Mandatory

13. Annual recordkeeping and reporting burden

| | |
|---|---|
| a. Number of respondents | 3,339 |
| b. Total annual responses | 10,833 |
| 1. Percentage of these responses collected electronically | 15 % |
| c. Total annual hours requested | 8,139 |
| d. Current OMB inventory | 13,065 |
| e. Difference | (4,926) |
| f. Explanation of difference | |
| 1. Program change | |
| 2. Adjustment | (4,926) |

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

| | |
|---|---|
| a. Total annualized capital/startup costs | 0 |
| b. Total annual costs (O&M) | 6 |
| c. Total annualized cost requested | 6 |
| d. Current OMB inventory | 4 |
| e. Difference | 2 |
| f. Explanation of difference | |
| 1. Program change | |
| 2. Adjustment | 2 |

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. P Application for benefits e. x Program planning or management
b. x Program evaluation f. ___ Research
c. ___ General purpose statistics g. ___ Regulatory or compliance
d. ___ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [✔] Recordkeeping b. [ ] Third party disclosure
c. [✔] Reporting
1. [✔] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually
7. [ ] Biennially 8. [ ] Other (describe)

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [✔] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)
Name: James Appel
Phone: (301) 713-2355

## 19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal Agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9

**NOTE:** The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It used plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention period for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of the provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

| Signature of Senior Official or designee | Date |
|---|---|
| | |

| Agency Certification (signature of Assistant Administrator, Deputy Assistant Administrator, Line Office Chief Information Officer, head of MB staff for L.O.s, or of the Director of a Program or StaffOffice) | |
|---|---|
| Signature<br>signed by Steven Wilson | Date<br>07/09/2008 |
| Signature of NOAA Clearance Officer | |
| Signature<br>signed by Sarah Brabson | Date<br>7-9-08 |

**SUPPORTING STATEMENT**
**SEAFOOD INSPECTION AND CERTIFICATION REQUIREMENTS**
**OMB CONTROL NO. 0648-0266**

## A. JUSTIFICATION

### 1. Explain the circumstances that make the collection of information necessary.

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program (Program) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and the Reorganization Plan No. 4 of 1970. The regulations for the Program are contained in 50 CFR Part 260. The program offers inspection grading and certification services including the use of official quality grade marks which indicate that specific products have been federally inspected. In addition, the NMFS inspection program is the only Federal entity which establishes quality grade standards for seafood marketed in the United States. Qualified participants are permitted to use the program's official quality grade marks on their products to facilitate trade of fishery products.

### 2. Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with all applicable Information Quality Guidelines.

Participants in the Program include all segments of the seafood industry from harvesters to retailers. When inspection services are desired, participants are requested to submit specific information pertaining to the type of inspection service needed [§260.15]. That is, applicants provide the Program information regarding the type of products to be inspected, the quantity, the location of the product, and the date when the inspection is needed. There are also application requirements (i.e., a letter from the participant) if there is an appeal on previous inspection results [§260.36]. Participants requesting regular inspection services on a contractual basis submit a contract [§260.96]. Any changes to the contract require a contract amendment, using the same form. Participants interested in using official grade marks are required to submit product labels and specifications for review and approval to ensure compliance with mandatory labeling regulations established by the United States (U.S.) Food and Drug Administration (FDA) as well as proper use of the Program's marks [§260.97(c)(12), (13), (14) and (15)].

Current regulations state requirements for approval of drawings and specifications prior to approval of facilities [§260.96(b) and (c)]. There are no respondents under this section. The Program will amend this part of the regulations in a future action.

In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under §260.15 of the regulations. These guidelines required that a facility's quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as identified personnel responsible for oversight of the system. A supplementary document

to this request, entitled "Development, Assessment, Approval, and Continuing Compliance Evaluation of HACCP-based Inspection Systems", a chapter from the NMFS Fishery Products Inspection Manual, describes in detail the requirements for participants choosing to receive NMFS HACCP-based inspection services.

HACCP requires continuing monitoring and record keeping by the facility's personnel. Although HACCP involves substantial self-monitoring by the industry, the HACCP-based program is not a self-certification program. It relies on unannounced system audits by NMFS. The frequency of audits is determined by the ability of the firm to monitor its operation. By means of these audits, NMFS reviews the records produced through the program participant's self-monitoring. The audits determine whether the participant's HACCP-based system is in compliance by checking for overall sanitation, accordance with good manufacturing practices, labeling, and other requirements. In addition, in-process reviews, end-product sampling, and laboratory analyses are performed by NMFS at frequencies based on the potential consumer risk associated with the product and/or the firm's history of compliance with the program's criteria.

The information collected is used to determine a participant's compliance with the program. The reported information, a HACCP plan, is needed only once. Other information is collected and kept by the participant as part of its routine monitoring activities. NMFS audits the participant's records on unannounced frequencies to further determine compliance.

The FDA implemented mandatory HACCP seafood safety requirements in December 1997. The FDA regulations [21 CFR Part 123] include some of the same reporting elements as the NMFS HACCP program. However, one of the significant differences is that the FDA regulation is mandatory for seafood processors and focuses on seafood safety only. The NMFS HACCP program is voluntary, is available to all segments of the seafood industry (from harvesters to retailers), and addresses not only seafood safety, but also wholesomeness (hygiene), economic integrity and seafood quality. There is a NMFS HACCP mark available to participants to assist them in marketing their products. FDA's mandatory program has no mark. Further, the FDA regulations require a HACCP plan only if a hazard analysis reveals a seafood safety hazard. NMFS requires a HACCP plan for all participants in the HACCP Program. The NMFS HACCP program also assures participants compliance with international trade standards.

As explained in the preceding paragraphs, the information gathered has utility. National Oceanic and Atmospheric Administration, National Marine Fisheries Service (NOAA, NMFS) will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with NOAA standards for confidentiality, privacy, and electronic information. See response #10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines. Prior to dissemination, the information will be subjected to quality control measures and a pre-dissemination review pursuant to Section 515 of Public Law 106-554.

**3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.**

The information collected does not involve the use of automated, electronic or other technological techniques. Much of the information for inspection requests is gathered over the phone and documented by the Program's inspection personnel. Examples of labels and specifications are generally submitted in hard copy to the Program's review staff for approval. Electronic submissions, via attachments to email, for example, are also acceptable. The form for Request for Inspection Services may be printed off the Program's Website at: http://seafood.nmfs.noaa.gov/InspectionRequest.pdf.

**4. Describe efforts to identify duplication.**

As mentioned in Question 2, the FDA HACCP regulations require some of the same reporting elements as the NMFS HACCP program. This statement includes reporting burden beyond what is required under the FDA regulations to better ensure seafood safety. In other words, an applicant's NMFS HACCP plan is acceptable under the FDA regulations so that no additional plan is needed for FDA. If, however, the applicant wishes to participant in the NMFS HACCP program and has an FDA HACCP plan, the FDA HACCP plan would be expanded to include the NMFS requirements which address not only seafood safety, but also wholesomeness (hygiene), economic fraud, and seafood quality.

**5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.**

Small businesses may voluntarily participate in the Program and respond to the collection. Specific instructions are provided, where needed, to all businesses to prevent submission of unnecessary information and to minimize the burden.

**6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.**

If the collection were not conducted, efficient operation of the Program would be jeopardized and would less serve the customers for whom it is intended.

**7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.**

For participants to continue to obtain the benefits of advertising the official Program marks and to ensure the Program's marks are being used with integrity, some of the collections are done at a frequency inconsistent with the Office of Management and Budget (OMB) guidelines. For example, HACCP participants submit their HACCP plan only once, but changes in the plan may occur whenever their processing operations dictate, which may be outside of the OMB guidelines. In addition, monitoring of the HACCP plan is an ongoing activity which is then audited by Program personnel at varying frequencies to determine the participant's compliance with the Program requirements.

The regulations for label approval [§260.97(b) (13) and (15)] require one more copy than recommended by OMB. The labels, once approved, are distributed to the applicant, the inspector in the facility, the regional inspection office, and the label approving officer for their records and future reference, which can be critical particularly if there is a question or dispute.

**8. Provide information on the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.**

A Federal Register notice was published on February 13, 2008 (73 FR 8292) for public comment. No comments were received.

**9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.**

No payments or gifts are made.

**10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.**

Participants in the Program are assured of the confidentiality of certain information, such as records of sanitation and HACCP plans, which may contain privileged trade information. The Department of Commerce, with the concurrence of the U.S. Department of Justice, determined that this information is protected from disclosure pursuant to the Freedom of Information Act Exemption (b)(4), 5 U.S.C. § 552(b)(4), which applies to trade secrets and commercial or financial information obtained from a person that is privileged or confidential.

**11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.**

No sensitive questions are asked.

**12. Provide an estimate in hours of the burden of the collection of information.**

The estimates below are based on data from Program personnel.

**§260.15 Application for Inspection Services.** The estimated time per response is an average based on the wide range of applicants. Regular applicants, for example, have made extra copies of the form with the standard information completed so that they simply fill in several additional blocks, which would likely require much less than 5 minutes, then fax it to the inspection office. New applicants, on the other hand, may take longer. They may provide the information over the

phone or we may fax them a blank form which they complete and fax in return. Also, not all of the blocks on the form are required to be completed before inspection services can be provided. Missing information may be inserted by the inspector at a later date and kept as an internal record.

Estimated Number of Respondents: 2,390
Estimated Number of Responses: 7,490
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 624.

**§260.36 Application for Appeal.** As mentioned in Question 2, this is simply a short letter notifying the inspection office that an appeal is requested.

Estimated Number of Respondents: 62
Estimated Number of Responses: 62
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 5.

**§260.96 Contract Completion.** This estimate includes new applicants, estimated at about 35 annually, and current participants who amend their contracts during the year. The burden estimate is considered equal for both situations.

Estimated Number of Respondents: 205
Estimated Number of Responses: 205
Estimated Time Per Response: 5 minutes
Estimated Total Annual Burden Hours: 17.

**§260.97(c)(12), (13), and (15) Label and Specification Submission.** This estimate includes not only completing the form, but also the estimate to develop a new specification or revise an existing one. The estimate also includes the time to compile, duplicate, and package the submission.

Estimated Number of Respondents: 542
Estimated Number of Respondents: 2,986
Estimated Time Per Response: 30 minutes
Estimated Total Annual Burden Hours: 1,493.

**§260.15 HACCP Participant Application**

**New Respondents**. These are applicants that are not currently in the NMFS HACCP Program, who need to develop a NMFS HACCP Plan, which as explained previously, is required only once. It is possible that if the applicant has an FDA HACCP plan, expansion of it to include NMFS requirements may take a little less time. The burden reflected is an average of response times in both situations.

Estimated Number of Respondents: 20
Estimated Number of Responses: 20

Estimated Time Per Response: 60 hours
Estimated Total Annual Burden Hours: 1,200.

**Current Respondents.** These are participants already in the NMFS HACCP Program, with an operating HACCP Plan. These participants are responsible for certain monitoring and record keeping functions as described in the manual release.

Estimated Number of Respondents: 120
Estimated Number of Responses: 120
Estimated Time Per Response: 40 hours
Estimated Total Annual Burden Hours: 4,800.

TOTAL RESPONDENTS: 3,339
TOTAL RESPONSES: 10,883
TOTAL BURDEN HOURS: 8,139

**13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in #12 above).**

Some of the information is faxed and some is mailed. The combined annual cost for copying, faxing or mailing is $6,000.

**14. Provide estimates of annualized cost to the Federal government.**

As this is a fee-for-service program as explained in Question 1, all of the costs to the Federal government for the collection are paid by the respondents.

**15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.**

There is no program change. Adjustments in burden: 1) estimated times for HACCP plans and reports have decreased, so that hours for these two information collections are 5,150 hours less; 2) responses have increased for the other information collections, resulting in an increase of 224 hours. The net decrease in hours is 4,926.

The increases in postage rates over the past three years account for the reporting/recordkeeping costs having been adjusted upward by $2,000 (rounded down to $1,999 in ROCIS).

**16. For collections whose results will be published, outline the plans for tabulation and publication.**

Results are not published.

**17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.**

Not applicable.

**18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.**

Not applicable.

## B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.

NOAA FORM 89-800
(1/92)
Prescribed by NOAA Inspection Manual 25

**U.S. DEPARTMENT OF COMMERCE**
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
NATIONAL MARINE FISHERIES SERVICE

CONTRACT NO.

DATE OF: ☐ CONTRACT ☐ AMEND. ☐ ADD.

ABOVE FOR AGENCY USE ONLY

## CONTRACT OF AGREEMENT FOR:

☐ **IN-PLANT INSPECTION SERVICE**
☐ **PLANT/VESSEL SANITATION SERVICE**
☐ **LOT INSPECTION**

☐ **REGULAR**
☐ **FEDERAL PROCUREMENT**

We, _____ located at _____, hereby make application for ☐ a contract ☐ an amendment to our contract ☐ an addendum to our contract for inspection service as follows:

| LOCATION OF OFFICIAL ESTABLISHMENT/ COLD STORAGE/DRY STORAGE | PRODUCTS COVERED |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

1. Sanitation and/or Inspection service to commence on _____ or as soon thereafter as appears practicable to the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, United States Department of Commerce (hereinafter referred to as NMFS).
2. NMFS will furnish the service of Federal inspectors to make inspection of the aforementioned ☐ sanitation and/or ☐ processed food products at the aforesaid designated official establishment and also furnish inspection reports in accordance with the applicable regulations of NMFS in effect at the time such service is rendered.
3. The applicant agrees to _____ minimum hours of inspection per week/month, at the currently established rates for the type of services rendered.
4. The Regulations contained in Part 260 of Title 50 CFR are hereby incorporated by reference and a copy is attached hereto. The Applicant agrees to all the provisions, conditions, and requirements set forth in the regulations and instructions contained in the Inspection Manual for type of services rendered.
5. Upon approval of this application by NMFS, it shall constitute ☐ a contract ☐ an amendment ☐ an addendum to contract no. _____ between the undersigned applicant and NMFS in accordance with the terms and conditions provided herein.
6. Additional provisions to this contract are ☐ attached hereto ☐ continued on the reverse.

| APPLICANT | APPROVAL |
|---|---|
| NAME | NATIONAL MARINE FISHERIES SERVICE |
| SIGNATURE | SIGNATURE OF APPROVING OFFICER |
| TITLE | TITLE |
| DATE | DATE |

SUPERSEDES NOAA FORMS 89-800 (01-73), (10-80), AND 89-829 (3-74).

OMB Control No.: 0648-0266
Expiration Date: 07/31/2008

# INFORMATION COLLECTION NOTIFICATION
## NOAA Form 88-800

This information collection is authorized under 50 CFR §260.96. The information will be used to register participants requesting regular inspection services on a contractual basis. Any change to the contract require a contract amendment, using this form. Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to the National Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to receive inspection services on a contract basis.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

OMB Control No.: 0648-0266
Expiration Date: 07/31/2008

NOAA form 89-814
Prescribed by NOAA Inspection Manual 25

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

# REQUEST FOR INSPECTION SERVICES

CONTRACT NUMBER:

FEDERAL TAX ID #:

TODAY'S DATE:

| NAME OF REQUESTER | | | **SERVICING AGENT'S NAME & PHONE NUMBER** | | |
|---|---|---|---|---|---|
| STREET ADDRESS | | | STREET ADDRESS | | |
| CITY | STATE | ZIP CODE | **CITY** | **STATE** | ZIP CODE |
| CONTACT NAME | PHONE NO. | FAX NO. | TYPE INSPECTION REQUESTED<br>___ **Lot Inspection Certificate**<br>___ **Export Health Certificate**<br>___ **Certificate of Origin**<br>___ **EU Certificate**<br>___ **Other:** | | |
| LOCATION OF PRODUCTS – NAME | | | | | |
| LOCATION OF PRODUCTS – STREET ADDRESS | | | SPECIAL INSTRUCTIONS (*Buyer Specifications, country requirements, etc.)*<br>___ **Market Specifications:**<br>___ **Product on FDA Hold?** | | |
| CITY | STATE | ZIP CODE | | | |
| ASSESS CHARGES TO: | | | DISPOSITION OF SAMPLES:<br>___ **Return** ___ **Destroy** ___ **Charity** | | |
| STREET ADDRESS<br>Same | | | INSPECT FOR:<br>___ **Quality & Condition**<br>___ **Minimum U.S. Grade Attributes**<br>___ **U.S. Grade A Attributes**<br>___ **Net Weight**<br>___ **Size or Count**<br>___ **Other:** **Origin:**_____ | | |
| CITY | STATE | ZIP CODE | | | |
| CERTIFICATE FORWARDED TO: | | | | | |
| STREET ADDRESS<br>Same | | | | | |
| CITY | STATE | ZIP CODE | | | |
| REMARKS | | | | | |

| LOT NUMBER | BRAND | PRODUCT | NUMBER OF CARTONS/ CASES & SIZE | TOTAL POUNDS |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| NAME OF SHIPPER *(For export only)* | | NAME OF CONSIGNEE (*For export only)* |
|---|---|---|
| ADDRESS | | ADDRESS |
| PORT OF EXPORT | VESSEL OR AIRLINE | PORT OF DESTINATION |
| APPLICANT (*Printed Name & Signature)* | | DATE |

**Information Collection Notification – NOAA Form 89-814**

This information collection is authorized under 50 CFR §260.15. The information will be used to record applicants requesting inspection services on non-contractual basis. Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden to the Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to receive inspection services on non-contract basis. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control Number.

OMB Control No.: 0648-0266
Expiration Date: 07/31/2008

NOAA FORM 89-819
(03-06)
Prescribed by NOAA Inspection Manual

U.S. DEPARTMENT OF COMMERCE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION
SEAFOOD INSPECTION PROGRAM

1. DATE SUBMITTED

2. PLANT CODE(S)

# SPECIFICATION AND LABEL SUBMITTAL ACTION REQUEST

**INSTRUCTIONS** – Please print for complete by typewriter. Submit a set of 5 specifications and/for labels with each product label indicated on form. All copies except field copy to be submitted to the address below or action. Field copy to be retained by requestor until specifications and/or labels are returned by Approving Officer.

**TO:** DOCUMENTATION APPROVAL and SUPPLY SERVICES
P.O. DRAWER 1207 – 3207 FREDERIC ST., SUITE B
PASCAGOULA, MISSISSIPPI 39568-1207

3. PROCESSOR OR PACKER (*Name, address and Phone Number*)

4. DISTRIBUTOR (*Name and full address*)

USDC No. (Item 5) to be assigned by Approving Officer. Indicate USDC Number of approved specifications or labels in Remarks when submitting replacements with minor changes, or when submitting or verification for cancellation. Indicate primary logo, packer or distributor name, or other identification for item 6. Use numbers only or item 9: 1 - No. Shield 2 - Combination Grade A & PUFI., 3 - PUFI Mark, 4 - Grade A, 5 - Lot Inspected Mark

| 5. USDC NUMBER | | 6. PRODUCT IDENTIFICATION (*Brand and identifying number if any*) | 7. COMMODITY (*Use official terminology including type, style and size; indicate in ounces or count/pounds. Enter 10 digit commodity code*) | | 8. CONTENT OR NET WEIGHT | 9. SHIELD CODE (See Above) |
|---|---|---|---|---|---|---|
| LABEL | SPEC. | | PRODUCT | COMMODITY CODE | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

10. USDC INSPECTOR (*Signature*) Inspector Number_____HACCP☐

COMPANY OFFICIAL (*Signature*)

11. HAVE SPECIFICATIONS AND/FOR LABELS BEEN REVIEWED FOR COMPLIANCE WITH USDC AND FDA REGULATIONS?
BY INSPECTOR? YES☐ NO☐ BY FIELD INSPECTION OFFICER? YES☐ NO☐

12. ACTION REQUESTED
☐LABEL/SPEC. REVIEW ☐NEW LABEL SKETCH/PROOF REVIEW ☐NEW LABEL APPROVAL (*FINAL*)
☐NEW SPEC. APPROVAL (*FINAL*) ☐REPLACEMENT SPEC. OR LABEL ☐CANCEL APPROVAL ☐OTHER (*SPECIFY IN REMARKS*)
☐USDA/FNS (CN) LABEL OR SPECS ACTION ☐EXTEND TEMPORARY APPROVAL (*SPECIFY IN REMARKS*)

APPROVAL BY THE USDC IS BASED ON THE INFORMATION SUPPLIED AND DOES NOT IMPLY CONCURRENCE FOR ACCEPTANCE BY OTHER FEDERAL STATE FOR LOCAL GOVERNMENTAL AGENCIES UNLESS SPECIFICALLY NOTED, NOR DOES IT RELIEVE THE COMPANY FROM COMPLIANCE WITH OTHER APPLICABLE LAWS, REGULATIONS OR RULINGS. THIS APPROVAL BECOMES VOID IF CHANGES ARE MADE IN THE SPECIFICATION OR LABEL WITHOUT THE CONCURRENCE OF THE USDC APPROVING OFFICER.

13. REMARKS (*Please initial*)

TO BE COMPLETED BY APPROVING OFFICE(S) ONLY

PROOF APPROVED FOR PRINTING ☐ AS IS ☐WITH CHANGES NOTED
☐Temporary Approval Expires
(Spec)_____ (Label)_____
☐Final Approval Label ☐Final approval Spec.
☐Disapproved label ☐Disapproved Spec.
☐Extends Approval ☐Cancelled
☐Reviewed

APPROVING OFFICER (*Signature*) DATE:

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USDA APPROVAL (*Signature*) DATE:

# INFORMATION COLLECTION NOTIFICATION
# NOAA Form 88-819

This information collection is authorized under 50 CFR §260.97(c)(12), (13), and (15). The information will be used to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration as well as the proper used of the official marks of the voluntary National Seafood Inspection Program. Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, to the National Seafood Inspection Program, 1315 East-West Highway, Silver Spring, MD 20910. This information is required in order to obtain the benefits of the use of official marks [50 CFR §260.86].

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

# Policies, Procedures, and Requirements for the Approval of Facilities and Systems

United States Department of Commerce

**Seafood Inspection Program**
1315 East-West Highway
Silver Spring, Maryland 20910
January 1, 2008

**Policies, Procedures, and Requirements for the Approval of Facilities and Systems**

## Authority

Authority for the Seafood Inspection Program to provide these services can be found within the Agricultural Marketing Act of 1946, the Fish and Wildlife Act of 1956, and the regulations promulgated under these authorities (i.e., 50 CFR Part 260).

## Introduction

Participants that process products under the USDC Seafood Inspection Program on a contract basis must receive approval of buildings, facilities, and the applicable processes prior to the inauguration of such service.

These establishments or vessels must be certified to meet U.S. Department of Commerce regulations governing the construction and maintenance of facilities and equipment, processing techniques, and employee practices in the production of fishery products for human consumption. Approved establishments are eligible to produce fishery products bearing an official inspection mark. (Facilities outside the United States currently are not eligible to have their products bear inspection marks, although the master cases may bear statements applicable to their status per Program policy.) Approved facilities are included on a list published on the Program's official website and periodically in hard copy. Inclusion on this list is contingent upon the firm's continued ability to maintain USDC requirements.

Approved establishments are verified by on-site audits to meet U.S. Food and Drug Administration and U.S. Department of Commerce regulations governing the construction and maintenance of facilities and equipment, processing techniques, and employer practices in the production of fishery products for human consumption. USDC approved establishments shall notify USDC of regulatory visits and findings. Participation in the USDC Seafood Inspection Program does not eliminate the responsibility and obligation of the industry participant to meet all federal and applicable state regulations and requirements.

There are three systems of participation as an approved facility, each of which offers differing methods of product inspection service by USDC personnel. One system requires the system be audited on a regular basis as defined later in the document and, while product bearing a USDC Inspection Mark is being produced, a USDC inspector is present ascertaining the quality level of the lot per applicable regulations and Program requirements. This method is referred to as Resident Inspection.

The second system which reduces the product inspection effort is called the Integrated Quality Assurance (IQA) Program and was established in the Federal Register, Volume 37, Number 161 on August 18, 1972. Audits of the system are also performed regularly. However the firm's quality assurance personnel provide assistance to the USDC inspector by inspecting all lots to the applicable US Grade or specification requirements. The USDC inspector then evaluates the system through a product verification system. This system does not necessarily require the USDC inspector to be present for all product inspection activity. However, it does require a USDC approved quality assurance system. All products inspected or verified through this system are eligible to bear a mark.

In July 1992, the USDC published a Federal Register notice announcing the availability of a new seafood inspection program based on Hazard Analysis Critical Control Point (HACCP) principles. In January 2000 this program was further enhanced to include the ISO 9001 Quality Management Standard. This program further reduces the inspection effort of the USDC personnel by partnering with industry participants and their responsibility for all food safety, wholesomeness, economic integrity, and quality concerns for the system and products produced at the firm. The firm is audited on varying levels based upon its compliance to the Program requirements.

This document has been developed to provide interested parties with the various policies, procedures, and requirements which must be met in order for facilities and systems to be approved by USDC. Participants may elect to contract in

any these of three programs. Under the IQA and the HACCP QMP, the company takes on the responsibility of documenting and implementing a quality system. USDC will then ensure that the quality system in place is adequate to control the critical functions by regular inspections of the system, known as audits. These audits will evaluate the quality system by examining product, processes, and records.

This document includes sections which explain the requirements of the Resident Inspection, IQA and HACCP QMP programs for documenting a system that will meet USDC requirements. The document is also a guide manual for use by interested parties in developing their own food safety and/or quality manual. The IQA and HACCP QMP will allow participants an opportunity to apply their existing quality systems more efficiently, receive the management benefits of producing safe, wholesome, and properly labeled products more consistently and obtain the marketing benefits of using marks associated with the Program.

In summary, these services are consistent with global activities to harmonize inspection protocols. In addition, USDC believes that the services will enhance the safety, wholesomeness, economic integrity, and quality of seafood available to consumers, as well as improve seafood industry quality assurance and regulatory oversight.

## Scope

Program policy is to encourage and assist interested parties in the development and implementation of management systems. The purpose of this policy is to facilitate the production and distribution of fishery products that are safe, wholesome, properly labeled, and is of desired uniform quality. Any facility, whether processing plant, retail operation, or vessel, foreign or domestic, may become part of this program.

The development and implementation of Integrated Quality Assurance or HACCP Quality Management systems is optional. However, their use should result in more efficient use of industry and USDC resources to inspect, grade, and certify fishery products. This document also provides guidance for the development, implementation, and operation of these systems, which will meet USDC approval.

## Definitions

1. **Applicant:** Any interested party who requests inspection service under the regulations in this part.
2. **Audit:** A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
3. **Auditor:** A person qualified to perform audits.
4. **Contamination:** The occurrence of a contaminant in fish due to microbial pathogens, chemicals, foreign material, spoilage, objectionable taints, unwanted or diseased matter, which may compromise fish safety or suitability.
5. **Control Point:** Any step in a process whereby biological, chemical, or physical factors may be controlled.
6. **Corrective Actions:** An action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.
7. **Critical Control Point (CCP):** A point, step, or procedure in a food process at which control can be applied, and a food hazard can as a result be prevented, eliminated, or reduced to acceptable levels.
8. **Critical Deficiency:** A hazardous deviation from plan requirements such that maintenance of the safety, wholesomeness, and economic integrity is absent; will result in unsafe, unwholesome, or misbranded product.
9. **Critical Limit:** The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point, or defect action point, to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
10. **Decision Tree:** A sequence of questions applied to each process step with an identified hazard to identify which process steps are CCPs. For the purpose of this Program this also applies to a DAP.

11. **Decomposition:** A persistent and distinct objectionable odor or flavor including texture breakdown caused by the deterioration of the product.
12. **Defect:** A condition found in a product which fails to meet essential quality, composition and/or labeling provisions of the appropriate product standards or specifications.
13. **Defect Action Point (DAP):** A point, step or procedure at which control can be applied and a defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated.
14. **Deviation:** Any specifically defined variation from a particular requirement.
15. **Establishment:** Any premises, buildings, structures, facilities, and equipment (including vehicles) used in the processing, handling, transporting, and storage of fish and fishery products.
16. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
17. **HACCP Plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety and control of defects which are significant for essential quality, composition, and/or labeling provisions in the segment of the food chain under consideration.
18. **Hazard:** A chance for, or the risk of, a biological, chemical, physical, or economic property in a food product that could violate established program criteria or cause the consumer distress or illness.
19. **Hazard analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
20. **High risk products:** Seafood that may pose a significant danger to the health of the public when prepared for consumption by conventional or traditional means. For example, ready-to-eat; heat and/or brown and serve products; products which may contain a microbial pathogen, biotoxin, or physical or chemical contaminant which may pose an unacceptable health risk at the time of consumption.
21. **Interested party:** Any person who has a financial interest in the applicable commodity, facility, or firm. This includes, but is not limited to, the United States and any instrumentality or agency thereof, any State, county, municipality, or common carrier, and any authorized agent in behalf of the foregoing.
22. **Lot:** A production unit as defined by mutual agreement between the processor and the USDC Seafood Inspection Program consisting of processed product of the same type, style, and size which has been produced under conditions as nearly uniform as possible. The quantity of product in a "lot" may not exceed that quantity which is produced during a specific production shift.
23. **Low risk products:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.
24. **Major Deficiency:** A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
25. **Minor Deficiency:** A failure of the part of the HACCP-based system relative to facility sanitation which is not likely to reduce materially the facility's ability to meet acceptable sanitation requirements.
26. **Monitoring Procedures:** Scheduled testing and/or observations recorded by the firm to report the findings at each CCP or DAP.
27. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
28. **Official Establishment:** Any establishment which has been approved by the Program and utilizes inspection service on a contract basis.
29. **Plant:** The premises, buildings, structures, and equipment (including, but not limited to, machines, utensils, and fixtures) employed or used with respect to the manufacture or production of processed products.
30. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions

providing the foundation for the HACCP system.

31. **Preventive Measure(s) (control measure):** Physical, chemical, or other factors that can be used to control an identified food safety hazard. For the purposes of this program, this also applies to a DAP.
32. **Process:** One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
33. **Processed Product:** Any fishery product or other food product covered under the regulations in this part which has been preserved by any recognized commercial process, including, but not limited to, canning, freezing, dehydrating, drying, the addition of chemical substances, or by fermentation.
34. **Product Form:** Products which are similar in appearance, species, and/or processing method. For example, raw shrimp, cooked shrimp, breaded shrimp, etc.
35. **Quality:** Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. The inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients.
36. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
37. **Risk:** The probability that exposure to a hazard will lead to negative consequences.
38. **Serious Deficiency:** A severe deviation from plan requirements such that maintenance of safety, wholesomeness, and economic integrity is prevented; and, if the situation is allowed to continue, may result in unsafe, unwholesome, or misbranded product.
39. **Severity:** The seriousness of the effect(s) of a hazard or defect.
40. **Specification:** A document stating requirements. A detailed document describing the materials, dimensions, and workmanship requirements of a product.
41. **Systems Audit:** On-site NOAA evaluation of the firm's effectiveness in following the plan after validation.
42. **Validation:** The collection and evaluation of scientific and technical information to determine if the system, when properly implemented, will effectively control the hazards and defects.
43. **Verification:** Those activities performed by the firm, other than monitoring that determine the system continues to be valid and is operating according to the plan.
44. **Wholesome:** The minimum basis of acceptability for human food purposes, of any fish or fishery product as defined in section 402 of the Federal Food, Drug, and Cosmetic Act, as amended.

## Application for Services

Firms which wish to receive facility inspection and certification services may apply orally or in writing to any inspector or officer of the Program at or nearest the place where service is desired or the appropriate Regional Inspection Branch. If application is made orally, it must be confirmed promptly in writing in the English language. As part of the application, the requesting party must provide the necessary information to perform the service including but not limited to: the name and address of the facility, the interest of the applicant, the purpose for which the service is desired, and whether the facility was inspected or certified by any other official party.

Failure to comply with these procedures may cause the application to be rejected. In addition, the Program may reject an application due to nonpayment for previous services rendered or if it appears that to perform the service would not be in the best interests of the Government. If the application is rejected, the applicant will be notified promptly of the reasons in writing. An application for such services may be withdrawn by the applicant at any time before the service is performed, provided that the applicant shall pay for any reimbursable time spent on the servicing of the application as well as for any expenses incurred.

The Regional Inspection Branch will provide the applicant with all necessary materials to inform

them of the program, its requirements, and policies.

**NOTE**: Firms which wish to have a more in-depth presentation of the Program and its requirements may request a meeting of all interested parties. This may incur a cost and should be discussed with the Regional Inspection Branch.

**Prior to USDC Validation of the System**

The firm should begin following their plan as soon as possible. The firm must adhere to the plan's provisions and keep all records associated with the tentatively approved plan for at least five (5), and not more than thirty (30), consecutive production days. The firm will contact the Regional Inspection Branch as soon as they believe the plan is functioning successfully and when they have records covering the minimum production days. The Regional Inspection Branch will schedule a site visit with the firm. The firm must verify through end-product examination that the process controls result in product which complies with all regulations and applicable quality standards or specifications. If documentation has not been previously provided, the firm must collect data prior to the site visit which will be sufficient to demonstrate this relationship. Firms attempting to document this relationship must collect data on not less than 20 percent of their lots using sampling plans comparable in statistical confidence to those in 50 CFR Part 260, with at least one lot representing each product form. The inspection records must be available to USDC personnel upon request. Although not required, USDC recommends that the firm submit end-item verification records with their QMP Plan. This will allow the firm to test their controls, provide plan reviewers more information, and possibly reduce the time and cost of the site visit.

**Note:** Firms may request the USDC perform the end item evaluation described above which can be done immediately prior to or during the validation of the system.

**Additional Requirements for IQA and HACCP Quality Management Program Plan**

**Review and Desk Audit**

In addition to the requirements and procedures described thus far, each applicant entering the IQA or HACCP QMP programs must submit a quality management plan which describes the policies and procedures the firm will use to ensure product and process quality. Model system templates are available through the USDC Seafood Inspection Program. At the request of the firm, USDC will provide consultation toward the development of the IQA or HACCP Quality Management Program plan on a fee basis.

Plans are submitted to the servicing Regional Inspection Branch for desk review. Reviews of the plan may require requests for changes, clarifications, deletions, etc., from the firm. The servicing region will work with the firm to finalize the development of the QMP Plan. A written review is sent to the firm indicating what changes, if any, are necessary prior to scheduling the site visit. After any identified changes have been made by the firm the Regional Inspection Branch will issue tentative approval of the plan and work with the firm to schedule a date to conduct the validation audit. All work of the assigned CSO and the Regional Inspection Branch is performed on a fee basis at established rates.

**Initial Assessment and Validation**

Once an application has been filed for this service, the Regional Inspection Branch will schedule a site visit with the firm and Program personnel will evaluate the buildings, premises, facilities, and food safety management system according to the requirements of the USDC Seafood Inspection Program and shall determine compliance to these requirements and any corrections that may be required. A full report will be provided detailing these findings.

The firm must verify through end-product examination that the process controls result in product which complies with all federal regulations and applicable Program requirements. If documentation has not been previously provided, the firm must collect data prior to the site visit which will be sufficient to demonstrate this relationship. This verification may be accomplished utilizing the product inspection services of the USDC Seafood

Inspection Program.

The audit performed on site will determine whether all of the hazards and CCPs (and defects/DAPs for the IQA and HACCP-QMP Program) have been identified, the food safety management and/or quality management plan is being followed and monitored by the firm, and is effectively controlling the identified product hazards and/or defects and processes concerned. The site visit will be conducted on a fee basis by personnel assigned based upon the demands of the audit. Firms applying for inclusion in either the IQA or HACCP QMP Programs must have records available covering not less than 5 production days for all processes and products requested for inclusion. The number and structure of the team will be determined by the size and complexity of the firm's process and nature of the hazards associated with the product and processes to be evaluated. All audits (initial and surveillance) will include conducting document and record reviews, evaluating sanitation and in-process observations, photographic evidence, and product verification. All reviews will be performed using accepted auditing practices based on international recognized audit standards. Conducting a combination of statistical reviews of records and finished product sample inspections will complete product verifications.

At least one lot for each product form under requested contract will be evaluated by USDC by inspecting samples of finished product. USDC inspection personnel may sample and audit product in excess of this guideline if necessary. Firms will be evaluated using the System Compliance Rating Criteria and other requirements as applicable. Firms determined to be acceptable may finalize a contract with the Program. If during this audit deficiencies are noted that prevent an acceptable rating, the firm may correct these deficiencies and request the audit team review these corrections prior to departing to determine system acceptability. In addition, for those participating in the IQA or HACCP-QMP Programs, a favorable audit will make all products under review during the audit, including the previous five (5) to thirty (30) production days evaluation during the audit, eligible to bear the appropriate official marks or advertising claim. Otherwise a successful audit with significant deficiencies corrected or on a corrective action plan will be necessary prior to completing a contract with the Program.

**Note for Vessels:** The CSO will accompany the vessel, if determined necessary, for an appropriate time period performing the background checks of critical control points and auditing the plan at one time. The officer may assist the quality assurance/management group on board the vessel in any alterations to bring the system toward approval and a successful audit. Once the work is performed, the officer is taken off the vessel as soon as is practicable. These procedural accommodations are made in recognition of possible space restrictions and to reduce the numbers of transfers at sea. Further it is expected that such a visit will only be necessary for high risk products such as cooked crab product.

### Label Review Procedures

All labels bearing an inspection mark or statement must be approved prior to use in accordance with requirements and procedures of the USDC Seafood Inspection Program.

### Changes to the Approved System

After the system has been approved, modifications may be made. The firm must notify the servicing Regional Inspection Branch, in writing (including faxes or e-mail), of any modifications in their food safety and/or quality system before implementing the changes. However, any changes to address a health or safety issue may be made without prior approval, but must be documented in a corrective action plan. The Regional Inspection Branch must be notified of these immediate changes within one working day.

As the food safety or quality system outlines the basic foundation and policies of the firm's program, changes to the plan must be approved in advance with Program management. However, the specific work procedures may change as necessary without prior approval, as long as they meet the Program's criteria. Prior to signing the contract, it will be determined which of the firm's documentation requires pre-approval.

## System Audits--Surveillance

Only with a valid contract and continued demonstrated compliance with all applicable laws and regulations and policies may 1) the firm be eligible to use official marks or other related statements and 2) firm-collected data be used by USDC personnel towards issuing applicable official certification of the firm's products or facility compliance. After the firm's system is approved, USDC will conduct audits at a minimum frequency—illustrated in the table below—to determine the firm's continued adherence to federal regulations and Program requirements. More frequent audits may be necessary for cause as determined by the Regional Inspection Branch.

| Resident and IQA Systems Audit Target Frequencies | | |
|---|---|---|
| **Processors** | **Retail** | **Vessels** |
| Once every calendar quarter | Once every six months | Once every calendar quarter |

IQA firms will have their systems audited at the above frequency as well, but will have their product quality audited at least once per week, as the workload demands. Firms in the HACCP QMP Program will be audited at the frequencies illustrated in the tables found in Appendix 1.

Note: Audit frequency for firms operating on a seasonal basis will be determined on a case-by-case basis using the guidance of the frequency listed in the chart above and the tables in Appendix 1. With regard to seasonal contracts, the firm must request in writing, to the servicing Regional Inspection Branch, to both suspend and reactivate the contract.

Firms that receive five (5) serious deficiencies or one (1) critical deficiency at the conclusion of an audit are deemed unreliable and will be addressed using the tightened audit procedures described below.

In addition, the policies and procedures for each class of operation described below will be followed.

*Vessels*

Firms must provide the appropriate Regional Inspection Branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. Firms must give the Regional Inspection Branch Office or the designated USDC Consumer Safety Officer notice prior to each port arrival, providing sufficient time for the Officer to audit the vessel when required. Failure to do so could result in the removal of the vessel from the Program.

A site visit of the vessel will be conducted at least once per year. The visit may not require the auditor to be on board during fishing, but may require the auditor to be present during off-loading. The other audits may be performed either by desk audit or during evaluation of storage of product in the off season as applicable. If the vessel receives an unreliable rating, it will be audited on a tightened level (as necessary) until the firm is back under compliance.

*Processing Establishments*

USDC personnel will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan. International facilities will be scheduled for site visit at a minimum of twice during the year. The remaining audits may be performed by desk audit review of documentation and records.

Processors which desire product certification for lots produced under their operation must either have an approved IQA or HACCP-QMP system, have the lots inspected by USDC for conformance during production, or USDC will inspect the product after it is produced using lot inspection services.

*Retail and Food Service Establishments*

USDC personnel will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan.

## Tightened Audit Procedures

A firm at the tightened frequency has demonstrated difficulties in administering their food safety and/or quality management and was therefore rated by the USDC Seafood Inspection Program as unreliable. If a Consumer Safety Officer rates a facility unreliable, he/she will rate the facility and immediately contact his/her Supervisor. The decision to rate a facility unreliable will be made prior to the Consumer

Safety Officer performing the exit interview. Facilities which are rated unreliable have a period of thirty days to take the necessary corrective actions to have the unreliable status removed. Failure to do so will result in the facility's removal from the approved list or the IQA or HACCP QMP Program. A firm in the IQA or HACCP QMP Program which is deemed unreliable may continue to use the mark or other applicable advertising privileges if consent by USDC is given for daily auditing of the firm. Consent will be on a case by case basis and granted only if USDC believes the nature of the condition which caused the firm to become unreliable can be adequately addressed through daily auditing. Daily auditing will be acceptable to the Program under the following conditions:

a. The firm must submit a corrective action plan to the Consumer Safety Officer (auditor) detailing how they will correct the problem.

b. The Consumer Safety Officer will review the corrective actions identified by the firm and will approve or disapprove them and notify his/her Supervisor. Daily auditing will continue until the issue is corrected, or up to a maximum of thirty calendar days.

c. Products may be certified during daily auditing. However, if any condition(s) exist(s) that is considered critical, no product certification will occur until the condition is corrected to the satisfaction of the USDC.

d. At the auditor's discretion, product compliance will be verified by end-item evaluation. No products covered by the contract will leave the firm without USDC approval.

e. Firms participating in the IQA or HACCP QMP programs deemed unreliable twice in a twelve month period will be removed from the respected program. Firms who have been removed may submit a request for reapplication after a period of three calendar months. Application will be accepted by USDC only if evidence of a change in management philosophy can be provided. Firms which have been removed from such programs may still be eligible to enter into full-time auditing of the facility, system, and product.

**Corrective Action Plans**

When applicable, the firm must submit a corrective action plan to the Consumer Safety Officer detailing how they will correct the problem. The corrective action plan must include, at a minimum, detailed descriptions of the following:

1. A statement of the problem
2. Identification of the person or persons responsible for addressing the situation
3. The methods to be used to correct the problem
4. A schedule which details the time frame to correct the problem
5. A statement with signatures of top management attesting to their commitment to correct the deficiency

The corrective action plan must be written in sufficient detail to provide USDC with all necessary information for its approval or disapproval.

**Appeal Procedures**

If a firm wishes to appeal an unreliable rating, they are to contact, in writing, the servicing Region Inspection Branch Chief. The facility must provide, in writing, 1) all pertinent information as to why it is believed the rating was determined in error and 2) the actions the firm has taken at that facility to address the perceived deficiency(ies) and ensure that the facility, processes, and products will meet applicable requirements. Once the Region Chief receives all information, he/she will investigate the matter and consult with, and gain approval of, the Chief Quality Officer in headquarters. The final determination will be communicated to the facility as soon as possible and a written report will follow.

**Analytical Testing and Product Verification**

The firm must perform periodic end-item verification of product compliance to program requirements. Both the firm and USDC must agree upon the firm's frequencies and end-item requirements, however samples for analytical testing must be collected and tested at least once

per year as part of their verification procedures. The level of analytical sampling per lot must be statistically sufficient to draw a proper conclusion and agreed upon by the USDC Seafood Inspection Program. Records of all analytical findings will be made available to USDC personnel during Systems Audits and at other times as necessary. As part of the system evaluation, USDC will have product tested analytically throughout the year as described in the Surveillance Sampling Program.

To determine whether the product produced at the firm meets specification and/or requirements, USDC will routinely perform a product audit on up to three (3) lots produced by the firm since the last Systems Audit. This information will be used to guide the auditor in his/her audit of the system. Product audits will be completed by conducting records reviews and finished product sample inspections. Additional lots may be sampled if the situation warrants. Lots must be defined by the firm and the definition agreed upon by the USDC Seafood Inspection Program.

**Use of Marks**

Participating firms are responsible for using the marks in accordance with the regulations set forth in 50 CFR Part 260 and the Policy and Guidelines for Advertising and Marking Products Inspected by the U.S. Department of Commerce. Firms may be issued official stamping devices to aid in affixing marks on cases or product if they meet program requirements. Facilities who have received official stamping devices must have written procedures in place to ensure security of the device and protecting it from misuse.

**Advertising Participation**

Firms who are successfully participating in the Approved Facility Program will be listed in the USDC Participants List for Firms, Facilities, and Products as an approved facility and will list the firm's name, all pertinent locations, and approved processes. This list is updated regularly on the Program's website and printed in hard copy twice per year. These firms may advertise their participation in the Program as if all advertisement claims are truthful and not misleading as to product certification. Advertisement forms may include flyers, banners, print media, other media, and statements on product. To make certain advertisements meet all regulations and Program requirements, it is strongly advised that participant claims be approved by the USDC Seafood Inspection Program prior to use.

**System Compliance Rating Criteria**

## 1.0 Management Controls and Responsibilities

*The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.*

### 1.1.0 Management Responsibilities

*1.1.1 Management commitment not properly implemented or communicated.*

Top management shall provide evidence of its commitment to the development and implementation of the food safety management system and to continually improving its effectiveness by: a) showing food safety is supported by the business objectives of the organization, b) communicating to the organization the importance of meeting food safety standards, statutory and regulatory requirements, as well as customer requirements relating to food safety, c) establishing a food safety policy, d) conducting management reviews, and e) ensuring the availability of resources.

**Deficiency: Critical**

*1.1.2 Food safety policy not prepared or properly implemented.*

Top management shall define, document and communicate its food safety policy. Top management shall ensure that the food safety policy a) is appropriate to the role of the organization in the food chain, b) conforms with both statutory and regulatory requirements and with mutually agreed food safety requirements of customers, c) is communicated, implemented, and maintained at all levels of the organization, d) is reviewed for continued suitability, e) adequately addresses communication, and f) is supported by measurable objectives.

**Deficiency: Serious**

*1.1.3 Food safety management system planning not properly performed.*

Top management shall ensure that a) planning of the food safety management system is properly carried out to meet all applicable requirements, and b) the integrity of the food safety management system is maintained when changes to the food safety management system are planned and implemented.

**Deficiency: Serious**

*1.1.4 Responsibility and authority not properly defined or communicated.*

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety management system. All personnel shall have responsibility to report problems with the food safety management system to identified person(s). Designated personnel shall have defined responsibility and authority to initiate and record actions

**Deficiency: Serious**

### 1.2.0 Food Safety Team

*1.2.1 Food safety team leader not appointed.*

Top management shall appoint a food safety team leader who, irrespective of other duties, shall have the responsibility and authority to: a) manage a food safety team and organize its work, b) ensure relative training and education of the team members, and c) ensure that the food safety management system is established, implemented, maintained and updated.

**Deficiency: Serious**

*1.2.2 Food safety team leader does not report to top management.*

The food safety team leader must report to the organization's top management and will inform them on the effectiveness and suitability of the food safety management system.

**Deficiency: Major**

*1.2.3 Food safety team is not interdisciplinary as applicable.*

The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards within the scope of the food safety management system. Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience.

**Deficiency: Major**

### 1.3.0 Communication

*1.3.1 Effective external communication not established, implemented, or maintained.*

To ensure that sufficient information on issues concerning food safety is available throughout the food chain, the organization shall establish, implement, and maintain effective arrangements for communicating with: a) suppliers and contractors, b) customers or consumers, in particular in relation to product information (including instructions regarding

intended use, specific storage requirements, and as appropriate, shelf life), enquiries, contracts or order handling including amendments, and customer feedback including customer complaints, c) statutory and regulatory authorities, and d) other organizations that have an impact on or will be affected by the effectiveness or updating of the food safety system.

The communication shall provide information on food safety aspects of the organization's products that may be relevant to other organizations in the food chain. This applies especially to known food safety hazards that need to be controlled by other organizations in the food chain. Records of communications shall be maintained. Food safety requirements from statutory and regulatory authorities and customers shall be available. Designated personnel shall have defined responsibility and authority to communicate information concerning food safety externally. Information obtained through external communication shall be included as input to all system updating and management reviews.
**Deficiency: Serious**

*1.3.2 Effective internal communication not established, implemented, or maintained.*
The organization shall establish, implement, and maintain effective arrangements for communicating with personnel on issues having an impact on food safety. In order to maintain the effectiveness of the food safety management system, the organization shall ensure that the food safety team is informed in a timely manner of changes, including but not limited to the following: a) products or new products, b) raw materials, ingredients and services, c) production systems and equipment, d) production premises, location of equipment, surrounding environment, e) cleaning and sanitation programs, f) packaging, storage, and distribution systems, g) personnel qualification level and/or allocation of responsibilities and authorizations, h) statutory and regulatory requirements, i) knowledge regarding food safety hazards and control measures, j) customer, sector, and other requirements which the organization observes, k) relevant enquiries from external interested parties, l) complaints indicating food safety hazards associated with the product, and m) other conditions which have an impact on food safety.

The food safety team shall ensure that this information is included in the updating of the food safety management system. Top management shall ensure that relevant information is included as input to management review.
**Deficiency: Serious**

**1.4.0 Emergency Preparedness and Response**
*1.4.1 Emergency response procedures not established, implemented or maintained..*
Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety relevant to the role of the organization in the food chain.
**Deficiency: Critical**

**1.5.0 Management Review**
*1.5.1 Management review not properly performed or documented.*
Top management shall review the organization's food safety management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the system, including the food safety and quality policy. Records from management reviews shall be maintained.

The input to management review shall include, but is not limited to information on: a) follow-up actions from previous management reviews, b) analysis of results of verification activities, c) changing circumstances that can affect food safety or quality, d) emergency situations, accidents, and withdrawals, e) reviewing results of system updating activities, f) review of communication activities including customer feed-back, and g) external audits or inspections. The data shall be presented in a manner that enables top management to relate the information to stated objectives of the food safety and quality management system.

The output from the management review shall include decisions and actions related to: a) assurance of food safety, b) improvement of the effectiveness of the food safety management system, c) resource needs, and d) revisions of the organization's food safety policy and objectives.
**Deficiency: Serious**

**1.6.0 Resource Management**
The organization shall provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system.

*1.6.1 Necessary human resource competencies not identified.*
The food safety team and the other personnel carrying out activities having an impact on food safety shall be competent and shall have appropriate education, training skills and experience. Where the

assistance of external experts is required for the development, implementation, operation, or assessment of the food safety management system, records of agreement or contracts defining the responsibility and authority of external experts shall be available.
**Deficiency: Serious**

*1.6.2 Personnel have not received documented training necessary for the proper function of the food system.*
The organization shall: a) identify the necessary competencies for personnel whose activities have an impact on food safety, b) provide training or take other action to ensure personnel have the necessary competencies, c) ensure that personnel responsible for monitoring, corrections, and corrective actions of the management system are trained, d) evaluate the implementation and the effectiveness of a), b), and c), e) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to food safety, f) ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety, and g) maintain appropriate records of training and action s described above.

Training must include the areas of HACCP, good manufacturing practices, and allergens to appropriate personnel. Each firm must have available a person who has been certified by NOAA for this program. In addition, copies of all certified personnel's certificates must on file with the firm. Per 21 CFR part 123, these duties are assigned only to properly trained personnel. For the IQA and QMP Program, properly trained will be any person who has passed the NOAA Certification Exam. However, failure of this element will not likely cause an immediate hazard or defect. Therefore it is rated as a Serious deficiency. Per 21 CFR part 123, these duties are assigned to only properly trained personnel. Failure of this element could lead to an immediate hazard or defect.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

- Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);
- Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and
- Performing the record review required by Sec. 123.8(a)(3). The trained individual need not be an employee of the processor.

**Deficiency: Serious/Critical**

*1.6.3 Insufficient infrastructure to implement and maintain the food safety system.*
The organization shall provide the resources for the establishment and maintenance of the infrastructure needed to implement a proper food safety system.
**Deficiency: Serious**

*1.6.4 Work environment is not properly established, managed, or maintained relative to food safety.*
The organization shall provide the resources for the establishment, management, and maintenance of the work environment needed to implement a proper food safety management system.
**Deficiency: Serious**

**1.7.0 Continual Improvement**
*1.7.1 Continuous improvement activities not performed.*
Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measure combinations, and corrective actions.
**Deficiency: Serious**

## 2.0 Food Safety

*The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.*

The organization shall plan and develop the processes needed for the realization of safe products. The organization shall implement, operate, and ensure the effectiveness of the planned activities and any changes to those activities. This includes pre-requisite programs as well as the HACCP plan.

**2.1.0 Operational Prerequisite Programs**

*2.1.1 Operational prerequisite programs not present or not effective.*

Each processor shall have and implement a written operational prerequisite procedures or similar document that is specific to each location where fish and fishery products are produced. The operational prerequisite programs shall be documented and shall include the following information for each program: a) food safety hazard(s) to be controlled by the program, b) control measure(s), c) monitoring procedures that demonstrate that the prerequisite programs are implemented; d) corrections and corrective actions to be taken if monitoring shows that the operational prerequisite programs are not in control; e) responsibilities and authorities; f) record(s) of monitoring.

**Deficiency: Serious**

*2.1.2 Operational prerequisite procedures not followed.*

This deficiency will be assessed if it is determined that the firm did not follow their written procedures, whether or not specific s deficiencies were observed.

**Deficiency: Serious**

**2.2.0 Hazard Analysis**

*2.2.1 Description of products, processes or control measures not properly performed.*

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, including the following, as appropriate: a) biological, chemical, and physical characteristics; b) composition of formulated ingredients, including additives and processing aids; c) origin; d) method of production; e) packaging and delivery methods; f) storage conditions and shelf life; g) preparation and/or handling before use or processing; h) food safety-related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses. The organization shall identify statutory and regulatory food safety requirements related to the above.

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis, including information on the following, as appropriate: a) product name or similar identification; b) composition; c) biological, chemical and physical characteristics relevant for food safety; d) intended shelf life and storage conditions; e) packaging; f) labeling relating to food safety and/or instructions for handling, preparation and usage; g) method(s) of distribution. The organization shall identify statutory and regulatory food safety requirements related to the above.

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis. Groups of users and, where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards shall be considered.

Flow diagrams shall be prepared for the products or process categories covered by the food safety management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards. Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following: a) the sequence and interaction of all steps in the operation; b) any outsourced processes and subcontracted work; c) where raw materials, ingredients and intermediate products enter the flow; d) where reworking and recycling take place; e) where end products, intermediate products, by-products and waste are released or removed. The food safety team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records.

All information described above shall be updated as necessary.

**Deficiency: Major**

*2.2.2 Hazard analysis not properly performed.*

The food safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded. Such hazard analysis must

also consider any products, including ingredients or additives, that may contain allergens as a significant hazard. Allergen assessment must also consider unintentional inclusion of an allergenic ingredient or additive. (21CFR123.6a)

The identification shall be based on a) the preliminary information and data collected according to the previous section, b) experience, c) external information including, to the extent possible, epidemiological and other historical data, and d) information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption. The step(s) (from raw materials, processing and distribution) at which each food safety hazard may be introduced shall be indicated.

When identifying the hazards, consideration shall be given to a) the steps preceding and following the specified operation, b) the process equipment, utilities/services and surroundings, and c) the preceding and following links in the food chain.

For each of the food safety hazards identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data. The justification for, and the result of, the determination shall be recorded.

A hazard assessment shall be conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met. Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the food safety hazard assessment shall be recorded.

Based on the hazard assessment, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels. In this selection, each of the control measures as determined shall be reviewed with respect to its effectiveness against the identified food safety hazards. The control measures selected shall be categorized as to whether they need to be managed through operational prerequisite programs or by the HACCP plan.

The existing control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence food safety, shall be described to the extent needed to conduct the hazard analysis. External requirements (e.g., from regulatory authorities or customers) that may impact the choice and the rigorousness of the control measures shall also be described.

The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following: a) its effect on identified food safety hazards relative to the strictness applied; b) its feasibility for monitoring (e.g., ability to be monitored in a timely manner to enable immediate corrections); c) its place within the system relative to other control measures; d) the likelihood of failure in the functioning of a control measure or significant processing variability; e) the severity of the consequence(s) in the case of failure in its functioning; f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s); g) synergistic effects (i.e., interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

Control measure categorized as belonging to the HACCP plan shall be implemented as such. The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.
**Deficiency: Serious/Critical**

*2.2.3 Hazard analysis not available.*
The hazard and defect analysis is the foundation of the HACCP plan. If the analysis is not performed, the entire plan and its efficacy is suspect. Firms must provide this analysis to the requesting Consumer Safety Officer in writing. If it is not provided and evidence suggests that it was performed but a written document is not available, a Serious deficiency will only be assessed. Otherwise, a Critical deficiency will be assessed.
**Deficiency: Serious/Critical**

**2.3.0 HACCP Plan**
*2.3.1 No written HACCP plan when one is required.*
Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. (21CFR123.6b)Firms must provide this plan to the requesting Consumer Safety Officer.
**Deficiency: Serious**

*2.3.2 Plan is not location and/or fish species specific.*

A HACCP plan shall be specific to:

1. Each location where fish and fishery products are processed by that processor; and
2. Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed are identical for all fish and fishery products so grouped or for all production methods so grouped.

**Deficiency: Major**

*2.3.3 Hazard(s) is not listed in the plan.*

The HACCP plan shall, at a minimum list the food safety hazards that are reasonably likely to occur and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

1. Natural toxins;
2. Microbiological contamination;
3. Chemical contamination;
4. Pesticides;
5. Drug residues;
6. Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
7. Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
8. Unapproved use of direct or indirect food or color additives or allergens; and
9. Physical hazards

In the event that one or more hazards are not identified, a deficiency will be assessed.

**Deficiency: Serious**

*2.3.4 Hazard(s) is not controlled.*

Firms may not have met the requirements of performing the hazard analysis or writing a required HACCP plan. However, controls may still be in place for the hazards identified by the Consumer Safety Officer. If it is determined that the controls are not in place, a Critical deficiency will be assessed.

**Deficiency: Critical**

*2.3.5 CCPs are not properly identified in the plan.*

The HACCP plan shall, at a minimum list the critical control points for each of the identified food safety hazards, including as appropriate:

1. Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
2. Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. (21CFR123.6c.2)

**Deficiency: Serious**

*2.3.6 Appropriate critical limit(s) is not listed in the plan.*

Critical limits shall be determined for the monitoring established for each critical control point. Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the end product is not exceeded. Critical limits shall be measurable. The rationale for the chosen critical limits shall be documented. Critical limits that are evaluated by observation (e.g., visually or sensorically) shall be supported by instructions or specifications and/or education and training. If evidence is present that the critical limits were improperly identified but those identified were followed, the deficiency will be assessed here. (21CFR123.6c.3)

**Deficiency: Serious**

*2.3.7 Critical limits not followed.*

Self Explanatory.

**Deficiency: Critical**

*2.3.8 Monitoring procedure stated in the plan is inadequate.*

Monitoring procedures shall be established for each critical limit. (21CFR123.6c.4) The results of monitoring will indicate whether the CCP is in or out of control. The system shall include all scheduled measurements or observations relative to the critical limit(s). The monitoring system shall consist of relevant procedures, instructions and records that cover the following: a) measurements or observations that provide results within an adequate time frame; b) monitoring devices used; c) applicable calibration methods; d) monitoring frequency; e) responsibility and authority related to monitoring and evaluation of monitoring results; f) record requirements and methods. The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed. Where allergen controls are not sufficient or proper or

identified allergens are not declared on product labels where appropriate, a critical deficiency will be assessed.
**Deficiency: Serious/Critical**

*2.3.9 Monitoring procedures not followed:*
Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed the firm is not in compliance with this item
**Deficiency: Serious**

*2.3.10 Corrective action listed in plan is not appropriate or adequate.*
Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented. Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated and the cause of the deviation is corrected (e.g., not injurious to health or adulterated).

A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

1. No product enters commerce that is either injurious to health, is otherwise adulterated as a result of the deviation, or does not meet Program requirements; and
2. The cause of the deviation is corrected. (21CFR123.7)

**Deficiency: Serious**

*2.3.11 Corrective action not taken*
Whenever a deviation from a critical limit, sanitation, monitoring or verification procedures occurs, a processor shall take corrective action. Processors shall develop written corrective action plans, which become part of their plans by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit.

A firm is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the conduct of the food safety management plan, the firm must file a corrective action report. All other deficiencies may possibly be averted in this checklist if corrective action reports are filed for each problem or situation. Failure to file a corrective action report will be considered a failure to take a corrective action and the firm will then not be in compliance with this item.

When a deviation from the plan occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:
1. Segregate and hold the affected product.
2. Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review.
3. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation or does not meet other program requirements;
4. Take corrective action, when necessary, to correct the cause of the deviation;
5. Perform or obtain timely reassessment of the system by an individual or individuals who have been properly trained to do so, to determine whether the plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the plan as necessary.

In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting action shall be maintained.
**Deficiency: Critical**

*2.3.12 Verification procedure stated in plan is inadequate.*
The HACCP plan shall list the verification procedures, and frequency thereof, that the processor will use. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.

Verification shall include, at a minimum:
1. Reassessment of the food safety management system. A reassessment of the adequacy of the plan whenever any changes occur that could affect the hazard analysis or alter the plan in any way or at least annually. (21CFR123.8a.1) Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished

product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10 of 21 CFR Part 123.

The system shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements.

2. Ongoing verification activities. Ongoing verification activities including:
   - A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
   - The calibration of process-monitoring instruments; and,
   - At the option of the processor, the performing of periodic end-product or in-process testing. (Note: Some end item testing is required as part of the HACCP QMP system. See Program requirements.) (21CFR123.8a.2)

3. Records review. (21CFR123.8a.3) A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:
   - The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
   - The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and
   - The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within 1 week of the day that the records are made.

4. Processors shall immediately follow corrective action procedures whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action. (21CFR123.8b)(See Corrective Action sections listed above.)

5. Reassessment of the hazard analysis. (21CFR123.8c) Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been properly trained in accordance with 21 CFR 123.10. (See 1.6.2)

6. Recordkeeping. (21CFR123.8d) All verification activities, including the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing, shall be documented and recorded and is subject to the recordkeeping requirements listed below.

The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures. Where necessary to ensure valid results, the measuring equipment and methods used a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards, where no such standards exist, the basis used for calibration or verification shall be recorded, b) shall be adjusted or re-adjusted as necessary, c) shall be identified to enable the calibration status to be determined, d) shall be safeguarded from adjustments that would invalidate the measurements results, and e) shall be protected from damage and deterioration. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.

The output of this activity shall be in a form suitable for the organization’s method of operations. Verification results shall be recorded and shall be communicated to the food safety team. Verification results shall be provided to enable the analysis of the

results of the verification activities. If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard, the affected lots of product shall be handled as potentially unsafe.

The organization shall conduct internal audits at planned intervals to determine whether the food safety management system a) conforms to the planned arrangements, to the food safety management system requirements established by the organization, and b) is effectively implemented and updated. An audit program shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any actions resulting from previous audits. The audit criteria, scope, frequency and methods shall be defined and documented. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate nonconformities and their causes.

The food safety team shall systematically evaluate the individual results of planned verification. If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity. The food safety team shall analyze the results of verification activities, including the results of the internal and external audits. The results of the analyses and the resulting activities shall be recorded and shall be reported, in an appropriate manner, to top management as input to the management review.

The monitoring system shall consist of relevant procedures, instructions and records that cover the following: a) measurements or observations that provide results within an adequate time frame; b) monitoring devices used; c) applicable calibration methods; d) monitoring frequency; e) responsibility and authority related to monitoring and evaluation of monitoring results; f) record requirements and methods.

**Deficiency: Serious**

*2.3.13 Verification procedures not followed.*

Verification procedures are those that provide for management to determine the overall effectiveness of the plan. Not following these procedures could ultimately cause the plan to fail or misidentify a hazard, defect, or control procedure. Since failure of these procedures will likely not immediately cause the plan to fail, it is rated at a Serious level. This item should be checked on a trend basis, not based on isolated incidences unless they are of such severity to warrant action. Firms must reassess their hazard analyses when information or other evidence indicates the need and at least yearly. The plan must be signed and dated by a management official responsible for the operation of the facility. The plan must be signed upon implementation and at least once each year.

**Deficiency: Serious**

**2.4.0 Control of Nonconformity**

*2.4.1 Traceability system inadequate.*

The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records. The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route of the end product. Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements (including those for firm registration and traceability relative to the Bioterrorism Act) and customer requirements and may, for example, be based on the end product lot identification.

**Deficiency: Serious**

*2.4.2 Improper handling of potentially unsafe products*

The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels, b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the food chain, or c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been affected by a nonconforming situation shall be held under control of the organization until they have been evaluated. If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal or recall. The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

Each lot of product affected by the nonconformity shall only be released as safe when any of the

following conditions apply: a) evidence other than the monitoring system demonstrates that the control measure have been effective; b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended; c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard(s) concerned.

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities: a) reprocessing or further processing within or outside the organization to ensure that the food safety hazard is eliminated or reduced to acceptable levels; b) destruction and/or disposal as waste.
**Deficiency: Serious**

*2.4.3 Withdrawals and recalls not designed or implemented properly.*
To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and b) the organization shall establish and maintain a documented procedure for

1) notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
2) handling of withdrawn products as well as affected lots of the products still in stock, and
3) the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe. The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review. The organization shall verify and record the effectiveness of the withdrawal program through the use of appropriate techniques (e.g. mock or practice withdrawal).
**Deficiency: Serious**

**2.5.0 Validation**
*2.5.1 Validation activities improperly performed*
The food safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations. Prior to implementation of control measures to be included in operational prerequisite programs and the HACCP plan and after any change therein, the organization shall validate that a) the selected control measures are capable of achieving the intended control of the food safety hazard(s) for which they are designated, and b) the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard(s) to obtain end products that meet the defined acceptable levels.

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed. Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end product characteristics, methods of distribution and/or intended use of the end product.
**Deficiency: Serious**

**2.6.0 Records**
*2.6.1 Inadequate information on records (Facility name and location, etc.)*
Based on the required information stated in 21 CFR Part 123.9a.
All records required by this part shall include:
1. The name and location of the processor or importer;
2. The date and time of the activity that the record reflects;
3. The signature or initials of the person performing the operation; and
4. Where appropriate, the identity of the product and the production code, if any.

**Deficiency: Major**

*2.6.2 Record data is missing.*
All records must be kept up-to-date. Entries must be made as they are measured. The records shall contain the actual values and observations obtained during monitoring or measurement. All time schedules outlined in the QMP plan must be maintained. Examples of non-compliance include: measurement observed to be taken but not entered on record; partial entry of information from monitoring procedures; initials for QA verification not recorded in a timely manner; etc. If record data is missing, a Major deficiency will be assessed.

All labels must be up-to-date. All labels must be kept on file by the firm. If labels are not up-to-date, a Serious deficiency will be assessed.

The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic

data and signatures.
**Deficiency: Major (Serious for Labels)**

*2.6.3 Records are inaccurate.*
All entries must be accurate or the record is meaningless. If calculations, time test measured, etc., are not correct, the box for this deficiency should be checked. Further, as the use of correction fluid or obliterating a record entry are not proper in the keeping of records, their routine use should be considered an inaccurate reading and the serious deficiency assigned. This deficiency will also be used for the compliance of product leaving the firm.
**Deficiency: Serious/Critical**

*2.6.4 Records are not available for inspection.*
If the firm is unable to supply the requested record(s) in a reasonable amount of time for inspector review, they are not in compliance with this item. If portions of a record are not available, the firm is not in compliance with this item. All required records shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.
**Deficiency: Critical**

*2.6.5 Documents or records are falsified.*
This item is self-explanatory. However, intent on the part of the firm or its representatives must be shown. For example, if an item on a record was shown to be corrected with correction fluid or other means of obliteration, the inspector must show that someone with, full knowledge, changed the entry to reflect a value that was not the value measured or observed. Otherwise, this will be considered an inaccurate entry.
**Deficiency: Critical**

## 3.0 SANITATION AND PREREQUISITE PROGRAMS

*The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.*

**References:** 21 CFR Part 110; 21 CFR Part 123.11(b); 50 CFR Parts 260.96-260.104

### 3.1.0 Sanitation Standard Operating Procedures and Prerequisite Programs

*3.1.1 Sanitation standard operating procedures or prerequisite programs not present or not effective.*
Each processor shall have and implement a written sanitation standard operating procedure (SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP shall specify how the processor would meet those sanitation conditions and practices that are to be monitored.
**Deficiency: Serious**

*3.1.2 Sanitation standard operating procedures not followed.*
This deficiency will be assessed if it is determined that the firm did not follow their written SSOPs, whether or not specific sanitation deficiencies were observed.
**Deficiency: Serious**

*3.1.3 Sanitation not monitored.*
Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in 21 CFR Part 110 and 123 that are both appropriate to the plant and the food being processed and relate to the following:

1. Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
3. Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
4. Maintenance of hand washing, hand sanitizing, and toilet facilities;
5. Protection of food, food packaging material, and food contact surfaces from adulteration with

lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
8. Exclusion of pests from the food plant.

The firm shall define the applicable frequencies of monitoring in their sanitation standard operating procedures and must adhere to these frequencies.
**Deficiency: Serious**

**3.2.0 Safety of Process Water**
Process water must be of suitable quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety or wholesomeness of the product. Available water must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or back flow from a contaminated source to the supply system or open vessels of water.

*3.2.1 Unsafe or unsanitary water supply.*
The water supply, including seawater, will be in compliance when by certification or direct testing the supply is found to meet the federal standards set forth by the Environmental Protection Agency or the World Health Organization as applicable. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.
**Deficiency: Serious/Critical**

*3.2.2 Water potability certificate not current*
Private supplies shall have testing performed at a minimum of every six (6) months. Certification of municipal or community systems should be secured at a minimum of once per year. Where used, seawater must meet processing use requirements and potability must be tested at a frequency sufficient to ensure the acceptability of the water source from that geographic area.
**Deficiency: Serious**

*3.2.3 Self water treatment performed improperly.*
Where water supply is treated (such as chlorinated, ozone, UV) on premises, equipment must be properly maintained and/or residual must be within acceptable limits based upon statutory, regulatory, and requirements of the end-user.
**Deficiency: Serious**

*3.2.4 No protection against backflow, back-siphonage, or other sources of contamination.*
A facility will be in compliance when all cross-connections are eliminated, backflow prevention devices are installed wherever backflow or siphonage may occur, or where other possible forms of contamination may be present. A diagram or chart of all such devices will be on file for review.
**Deficiency: Serious**

*3.2.5 Inadequate supply of water and hot water.*
The water supply shall be sufficient for the operation intended. Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant. Water shall be sufficient to properly convey sewage and liquid disposable waste from the plant. Running water at a suitable temperature and under pressure as needed, shall be provided in all areas where required for processing of food, for the cleaning of equipment, utensils and food packaging, or for employee sanitary facilities.

Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a luke-warm supply of water is present in sufficient quantities for the tasks it will perform in the facility, the plant is in compliance. The supply must also be easily accessible for its proper use.
**Deficiency: Minor(Lack of hot water)/Major (Lack of sufficient water supply)**

*3.2.6 Ice not manufactured, handled, or used in a sanitary manner.*
A facility will be in compliance when potable water is used for manufacturing ice, when the manufacturing equipment is clean, and the ice only contacts impervious surfaces; the ice holding containers are clean and made of appropriate impervious material; handling equipment is clean and appropriate for food contact; and ice is properly used.

For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks must be made at a minimum of every six (6) months on ice received.
**Deficiency: Major/Critical**

*3.2.7 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.3.0 Food Contact Surfaces**
*3.3.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product adulteration or contamination.*
Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it can be properly cleaned and inspected. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for its intended purpose or there is reuse of single-service items, then the facility is also out of compliance.

Seams on product-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Product-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food and, if applicable, cleaning compounds and sanitizing agents. Food containers and food-packaging materials that are safe and suitable are to be used. Product-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
**Deficiency: Serious/Critical**

*3.3.2 Equipment and utensils not maintained in proper repair or removed when necessary. (Food contact surfaces)*
All food contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Failure to provide these conditions will result in non-compliance. Assessment of this deficiency will be made relative to the risk of the product at that stage of production. For example, if the equipment under consideration is being used for handling product after a kill step in the process, this product is higher risk and therefore the deviation is more significant.
**Deficiency: Major (Serious for products at a high risk stage of processing)**

*3.3.3 Food contact surfaces not cleaned or sanitized before use, after interruptions, or as necessary.*
Food contact surfaces and food containers must be adequately cleaned using proper techniques to remove dirt and debris and must be adequately sanitized. Sanitizers must be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered non-compliance. Risk should be considered when assessing this deficiency. Product leaving a cooker to be packaged and frozen will have a higher level of risk than a raw fish at receiving.
**Deficiency: Serious/Critical**

*3.3.4 Concentrations of cleaners and sanitizers are not effective, safe, or routinely checked.*
All sanitizing agents (e.g., hand sanitizers, equipment sanitizers, etc) must be used in the proper concentration and in the manner prescribed in the usage instructions to be effective.
**Deficiency: Major**

*3.3.5 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.4.0 Prevention of Cross Contamination**
*3.4.1 Grounds condition can permit contaminants to enter the facility.*
There shall be no conditions on the grounds such as dusty roads or parking lots, standing or ponding water, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc.
**Deficiency: Minor/Major**

*3.4.2 Facility*
*3.4.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product contamination. Insufficient lighting for the applicable operation.*
Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls and ceilings, as well as for visual

inspections. If the rooms (including restrooms and employee breakrooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include insufficient lighting, improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.
**Deficiency: Major**

*3.4.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.*
There must be sufficient separation between different activities in the processing, packaging and handling of food products such as 1) separation between activities, 2) layout of facility (employee traffic) 3) product sequencing and 4) product display. This includes the complete separation of living/sleeping quarters or heavy maintenance areas from food-handling areas. The food product should flow easily from one stage to another and not be allowed to come into contact with non-food contact surfaces if exposed. In addition, the layout of the facility should not be such that product contamination/adulteration is likely due to issues such as heavy employee traffic through work areas. Production is not organized and scheduled in a manner which precludes cross-contamination or cross-contact of product by allergens. Adequate separation can be by physical barrier, time, space, etc. Sanitary handling procedures and processing methods during operations are to be in place to protect food against contamination to include physical protection from airborne contamination.

Retail product displays should be arranged so that there is sufficient separation to assure that no cross-contamination can occur between raw, cooked, and live product.

Food manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food grade animal feed or inedible products unless there is no reasonable possibility for the contamination of human food.
**Deficiency: Serious/Critical**

*3.4.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.*
*3.4.3.1 Areas directly affecting product or packaging material.*
For those areas that will directly affect product or primary packaging materials, (packaging immediately surrounding product), the roof, ceiling, walls, floors, the storage of ingredients or materials that permits cross-contamination or cross-contact by allergens or ingredients, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.
**Deficiency: Serious**

*3.4.3.2 Other.*
For areas in the facility other than in 3.4.3.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.
**Deficiency: Major**

*3.4.4 Cleaning methods permit adulteration or contamination.*
Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will cause the facility to be in non-compliance. Examples of non-compliance include but are not limited to inadvertent touching of product or product surfaces with wash water, detergent, sanitizers, etc., during production.
**Deficiency: Serious (Critical for products at a high risk stage of production)**

*3.4.5 Finished product/primary packaging material not properly covered or protected.*
Finished product must be packaged, covered or protected so as to not permit contamination or adulteration prior to shipment and during transportation. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.
**Deficiency: Major/Serious**

*3.4.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-food contact surfaces)*
All non-food contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of all additional equipment or areas of equipment and utensils not referred to in item 3.4.3.1 above is insufficient and may allow indirect product contamination.
**Deficiency: Minor (Major for products at a high risk stage of production)**

*3.4.7 Non-food contact surfaces, equipment, or areas not cleaned before use.*
Non-food contact areas must also be cleaned prior to use. Areas such as walls, ceilings, floors, as well as equipment must also be cleaned prior to use. However, sanitizing is not required.
**Deficiency: Major**

*3.4.8 Processing or food handling personnel do not maintain a high degree of personal cleanliness.*
All persons, while in food preparation or handling areas shall wear clean outer garments and conform to hygienic practices while on duty, to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.
**Deficiency: Major/Serious**

*3.4.9 Processing or food handling personnel do not take necessary precautions to prevent adulteration or contamination of food.*
All persons, while in a food preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. After washing, the hands must be sanitized.

2. Remove all insecure jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized or properly covered.

3. If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If gloves are used they will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.

4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.

5. Not expectorate; nor store clothing or other personal belongings; not eat food or drink beverages; nor use tobacco in any form in areas where food or food ingredients are exposed, or in areas used for food processing, storage of food ingredients and/or packaging materials, washing of equipment and utensils, or in production areas.

6. Take other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

7. Using sanitary handling procedures during operations to protect food against contamination, e.g., picking up dropped food from the floor.

**Deficiency: Serious/Critical**

*3.4.10 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.5.0 Handwashing, Hand Sanitizing, and Toilet Facilities**
*3.5.1 Hand washing and hand sanitizing stations not present or conveniently located.*
Hand washing and hand sanitizing stations must be present and located properly and in sufficient numbers to provide employees ease of their use. Devices or fixtures, such as water control valves, shall be so designed and constructed to protect against recontamination of clean, sanitized hands.
**Deficiency: Serious (Critical for products at a high risk stage of production)**

*3.5.2 Improper disposal of toilet waste or sewage.*
A facility is in compliance when sewage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewage system.
**Deficiency: Critical**

*3.5.3 Inadequate supplies/signs for employees.*
The restrooms and hand-washing stations must provide supplies such as toilet paper, soap, waste containers, running water (see 3.2.5), sanitary towel service or suitable drying devices, etc., sufficient to meet employees' needs. Readily understandable signs directing employees handling unprotected food, food packaging materials, or food contact surfaces to wash and sanitize their hands at the proper frequency. Refuse receptacles shall be constructed and maintained in a manner that protects against contamination of food.
**Deficiency: Major/Serious**

*3.5.4 Insufficient number of functional toilets.*
The facility must have one operable, clean, in good repair, conveniently accessible toilet per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of

one-third (1/3) of the total number of bowls required. Facilities shall be maintained in a sanitary condition with self-closing doors that do not open directly into areas where food is exposed to airborne contamination, except where alternate means of protection have been implemented.
**Deficiency: Major/Serious**

*3.5.5 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.6.0 Protection From Adulteration**
*3.6.1 Condensation or other deleterious sources present.*
Adequate physical protection of food from adulterants that may drip, drain, or be drawn into the food must be in place. Provide adequate physical protection or separation of food during processing (filling, packaging, assembling, etc.) to protect from contamination. If any condensation, overhead leaks, water splash or other conditions occur that may result in the adulteration of product or primary packaging material, the facility is in non-compliance for this item.
**Deficiency: Critical**

*3.6.2 Adequate air exchange does not exist.*
A facility is in compliance when adequate air exchange exists to preclude the development of foul odors or contamination of product.
**Deficiency: Minor (Only for products at a high risk stage of production)**

*3.6.3 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.7.0 Proper Labeling, Use, and Storage of Toxic Compounds**
Plant chemicals are cleaners, sanitizers, rodenticides, insecticides, food grade machine lubricants, etc. They must be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

A facility will be in compliance when the chemicals are used according to manufacturer's instructions and recommendations and stored in an area of limited access away from food handling or manufacturing. All chemicals must be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA approval.

Only the following toxic materials may be used or stored in a plant where food is processed or exposed: a) those required to maintain clean and sanitary equipment and surfaces, b) those necessary for use in laboratory testing procedures, c) those necessary for plant and equipment maintenance and operation, and d) those necessary for use in the plant's operations.

*3.7.1 Chemical(s) improperly used or handled.*
**Deficiency: Critical**
*3.7.2 Chemical(s) improperly stored.*
**Deficiency: Serious**
*3.7.3 Chemical(s) improperly labeled.*
**Deficiency: Major**
*3.7.4 Material Safety Data Sheets (MSDS) not available for all chemicals in use at the facility.*
**Deficiency: Serious**

*3.7.5 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.8.0 Control of Employee Health Conditions**
*3.8.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.*
No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management shall require employees to report illness or injury to supervisors.
**Deficiency: Serious**

*3.8.2 Other areas covered by the CGMPs.*
**Deficiency: Minor**

**3.9.0 Exclusion of Pests**
The presence of rodents, insects, and other animals in the facility must not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

*3.9.1 Harborage and attractant areas present.*
The facility and grounds are free of harborage areas. These include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are to be properly constructed. If the plant grounds are bordered by grounds not under the operator's control and these grounds are not maintained in a proper manner with regard to this element, care shall be exercised in the facility to exclude pests that may be a source of contamination

by the means outlined in the other areas of this element.
**Deficiency: Major**

*3.9.2 Pest control measures not effective.*
*3.9.2.1 Exclusion*
Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4 ") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air Curtains for entranceways in food establishments. Strip curtains must run the entire opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas of the plant where food is transferred or processed.
**Deficiency: Major**

*3.9.2.2 Extermination*
Birds--Nesting areas must be eliminated.
Insects--There should not be a significant number of insects present in the facility. Insect electrocution devices, when used, must be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.
Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal droppings present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags that may be excessive. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.
**Deficiency: Major/Serious**

*3.9.3 Improper disposal of processing waste.*
A facility is in compliance with regard to processing wastes when they are placed in proper containers, placed at appropriate locations throughout the plant, and removed frequently.
**Deficiency: Serious**

*3.9.4 Inadequate housekeeping.*
Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.
**Deficiency: Minor**

*3.9.5 No written pest control program.*
Self explanatory. Diagrams of bait station locations at the facility shall be maintained and kept available for review.
**Deficiency: Serious**

*3.9.6 Pesticides not applied by a licensed individual.*
Self explanatory. However, in some locations, particularly outside the United States, licensing is not performed. In such instances the application shall be performed by a trained individual.
**Deficiency: Serious**

*3.9.7 Other areas covered by the CGMPs.*
**Deficiency: Minor**

## 4.0 Quality System

*The elements of this section apply to participants in the Integrated Quality Assurance Program and the HACCP Quality Management Program in the evaluation of facilities, processes and systems. This section may also apply if requested specifically.*

### 4.1.0 Management Responsibilities

*4.1.1 Management commitment not properly implemented or communicated.*
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and to continually improving its effectiveness by: a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing a quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.
**Deficiency: Critical**

*4.1.2 Food quality policy not prepared or properly implemented.*
Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. Top management shall ensure that the quality policy a) is appropriate to the role of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.
**Deficiency: Serious**

*4.1.3 Quality system planning not properly performed.*

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Top management shall ensure that a) the planning of the quality management system is carried out as well as the quality objectives, b) the integrity f the quality management system is maintained when changes to the quality management system are planned and implemented.

**Deficiency: Serious**

*4.1.4 Responsibility and authority not properly defined or communicated.*

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

**Deficiency: Serious**

**4.2.0 Quality Team**

*4.2.1 Quality team leader not appointed.*

Top management shall appoint a quality team leader who, irrespective of other responsibilities, shall have the responsibility and authority to: a) ensure that processes needed for the quality management system are established, implemented and maintained, b) report to top management on the performance of the quality management system and any need for improvement, and c) ensure the promotion of awareness of customer requirements throughout the organization.

**Deficiency: Serious**

**4.3.0 Internal Communication**

*4.3.1 Effective internal communication not established, implemented, or maintained.*

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

**Deficiency: Serious**

**4.4.0 Management Review**

*4.4.1 Management review not properly performed or documented..*

Top management shall review the organization's quality management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the system, including the quality policy and objectives. Records from management reviews shall be maintained.

The input to management review shall include information on: a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.

The output from the management review shall include decisions and actions related to: a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.

**Deficiency: Serious**

**4.5.0 Resource Management**

The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.

*4.5.1 Necessary human resource competencies not identified.*

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

**Deficiency: Serious**

*4.5.2 Personnel have not received documented training necessary for the proper function of the quality system.*

The organization shall: a) identify the necessary competencies for personnel performing work affecting product quality, b) provide training or take other action to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to the quality objectives, f) maintain appropriate records of training and action s described above.

**Deficiency: Critical**

*4.5.3 Insufficient infrastructure to implement and maintain the food quality system.*

The organization shall provide the resources for the establishment and maintenance of the infrastructure needed to implement a proper quality management system.

**Deficiency: Serious**

*4.5.4 Work environment is not properly established, managed, or maintained relative to food quality.*
The organization shall provide the resources for the establishment, management, and maintenance of the work environment needed to achieve conformity to product requirements.
**Deficiency: Serious**

**4.6.0 Quality Manual**
*4.6.1 Quality manual is inadequate.*
Every IQA or HACCP QMP processor, as applicable, shall have and implement a written quality manual which covers each of the elements delineated in the Quality System Requirements. Firms must provide this plan to the requesting Consumer Safety Officer.

The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.
**Deficiency: Serious**

*4.6.2 Defect action plan is not adequate to control product quality characteristics.*
Every processor, as applicable, shall have and implement a written Defect Action Plan and a quality defect analysis for products that will either bear an inspection mark or will be advertised as under the NOAA Seafood Inspection Program. Firms must provide this plan to the requesting Consumer Safety Officer.
**Deficiency: Serious**

*4.6.3 Defect action plan/quality manual not followed.*
This deficiency will be assessed if the firm did not follow the policies outlined in their Quality manual or did not follow the procedures listed in their defect action plan. This deficiency will be assessed whether or not it was determined that product was affected.
**Deficiency: Critical**

**4.7.0 Product requirements and specifications.**
*4.7.1 Product characteristics not properly described including raw materials, ingredients, and end product.*
All raw materials, ingredients and food contact materials shall be described in documents to the extent needed to conduct the hazard and defect analysis, including the following: a)biological, chemical, and physical characteristics, b)composition of formulated ingredients including additives and processing aids, c)origin, d)method of production, e)packaging and delivery methods, f)storage conditions and shelf life, g)preparation and/or handling before use or processing, and h)food safety and quality related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses.

The characteristics of end products shall be described in documents to the extent needed to conduct the hazard and defect analysis, including information as appropriate on the following: a)product name or similar identification, b)composition, c)biological, chemical, and physical characteristics relevant to food safety and quality, d)intended shelf life and storage conditions, e)packaging, f)labeling relating to food safety and quality, and/or instructions for handling, preparation, and usage, and g)methods of distribution.

The customer requirements, including any requested changes, are to be reviewed before a commitment to supply a product is provided to the customer (e.g. submission of a tender, acceptance of a contract or order) to ensure that: a)identified customer requirements are clearly defined for the product, b)where the customer provides no written statement of requirement, the order requirements are confirmed before acceptance, c)contract or order requirements differing from those previously expressed are resolved, and d)the organization has the ability to meet the customer requirements for the product. The results of reviews and subsequent follow-up are to be recorded.

The organization shall identify statutory and regulatory quality requirements to the above and these descriptions are to be kept properly updated.
**Deficiency: Serious**

*4.7.2 Intended use and reasonably expected handling of the product not properly considered.*
The intended use, the reasonably expected handling of the end product, and unintended but reasonably expected mishandling and misuse of the end product shall be considered and be described in documents to the extent needed to conduct the hazard and defect analysis. Groups of users and where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards, or product defects, shall be considered. The descriptions shall be kept updated.
**Deficiency: Major**

*4.7.3 Product requirements not discussed and agreed with the customer.*
The organization shall implement effective liaison with its customers, with the aim of meeting customer requirements. The organization shall define communication requirements relating to product information and order handling, including amendments. Such communication shall be recorded and must include customer agreement to the terms.
**Deficiency: Serious**

*4.7.4 Labels and/or specifications are inadequate.*
Title 50 of the Code of Federal Regulations (CFR) requires that establishments contracting for fishery product inspection service obtain NOAA approval of labels prior to use on products packed under Federal inspection, regardless of whether or not they bear official inspection or grade marks. Additionally, the "Policy for Advertising Services and Marks" identifies additional labeling and advertising of marks and services that must be approved prior to use. The Regulations Governing Processed Fishery Products require that specifications for all products for which U.S. Standards for Grades are not available be approved by the Secretary of Commerce and that end--product samples, when requested, be evaluated to determine their compliance with approved specifications prior to NOAA inspection and certification of such products.
**Deficiency: Serious**

*4.7.5 Nonconforming product is improperly controlled.*
The manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

The manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented.

The manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.
**Deficiency: Critical**

**4.8.0 Purchasing**
*4.8.1 Evaluation, re-evaluation, and selection criteria for suppliers are not established.*
The manufacturer shall establish and maintain the requirements (including safety, wholesomeness, proper labeling, and quality requirements) that must be met by suppliers, contractors, and consultants. The manufacturer shall:

a) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
b) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.
c) Establish and maintain quality records of acceptable suppliers, contractors, and consultants.

**Deficiency: Major**

*4.8.2 Purchasing documents are not clear, reviewed, approved, or adequate.*
The manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including food safety and quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the safety or quality of a finished product. The manufacturer shall review and approve purchasing documents for adequacy of the specified requirements prior to release.
**Deficiency: Serious**

*4.8.3 Verification of purchased product not properly performed or documented.*
The manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise

received product and services conform to specified requirements including any arrangements by the customer. Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.
**Deficiency: Serious**

*4.8.4 Customer property not properly maintained or controlled.*
The manufacturer shall establish and maintain documented procedures for the control of verification, storage, and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer.

Verification by the manufacturer does not absolve the customer of the responsibility to provide acceptable product.
**Deficiency: Serious**

**4.9.0 Measurement, Analysis, and Improvement**
*4.9.1 Customer satisfaction/dissatisfaction data not maintained or monitored.*
The organization shall monitor information and data on customer satisfaction or dissatisfaction. The methods and measures for obtaining this information and data including the nature and frequency of reviews shall be defined and documented.
**Deficiency: Serious**

*4.9.2 Internal audits not established or properly performed.*
The organization shall conduct internal audits at planned intervals to determine whether the food safety and quality management system a)conforms to the planned arrangements, to the management system requirements established by the organization, and to the applicable regulatory requirements, and b)is effectively implemented and updated.

An audit program shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits. The audit criteria, scope, frequency, and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification audits.
**Deficiency: Serious**

*4.9.4 Analysis of data and continuous improvement not properly performed with regard to the system.*
The organization shall collect data generated by measuring and monitoring activities and other relevant sources as a means of determining the effectiveness of the management system and for identifying where improvements can be made. The organization shall analyze applicable data to provide information on: a)the suitability, effectiveness and adequacy of the system, b)process operation trends, c)customer satisfaction and dissatisfaction, d)conformance to customer requirements, e)characteristics of processes and products and their trends, and f)suppliers.
**Deficiency: Serious**

## 5.0 Food Security

*This section outlines the elements found in federal guidance on food security systems and as such only applies if requested.*

**5.1.0 Management**
*5.1.1 A comprehensive food security plan has not been written, implemented, and periodically reviewed by the processor.*
A comprehensive food security plan must be written, implemented and periodically reviewed. Such a plan should consider:
1. Preparing for the possibility of tampering or other malicious, criminal, or terrorist actions
- assigning responsibility for security to knowledgeable individual(s)
- conducting an initial assessment of food security procedures and operations, which we recommend be kept confidential
- having a security management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected product
- planning for emergency evacuation, including preventing security breaches during evacuation
- maintaining any floor or flow plan in a secure, off-site location
- becoming familiar with the emergency response system in the community
- making management aware of 24-hour contact information for local, state, and federal

police/fire/rescue/health/homeland security agencies
- making staff aware of who in management they should alert about potential security problems (24-hour contacts)
- promoting food security awareness to encourage all staff to be alert to any signs of tampering or other malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and reporting any findings to identified management (for example, providing training, instituting a system of rewards, building security into job performance standards)
- having an internal communication system to inform and update staff about relevant security issues
- having a strategy for communicating with the public (for example, identifying a media spokesperson, preparing generic press statements and background information, and coordinating press statements with appropriate authorities)

Supervision
- providing an appropriate level of supervision to all staff, including cleaning and maintenance staff, contract workers, data entry and computer support staff, and especially, new staff
- conducting routine security checks of the premises, including automated manufacturing lines, utilities and critical computer data systems (at a frequency appropriate to the operation) for signs of tampering or malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions

Recall strategy
- identifying the person responsible, and a backup person
- providing for proper handling and disposition of recalled product
- identifying customer contacts, addresses and phone numbers

Investigation of suspicious activity
- investigating threats or information about signs of tampering or other malicious, criminal, or terrorist actions
- alerting appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions

Evaluation program
- evaluating the lessons learned from past tampering or other malicious, criminal, or terrorist actions and threats
- reviewing and verifying, at least annually, the effectiveness of the security management program (for example, using knowledgeable in-house or third party staff to conduct tampering or other malicious, criminal, or terrorist action exercises and mock recalls and to challenge computer security systems), revising the program accordingly, and keeping this information confidential
- performing random food security inspections of all appropriate areas of the facility (including receiving and warehousing, where applicable) using knowledgeable in-house or third party staff, and keeping this information confidential
- verifying that security contractors are doing an appropriate job, when applicable

**Deficiency: Critical**

**5.2.0 Human Element**

*5.2.1 Access to plant or sensitive areas of the facility (by employees or visitors) is not sufficiently restricted to authorized personnel.*

***Deficiency: Serious***

*5.2.2 Appropriate controls are not required of employees for gaining access to the facility.*

***Deficiency: Serious***

*5.2.3 Hiring practices do not include a screening process.*

**Deficiency: Serious**

Self-explanatory.

**5.3.0 Facility**

*5.3.1 Facility, including outside premises, grounds, and perimeter, are not properly secure.*

Self-explanatory.

**Deficiency: Critical**

**5.4.0 Operations**

*5.4.1 Raw material suppliers are not subject to a documented approval/screening process.*

***Deficiency: Critical***

*5.4.2 Supplier COCs or invoices do not address the subject of product origin and food security.*

***Deficiency: Serious***

*5.4.3 Product integrity is not assured from time of shipping raw materials to processor through delivery of finished product to end-user.*

**Deficiency: Serious/Critical**

Self-explanatory.

**Appendix 1**

## HACCP Quality Management Program Audit Frequency

| | Systems Audit Target Frequencies | | | Deficiencies | | | |
|---|---|---|---|---|---|---|---|
| **Facility Rating** | **Processors** | **Retail** | **Vessels** | **Minor** | **Major** | **Serious** | **Critical** |
| **Reduced** | Once every calendar quarter | Once every six months | N/A | **0-6** | **0-5** | **1** | **0** |
| **Normal** | Once every month | Once every calendar quarter | Once every calendar quarter | **≥7** | **6-10** | **2-4** | **0** |
| **Tightened** | Daily until corrected | Daily until corrected | As necessary until corrected | **NA** | **≥11** | **≥5** | **≥1** |
| **Requirements to be Audited at a Reduced Frequency** | Three consecutive audits at Reduced Rating | Three consecutive audits at Reduced Rating | N/A | | | | |

Audit frequency for firms operating on a seasonal basis will be determined on a case-by-case basis using the guidance of the frequency listed in the chart above. With regard to seasonal contracts, the firm must request in writing, to the servicing Regional Inspection Branch, to both suspend and reactivate the contract.

## Chain Retail Store Audit Frequency

Firms which operate a chain of stores may have the stores under the program sampled as outlined in the chart below (provided they have an established approved Quality Assurance System).

Table 3

| | Stores to Sample Per Calendar Quarter | | |
|---|---|---|---|
| **Number of Facilities** | **Reduced** | **Normal** | **Tightened** |
| 2 - 4 | 1 | 2 | ALL |
| 5 - 8 | 3 | 4 | 5 |
| 9 - 12 | 4 | 6 | 8 |
| 13 - 16 | 6 | 8 | 10 |
| 17 - 20 | 8 | 10 | 13 |
| 21 - 30 | 9 | 13 | 18 |
| 31 - 40 | 10 | 15 | 21 |
| 41 - 70 | 10 | 18 | 25 |
| 71 - 100 | 10 | 19 | 30 |
| 101 or more | 10 | 20 | 35 |

In addition, the following criteria apply:

1. All firms will begin at Tightened sampling. After two successive calendar quarters the firm will move to Normal sampling. After two successive calendar quarters at Normal sampling, the firm will move to reduced sampling.
2. No stores in the sample may be considered unreliable. If a store in the sample is deemed unreliable (Five Serious deficiencies or One Critical deficiency), the Firm's Quality Assurance System is suspect. USDC will perform an audit on the total Quality Assurance System for the next thirty days. This audit will include the sampling of additional stores.
3. If after the audit the Quality Assurance System is deemed under control, the firm will be sampled at the Tightened level and the system begins again.
4. If the Quality Assurance System is deemed to not be performing as designed, Regional Management will evaluate the company's entire program and suggest the necessary changes to continue in the Program. This evaluation may result in a permanent or temporary removal from the program.
5. During this thirty day period the stores may continue to use all advertisement claims.
6. If the sample of stores does not meet the above requirements, then each store in the chain must be audited on its own until such time as the Quality Assurance System has been re-approved.

**Appendix 2**

## Product Verification for IQA Facilities

To assess the plant's QA ability to evaluate accurately a product's degree of compliance with its applicable standard, specification, or other approved document, the USDC inspector must sample and inspect the product(s) produced for USDC certification. The inspector's results are then compared to the results obtained and reported by the plant's QA department to determine whether any significant differences exist. The plant is required to sample, inspect, and record the findings of each lot produced. The inspector is required to sample and inspect (verify) a certain percentage of the lots produced. It is extremely important that the verification samples and inspections be conducted on an unscheduled, random basis, and independently from the plant sampling and inspection. This independence of sampling and inspection, and recording of inspection findings is necessary to satisfy the verifications objectives under the IQA system.

Note: The independent sampling and inspection for product verification does not mean that the USDC inspector takes no action if his/her inspection results indicate a potential or actual rejection of a production lot currently being processed.

There are three instances where the inspector will notify the plant QA department of potential or actual product rejections when verifying a product being processed.

*Absolute Factors:* For factors such as flavor and odor, health hazard situations, scores below 81 – in the case of a US Grade A product, or for any reason that the product cannot pass inspection, the plant QA will be notified immediately. If the plant QA has found similar results and is taking appropriate action, no penalty, i.e., a major or minor deviation, will be assessed. However, if the plant QA is unaware of the problem, a major deviation will be assessed and the lot placed on "hold" for proper disposition, i.e., reworking, destruction, appeal, etc.

*Acceptance/Rejection Levels for Scores:* When the acceptance number for scores has been reached, for example, 1 for a sample size of 6, 2 for a sample size of 13, etc., the plant QA will be notified of a potential rejection. When acceptance numbers have been reached, the inspector will review the plant QA records to determine whether similar results have been found and corrective action taken. If so, the inspector will take no action. If the plant QA does not have similar findings, it will be advised of a potential rejection and a minor deviation will be assessed. It should be noted that if a sample size of 3 is used, there is no mechanism for alerting the plant QA since the acceptance number is 0. Some plants may wish to increase the sample size to 6 in this instance – prior to the start of production.

*Averages:* For factors in which acceptance is based on an overall average, a running computation will be kept. When the "W" number is exceeded, the inspector will notify the QA department of a potential rejection. When the "W" number has been exceeded, the inspector will review the plant QA records to determine whether similar results have been found and corrective action taken. If so, the inspector will take no action. If the plant QA does not have similar findings, it will be advised of a potential rejection and a minor deviation will be assessed.

In the above situations the inspector must keep in mind that this does not mean that he/she is to work so closely with QA as to diminish the independent nature of USDC and plant QA activities. The inspector must remember that USDC is verifying what the plant QA is doing – not working so closely with it as to influence QA results to agree with those found by USDC.

**Product Group:** For verification purposes, products which are similar in appearance and scoring factors (or other inspection criteria) may be combined to represent one product group. Products grouped in this

manner will be identified in the QA plan on a plant-by-plant basis as approved by USDC. A product group is considered to be but one product when determining the product verification rate.

**Product Verification Rate:** The minimum number of products to be verified by the inspector will depend upon the total number of products produced since the last Group 1 verification. (The time period between successive product verifications will not exceed one production week.) The following product rate table is used to determine the minimum number of products that require verification.

| Total Number of Products Processed since the Last Group 1 Verification | Minimum Number of Products to Verify |
|---|---|
| 1 | 1 |
| 2 – 4 | 2 |
| 5 – 8 | 3 |
| 9 – 13 | 4 |
| 14 – 19 | 5 |
| 20 or more | 6 |

Based on the product rate table, the particular products to be verified will be randomly selected from the total number of products produced since the last product verification; except in those cases where all products must be verified or as noted below.

After a particular product has been verified and found to be acceptable, it may be excluded from further applications of product verification until all other products produced have been verified; except when an audit indicates potential noncompliance.

When there is reason to suspect that a particular product is not in compliance and QA has not taken appropriate action, that product will be verified.

**Selection of Lots from each Product:** Following the random selection of products to be verified, the number of lots of each product must be selected. This may be accomplished in either of two ways.

1) Random Selection from All Lots: For each product to be verified, randomly select 25 percent of all lots produced since the last Group 1 verification. More than 25 percent of the lots may be selected and verified if results indicate the need. If less than 4 lots are available, select 1 lot at random to verify. Otherwise, use the following rule: When the percentage calculation yields a decimal part of 0.25, round down; if the decimal part is 0.50 or 0.75, then round up. For example, if 9 lots are available, then 2 lots would be verified; whereas, if 10 or 11 lots are available, then 3 lots would be verified.

2) Random Selection of Lots from each of Five Possible Lot Size Classes: To use this method, all lots of a product produced since the last Group 1 verification are assigned to a lot size class depending on the sample size each lot would require using the single sampling plans contained in 50 CFR 260.61 as follows:

| Lot Size Class | Sample Size Required for Inspection |
|---|---|
| 1 | 3 |
| 2 | 6 |
| 3 | 13 |
| 4 | 21 |
| 5 | 29 |

Note: Lot size class 5 includes all lot sizes requiring (per 50 CFR 260.61) sample sizes of 29 or more. For lots in this class a sample size of 29 will be drawn.

For example, those lots of a product to be verified that would require a sample of 3 units make up lot size class 1. Then from each lot size class, randomly select 25 percent of the applicable lots. More than 25 percent of the lots may be selected and verified if results indicate the need. If less than 4 lots are available, select 1 lot at random to verify. Otherwise, use the following rule: When the percentage calculation yields a decimal part of 0.25, round down; if the decimal part is 0.50 or 0.75, then round up. For example, if 9 lots are available, then 2 lots would be verified; whereas, if 10 or 11 lots are available, then 3 lots would be verified.

The inspector has the option of using either of the above two methods. In some cases the lot size class method may reduce the total number of sample units needed to perform product verification. The product(s)/lot(s) rates specified above serve only as minimum requirements. The inspector may increase these rates provided that the total number of products, lot, and sample units are within the inspector's capability to verify.

**Selection of Sample Units:** Only single sampling plans as specified by lot size in 50 CFR 260.61 will be used by the inspector when verifying each selected lot. A maximum of 29 sample units per lot will be used.

**Product Examination and Quality Assurance Records Review:** A product verification consists of examining the product sample units and reviewing and evaluating all plant QA records covering the particular product(s)/lot(s) selected for verification.

Verification Factors: For each product, the verification factors (as applicable) are:

1. Net Weight
2. Pressed Weight
3. Count
4. Scored Grade Factors (Items rated by score points will be evaluated individually. However, for purposes of determining verification acceptance, not more than one deviation may be counted for all scored grade factors.)
5. Total Score
6. Percent Fish Flesh
7. Flavor and Odor
8. Container Integrity
9. Other product characteristics per approved specifications, standards, standards of identity, etc.

Once a product is selected for product verification a complete examination is made for all factors which can be determined on the product. Some factors such as net weight, flesh content, pressed weight, and total score point will be verified by statistical means. The deviations noted between USDC verification and plant generated results will be the primary basis for determining continued reliability of a processor's QA program. Consideration by the inspector and his/her supervisor will be given to the type of deviation, the severity, and the frequency of their occurrence when making decisions about the processor's continued reliability.

**Classifying Deviations:** The plant data and information needed for comparison with USDC examination results shall be obtained from product score sheets, certificates, laboratory test reports, and other documents pertinent to product evaluation. Deviations are classified into two categories: Minor and Major.

*Minor Deviation:* A minor deviation is a failure of a part of a quality assurance system, or a difference between USDC and plant quality assurance product evaluation results which, in itself, is not likely to reduce materially the effectiveness or reliability of the quality assurance system, or result in the uncertainty of a product's disposition.

*Major Deviation:* A major deviation is a failure of one or more parts of a quality assurance system, or a difference between USDC and plant quality assurance product evaluation results which will reduce materially the effectiveness or reliability of a quality assurance system, or results in the uncertainty of a product's disposition.

Following are some common deviations with their classifications:

| Deviation | Minor | Major |
|---|---|---|
| Plant QA evaluation indicates product is one or more grade level(s) above USDC verification. | | X |
| Plant QA evaluation indicates product is one or more grade level(s) below USDC verification. | X | |
| QA evaluation results for individual factor(s) or groups of factors which are not statistically reviewed deviate from USDC verification results by a substantial margin as adjudged by the USDC inspector | X | |
| Inaccurate, incomplete or missing records. | | X |
| Verification(s) indicate QA evaluation or records inaccurate as to meeting requirements or specifications. | | X |
| Verification(s) indicate statistical significant deviation from QA evaluation for measurable factors (averages only). | Attachment 7 | |
| Verification(s) of quality assurance records show incorrect procedure(s). | | X |
| Verification results indicate incorrect assessment of acceptability and/or disposition of lot(s). | | X |

Significant deviations are defined as: 1) USDC results statistically indicate that a product standard is not satisfied, or 2) USDC/Plant results are not in statistical agreement.

**Verification Acceptance Plan for Group 1 Deviations:**

**Minors**

| Number of Verifications | Acceptance Number |
|---|---|
| **1 – 2** | **1** |
| **3 – 4** | **2** |
| **5 – 7** | **3** |
| **8 – 10** | **4** |
| **11 – 14** | **5** |
| **15 – 17** | **6** |
| **18 – 20** | **7** |
| **21 – 25** | **8** |
| **26 – 29** | **9** |
| **30 or more** | **10** |

**Majors**

| Number of Verifications | Acceptance Number |
|---|---|
| **1 – 7** | **1** |
| **8 – 16** | **2** |
| **17 – 28** | **3** |
| **29 or more** | **4** |

**Unreliable Status:** The plant's QA program under product verification(s) will be considered to be unreliable when one or more of the following occur:

1. No corrective action is initiated on program deviations.
2. Minor deviations exceed acceptance numbers during 3 out of any 5 consecutive product verification periods of evaluation.
3. Major deviations exceed acceptance numbers during 2 out of 5 consecutive product verification periods of evaluation.

Reporting Unreliability: Findings of unreliability will be reported by the Regional Inspection Office to the Headquarters Office and the National Seafood Inspection Laboratory so that a determination can be made as to an establishment's continued participation in the IQA program. If a determination of unreliability is made, certification will no longer be based on contractor QA results, and products will be certified only when a USDC inspector is present during processing. This may require USDC to increase inspection manpower during the unreliable period. The firm will be notified of this action in writing. To regain IQA Program approval, reliability must be re-established. This will be determined by a system audit and satisfactory review.

# SUBCHAPTER C—REGULATIONS AND STANDARDS UNDER THE AGRICULTURAL MARKETING ACT OF 1946 AND THE EGG PRODUCTS INSPECTION ACT—(Continued)

## PART 53—LIVESTOCK (GRADING, CERTIFICATION, AND STANDARDS)

### Subpart A—Regulations

DEFINITIONS

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53.2 Designation of official certificates, memoranda, marks, other identifications, for purposes of the Agricultural Marketing Act.

ADMINISTRATION

53.3 Authority.

SERVICE

53.4 Kind of service.
53.5 Availability of service.
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53.9 Order of furnishing service.
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53.11 Withdrawal of application or request for service.
53.12 Authority of agent.
53.13 Denial or withdrawal of service.
53.14 Financial interest of official grader.
53.15 Accessibility to livestock.
53.16 Official certificates.
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CHARGES FOR SERVICE

53.18 Fees and other charges for service.
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MISCELLANEOUS

53.20 Identification.
53.21 Errors in service.

### Subpart B [Reserved]

AUTHORITY: 7 U.S.C. 1621–1627.

SOURCE: 42 FR 53902, Oct. 4, 1977, unless otherwise noted.

## Subpart A—Regulations

DEFINITIONS

### § 53.1 Meaning of words.

Words used in this subpart in the singular form shall be deemed to import the plural, and vice versa, as the case may demand. For the purposes of such regulations, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

*Acceptance service.* The service established and conducted under the regulations for the determination and certification or other identification of the compliance of livestock with specifications.

*Act.* The Agricultural Marketing Act of 1946 (Title II of the act of Congress approved August 14, 1946, 60 Stat. 1087, as amended by Pub. L. 272, 84th Cong., 69 Stat. 553, 7 U.S.C. 1621–1627).

*Administrator.* The Administrator of the Agricultural Marketing Service, or any officer or employee of the Agricultural Marketing Service to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

*Agricultural Marketing Service.* The Agricultural Marketing Service of the Department.

*Applicant.* Any person who has applied for service under the regulations.

*Branch.* The Livestock Market News Branch of the Division.

*Chief.* The Chief of the Branch, or any officer or employee of the Branch to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

*Class.* A subdivision of livestock based on essential physical characteristics that differentiate between major groups of the same kind of species.

*Compliance.* Conformity of livestock to the specifications under which the livestock was purchased or sold, with particular reference to the weight, quality or other characterics of livestock.

*Cooperative agreement.* A cooperative agreement between the Agricultural Marketing Service and another Federal agency or a State agency, or other agency, organization or person as specified in the Agricultural Marketing Act of 1946, as amended, for conducting the service.

*Department*. The United States Department of Agriculture.

*Director*. The Director of the Division or any officer or employee of the Division to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

*Division*. Livestock, Poultry, Grain and Seed Division.

*Financially interested person*. Any person having a financial interest in the livestock involved, including but not limited to the shipper, receiver, producer, seller, buyer, or carrier of the livestock or products.

*Grade*. (1) As a noun, this term means an important commercial subdivision of livestock based on certain definite and preference determining factors, such as, but not limited to, conformation, finish, and muscling in livestock.

(2) As a verb, this term means to determine the class, grade, or other quality of livestock according to applicable standards for such livestock.

*Grading service*. The service established and conducted under the regulations for the determination and certification or other identification of the class, grade, or other quality of livestock under standards.

*Legal holiday*. Those days designated as legal public holidays in title 5, United States Code, section 6103(a).

*Livestock*. Cattle, sheep, swine, or goats.

*Official grader*. An employee of the Department or other person authorized by the Department to determine and certify or otherwise identify the class, grade, other quality, or compliance of livestock under the regulations.

*Person*. Any individual, partnership, corporation, or other legal entity, or Government agency.

*Regulations*. The regulations in this subpart.

*Service*. Grading service or acceptance service.

*Specifications*. Description with respect to the class, grade, other quality, quantity or condition of livestock approved by the Administrator, and available for use by the industry regardless of the origin of the descriptions.

*Standards*. The standards of the Department contained in Official United States Standards for Grades of: Carcass Beef; Veal and Calf Carcasses; Lamb, Yearling Mutton, and Mutton Carcasses; and, Pork Carcasses.

*Supervisor*. An official person designated by the Director or Chief to supervise and maintain uniformity and accuracy of service under the regulations.

[42 FR 53902, Oct. 4, 1977, as amended at 63 FR 72101, Dec. 31, 1998]

### § 53.2 Designation of official certificates, memoranda, marks, other identifications, for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Pub. L. 272, 84th Congress, provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed below shall have the respective meanings specified:

(a) *Official certificate* means any form of certification, either written or printed, including that prescribed in § 53.16, used under the regulations to certify with respect to the inspection, class, grade, quality, size, quantity, or condition of livestock with applicable specifications.

(b) *Official memorandum* means any initial record of findings made by an authorized person in the process of grading, determining compliance, or inspecting, pursuant to the regulations, any processing or plant–operation report made by an authorized person in connection with grading, determining compliance, inspecting, or sampling under the regulations, and any report made by an authorized person of services performed pursuant to the regulations.

(c) *Official mark* or *other official identification* means any form of mark or other identification, used under the regulations in marking livestock thereof, to show inspection, class,

# FISH & WILDLIFE SERVICE ACT OF 1956, with amendments



## § 742a. Declaration of policy

The Congress declares that the fish, shellfish, and wildlife resources of the Nation make a material contribution to our national economy and food supply, as well as a material contribution to the health, recreation, and well-being of our citizens; that such resources are a living, renewable form of national wealth that is capable of being maintained and greatly increased with proper management, but equally capable of destruction if neglected or unwisely exploited; that such resources afford outdoor recreation throughout the Nation and provide employment, directly or indirectly, to a substantial number of citizens; that the fishing industries strengthen the defense of the United States through the provision of a trained seafaring citizenry and action-ready fleets of seaworthy vessels; that the training and sport afforded by fish and wildlife resources strengthen the national defense by contributing to the general health and physical fitness of millions of citizens; and that properly developed, such fish and wildlife resources are capable of steadily increasing these valuable contributions to the life of the Nation.

The Congress further declares that the fishing industry, in its several branches, can prosper and thus fulfill its proper function in national life only if certain fundamental needs are satisfied by means that are consistent with the public interest and in accord with constitutional functions of governments. Among these needs are:

**(1)** Freedom of enterprise—freedom to develop new areas, methods, products, and markets in accordance with sound economic principles, as well as freedom from unnecessary administrative or legal restrictions that unreasonably conflict with or ignore economic needs;

**(2)** Protection of opportunity—maintenance of an economic atmosphere in which domestic production and processing can prosper; protection from subsidized competing products; protection of opportunity to fish on the high seas in accordance with international law;

**(3)** Assistance—assistance consistent with that provided by the Government for industry generally, such as is involved in promoting good industrial relations, fair trade standards, harmonious labor relations, better health standards and sanitation; and including, but not limited to—

**(a)** services to provide current information on production and trade, market promotion and development, and an extension service,

**(b)** research services for economic and technologic development and resource conservation, and

**(c)** resource management to assure the maximum sustainable production for the fisheries.

The Congress further declares that the provisions of this Act are necessary in order to accomplish the objective of proper resource

development, and that this Act shall be administered with due regard to the inherent right of every citizen and resident of the United States to engage in fishing for his own pleasure, enjoyment, and betterment, and with the intent of maintaining and increasing the public opportunities for recreational use of our fish and wildlife resources, and stimulating the development of a strong, prosperous, and thriving fishery and fish processing industry.

## 742b. United States Fish and Wildlife Service

**(a) Assistant Secretary for Fish and Wildlife**
There is established within the Department of the Interior the position of Assistant Secretary for Fish and Wildlife. Such Assistant Secretary shall be appointed by the President, by and with the advice and consent of the Senate, and shall be compensated at the same rate as other Assistant Secretaries.

**(b) Establishment; Director of United States Fish and Wildlife Service; appointment; qualifications**
There is established within the Department of the Interior the United States Fish and Wildlife Service. The functions of the United States Fish and Wildlife Service shall be administered under the supervision of the Director, who shall be subject to the supervision of the Assistant Secretary for Fish and Wildlife. The Director of the United States Fish and Wildlife Service shall be appointed by the President, by and with the advice and consent of the Senate. No individual may be appointed as the Director unless he is, by reason of scientific education and experience, knowledgeable in the principles of fisheries and wildlife management.

**(c) Succession to United States Fish and Wildlife Service and Bureau of Sport Fisheries and Wildlife**
The United States Fish and Wildlife Service established by subsection (b) of this section shall succeed to and replace the United States Fish and Wildlife Service (as constituted on June 30, 1974) and the Bureau of Sport Fisheries and Wildlife (as constituted on such date). All laws and regulations in effect on June 30, 1974, which relate to matters administered by the Department of the Interior through the United States Fish and Wildlife Service (as constituted on such date) and the Bureau of Sport Fisheries and Wildlife (as constituted on such date) shall remain in effect.

**(d) Functions and responsibilities of Secretary of the Interior**
All functions and responsibilities placed in the Department of the Interior or any official thereof by this Act shall be included among the functions and responsibilities of the Secretary of the Interior, as the head of the Department, and shall be carried out under his direction pursuant to such procedures or delegations of authority as he may deem advisable and in the public interest.

## 742b–1. Assistant Director for Wildlife and Sport Fish Restoration Programs

**(a) Establishment**
There is established in the United States Fish and Wildlife Service of the Department of the Interior the position of Assistant Director for Wildlife and Sport Fish Restoration Programs.

**(b) Superior**
The Assistant Director for Wildlife and Sport Fish Restoration Programs shall report directly to the Director of the United States Fish and Wildlife Service.

**(c) Responsibilities**
The Assistant Director for Wildlife and Sport Fish Restoration Programs shall be responsible for the administration, management, and oversight of the Federal Assistance Program for State Wildlife and Sport Fish Restoration under the Pittman-Robertson Wildlife Restoration Act (16 U.S.C. 669 et seq.) and the Dingell-Johnson Sport Fish Restoration Act (16 U.S.C. 777 et seq.).

## 742c. Loans for financing or refinancing of cost of purchasing, constructing, equipping, maintaining, repairing, or operating commercial fishing vessels or gear

**(a) Authorization**
The Secretary of the Interior is authorized, under such rules and regulations and under such terms and conditions as he may prescribe, to make loans for financing or refinancing of the cost of purchasing, constructing, equipping, maintaining, repairing, or operating new or used commercial fishing vessels or gear.

**(b) Conditions**
Any loans made under the provisions of this section shall be subject to the following restrictions:

> **(1)** Bear an interest rate of not less than (a) a rate determined by the Secretary of the Treasury, taking into consideration the average market yield on outstanding Treasury obligations of comparable maturity, plus (b) such additional charge, if any, toward covering other costs of the program as the Secretary may determine to be consistent with its purpose.
>
> **(2)** Mature in not more than ten years, except that where a loan is for all or part of the costs of constructing a new fishing vessel, such period may be fourteen years.
>
> **(3)** No financial assistance shall be extended pursuant to this section unless reasonable financial assistance applied for is not otherwise available on reasonable terms.
>
> **(4)** Loans shall be approved only upon the furnishing of such security or other reasonable assurance of repayment as the Secretary may require considering the objectives of this section which are to upgrade commercial fishing vessels and gear and to provide reasonable financial assistance not otherwise available to commercial fishermen. The proposed collateral for a loan must be of such a nature that, when considered with the integrity and ability of the management, and the applicant's past and prospective earnings, repayment of the loan will be reasonably assured.

**(5)** The applicant shall possess the ability, experience, resources, and other qualifications necessary to enable him to operate and maintain new or used commercial fishing vessels or gear.

**(6)** Before the Secretary approves a loan for the purchase or construction of a new or used vessel which will not replace an existing commercial fishing vessel, he shall determine that the applicant's contemplated operation of such vessel in a fishery will not cause economic hardship or injury to the efficient vessel operators already operating in that fishery.

**(7)** An applicant for a fishery loan must be a citizen or national of the United States.

**(8)** Within the meaning of this section, a corporation, partnership, or association shall not be deemed to be a citizen of the United States unless the Secretary determines that it satisfactorily meets all of the requirements set forth in sections 802 and 803 of title 46, Appendix, for determining the United States citizenship of a corporation, partnership, or association operating a vessel in the coastwise trade.

**(9)**

**(A)** The nationality of an applicant shall be established to the satisfaction of the Secretary. Within the meaning of this section, no corporation, partnership, or association organized under the laws of American Samoa shall be deemed a national of the United States unless 75 per centum of the interest therein is owned by nationals of the United States, citizens of the United States, or both, and in the case of a corporation, unless its president or other chief executive officer and the chairman of its board are nationals or citizens of the United States and unless no more of its directors than a minority of the number necessary to constitute a quorum are nonnationals and noncitizens.

**(B)** Seventy-five per centum of the interest in a corporation shall not be deemed to be owned by nationals of the United States, citizens of the United States, or both,

**(i)** if the title to 75 per centum of its stock is not vested in such nationals and citizens free from any trust or fiduciary obligation in favor of any person not a national or citizen of the United States; or

**(ii)** if 75 per centum of the voting power in such corporation is not vested in nationals of the United States, citizens of the United States, or both; or

**(iii)** if through any contract or understanding it is so arranged that more than 25 per centum of the voting power may be exercised, directly or indirectly, in behalf of any person who is not a national or citizen of the United States; or

**(iv)** if by any other means whatsoever control of any interest in the corporation in excess of 25 per centum is conferred upon or permitted to be exercised by any person who is not a national or citizen of the United States.

**(c) Fisheries loan fund; interest payments on appropriations available as capital to the fund less average undispersed cash balance**

There is created a fisheries loan fund, which shall be used by the Secretary as a revolving fund to make loans for financing and refinancing under this section. Any funds received by the Secretary on or before September 30, 1986, in payment of principal or interest on any loans so made shall be deposited in the fund and be available for making additional loans under this section. Any funds received in the fisheries loan fund after September 30, 1986, shall be covered into the Treasury as miscellaneous receipts. There is authorized to be appropriated to the fisheries loan fund the sum of $20,000,000 to provide initial capital.

**(d) Modification of loan contract**

The Secretary, subject to the specific limitations in this section, may consent to the modification, with respect to the rate of interest, time of payment of any installment of principal, or security, of any loan contract to which he is a party.

**(e) Chartering vessels; loans to Alaskan earthquake victims; termination date**

The Secretary is authorized under such terms and conditions and pursuant to regulations prescribed by him to use the funds appropriated under this section to make loans to commercial fishermen for the purpose of chartering fishing vessels pending the construction or repair of vessels lost, destroyed, or damaged by the earthquake of March 27, 1964, and subsequent tidal waves related thereto: Provided, That any loans made under this subsection shall only be repaid from the net profits of the operations of such chartered vessels, which profits shall be reduced by such reasonable amount as determined by the Secretary for the salary of the fishermen chartering such vessels. The funds authorized herein shall not be available for such loans after June 30, 1966.

## 742c–1. Investment in obligations of the United States; proceeds to be used for fisheries

All moneys in the Fisheries Loan Fund established under Section [1] 742c of this title shall be invested by the Secretary of Commerce in obligations of the United States, except so much as shall be currently needed for loans or administrative expenses authorized under the Fisheries Loan Fund. All accrued proceeds from such investment shall be, subject to amounts provided in advance by appropriations, credited by the Secretary of the Treasury to the debt of the Secretary of Commerce incurred under section 1105(d) of the Merchant Marine Act, 1936 [46 App. U.S.C. 1275 (d)], as amended, in connection with fisheries financing under title XI of the Merchant Marine Act, 1936 [46 App. U.S.C. 1271 et seq.], as amended, for so long as such debt exists. All accrued proceeds from such investment, after such debt has been liquidated, shall be, subject to amounts provided in advance by appropriations, credited to the fisheries portion of the Federal Ship Financing Fund established under section 1102 of the Merchant Marine Act, 1936 [46 App. U.S.C. 1272], as amended,

and used for the fisheries purposes provided in title XI of the Merchant Marine Act, 1936, as amended.

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[1] So in original. Probably should not be capitalized.

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## 742d. Investigations; preparation and dissemination of information; reports

**(a)** [1] The Secretary shall conduct continuing investigations, prepare and disseminate information, and make periodical reports to the public, to the President, and to Congress, with respect to the following matters:

**(1)** The production and flow to market of fish and fishery products domestically produced, and also those produced by foreign producers which affect the domestic fisheries;

**(2)** The availability and abundance and the biological requirements of the fish and wildlife resources;

**(3)** The competitive economic position of the various fish and fishery products with respect to each other, and with respect to competitive domestic and foreign-produced commodities;

**(4)** The collection and dissemination of statistics on commercial and sport fishing;

**(5)** The collection and dissemination of statistics on the nature and availability of wildlife, progress in acquisition of additional refuges and measures being taken to foster a coordinated program to encourage and develop wildlife values;

**(6)** The improvement of production and marketing practices in regard to commercial species and the conduct of educational and extension services relative to commercial and sport fishing, and wildlife matters;

**(7)** Any other matters which in the judgment of the Secretary are of public interest in connection with any phases of fish and wildlife operations.

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[1] So in original. No subsec. (b) has been enacted.

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## 742d–1. Studies of effects in use of chemicals

The Administrator of the Environmental Protection Agency is authorized and directed to undertake comprehensive continuing studies on the effects of insecticides, herbicides, fungicides and pesticides, upon the fish and wildlife resources of the United States, for the purpose of determining the amounts, percentages, and formulations of such chemicals that are lethal to or injurious to fish and wildlife and

the amounts, percentages, mixtures, or formulations that can be used safely, and thereby prevent losses of fish and wildlife from such spraying, dusting, or other treatment.

## 742e. Transfer of functions to Secretary

How Current is This?

**(a) Functions of Secretaries of Agriculture, Commerce, etc.**
There shall be transferred to the Secretary all functions of the Secretary of Agriculture, the Secretary of Commerce, and the head of any other department or agency, as determined by the Director of the Office of Management and Budget to relate primarily to the development, advancement, management, conservation, and protection of commercial fisheries; but nothing in this section shall be construed to modify the authority of the Department of State or the Secretary of State to negotiate or enter into any international agreements, or conventions with respect to the development, management, or protection of any fisheries and wildlife resources or with respect to international commissions operating under conventions to which the United States is a party.

**(b) Transfer of personnel, property, records, etc.**
There shall be transferred to the Department of the Interior so much of the personnel, property, facilities, records, and unexpended balances of appropriations, allocations, and other funds (available or to be made available) as the Director of the Office of Management and Budget determines to be necessary in connection with the exercise of any functions transferred to the Secretary pursuant to subsection (a) of this section.

**(c) Cooperation of other departments and agencies**
The Secretary may request and secure the advice or assistance of any department or agency of the Government in carrying out the provisions of this Act, and any such department or agency which furnishes advice or assistance to the Secretary may expend its own funds for such purposes, with or without reimbursement from the Secretary as may be agreed upon between the Secretary and the department or agency.

## 742f. Powers of Secretaries of the Interior and Commerce

**(a) Policies, procedures, and recommendations**
The Secretary of the Interior, with such advice and assistance as he may require from the Assistant Secretary for Fish and Wildlife, shall consider and determine the policies and procedures that are necessary and desirable in carrying out efficiently and in the public interest the laws relating to fish and wildlife. The Secretary, with the assistance of the departmental staff herein authorized, shall—

> **(1)** develop and recommend measures which are appropriate to assure the maximum sustainable production of fish and fishery products and to prevent unnecessary and excessive fluctuations in such production;
>
> **(2)** study the economic condition of the industry, and whenever he determines that any segment of the domestic fisheries has been seriously

disturbed either by wide fluctuation in the abundance of the resource supporting it, or by unstable market or fishing conditions or due to any other factors he shall make such recommendations to the President and the Congress as he deems appropriate to aid in stabilizing the domestic fisheries;

**(3)** develop and recommend special promotional and informational activities with a view to stimulating the consumption of fishery products whenever he determines that there is a prospective or actual surplus of such products; and

**(4)** take such steps as may be required for the development, advancement, management, conservation, and protection of fish and wildlife resources including, but not limited to, research, development of existing facilities, and acquisition by purchase or exchange of land and water, or interests therein.

**(b) Gifts, devises, or bequests for performance of activities and services of United States Fish and Wildlife Service; restrictive or affirmative covenants or conditions of servitude; separate account in Treasury; disbursement orders; gifts or bequests to United States for Federal tax purposes**

**(1)** In furtherance of the purposes of this Act, the Secretary of the Interior is authorized to accept any gifts, devises, or bequests of real and personal property, or proceeds therefrom, or interests therein, for the benefit of the United States Fish and Wildlife Service, in performing its activities and services. Such acceptance may be subject to the terms of any restrictive or affirmative covenant, or condition of servitude, if such terms are deemed by the Secretary to be in accordance with law and compatible with the purpose for which acceptance is sought.

**(2) Use of gifts, devises, and bequests.—**

**(A) In general.—** Any gifts and bequests of money and proceeds from the sales of other property received as gifts or bequests pursuant to this subsection shall be deposited in a separate account in the Treasury and shall be disbursed upon order of the Secretary for the benefit of programs administered by the United States Fish and Wildlife Service.

**(B) Gifts, devises, and bequests to particular refuges.—**

**(i) Disbursal.—** Any gift, devise, or bequest made for the benefit of a particular national wildlife refuge or complex of geographically related refuges shall be disbursed only for the benefit of that refuge or complex of refuges and without further appropriations.

**(ii) Matching.—** Subject to the availability of appropriations and the requirements of the National Wildlife Refuge Administration Act of 1966 (16 U.S.C. 668dd et seq.) and other applicable law, the Secretary may provide funds to match gifts, devises, and bequests made for the benefit of a particular national wildlife refuge or complex of geographically related refuges. With respect to each gift, devise, or bequest, the amount of Federal funds may not exceed the amount (or, in the case of property or in-kind services, the fair market value) of the gift, devise, or bequest.

**(3)** For the purpose of Federal income, estate, and gift taxes, property, or proceeds therefrom, or interests therein, accepted under this subsection shall be considered as a gift or bequest to the United States.

**(c) Volunteer services; incidental expenses; Federal employee status; authorization of appropriations**

**(1)** The Secretary of the Interior and the Secretary of Commerce may each recruit, train, and accept, without regard to the provisions of title 5, the services of individuals without compensation as volunteers for, or in aid of programs conducted by either Secretary through the United States Fish and Wildlife Service or the National Oceanic and Atmospheric Administration.

**(2)** The Secretary of the Interior and the Secretary of Commerce are each authorized to provide for incidental expenses such as transportation, uniforms, lodging, awards (including nominal cash awards) and recognition, and subsistence of such volunteers without regard to their places of residence.

**(3)** Except as otherwise provided in this subsection, a volunteer shall not be deemed a Federal employee and shall not be subject to the provisions of law relating to Federal employment, including those relative to hours of work, rates of compensation, leave, unemployment compensation, and Federal employee benefits.

**(4)** For the purpose of the tort claim provisions of title 28, a volunteer under this subsection shall be considered a Federal employee.

**(5)** For the purposes of subchapter I of chapter 81 of title 5, relating to compensation to Federal employees for work injuries, volunteers under this subsection shall be deemed employees of the United States within the meaning of the term “employees” as defined in section 8101 of title 5, and the provisions of that subchapter shall apply.

**(6) Senior volunteer corps.—** The Secretary of the Interior may establish a Senior Volunteer Corps, consisting of volunteers over the age of 50. To assist in the recruitment and retention of the volunteers, the Secretary may provide for additional incidental expenses to members of the Corps beyond the incidental expenses otherwise provided to volunteers under this subsection. The members of the Corps shall be subject to the other provisions of this subsection.

**(d) Community partnership enhancement**

**(1) Definition of partner organization**
In this subsection, the term “partner organization” means an organization that—

**(A)** draws its membership from private individuals, organizations, corporations, academic institutions, or State or local governments;

**(B)** is established to promote the understanding of, education relating to, and the conservation of the fish, wildlife, plants, and cultural and

historical resources of a particular refuge or complex of geographically related refuges; and

**(C)** is described in section 501 (c)(3) of title 26 and is exempt from taxation under section 501(a) of that title.

**(2) Cooperative agreements**

**(A) In general**
Notwithstanding chapter 63 of title 31, the Secretary of the Interior may negotiate and enter into a cooperative agreement with a partner organization, academic institution, State or local government agency, or other person to implement one or more projects or programs for a refuge or complex of geographically related refuges in accordance with the purposes of this subsection and in compliance with the policies of other relevant authorities, regulations, and policy guidance.

**(B) Projects and programs**
Subject to the requirements of the National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd et seq.) and other applicable law, and such terms and conditions as the Secretary determines to be appropriate, the Secretary may approve projects and programs for a refuge or complex of geographically related refuges that—

**(i)** promote the stewardship of resources of the refuge through habitat maintenance, restoration, and improvement, biological monitoring, or research;

**(ii)** support the operation and maintenance of the refuge through constructing, operating, maintaining, or improving the facilities and services of the refuge;

**(iii)** increase awareness and understanding of the refuge and the National Wildlife Refuge System through the development, publication, or distribution of educational materials and products;

**(iv)** advance education concerning the purposes of the refuge and the mission of the System through the use of the refuge as an outdoor classroom and development of other educational programs; or

**(v)** contribute financial resources to the refuge, under terms that require that the net revenues be used exclusively for the benefit of the refuge, through donation of net revenues from the sale of educational materials and products and through encouragement of gifts, devises, and bequests.

**(C) Federal funding and ownership**

**(i)** Matching Subject to the availability of appropriations and the requirements of the National Wildlife Refuge Administration

Act of 1966 (16 U.S.C. 668dd et seq.) and other applicable law, the Secretary may provide funds to match non-Federal funds donated under a cooperative agreement under this paragraph. With respect to each project or program, the amount of funds provided by the Secretary may not exceed the amount of the non-Federal funds donated through the project or program.

**(ii)** Use of Federal funds Any Federal funds used to fund a project or program under a cooperative agreement may be used only for expenses directly related to the project or program and may not be used for operation or administration of any non-Federal entity.

**(iii)** Ownership of facilities Any new facility, improvement to an existing facility, or other permanent improvement to a refuge constructed under this subsection shall be the property of the United States Government.

**(D) Treasury account**
Amounts received by the Secretary of the Interior as a result of projects and programs under subparagraph (B) shall be deposited in a separate account in the Treasury. Amounts in the account that are attributable to activities at a particular refuge or complex of geographically related refuges shall be available to the Secretary of the Interior, without further appropriation, to pay the costs of incidental expenses related to volunteer activities, and to carry out cooperative agreements for the refuge or complex of refuges.

**(e) Refuge education program enhancement**

**(1) Guidance**
Not later than 1 year after October 5, 1998, the Secretary of the Interior shall develop guidance for refuge education programs to further the mission of the National Wildlife Refuge System and the purposes of individual refuges through—

**(A)** providing outdoor classroom opportunities for students on national wildlife refuges that combine educational curricula with the personal experiences of students relating to fish, wildlife, and plants and their habitat and to the cultural and historical resources of the refuges;

**(B)** promoting understanding and conservation of fish, wildlife, and plants and cultural and historical resources of the refuges; and

**(C)** improving scientific literacy in conjunction with both formal and nonformal education programs.

**(2) Refuge programs**
Based on the guidance developed under paragraph (1), the Secretary of the Interior may develop or enhance refuge education programs as appropriate, based on the resources of individual refuges and the opportunities available for such programs in State, local, and private schools. In developing and implementing each program, the Secretary should cooperate with State and

local education authorities, and may cooperate with partner organizations in accordance with subsection (d) of this section.

**(f) Authorization of appropriations**
There is authorized to be appropriated to the Secretary of the Interior to carry out subsections (b), (c), (d), and (e) of this section $2,000,000 for each of fiscal years 2004 through 2009.

## 742f–1. Projects

**(1) In general**
Subject to the availability of appropriations, the Secretary of the Interior shall carry out a project at 2 or more national wildlife refuges or complexes of geographically related refuges in each United States Fish and Wildlife Service region.

**(2) Volunteer coordinator**
Each project shall provide for the employment of a full-time volunteer coordinator for the refuge or complex of geographically related refuges. The volunteer coordinator shall be responsible for recruiting, training, and supervising volunteers. The volunteer coordinator may be responsible for assisting partner organizations in developing projects and programs under cooperative agreements under section 742f (d) of this title and coordinating volunteer activities with partner organizations to carry out the projects and programs.

**(3) Report**
Not later than 3 years after October 16, 2004, and every 3 years thereafter, the Secretary of the Interior shall submit a report to the Committee on Resources of the House of Representatives and the Committee on Environment and Public Works of the Senate evaluating and making recommendations regarding the projects.

**(4) Authorization of appropriations**
There is authorized to be appropriated to carry out this subsection $2,000,000 for for [1] each fiscal year through fiscal year 2009.

## 742g. Cooperation with State Department

**(a) Representation at international meetings**
The Secretary shall cooperate to the fullest practicable extent with the Secretary of State in providing representation at all meetings and conferences relating to fish and wildlife in which representatives of the United States and foreign countries participate.

The Secretary of State shall designate the Secretary of the Interior or the Assistant Secretary for Fish and Wildlife, or a person designated by the Secretary of the Interior to represent the Department of the Interior, as a member of the United States delegation attending such meetings and conferences and also as a member of the negotiating team of any such delegation.

**(b) Consultation with officials responsible for technical and economic aid**
The Secretary of State and all other officials having responsibilities in the fields of technical and economic aid to foreign nations shall consult with the Secretary in all

cases in which the interests of fish and wildlife are involved, with a view to assuring that such interests are adequately represented at all times.

**(c) International negotiations**
Notwithstanding any other provision of law, the Secretary shall be represented in all international negotiations conducted by the United States pursuant to section 1351 of title 19, in any case in which fish products are directly affected by such negotiations.

**(d) Consultation with governmental, private nonprofit, and other organizations**
The Secretary shall consult periodically with the various governmental, private nonprofit, and other organizations and agencies which have to do with any phase of fish and wildlife with respect to any problems that may arise in connection with such fish and wildlife.

## 742h. Reports on fishery products

**(a)** Repealed. Pub. L. 96–470, title I, § 103(a), Oct. 19, 1980, 94 Stat. 2237.

**(b)** The Secretary is authorized to make a report to the President and the Congress, and, when requested by the United States International Trade Commission in connection with section 1364 of title 19, or when an investigation is made under the Tariff Act of 1930 (19 U.S.C. 1332), the Secretary is authorized to make a report to such Commission, concerning the following matters with respect to any fishery product which is imported into the United States, or such reports may be made upon a request from any segment of the domestic industry producing a like or directly competitive product—

**(1)** whether there has been a downward trend in the production, employment in the production, or prices, or a decline in the sales, of the like or directly competitive product by the domestic industry; and

**(2)** whether there has been an increase in the imports of the fishery products into the United States, either actual or relative to the production of the like or directly competitive product produced by the domestic industry.

## 742i. Effect on rights of States and international commissions

Nothing in this Act shall be construed

**(1)** to interfere in any manner with the rights of any State under the Submerged Lands Act [43 U.S.C. 1301 et seq.] or otherwise provided by law, or to supersede any regulatory authority over fisheries exercised by the States either individually or under interstate compacts; or

**(2)** to interfere in any manner with the authority exercised by any International Commission established under any treaty or convention to which the United States is a party.

## 742j. Authorization of appropriations

There are hereby authorized to be appropriated such sums as may be necessary to carry out the provisions of this Act.

## 742j–1. Airborne hunting

**(a) Prohibition; penalty**
Any person who—

> **(1)** while airborne in an aircraft shoots or attempts to shoot for the purpose of capturing or killing any bird, fish, or other animal; or
>
> **(2)** uses an aircraft to harass any bird, fish, or other animal; or
>
> **(3)** knowingly participates in using an aircraft for any purpose referred to in paragraph (1) or (2);

shall be fined not more than $5,000 or imprisoned not more than one year, or both.

**(b) Exception; report of State to Secretary**

> **(1)** This section shall not apply to any person if such person is employed by, or is an authorized agent of or is operating under a license or permit of, any State or the United States to administer or protect or aid in the administration or protection of land, water, wildlife, livestock, domesticated animals, human life, or crops, and each such person so operating under a license or permit shall report to the applicable issuing authority each calendar quarter the number and type of animals so taken.
>
> **(2)** In any case in which a State, or any agency thereof, issues a permit referred to in paragraph (1) of this subsection, it shall file with the Secretary of the Interior an annual report containing such information as the Secretary shall prescribe, including but not limited to—
>
> > **(A)** the name and address of each person to whom a permit was issued;
> >
> > **(B)** a description of the animals authorized to be taken thereunder, the number of animals authorized to be taken, and a description of the area from which the animals are authorized to be taken;
> >
> > **(C)** the number and type of animals taken by such person to whom a permit was issued; and
> >
> > **(D)** the reason for issuing the permit.

**(c) “Aircraft” defined**
As used in this section, the term “aircraft” means any contrivance used for flight in the air.

**(d) Enforcement; regulations; arrest; search; issuance and execution of warrants and process; cooperative agreements**
The Secretary of the Interior shall enforce the provisions of this section and shall promulgate such regulations as he deems necessary and appropriate to carry out such enforcement. Any employee of the Department of the Interior authorized by the Secretary of the Interior to enforce the provisions of this section may, without warrant, arrest any person committing in his presence or view a violation of this section or of any regulation issued hereunder and take such person immediately for examination or trial before an officer or court of competent jurisdiction; may execute any warrant or other process issued by an officer or court of competent jurisdiction for the enforcement of the provisions of this section; and may, with or without a warrant, as authorized by law, search any place. The Secretary of the Interior is authorized to enter into cooperative agreements with State fish and wildlife agencies or other appropriate State authorities to facilitate enforcement of this section, and by such agreements to delegate such enforcement authority to State law enforcement personnel as he deems appropriate for effective enforcement of this section. Any judge of any court established under the laws of the United States, and any United States magistrate judge may, within his respective jurisdiction, upon proper oath or affirmation showing probable cause, issue warrants in all such cases.

**(e) Forfeiture**
All birds, fish, or other animals shot or captured contrary to the provisions of this section, or of any regulation issued hereunder, and all guns, aircraft, and other equipment used to aid in the shooting, attempting to shoot, capturing, or harassing of any bird, fish, or other animal in violation of this section or of any regulation issued hereunder shall be subject to forfeiture to the United States.

**(f) Certain customs laws applied**
All provisions of law relating to the seizure, forfeiture, and condemnation of a vessel for violation of the customs laws, the disposition of such vessel or the proceeds from the sale thereof, and the remission or mitigation of such forfeitures, shall apply to the seizures and forfeitures incurred, or alleged to have been incurred, under the provisions of this section, insofar as such provisions of law are applicable and not inconsistent with the provisions of this section; except that all powers, rights, and duties conferred or imposed by the customs laws upon any officer or employee of the Treasury Department shall, for the purposes of this section, be exercised or performed by the Secretary of the Interior or by such persons as he may designate.

## 742j–2. Uniform allowance

Notwithstanding subsection [1] 5901(a) of title 5, the uniform allowance for each uniformed employee of the United States Fish and Wildlife Service may be up to $400 annually.

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[1] So in original. Probably should be “section”.

# TITLE 5--APPENDIX
## REORGANIZATION PLANS
### REORGANIZATION PLAN NO. 4 OF 1970
### NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

**Section 1. Transfers to Secretary of Commerce**

The following are hereby transferred to the Secretary of Commerce:

(a) All functions vested by law in the Bureau of Commercial Fisheries of the Department of the Interior or in its head, together with all functions vested by law in the Secretary of the Interior or the Department of the Interior which are administered through that Bureau or are primarily related to the Bureau, exclusive of functions with respect to (1) Great Lakes fishery research and activities related to the Great Lakes Fisheries Commission, (2) Missouri River Reservoir research, (3) the Gulf Breeze Biological Laboratory of the said Bureau at Gulf Breeze, Florida, and (4) Trans-Alaska pipeline investigations.

(b) The functions vested in the Secretary of the Interior by the Act of September 22, 1959 (Public Law 86-359, 73 Stat. 642, 16 U.S.C. 760e-760g; relating to migratory marine species of game fish).

(c) The functions vested by law in the Secretary of the Interior, or in the Department of the Interior or in any officer or instrumentality of that Department, which are administered through the Marine Minerals Technology Center of the Bureau of Mines.

(d) All functions vested in the National Science Foundation by the National Sea Grant College and Program Act of 1966 (80 Stat. 998), as amended (33 U.S.C. 1121 et seq.).

(e) Those functions vested in the Secretary of Defense or in any officer, employee, or organizational entity of the Department of Defense by the provision of Public Law 91-144, 83 Stat. 326, under the heading "Operation and maintenance, general" with respect to "surveys and charting of northern and northwestern lakes and connecting waters," or by other law, which come under the mission assigned as of July 1, 1969, to the United States Army Engineer District, Lake Survey, Corps of Engineers, Department of the Army and relate to (1) the conduct of hydrographic surveys of the Great Lakes and their outflow rivers, Lake Champlain, New York State Barge Canals, and the Minnesota-Ontario border lakes, and the compilation and publication of navigation charts, including recreational aspects, and the Great Lakes Pilot for the benefit and use of the public, (2) the conception, planning, and conduct of basic research and development in the fields of water motion, water characteristics, water quantity, and ice and snow, and (3) the publication of data and the results of research projects in forms useful to the Corps of Engineers and the public, and the operation of a Regional Data Center for the collection, coordination, analysis, and the furnishing to interested agencies of data relating to water resources of the Great Lakes.

(f) So much of the functions of the transferor officers and agencies referred to in or affected by the foregoing provisions of this section as is incidental to or necessary for the performance by or under the Secretary of Commerce of the functions transferred by those provisions or relates primarily to those functions. The transfers to the Secretary of Commerce made by this section shall be deemed to include the transfer of authority, provided by law, to prescribe regulations relating primarily to the transferred functions.

**Sec. 2. Establishment of Administration**

(a) There is hereby established in the Department of Commerce an agency which shall be known as the National Oceanic and Atmospheric Administration, hereinafter referred to as the "Administration."

(b) There shall be at the head of the Administration the Administrator of the National Oceanic and Atmospheric Administration, hereinafter referred to as the "Administrator." The Administrator shall be appointed by the President, by and with the advice and consent of the Senate, and shall be compensated at the rate now or hereafter provided for Level III of the Executive Schedule Pay Rates (5 U.S.C. 5314).

(c) There shall be in the Administration a Deputy Administrator of the National Oceanic and Atmospheric Administration who shall be appointed by the President, by and with the advice and consent of the Senate, and shall be compensated at the rate now or hereafter provided for Level IV of the Executive Schedule Pay Rates (5 U.S.C. 5315). The Deputy Administrator shall perform such functions as the Administrator shall from time to time assign or delegate, and shall act as Administrator during the absence or disability of the Administrator or in the event of a vacancy in the office of Administrator.

(d) There shall be in the Administration a Chief Scientist of the National Oceanic and Atmospheric Administration who shall be appointed by the President, by and with the advice and consent of the Senate, and shall be compensated at the rate now or hereafter provided for Level V of the Executive Schedule Pay Rates (5 U.S.C. 5316). The Chief Scientist shall be the

principal scientific adviser to the Administrator, and shall perform such other duties as the Administrator may direct. The Chief Scientist shall be an individual who is, by reason of scientific education and experience, knowledgeable in the principles of oceanic, atmospheric, or other scientific disciplines important to the work of the Administration. [As amended Pub. L. 94-461, § 4(c)(1), Oct. 8, 1976, 90 Stat. 1969; Pub. L. 99-659, title IV, § 407(d), Nov. 14, 1986, 100 Stat. 3739.]

(e)(1) There shall be in the Administration a General Counsel and five Assistant Administrators, one of whom shall be the Assistant Administrator for Coastal Zone Management and one of whom shall be the Assistant Administrator for Fisheries. The General Counsel and each Assistant Administrator shall be appointed by the Secretary, subject to approval of the President, and shall be compensated at a rate now or hereafter provided for level V of the Executive Schedule Pay Rates (5 U. S.C. 5316).

(2) The General Counsel shall serve as the chief legal officer for all legal matters which may arise in connection with the conduct of the functions of the Administration.

(3) The Assistant Administrator for Coastal Zone Management shall be an individual who is, by reason of background and experience, especially qualified to direct the implementation and administration of the Coastal Zone Management Act of 1972 (16 U.S.C. 1451 et seq.).

(4) The Assistant Administrator for Fisheries shall be responsible for all matters related to living marine resources which may arise in connection with the conduct of the functions of the Administration. [As amended Pub. L. 95-219, § 3(a)(1), Dec. 28, 1977, 91 Stat. 1613.]

(f) The President may appoint in the Administration, by and with the advice and consent of the Senate, two commissioned officers to serve at any one time as the designated heads of two principal constituent organizational entities of the Administration, or the President may designate one such officer as the head of such an organizational entity and the other as head of the commissioned corps of the Administration. Any such designation shall create a vacancy on the active list and the officer while serving under this subsection shall have the rank, pay, and allowances of a rear admiral (upper half).

(g) Any commissioned officer of the Administration who has served under (d) or (f) and is retired while so serving or is retired after the completion of such service while serving in a lower rank or grade, shall be retired with the rank, pay, and allowances authorized by law for the highest grade and rank held by him; but any such officer, upon termination of his appointment in a rank above that of captain, shall, unless appointed or assigned to some other position for which a higher rank or grade is provided, revert to the grade and number he would have occupied had he not served in a rank above that of captain and such officer shall be an extra number in that grade.

**Sec. 3. Performance of Transferred Functions**

The provisions of sections 2 and 4 of Reorganization Plan No. 5 of 1950 (64 Stat. 1263) shall be applicable to the functions transferred hereunder to the Secretary of Commerce.

**Sec. 4. Incidental Transfers**

(a) So much of the personnel, property, records, and unexpended balances of appropriations, allocations, and other funds employed, used, held, available, or to be made available in connection with the functions transferred to the Secretary of Commerce by this reorganization plan as the Director of the Office of Management and Budget shall determine shall be transferred to the Department of Commerce at such time or times as the Director shall direct.

(b) Such further measures and dispositions as the Director of the Office of Management and Budget shall deem to be necessary in order to effectuate the transfers referred to in subsection (a) of this section shall be carried out in such manner as he shall direct and by such agencies as he shall designate.

(c) The personnel, property, records, and unexpended balances of appropriations, allocations, and other funds of the Environmental Science Services Administration shall become personnel, property, records, and unexpended balances of the National Oceanic and Atmospheric Administration or of such other organizational entity or entities of the Department of Commerce as the Secretary of Commerce shall determine.

(d) The Commissioned Officer Corps of the Environmental Science Services Administration shall become the Commissioned Officer Corps of the National Oceanic and Atmospheric Administration. Members of the Corps, including those appointed hereafter, shall be entitled to all rights, privileges, and benefits heretofore available under any law to commissioned officers of the Environmental Science Services Administration, including those rights, privileges, and benefits heretofore accorded by law to commissioned officers of the former Coast and Geodetic Survey.

(e) Any personnel, property, records, and unexpended balances of appropriations, allocations, and other funds of the Bureau of Commercial Fisheries not otherwise transferred shall become personnel, property, records, and unexpended balances of such

organizational entity or entities of the Department of the Interior as the Secretary of the Interior shall determine.

**Sec. 5. Interim Officers**

(a) The President may authorize any person who immediately prior to the effective date of this reorganization plan held a position in the executive branch of the Government to act as Administrator until the office of Administrator is for the first time filled pursuant to provisions of this reorganization plan or by recess appointment, as the case may be.

(b) The President may similarly authorize any such person to act as Deputy Administrator and authorize any such person to act as Associate Administrator.

(c) The President may similarly authorize a member of the former Commissioned Officer Corps of the Environmental Science Services Administration to act as the head of one principal constituent organizational entity of the Administration.

(d) The President may authorize any person who serves in an acting capacity under the foregoing provisions of this section to receive the compensation attached to the office in respect of which he so serves. Such compensation, if authorized, shall be in lieu of, but not in addition to, other compensation from the United States to which such person may be entitled.

**Sec. 6. Abolitions**

(a) Subject to the provisions of this reorganization plan, the following, exclusive of any functions, are hereby abolished:

(1) The Environmental Science Services Administration in the Department of Commerce (established by Reorganization Plan No. 2 of 1965, 79 Stat. 1318), including the offices of Administrator of the Environmental Science Administration and Deputy Administrator of the Environmental Science Services Administration.

(2) The Bureau of Commercial Fisheries in the Department of the Interior (16 U.S.C. 742b), including the office of Director of the Bureau of Commercial Fisheries.

(b) Such provisions as may be necessary with respect to terminating any outstanding affairs shall be made by the Secretary of Commerce in the case of the Environmental Science Services Administration and by the Secretary of the Interior in the case of the Bureau of Commercial Fisheries.

260.103 Operations and operating procedures shall be in accordance with an effective sanitation program.
260.104 Personnel.

LABELING REQUIREMENTS

260.200–260.201 [Reserved]

AUTHORITY: Sec. 6, 70 Stat. 1122, 16 U.S.C. 742e; secs. 203, 205, 60 Stat. 1087, 1090 as amended; 7 U.S.C. 1622, 1624; Reorganization Plan No. 4 of 1970 (84 Stat. 2090).

SOURCE: 31 FR 16052, Dec. 15, 1966, unless otherwise noted.

## Subpart A—Inspection and Certification of Establishments and Fishery Products for Human Consumption

### § 260.1 Administration of regulations.

The Secretary of Commerce is charged with the administration of the regulations in this part except that he may delegate any or all of such functions to any officer or employee of the National Marine Fisheries Service of the Department in his discretion.[1]

[36 FR 21037, Nov. 3, 1971]

DEFINITIONS

### § 260.6 Terms defined.

Words in the regulations in this part in the singular form shall be deemed to import the plural and vice versa, as the case may demand. For the purposes of the regulations in this part, unless the context otherwise requires, the following terms shall have the following meanings:

*Acceptance number.* ''Acceptance number'' means the number in a sampling plan that indicates the maximum number of deviants permitted in a sample of a lot that meets a specific requirement.

*Act.* ''Act'' means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087 et seq., as amended; 7 U.S.C. 1621 et seq.).

*Applicant.* ''Applicant'' means any interested party who requests inspection service under the regulations in this part.

*Case.* ''Case'' means the number of containers (cased or uncased) which, by the particular industry are ordinarily packed in a shipping container.

*Certificate of loading.* ''Certificate of loading'' means a statement, either written or printed, issued pursuant to the regulations in this part, relative to check-loading of a processed product subsequent to inspection thereof.

*Certificate of sampling.* ''Certificate of sampling'' means a statement, either written or printed issued pursuant to the regulations in this part, identifying officially drawn samples and may include a description of condition of containers and the condition under which the processed product is stored.

*Class.* ''Class'' means a grade or rank of quality.

*Condition.* ''Condition'' means the degree of soundness of the product which may affect its merchantability and includes, but is not limited to those factors which are subject to change as a result of age, improper preparation and processing, improper packaging, improper storage, or improper handling.

*Department.* ''Department'' means the U.S. Department of Commerce.

*Deviant.* ''Deviant'' means a sample unit affected by one or more deviations or a sample unit that varies in a specifically defined manner from the requirements of a standard, specification, or other inspection document.

*Deviation.* ''Deviation'' means any specifically defined variation from a particular requirement.

*Director.* ''Director'' means the Director of the National Marine Fisheries Service.

[1] All functions of the Department of Agriculture which pertain to fish, shellfish, and any products thereof, now performed under the authority of title II of the Act of August 14, 1946, popularly known as the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627) including but not limited to the development and promulgation of grade standards, the inspection and certification, and improvement of transportation facilities and rates for fish and shellfish and any products thereof, were transferred to the Department of the Interior by the Director of the Budget (23 FR 2304) pursuant to section 6(a) of the Act of Aug. 8, 1956, popularly known as the Fish and Wildlife Act of 1956 (16 U.S.C. 742e). Reorganization Plan No. 4 of 1970 (84 Stat. 2090) transferred, among other things, such functions from the U.S. Department of the Interior to the U.S. Department of Commerce.

*Establishment.* ''Establishment'' means any premises, buildings, structures, facilities, and equipment (including vehicles) used in the processing, handling, transporting, and storage of fish and fishery products.

*Inspection certificate.* ''Inspection certificate'' means a statement, either written or printed, issued pursuant to the regulations in this part, setting forth in addition to appropriate descriptive information relative to a processed product, and the container thereof, the quality and condition, or any part thereof, of the product and may include a description of the conditions under which the product is stored.

*Inspection service.* ''Inspection service'' means:

(1) The sampling pursuant to the regulations in this part;

(2) The determination pursuant to the regulations in this part of:

(i) Essential characteristics such as style, type, size, or identity of any processed product which differentiates between major groups of the same kind;

(ii) The class, quality, and condition of any processed product, including the condition of the container thereof by the examination of appropriate samples;

(3) The issuance of any certificate of sampling, inspection certificates, or certificates of loading of a processed product, or any report relative to any of the foregoing; or

(4) Performance by an inspector of any related services such as to observe the preparation of the product from its raw state through each step in the entire process; or observe conditions under which the product is being harvested, prepared, handled, stored, processed, packed, preserved, transported, or held; or observe sanitation as a prerequisite to the inspection of the processed product, either on a contract basis or periodic basis; or checkload the inspected processed product in connection with the marketing of the product, or any other type of service of a consultative or advisory nature related herewith.

*Inspector.* ''Inspector'' means any employee of the Department authorized by the Secretary or any other person licensed by the Secretary to investigate, sample, inspect, and certify in accordance with the regulations in this part to any interested party the class, quality and condition of processed products covered in this part and to perform related duties in connection with the inspection service.

*Interested party.* ''Interested party'' means any person who has a financial interest in the commodity involved.

*Licensed sampler.* ''Licensed sampler'' means any person who is authorized by the Secretary to draw samples of processed products for inspection service, to inspect for identification and condition of containers in a lot, and may, when authorized by the Secretary, perform related services under the act and the regulations in this part.

*Lot.* ''Lot'' has the following meanings:

(1) For the purpose of charging fees and issuing certificates, ''Lot'' means any number of containers of the same size and type which contain a processed product of the same type and style located in the same or adjacent warehouses and which are available for inspection at any one time: *Provided,* That:

(i) Processed products in separate piles which differ from each other as to grade or other factors may be deemed to be separate lots;

(ii) Containers in a pile bearing an identification mark different from other containers of such processed product in that pile, if determined to be of lower grade or deficient in other factors, may be deemed to be a separate lot; and

(iii) If the applicant requests more than one inspection certificate covering different portions of such processed product, the quantity of the product covered by each certificate shall be deemed to be a separate lot.

(2) For the purpose of sampling and determining the grade or compliance with a specification, ''Lot'' means each pile of containers of the same size and type containing a processed product of the same type and style which is separated from other piles in the same warehouse, but containers in the same pile bearing an identification mark different from other containers in that

pile may be deemed to be a separate lot.

*Official establishment.* ''Official establishment'' means any establishment which has been approved by National Marine Fisheries Service, and utilizes inspection service on a contract basis.

*Officially drawn sample.* ''Officiallydrawn sample'' means any sample that has been selected from a particular lot by an inspector, licensed sampler, or by any other person authorized by the Secretary pursuant to the regulations in this part.

*Person.* ''Person'' means any individual, partnership, association, business trust, corporation, any organized group of persons (whether incorporated or not), the United States (including, but not limited to, any corporate agencies thereof), any State, county, or municipal government, any common carrier, and any authorized agent of any of the foregoing.

*Plant.* ''Plant'' means the premises, buildings, structures, and equipment (including, but not being limited to, machines, utensils, and fixtures) employed or used with respect to the manufacture or production of processed products.

*Processed product.* ''Processed product'' means any fishery product or other food product covered under the regulations in this part which has been preserved by any recognized commercial process, including, but not limited to, canning, freezing, dehydrating, drying, the addition of chemical substances, or by fermentation.

*Quality.* ''Quality'' means the inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients.

*Rejection number.* ''Rejection number'' means the number in a sampling plan that indicates the minimum number of deviants in a sample that will cause a lot to fail a specific requirement.

*Sample.* ''Sample'' means any number of sample units to be used for inspection.

*Sample unit.* ''Sample unit'' means a container and/or its entire contents, a portion of the contents of a container or other unit of commodity, or a composite mixture of a product to be used for inspection.

*Sampling.* ''Sampling'' means the act of selecting samples of processed products for the purpose of inspection under the regulations in this part.

*Secretary.* ''Secretary'' means the Secretary of the Department or any other officer or employee of the Department authorized to exercise the powers and to perform the duties of the Secretary in respect to the matters covered by the regulations in this part.

*Shipping container.* ''Shipping container'' means an individual container designed for shipping a number of packages or cans ordinarily packed in a container for shipping or designed for packing unpackaged processed products for shipping.

*Unofficially drawn sample.* ''Unofficially drawn sample'' means any sample that has been selected by any person other than an inspector or licensed sampler, or by any other person not authorized by the Director pursuant to the regulations in this part.

*Wholesome.* ''Wholesome'' means the minimum basis of acceptability for human food purposes, of any fish or fishery product as defined in section 402 of the Federal Food, Drug, and Cosmetic Act, as amended.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 21037, Nov. 3, 1971]

### § 260.7 Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946 provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications and devices for making such marks or identifications, issued or authorized under section 203 of said act, and certain misrepresentations concerning the inspection or grading of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed below shall have the respective meanings specified:

*Official certificate.* ''Official certificate'' means any form of certification, either written or printed, including those defined in § 260.6, used under this part to certify with respect to the inspection, class, grade, quality, size, quantity, or condition of products (including the compliance of products with applicable specifications).

*Official device.* ''Official device'' means a stamping appliance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Director for the purpose of applying any official mark or other identification to any product or the packaging material thereof.

*Official identification.* ''Official identification'' means any United States (U.S.) standard designation of class, grade, quality, size, quantity, or condition specified in this part or any symbol, stamp, label, or seal indicating that the product has been graded or inspected and/or indicating the class, grade, quality, size, quantity, or condition of the product approved by the Director and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product.

*Official mark.* ''Official mark'' means the grade mark, inspection mark, combined form of inspection and grade mark, and any other mark, or any variations in such marks, including those prescribed in § 260.86, approved by the Secretary and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product, stating that the product was graded or inspected or both, or indicating the appropriate U.S. Grade or condition of the product, or for the purpose of maintaining the identity of products graded or inspected or both under this part.

*Official memorandum.* ''Official memorandum'' means any initial record of findings made by an authorized person in the process of grading, inspecting, or sampling pursuant to this part, any processing or plant-operation report made by an authorized person in connection with grading, inspecting, or sampling under this part, and any report made by an authorized person of services performed pursuant to this part.

INSPECTION SERVICE

### § 260.12 Where inspection service is offered.

Inspection service may be furnished wherever an inspector or licensed sampler is available and the facilities and conditions are satisfactory for the conduct of such service.

### § 260.13 Who may obtain inspection service.

An application for inspection service may be made by any interested party, including, but not limited to, the United States and any instrumentality or agency thereof, any State, county, municipality, or common carrier, and any authorized agent in behalf of the foregoing.

### § 260.14 How to make application.

An application for inspection service may be made to the officer of inspection or to any inspector, at or nearest the place where the service is desired. An up-to-date list of the Inspection Field Offices of the Department may be obtained upon request to the Director. Satisfactory proof that the applicant is an interested party shall be furnished.

### § 260.15 Information required in connection with application.

Application for inspection service shall be made in the English language and may be made orally (in person or by telephone), in writing, or by telegraph. If an application for inspection service is made orally, such application shall be confirmed promptly in writing. In connection with each application for inspection service, there shall be furnished such information as may be necessary to perform an inspection on the processed product for which application for inspection is made, including but not limited to, the name of the product, name and address of the packer or plant where such product was packed, the location of the product, its lot or car number, codes or other identification marks, the number of containers, the type and size of the containers, the interest of the applicant in the product, whether the lot has been inspected previously to the application by any Federal agency and the purpose for which inspection is desired.

### § 260.16 Filing of application.

An application for inspection service shall be regarded as filed only when made in accordance with the regulations in this part.

### § 260.17 Record of filing time.

A record showing the date and hour when each application for inspection or for an appeal inspection is received shall be maintained.

### § 260.18 When application may be rejected.

An application for inspection service may be rejected by the Secretary (a) for noncompliance by the applicant with the regulations in this part, (b) for nonpayment for previous inspection services rendered, (c) when the product is not properly identifiable by code or other marks, or (d) when it appears that to perform the inspection service would not be to the best interests of the Government. Such applicant shall be promptly notified of the reason for such rejection.

### § 260.19 When application may be withdrawn.

An application for inspection service may be withdrawn by the applicant at any time before the inspection is performed: *Provided*, That, the applicant shall pay at the hourly rate prescribed in § 260.70 for the time incurred by the inspector in connection with such application, any travel expenses, telephone, telegraph or other expenses which have been incurred by the inspection service in connection with such application.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 18738, Sept. 21, 1971]

### § 260.20 Disposition of inspected sample.

Any sample of a processed product that has been used for inspection may be returned to the applicant, at his request and expense; otherwise it shall be destroyed, or disposed of to a charitable institution.

### § 260.21 Basis of inspection and grade or compliance determination.

(a) Inspection service shall be performed on the basis of the appropriate U.S. standards for grades of processed products, Federal, Military, Veterans Administration or other government agency specifications, written contract specification, or any written specification or instruction which is approved by the Secretary.

(b) Unless otherwise approved by the Director compliance with such grade standards, specifications, or instructions shall be determined by evaluating the product, or sample, in accordance with the requirements of such standards, specifications, or instructions: *Provided*, That when inspection for quality is based on any U.S. grade standard which contains a scoring system the grade to be assigned to a lot is the grade indicated by the average of the total scores of the sample units: *Provided further*, That:

(1) Such sample complies with the applicable standards of quality promulgated under the Federal Food, Drug, and Cosmetic Act;

(2) Such sample complies with the product description;

(3) Such sample meets the indicated grade with respect to factors of quality which are not rated by score points; and

(4) With respect to those factors of quality which are rated by score points, each of the following requirements is met:

(i) None of the sample units falls more than one grade below the indicated grade because of any quality factor to which a limiting rule applies;

(ii) None of the sample units falls more than 4 score points below the minimum total score for the indicated grade; and

(iii) The number of sample units classed as deviants does not exceed the applicable acceptance number indicated in the sampling plans contained in § 260.61. A ''deviant,'' as used in this paragraph, means a sample unit that falls into the next grade below the indicated grade but does not score more than 4 points below the minimum total score for the indicated grade.

(5) If any of the provisions contained in paragraphs (b)(3) and (4) of this section are not met the grade is determined by considering such provisions in connection with succeedingly lower

grades until the grade of the lot, if assignable, is established.

### § 260.22 Order of inspection service.

Inspection service shall be performed, insofar as practicable, in the order in which applications therefor are made except that precedence may be given to any such applications which are made by the United States (including, but not being limited to, any instrumentality or agency thereof) and to any application for an appeal inspection.

### § 260.23 Postponing inspection service.

If the inspector determines that it is not possible to accurately ascertain the quality or condition of a processed product immediately after processing because the product has not reached equilibrium in color, or drained weight, or for any other substantial reason, he may postpone inspection service for such period as may be necessary.

### § 260.24 Financial interest of inspector.

No inspector shall inspect any processed product in which he is directly or indirectly financially interested.

### § 260.25 Forms of certificates.

Inspection certificates, certificates of sampling or loading, and other memoranda concerning inspection service shall be issued on forms approved by the Secretary.

### § 260.26 Issuance of certificates.

(a) An inspection certificate may be issued only by an inspector: *Provided*, That, another employee of the inspection service may sign any such certificate covering any processed product inspected by an inspector when given power of attorney by such inspector and authorized by the Secretary, to affix the inspector's signature to an inspection certificate which has been prepared in accordance with the facts set forth in the notes, made by the inspector, in connection with the inspection.

(b) A certificate of loading shall be issued and signed by the inspector or licensed sampler authorized to check the loading of a specific lot of processed products: *Provided*, That, another employee of the inspection service may sign such certificate of loading covering any processed product checkloaded by an inspector or licensed sampler when given power of attorney by such inspector or licensed sampler and authorized by the Secretary to affix the inspector's or licensed sampler's signature to a certificate of loading which has been prepared in accordance with the facts set forth in the notes made by the inspector or licensed sampler in connection with the checkloading of a specific lot of processed products.

### § 260.27 Issuance of corrected certificates.

A corrected inspection certificate may be issued by the inspector who issued the original certificate after distribution of a certificate if errors, such as incorrect dates, code marks, grade statements, lot or car numbers, container sizes, net or drained weights, quantities, or errors in any other pertinent information require the issuance of a corrected certificate. Whenever a corrected certificate is issued, such certificate shall supersede the inspection certificate which was issued in error and the superseded certificate shall become null and void after the issuance of the corrected certificate.

### § 260.28 Issuance of an inspection report in lieu of an inspection certificate.

A letter report in lieu of an inspection certificate may be issued by an inspector when such action appears to be more suitable than an inspection certificate: *Provided*, That, the issuance of such report is approved by the Secretary.

### § 260.29 Disposition of inspection certificates.

The original of any inspection certificate, issued under the regulations in this part, and not to exceed four copies thereof, if requested prior to issuance, shall be delivered or mailed promptly to the applicant, or person designated by the applicant. All other copies shall

be filed in such manner as the Secretary may designate. Additional copies of any such certificates may be supplied to any interested party as provided in § 260.78.

### § 260.30 Report of inspection results prior to issuance of formal report.

Upon request of any interested party, the results of an inspection may be telegraphed or telephoned to him, or to any other person designated by him, at his expense.

APPEAL INSPECTION

### § 260.36 When appeal inspection may be requested.

An application for an appeal inspection may be made by any interested party who is dissatisfied with the results of an inspection as stated in an inspection certificate, if the lot of processed products can be positively identified by the inspection service as the lot from which officially drawn samples were previously inspected. Such application shall be made within thirty (30) days following the day on which the previous inspection was performed, except upon approval by the Secretary the time within which an application for appeal inspection may be made, may be extended.

### § 260.37 Where to file for an appeal inspection and information required.

(a) Application for an appeal inspection may be filed with:

(1) The inspector who issued the inspection certificate on which the appeal covering the processed product is requested; or

(2) The inspector in charge of the office of inspection at or nearest the place where the processed product is located.

(b) The application for appeal inspection shall state the location of the lot of processed products and the reasons for the appeal; and date and serial number of the certificate covering inspection of the processed product on which the appeal is requested, and such application may be accompanied by a copy of the previous inspection certificate and any other information that may facilitate inspection. Such application may be made orally (in person or by telephone), in writing, or by telegraph. If made orally, written confirmation shall be made promptly.

### § 260.38 When an application for an appeal inspection may be withdrawn.

An application for appeal inspection may be withdrawn by the applicant at any time before the appeal inspection is performed: *Provided*, That the applicant shall pay at the hourly rate prescribed in § 260.70, for the time incurred by the inspector in connection with such application, any travel expenses, telephone, telegraph, or other expenses which have been incurred by the inspection service in connection with such application.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 18738, Sept. 21, 1971]

### § 260.39 When appeal inspection may be refused.

An application for an appeal inspection may be refused if:

(a) The reasons for the appeal inspection are frivolous or not substantial;

(b) The quality or condition of the processed product has undergone a material change since the inspection covering the processed product on which the appeal inspection is requested;

(c) The lot in question is not, or cannot be made accessible for the selection of officially drawn samples;

(d) The lot relative to which appeal inspection is requested cannot be positively identified by the inspector as the lot from which officially drawn samples were previously inspected; or

(e) There is noncompliance with the regulations in this part. Such applicant shall be notified promptly of the reason for such refusal.

### § 260.40 Who shall perform appeal inspection.

An appeal inspection shall be performed by an inspector or inspectors (other than the one from whose inspection the appeal is requested) authorized for this purpose by the Secretary and, whenever practical, such appeal inspection shall be conducted jointly by two such inspectors: *Provided*, That the inspector who made the inspection on which the appeal is requested may be authorized to draw the samples when

another inspector or licensed sampler is not available in the area where the product is located.

### § 260.41 Appeal inspection certificate.

After an appeal inspection has been completed, an appeal inspection certificate shall be issued showing the results of such appeal inspection; and such certificate shall supersede the inspection certificate previously issued for the processed product involved. Each appeal inspection certificate shall clearly identify the number and date of the inspection certificate which it supersedes. The superseded certificate shall become null and void upon the issuance of the appeal inspection certificate and shall no longer represent the quality or condition of the processed product described therein. The inspector or inspectors issuing an appeal inspection certificate shall forward notice of such issuance to such persons as he considers necessary to prevent misuse of the superseded certificate if the original and all copies of such superseded certificate have not previously been delivered to the inspector or inspectors issuing the appeal inspection certificate. The provisions in the regulations in this part concerning forms of certificates, issuance of certificates, and disposition of certificates shall apply to appeal inspection certificates, except that copies of such appeal inspection certificates shall be furnished all interested parties who received copies of the superseded certificate.

## LICENSING OF SAMPLERS AND INSPECTORS

### § 260.47 Who may become licensed sampler.

Any person deemed to have the necessary qualifications may be licensed as a licensed sampler to draw samples for the purpose of inspection under the regulations in this part. Such a license shall bear the printed signature of the Secretary, and shall be countersigned by an authorized employee of the Department. Licensed samplers shall have no authority to inspect processed products under the regulations in this part except as to identification and condition of the containers in a lot. A licensed sampler shall perform his duties pursuant to the regulations in this part as directed by the Director.

### § 260.48 Application to become a licensed sampler.

Application to become a licensed sampler shall be made to the Secretary on forms furnished for that purpose. Each such application shall be signed by the applicant in his own handwriting, and the information contained therein shall be certified by him to be true, complete, and correct to the best of his knowledge and belief, and the application shall contain or be accompanied by:

(a) A statement showing his present and previous occupations, together with names of all employers for whom he has worked, with periods of service, during the 10 years previous to the date of his application;

(b) A statement that, in his capacity as a licensed sampler, he will not draw samples from any lot of processed products with respect to which he or his employer is an interested party;

(c) A statement that he agrees to comply with all terms and conditions of the regulations in this part relating to duties of licensed samplers; and

(d) Such other information as may be requested.

### § 260.49 Inspectors.

Inspections will ordinarily be performed by employees under the Secretary who are employed as Federal Government employees for that purpose. However, any person employed under any joint Federal-State inspection service arrangement may be licensed, if otherwise qualified, by the Secretary to make inspections in accordance with this part on such processed products as may be specified in his license. Such license shall be issued only in a case where the Secretary is satisfied that the particular person is qualified to perform adequately the inspection service for which such person is to be licensed. Each such license shall bear the printed signature of the Secretary and shall be countersigned by an authorized employee of the Department. An inspector shall perform his duties pursuant to the regulations in this part as directed by the Director.

### § 260.50 Suspension or revocation of license of licensed sampler or licensed inspector.

Pending final action by the Secretary, the Director may, whenever he deems such action necessary, suspend the license of any licensed sampler, or licensed inspector, issued pursuant to the regulations in this part, by giving notice of such suspension to the respective licensee, accompanied by a statement of the reasons therefor. Within 7 days after the receipt of the aforesaid notice and statement of reasons by such licensee, he may file an appeal, in writing, with the Secretary supported by any argument or evidence that he may wish to offer as to why his license should not be suspended or revoked. After the expiration of the aforesaid 7 day period and consideration of such argument and evidence, the Secretary shall take such action as he deems appropriate with respect to such suspension or revocation.

### § 260.51 Surrender of license.

Upon termination of his services as a licensed sampler or licensed inspector, or suspension or revocation of his license, such licensee shall surrender his license immediately to the office of inspection serving the area in which he is located. These same provisions shall apply in a case of an expired license.

## SAMPLING

### § 260.57 How samples are drawn by inspectors or licensed samplers.

An inspector or a licensed sampler shall select samples, upon request, from designated lots of processed products which are so placed as to permit thorough and proper sampling in accordance with the regulations in this part. Such person shall, unless otherwise directed by the Secretary, select sample units of such products at random, and from various locations in each lot in such manner and number, not inconsistent with the regulations in this part, as to secure a representative sample of the lot. Samples drawn for inspection shall be furnished by the applicant at no cost to the Department.

### § 260.58 Accessibility for sampling.

Each applicant shall cause the processed products for which inspection is requested to be made accessible for proper sampling. Failure to make any lot accessible for proper sampling shall be sufficient cause for postponing inspection service until such time as such lot is made accessible for proper sampling.

### § 260.59 How officially drawn samples are to be identified.

Officially drawn samples shall be marked by the inspector or licensed sampler so such samples can be properly identified for inspection.

### § 260.60 How samples are to be shipped.

Unless otherwise directed by the Secretary, samples which are to be shipped to any office of inspection shall be forwarded to the office of inspection serving the area in which the processed prodcuts from which the samples were drawn is located. Such samples shall be shipped in a manner to avoid, if possible, any material change in the quality or condition of the sample of the processed product. All transportation charges in connection with such shipments of samples shall be at the expense of the applicant and wherever practicable, such charges shall be prepaid by him.

### § 260.61 Sampling plans and procedures for determining lot compliance.

(a) Except as otherwise provided for in this section in connection with inplant inspection and unless otherwise approved by the Secretary, samples shall be selected from each lot in the exact number of sample units indicated for the lot size in the applicable single sampling plan or, at the discretion of the inspection service, any comparable multiple sampling plan: *Provided*, That at the discretion of the inspection service the number of sample units selected may be increased to the exact number of sample units indicated for any one of the larger sample sizes provided for in the appropriate plans.

(b) Under the single sampling plans with respect to any specified requirement:

(1) If the number of deviants (as defined in connection with the specific requirements) in the sample does not exceed the acceptance number prescribed for the sample size the lot meets the requirement;

(2) If the number of deviants (as defined in connection with the specific requirement) in the sample exceeds the acceptance number prescribed for the sample size the lot fails the requirement.

(c) Under the multiple sampling plans inspection commences with the smallest sample size indicated under the appropriate plan and with respect to any specified requirement:

(1) If the number of deviants (as defined in connection with the specific requirement) in the sample being considered does not exceed the acceptance number prescribed for that sample size the lot meets the requirement;

(2) If the number of deviants (as defined in connection with the specific requirement) in the sample being considered equals or exceeds the rejection number prescribed for that sample size the lot fails the requirement; or

(3) If the number of deviants (as defined in connection with the specific requirement) in the sample being considered falls between the acceptance and rejection numbers of the plan, additional sample units are added to the sample so that the sample thus cumulated equals the next larger cumulative sample size in the plan. It may then be determined that the lot meets or fails the specific requirement by considering the cumulative sample and applying the procedures outlined in paragraphs (c)(1) and (2) of this section or by considering successively larger samples cumulated in the same manner until the lot meets or fails the specific requirement.

(d) If in the conduct of any type of inplant inspection the sample is examined before the lot size is known and the number of sample units exceeds the prescribed sample size for such lot but does not equal any of the prescribed larger sample sizes the lot may be deemed to meet or fail a specific requirement in accordance with the following procedure:

(1) If the number of deviants (as defined in connection with the specific requirement) in the nonprescribed sample does not exceed the acceptance number of the next smaller sample size the lot meets the requirements;

(2) If the number of deviants (as defined in connection with the specific requirement) in the nonprescribed sample equals the acceptance number prescribed for the next larger sample size additional sample units shall be selected to increase the sample to the next larger prescribed sample size;

(3) If the number of deviants (as defined in connection with the specific requirement) in the nonprescribed sample exceeds the acceptance number prescribed for the next larger sample size the lot fails the requirement.

(e) In the event that the lot compliance determination provisions of a standard or specification are based on the number of specified deviations instead of deviants the procedures set forth in this section may be applied by substituting the word ''deviation'' for the word ''deviant'' wherever it appears.

(f) Sampling plans referred to in this section are those contained in Tables I, II, III, IV, V, and VI which follow or any other plans which are applicable. For processed products not included in these tables, the minimum sample size shall be the exact number of sample units prescribed in the table, container group, and lot size that, as determined by the inspector, most closely resembles the product, type, container size and amount of product to be samples.

SINGLE SAMPLING PLANS AND ACCEPTANCE LEVELS

TABLE I—CANNED OR SIMILARLY PROCESSED FISHERY PRODUCTS, AND PRODUCTS THEREOF CONTAINING UNITS OF SUCH SIZE AND CHARACTER AS TO BE READILY SEPARABLE

| Container size group | Lot size (number of containers) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| GROUP 1 | | | | | | | | | |
| Any type of container of less volume than that of a No. 300 size can (300×407) | 3,600 or less | 3,601–14,400 | 14,401–48,000 | 48,001–96,000<br>96,001–156,000 | 156,001–228,000 | 228,001–300,000 | 300,001–420,000 | Over 420,000 | |
| GROUP 2 | | | | | | | | | |
| Any type of container of a volume equal to or exceeding that of a No. 300 size can, but not exceeding that of a No. 3 cylinder size can (404×700) | 2,400 or less | 2,401–12,000 | 12,001–24,000 | 24,001–48,000<br>48,001–72,000 | 72,001–108,000 | 108,001–168,000 | 168,001–240,000 | Over 240,000 | |
| GROUP 3 | | | | | | | | | |
| Any type of container of a volume exceeding that of a No. 3 cylinder size can, but not exceeding that of a No. 12 size can (603×812) | 1,200 or less | 1,201–7,200 | 7,201–15,000 | 15,001–24,000 | 24,001–36,000 | 36,001–60,000 | 60,001–84,000 | 84,001–120,000 | Over 120,000 |
| GROUP 4 | | | | | | | | | |
| Any type of container of a volume exceeding that of a No. 12 size can, but not exceeding that of a 5-gallon container | 200 or less | 201–800 | 801–1,600 | 1,601–2,400 | 2,401–3,600 | 3,601–8,000 | 8,001–16,000 | 16,001–28,000<br>Over 28,000 | |
| GROUP 5 | | | | | | | | | |
| Any type of container of a volume exceeding that of a 5-gallon container | 25 or less | 26–80 | 81–200 | 201–400 | 401–800 | 801–1,200 | 1,201–2,000 | 2,001–3,200 | Over 3,200 |

SINGLE SAMPLING PLANS AND ACCEPTANCE LEVELS—Continued

TABLE I—CANNED OR SIMILARLY PROCESSED FISHERY PRODUCTS, AND PRODUCTS THEREOF CONTAINING UNITS OF SUCH SIZE AND CHARACTER AS TO BE READILY SEPARABLE

| Container size group | Lot size (number of containers) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Single sampling plans[1] | | | | | | | | |
| Sample size (number of sample units)[2] | 3 | 6 | 13 | 21 | 29 | 38 | 48 | 60 | 72 |
| Acceptance number | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |

[1] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[2] The sample units for the various container size groups are as follows: Groups 1, 2, and 3—1 container and its entire contents. Groups 4 and 5—approximately 2 pounds of product. When determined by the inspector that a 2-pound sample unit is inadequate, a larger sample unit may be substituted.

TABLE II—FROZEN OR SIMILARLY PROCESSED FISHERY PRODUCTS, AND PRODUCTS THEREOF CONTAINING UNITS OF SUCH SIZE AND CHARACTER AS TO BE READILY SEPARABLE

| Container size group | Lot size (number of containers) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| GROUP 1 | | | | | | | | | |
| Any type of container of 1 pound or less net weight | 2,400 or less | 2,401–12,000 | 12,001–24,000 | 24,001–48,000 | 48,001–72,000 | 72,001–108,000 | 108,001–168,000 | 168,001–240,000 | Over 240,000 |
| GROUP 2 | | | | | | | | | |
| Any type of container over 1 pound but not over 4 pounds net weight | 1,800 or less | 1,801–8,400 | 8,401–18,000 | 18,001–36,000 | 36,001–60,000 | 60,001–96,000 | 96,001–132,000 | 132,001–168,000 | Over 168,000 |
| GROUP 3 | | | | | | | | | |
| Any type of container over 4 pounds but not over 10 pounds net weight | 900 or less | 901–3,600 | 3,601–10,800 | 10,801–18,000 | 18,001–36,000 | 36,001–60,000 | 60,001–84,000 | 84,001–120,000 | Over 120,000 |
| GROUP 4 | | | | | | | | | |
| Any type of container over 10 pounds but not over 100 pounds net weight | 200 or less | 201–800 | 801–1,600 | 1,601–2,400 | 2,401–3,600 | 3,601–8,000 | 8,001–16,000 | 16,001–28,000 | Over 28,000 |

| GROUP 5 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Any type of container over 100 pounds net weight ..... | 25 or less | 26–80 | 81–200 | 201–400 | 401–800 | 801–1,200 | 1,201–2,000 | 2,001–3,200 | Over 3,200 |
| | Single sampling plans [1] | | | | | | | | |
| Sample size (number of sample units) [2] ..... | 3 | 6 | 13 | 21 | 29 | 38 | 48 | 60 | 72 |
| Acceptance number ..... | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

[1] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[2] The sample units for the various container size groups are as follows: Groups 1, 2, and 3—1 container and its entire contents. Groups 4 and 5—approximately 3 pounds of product. When determined by the inspector that a 3-pound sample unit is inadequate, a larger sample unit or 1 or more containers and their entire contents may be substituted for 1 or more sample units of 3 pounds.

## TABLE III—CANNED, FROZEN, OR OTHERWISE PROCESSED FISHERY AND RELATED PRODUCTS, AND PRODUCTS THEREOF OF A COMMINUTED, FLUID, OR HOMOGENEOUS STATE

| Container size group [1] | Lot size (number of containers) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| GROUP 1 | | | | | | | | | |
| Any type of container of 12 ounces or less ..... | 5,400 or less | 5,401–21,600 | 21,601–62,400 | 62,401–112,000 | 112,001–174,000 | 174,001–240,000 | 240,001–360,000 | 360,001–480,000 | Over 480,000 |
| GROUP 2 | | | | | | | | | |
| Any type of container over 12 ounces but not over 60 ounces .... | 3,600 or less | 3,601–14,400 | 14,401–48,000 | 48,001–96,000 | 96,001–156,000 | 156,001–228,000 | 228,001–300,000 | 300,001–420,000 | Over 420,000 |
| GROUP 3 | | | | | | | | | |
| Any type of container over 60 ounces but not over 160 ounces .. | 1,800 or less | 1,801–8,400 | 8,401–18,000 | 18,001–60,000 | 36,001–60,000 | 60,001–96,000 | 96,001–132,000 | 132,001–168,000 | Over 168,000 |
| GROUP 4 | | | | | | | | | |
| Any type of container over 160 ounces but not over 10 gallons or 100 pounds whichever is applicable ..... | 200 or less | 201–800 | 801–1,600 | 1,601–3,200 | 3,201–8,000 | 8,001–16,000 | 16,001–24,000 | 24,001–32,000 | Over 32,000 |
| GROUP 5 | | | | | | | | | |
| Any type of container over 10 gallons or 100 pounds whichever is applicable ..... | 25 or less | 26–80 | 81–200 | 201–400 | 401–800 | 801–1,200 | 1,201–2,000 | 2,001–3,200 | Over 3,200 |

TABLE III—CANNED, FROZEN, OR OTHERWISE PROCESSED FISHERY AND RELATED PRODUCTS, AND PRODUCTS THEREOF OF A COMMINUTED, FLUID, OR HOMOGENEOUS STATE—Continued

| Container size group [1] | Lot size (number of containers) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| Single sampling plans [2] | | | | | | | | | |
| Sample size (number of sample units) [3] | 3 | 6 | 13 | 21 | 29 | 38 | 48 | 60 | 72 |
| Acceptance number | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

[1] Ounces pertain to either fluid ounces of volume or avoirdupois ounces of net weight whichever is applicable for the product involved.

[2] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[3] The sample units for the various container size groups are as follows: Groups 1, 2, and 3—1 container and its entire contents. A smaller sample unit may be substituted in group 3 at the inspector's discretion. Groups 4, 5, and 6—approximately 16 ounces of product. When determined by the inspector that a 16-ounce sample unit is inadequate, a larger sample unit may be substituted.

TABLE IV—DEHYDRATED FISHERY AND RELATED PRODUCTS

| Container size group | Lot size (number of containers) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| GROUP 1 | | | | | | | | | |
| Any type of container of 1 pound or less net weight | 1,800 or less | 1,801–8,400 | 8,401–18,000 | 18,001–36,000 | 36,001–60,000 | 60,001–96,000 | 96,001–132,000 | 132,001–168,000 | Over 168,000 |
| GROUP 2 | | | | | | | | | |
| Any type of container over 1 pound but not over 6 pounds net weight | 900 or less | 901–3,600 | 3,601–10,800 | 10,801–18,000 | 18,001–36,000 | 36,001–60,000 | 60,001–84,000 | 84,001–120,000 | Over 120,000 |
| GROUP 3 | | | | | | | | | |
| Any type of container over 6 pounds but not over 20 pounds net weight | 200 or less | 201–800 | 801–1,600 | 1,601–3,200 | 3,201–8,000 | 8,001–16,000 | 16,001–24,000 | 24,001–32,000 | Over 32,000 |
| GROUP 4 | | | | | | | | | |
| Any type of container over 20 pounds but not over 100 pounds net weight | 48 or less | 49–400 | 401–1,200 | 1,201–2,000 | 2,001–2,800 | 2,801–6,000 | 6,001–9,600 | 9,601–15,000 | Over 15,000 |

| GROUP 5<br>Any type of container over 100 pounds net weight | 16 or less | 17–80 | 81–200 | 201–400 | 401–800 | 801–1,200 | 1,201–2,000 | 2,001–3,200 | Over 3,200 |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Single sampling plans [1] | | | | | |
| Sample size (number of sample units) [2] | 3 | 6 | 13 | 21 | 29 | 38 | 48 | 60 | 72 |
| Acceptance number | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

[1] For extension of the single sample sizes beyond 72 sample units, refer to table V of this section; for multiple sampling plans comparable to the various single sampling plans refer to table VI of this section.

[2] The sample units for the various container size groups are as follows: Group 1—1 container and its entire contents. Groups 2, 3, 4, and 5—1 container and its entire contents or a smaller sample unit when determined by the inspector to be adequate.

## TABLE V—SINGLE SAMPLING PLANS FOR USE IN INCREASING SAMPLE SIZE BEYOND 72 SAMPLE UNITS

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sample size, *n* | 84 | 96 | 108 | 120 | 132 | 144 | 156 | 168 | 180 | 192 | 204 | 216 | 230 | 244 | 258 | 272 | 286 | 300 | 314 | 328 | 342 | 356 | 370 | 384 | 400 |
| Acceptance numbers, *c* | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 |

## MULTIPLE SAMPLING PLANS [1],P0,6/7

## TABLE VI—MULTIPLE SAMPLING PLANS COMPARABLE TO THE INDICATED SINGLE SAMPLING PLANS

| Indicated single sampling plan: | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Single sample size, *n* | 6 | | | 13 | | | 21 | | | 29 | | | 38 | | | 48 | | | 60 | | | 72 | | |
| Acceptance numbers, *c* | 1 | | | 2 | | | 3 | | | 4 | | | 5 | | | 6 | | | 7 | | | 8 | | |
| Cumulative sample sizes, $n_c$, and acceptance numbers, *c*, and rejection numbers, *r*, for multiple sampling. | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* | $n_c$ | *c* | *r* |
| | 4 | 0 | 2 | 8 | 0 | 3 | 10 | 0 | 3 | 12 | 0 | 4 | 14 | 0 | 4 | 16 | 0 | 4 | 18 | 0 | 5 | 22 | 0 | 5 |
| | 6 | 0 | 2 | 10 | 0 | 3 | 14 | 1 | 4 | 16 | 0 | 4 | 20 | 0 | 5 | 24 | 1 | 5 | 28 | 1 | 6 | 32 | 1 | 7 |
| | 8 | 1 | 2 | 12 | 1 | 3 | 18 | 1 | 4 | 20 | 1 | 5 | 26 | 1 | 6 | 32 | 2 | 6 | 38 | 2 | 7 | 42 | 2 | 8 |
| | | | | 14 | 2 | 3 | 22 | 2 | 5 | 24 | 2 | 5 | 32 | 2 | 6 | 40 | 3 | 8 | 48 | 3 | 8 | 52 | 3 | 9 |
| | | | | | | | 26 | 4 | 5 | 28 | 3 | 6 | 38 | 3 | 7 | 48 | 4 | 8 | 58 | 4 | 8 | 62 | 5 | 10 |
| | | | | | | | | | | 32 | 3 | 6 | 44 | 6 | 7 | 56 | 7 | 8 | 68 | 8 | 9 | 72 | 6 | 10 |
| | | | | | | | | | | 36 | 5 | 6 | | | | | | | | | | 82 | 9 | 10 |

[1] These multiple sampling plans may be used in lieu of the single sampling plans listed at the heading of each column.

### § 260.62 Issuance of certificate of sampling.

Each inspector and each licensed sampler shall prepare and sign a certificate of sampling to cover the samples drawn by the respective person, except that an inspector who inspects the samples which he has drawn need not prepare a certificate of sampling. One copy of each certificate of sampling prepared shall be retained by the inspector or licensed sampler (as the case may be) and the original and all other copies thereof shall be disposed of in accordance with the instructions of the Secretary.

### § 260.63 Identification of lots sampled.

Each lot from which officially drawn samples are selected shall be marked in such manner as may be prescribed by the Secretary, if such lots do not otherwise possess suitable identification.

## FEES AND CHARGES

### § 260.69 Payment fees and charges.

Fees and charges for any inspection service shall be paid by the interested party making the application for such service, in accordance with the applicable provisions of the regulations in this part, and, if so required by the person in charge of the office of inspection serving the area where the services are to be performed, an advance of funds prior to rendering inspection service in an amount suitable to the Secretary, or a surety bond suitable to the Secretary, may be required as a guarantee of payment for the services rendered. All fees and charges for any inspection service, performed pursuant to the regulations in this part shall be paid by check, draft, or money order made payable to the National Marine Fisheries Service. Such check, draft, or money order shall be remitted to the appropriate regional or area office serving the geographical area in which the services are performed, within ten (10) days from the date of billing, unless otherwise specified in a contract between the applicant and the Secretary, in which latter event the contract provisions shall apply.

[36 FR 21038, Nov. 3, 1971]

### § 260.70 Schedule of fees.

(a) Unless otherwise provided in a written agreement between the applicant and the Secretary, the fees to be charged and collected for any inspection service performed under the regulations in this part at the request of the United States, or any other agency or instrumentality thereof, will be published as a notice in the FEDERAL REGISTER and will be in accordance with § 260.81.

(b) Fees are reviewed annually to ascertain that the hourly fees charged are adequate to recover the costs of the services rendered.

(1) The TYPE I (Contract Inspection) hourly fee is determined by dividing the estimated annual costs by the estimated annual billable hours.

(2) The TYPE II (Lot Inspection) hourly fee is determined by adding a factor of 50 percent to the TYPE I fee, to cover additional costs (down-time, etc.) associated with conducting lot inspection services.

(3) The TYPE III (Miscellaneous and Consulting) hourly fee is determined by adding a factor of 25 percent to the TYPE I fee, to cover the additional costs (down-time, etc.) associated with conducting miscellaneous inspection services.

[48 FR 24901, June 3, 1983]

### § 260.71 [Reserved]

### § 260.72 Fees for inspection service performed under cooperative agreement.

The fees to be charged and collected for any inspection or similar service performed under cooperative agreement shall be those provided for by such agreement.

### § 260.73 Disposition of fees for inspections made under cooperative agreement.

Fees for inspection under a cooperative agreement with any State or person shall be disposed of in accordance with the terms of such agreement. Such portion of the fees collected under a cooperative agreement as may be due the United States shall be remitted in accordance with § 260.69.

### § 260.74 Fee for appeal inspection.

The fee to be charged for an appeal inspection shall be at the rates prescribed in this part for other inspection services: *Provided*, That, if the result of any appeal inspection made for any applicant, other than the United States or any agency or instrumentality thereof, discloses that a material error was made in the inspection on which the appeal is made, no inspection fee shall be assessed.

### § 260.76 [Reserved]

### § 260.77 Fees for score sheets.

If the applicant for inspection service requests score sheets showing in detail the inspection of each container or sample inspected and listed thereon, such score sheets may be furnished by the inspector in charge of the office of inspection serving the area where the inspection was performed; and such applicant shall be changed at the rate of $2.75 for each 12 sampled units, or fraction thereof, inspected and listed on such score sheets.

### § 260.78 Fees for additional copies of inspection certificates.

Additional copies of any inspection certificate other than those provided for in § 260.29, may be supplied to any interested party upon payment of a fee of $2.75 for each set of five (5) or fewer copies.

### § 260.79 Travel and other expenses.

Charges may be made to cover the cost of travel and other expenses incurred in connection with the performance of any inspection service, including appeal inspections: *Provided*, That, if charges for sampling or inspection are based on an hourly rate, an additional hourly charge may be made for travel time including time spent waiting for transportation as well as time spent traveling, but not to exceed 8 hours of travel time for any one person for any one day: *And provided further*, That, if travel is by common carrier, no hourly charge may be made for travel time outside the employee's official work hours.

### § 260.80 Charges for inspection service on a contract basis.

Irrespective of fees and charges prescribed in the foregoing sections, the Secretary may enter into a written memorandum of understanding or contract, whichever may be appropriate, with any administrative agency charged with the administration of a marketing order effective pursuant to the Agricultural Marketing Agreement Act of 1937, as revised (16 U.S.C. 661 et seq.) for the making of inspections pursuant to said agreement or order on such basis as will reimburse the National Marine Fisheries Service of the Department for the full cost of rendering such inspection service as may be determined by the Secretary. Likewise, the Secretary may enter into a written memorandum of understanding or contract, whichever may be appropriate, with an administrative agency charged with the administration of a similar program operated pursuant to the laws of any State.

[36 FR 21038, Nov. 3, 1971]

### § 260.81 Readjustment and increase in hourly rates of fees.

(a) When Federal Pay Act increases occur, the hourly rates for inspection fees will automatically be increased on the effective date of the pay act by an amount equal to the increase received by the average GS grade level of fishery product inspectors receiving such pay increases.

(b) The hourly rates of fees to be charged for inspection services will be subject to review and reevaluation for possible readjustment not less than every 3 years: *Provided*, That, the hourly rates of fees to be charged for inspection services will be immediately reevaluated as to need for readjustment with each Federal Pay Act increase.

[35 FR 15925, Oct. 9, 1970]

## MISCELLANEOUS

### § 260.84 Policies and procedures.

The policies and procedures pertaining to any of the inspection services are contained within the NMFS Fishery Products Inspection Manual.

The policies and procedures are available from the Secretary to any interested party by writing to Document Approval and Supply Services Branch, Inspection Services Division, P.O. Drawer 1207, 3207 Frederic St., Pascagoula, MS 39568–1207.

[61 FR 9369, Mar. 8, 1996]

### § 260.86 Approved identification.

(a) *Grade marks:* The approved grade mark or identification may be used on containers, labels, or otherwise indicated for any processed product that:

(1) Has been packed under inspection as provided in this part to assure compliance with the requirements for wholesomeness established for the raw product and of sanitation established for the preparation and processing operations, and (2) has been certified by an inspector as meeting the requirements of such grade, quality or classification.

The grade marks approved for use shall be similar in form and design to the examples of Figures 1 to 5 of this section.

Shield using red, white, and blue background or other colors appropriate for label.

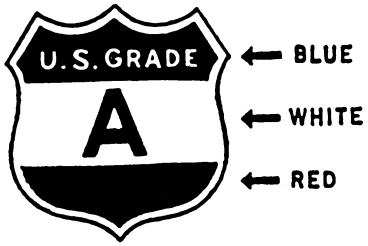


FIGURE 1

Shield with plain background.


FIGURE 2

U.S. GRADE A

FIGURE 3

U.S.
GRADE
B

FIGURE 4

U.S.
GRADE
C

FIGURE 5

(b) *Inspection marks:* The approved inspection marks may be used on containers, labels, or otherwise indicated for any processed product that:

(1) Has been packed under inspection as provided in this part to assure compliance with the requirements for wholesomeness established for the raw product and of sanitation established for the preparation and processing operations, and (2) has been certified by

an inspector as meeting the requirements of such quality or grade classification as may be approved by the Secretary.

The inspection marks approved for use shall be similar in form and design to the examples in Figures 6, 7, and 8 of this section.

Statement enclosed within a circle.


FIGURE 6

Statement without the use of the circle.

PACKED UNDER
FEDERAL
INSPECTION

U.S. DEPARTMENT
OF COMMERCE

FIGURE 7

Statement without the use of the circle.

PACKED BY

---

---

UNDER FEDERAL INSPECTION
U.S. DEPT. OF COMMERCE

FIGURE 8

(c) *Combined grade and inspection marks:* The grade marks set forth in paragraph (a) of this section, and the inspection marks, Figures 7 and 8, set forth in paragraph (b) of this section, may be combined into a consolidated grade and inspection mark for use on processed products that have been packed under inspection as provided in this part.

(d) *Products not eligible for approved identification:* Processed products which have not been packed under inspection as provided in this part shall not be identified by approved grade or inspection marks, but such products may be inspected on a lot inspection basis as provided in this part and identified by an authorized representative of the Department by stamping the shipping cases and inspection certificate(s) covering such lot(s) as appropriate, with marks similar in form and design to the examples in Figures 9 and 10 of this section.


FIGURE 9


FIGURE 10

(e) *Removal of labels bearing inspection marks:* At the time a lot of fishery products is found to be mislabeled and the labels on the packages are not removed within ten (10) consecutive calendar days, the following procedure shall be applicable:

(1) The processor, under the supervision of the inspector, shall clearly and conspicuously mark all master cases in the lot by means of a ''rejected by USDC Inspector'' stamp provided by the Department.

(2) The processor shall be held accountable to the Department for all mislabeled products until the products are properly labeled.

(3) Clearance for the release of the relabeled products shall be obtained by the processor from the inspector.

(f) Users of inspection services having an inventory of labels which bear official approved identification marks stating ''U.S. Department of the Interior'' or otherwise referencing the Interior Department, will be permitted to use such marks until December 31, 1971, except that upon written request the Director, National Marine Fisheries Service, may extend such period for the use of specific labels.

[36 FR 4609, Mar. 10, 1971]

### § 260.88 Political activity.

All inspectors and licensed samplers are forbidden, during the period of their respective appointments or licenses, to take an active part in political management or in political campaigns. Political activities in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, or any measure to be voted upon, are prohibited. This applies to all appointees or licensees, including, but not limited to, temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of this section will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

### § 260.90 Compliance with other laws.

None of the requirements in the regulations in this part shall excuse failure to comply with any Federal, State, county, or municipal laws applicable to the operation of food processing establishments and to processed food products.

### § 260.91 Identification.

Each inspector and licensed sampler shall have in his possession at all times and present upon request, while on duty, the means of identification furnished by the Department to such person.

### § 260.93 Debarment and suspension.

(a) *Debarment.* Any person may be debarred from using or benefiting from the inspection service provided under the regulations of this subchapter or under the terms of any inspection contract, and such debarment may apply to one or more plants under his control, if such person engages in one or more of the following acts or activities:

(1) Misrepresenting, misstating, or withholding any material or relevant facts or information in conjunction with any application or request for an inspection contract, inspection service, inspection appeal, lot inspection, or other service provided for under the regulations of this subchapter.

(2) Using on a processed product any label which displays any official identification, official device, or official mark, when the label is not currently approved for use by the Director or his delegate.

(3) Using on a processed product any label which displays the words ''Packed Under Federal Inspection, U.S. Department of Commerce'', or which displays any official mark, official device, or official identification, or which displays a facsimile of the foregoing, when such product has not been inspected under the regulations of this subchapter.

(4) Making any statement or reference to the U.S. Grade of any processed product or any inspection service provided under the regulations of this subchapter on the label or in the advertising of any processed product, when such product has not been inspected under the regulations of this subchapter.

(5) Making, using, issuing or attempting to issue or use in conjunction with the sale, shipment, transfer or advertisement of a processed product any certificate of loading, certificate of sampling, inspection certificate, official device, official identification, official mark, official document, or score sheet which has not been issued, approved, or authorized for use with such product by an inspector.

(6) Using any of the terms ''United States'', ''Officially graded'', ''Officially inspected'', ''Government inspected'', ''Federally inspected'', ''Officially sampled'', or words of similar import or meanings, or using any official device, official identification, or official mark on the label, on the shipping container, or in the advertising of any processed product, when such product has not been inspected under the regulations of this subchapter.

(7) Using, attempting to use, altering or reproducing any certificate, certificate form, design, insignia, mark, shield, device, or figure which simulates in whole or in part any official mark, official device, official identification, certificate of loading, certificate of sampling, inspection certificate or other official certificate issued pursuant to the regulations of this subchapter.

(8) Assaulting, harassing, interfering, obstructing or attempting to interfere or obstruct any inspector or sampler in the performance of his duties under the regulations of this subchapter.

(9) Violating any one or more of the terms of any inspection contract or the provisions of the regulations of this subchapter.

(10) Engaging in acts or activities which destroy or interfere with the purposes of the inspection program or which have the effect of undermining the integrity of the inspection program.

(b) *Temporary suspension.* (1) Whenever the Director has reasonable cause to believe that any person has engaged in any act or activity described in paragraph (a) of this section, and in such act or activity, in the judgment of the Director, would cause serious and irreparable injury to the inspection program and services provided under the regulations of this subchapter, the Director may, without a hearing, temporarily suspend, either before or after the institution of a debarment hearing, the inspection service provided under the regulations of this subchapter or under any inspection contract for one or more plants under the control of such person. Notice of suspension shall be served by registered or certified mail, return receipt requested, and the notice shall specifically state those acts or activities of such person which are the bases for the suspension. The suspension shall become effective five (5) days after receipt of the notice.

(2) Once a person has received a notice of a temporary suspension, a debarment hearing will be set for 30 days after the effective date of the suspension. Within 60 days after the completion of the debarment hearing, the Hearing Examiner shall determine, based upon evidence of record, whether the temporary suspension shall be continued or terminated. A temporary suspension shall be terminated by the Hearing Examiner if he determines that the acts or activities, which were the bases for the suspension, did not occur or will not cause serious and irreparable injury to the inspection program and services provided under the regulations of this subchapter. This determination of the Hearing Examiner on the continuation or termination of the temporary suspension shall be final and there shall be no appeal of this determination. The initial decision by the Hearing Examiner on the debarment shall be made in accordance with

paragraph (b)(1), *Decisions*, of this section.

(3) After a debarment hearing has been instituted against any person by a suspension, such suspension will remain in effect until a final decision is rendered on the debarment in accordance with the regulations of this section or the temporary suspension is terminated by the Hearing Examiner.

(4) When a debarment hearing has been instituted against any person not under suspension, the Director may, in accordance with the regulations of this paragraph (b) temporarily suspend such person, and the suspension will remain in effect until a final decision on the debarment is rendered in accordance with the regulations of this section or the temporary suspension is terminated by the Hearing Examiner.

(c) *Hearing Examiner.* All hearing shall be held before a Hearing Examiner appointed by the Secretary or the Director.

(d) *Hearing.* If one or more of the acts or activities described in paragraph (a) of this section have occurred, the Director may institute a hearing to determine the length of time during which the person shall be debarred and those plants to which the debarment shall apply. No person may be debarred unless there is a hearing, as prescribed in this section, and it has been determined by the Hearing Examiner, based on evidence of record, that the one or more of the activities described in paragraph (a) of this section have occurred. Any debarment or suspension must be instituted within two (2) years of the time when such acts or activities described in paragraph (a) of this section have occurred.

(e) *Notice of hearing.* The Director shall notify such person of the debarment hearing by registered or certified mail, return receipt requested. The notice shall set forth the time and place of the hearing, the specific acts or activities which are the basis for the debarment hearing, the time period of debarment being sought, and those plants to which the debarment shall apply. Except for the debarment hearing provided for in paragraph (b) of this section the hearing will be set for a time not longer than 120 days after receipt of the notice of hearing.

(f) *Time and place of hearing.* The hearing shall be held at a time and place fixed by the Director: *Provided, however,* The Hearing Examiner may, upon a proper showing of inconvenience, change the time and place of the hearing. Motions for change of time or place of the hearing must be mailed to or served upon the Hearing Examiner no later than 10 days before the hearing.

(g) *Right to counsel.* In all proceedings under this section, all persons and the Department of Commerce shall have the right to be represented by counsel, in accordance with the rules and regulations set forth in title 43, Code of Federal Regulations, part 1.

(h) *Form, execution, and service of documents.* (1) All papers to be filed under the regulations in this section shall be clear and legible; and shall be dated, signed in ink, contain the docket description and title of the proceeding, if any, and the address of the signatory. Five copies of all papers are required to be filed. Documents filed shall be executed by:

(i) The person or persons filing same,

(ii) by an authorized officer thereof if it be a corporation or,

(iii) by an attorney or other person having authority with respect thereto.

(2) All documents, when filed, shall show that service has been made upon all parties to the proceeding. Such service shall be made by delivering one copy to each party in person or by mailing by first-class mail, properly addressed with postage prepaid. When a party has appeared by attorney or other representative, service on such attorney or other representative will be deemed service upon the party. The date of service of document shall be the day when the matter served is deposited in the U.S. mail, shown by the postmark thereon, or is delivered in person, as the case may be.

(3) A person is deemed to have appeared in a hearing by the filing with the Director a written notice of his appearance or his authority in writing to appear on behalf of one of the persons to the hearing.

(4) The original of every document filed under this section and required to

be served upon all parties to a proceeding shall be accompanied by a certificate of service signed by the party making service, stating that such service has been made upon each party to the proceeding. Certificates of service may be in substantially the following form:

I hereby certify that I have this day served the foregoing document upon all parties of record in this proceeding by: (1) Mailing postage prepaid, (2) delivering in person, a copy to each party.

Dated at _____ this _____ day of _____, 19____

Signature _____

(i) *Procedures and evidence.* (1) All parties to a hearing shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the Hearing Examiner at the outset of or during the hearing.

(2) Technical rules of evidence shall not apply to hearings conducted pursuant to this section, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary.

(j) *Duties of Hearing Examiner.* The Hearing Examiner shall have the authority and duty to:

(1) Take or cause depositions to be taken.

(2) Regulate the course of the hearings.

(3) Prescribe the order in which evidence shall be presented.

(4) Dispose of procedural requests or similar matters.

(5) Hear and initially rule upon all motions and petitions before him.

(6) Administer oaths and affirmations.

(7) Rule upon offers of proof and receive competent, relevant, material, reliable, and probative evidence.

(8) Control the admission of irrelevant, immaterial, incompetent, unreliable, repetitious, or cumulative evidence.

(9) Hear oral arguments if the Hearing Examiner determined such requirement is necessary.

(10) Fix the time for filing briefs, motions, and other documents to be filed in connection with hearings.

(11) Issue the initial decision and dispose of any other pertinent matters that normally and properly arise in the course of proceedings.

(12) Do all other things necessary for an orderly and impartial hearing.

(k) *The record.* (1) The Director will designate an official reporter for all hearings. The official transcript of testimony taken, together with any exhibits and briefs filed therewith, shall be filed with the Director. Transcripts of testimony will be available in any proceeding under the regulations of this section, at rates fixed by the contract between the United States of America and the reporter. If the reporter is an employee of the Department of Commerce, the rate will be fixed by the Director.

(2) The transcript of testimony and exhibits, together with all briefs, papers, and all rulings by the Hearing Examiner shall constitute the record. The initial decision will be predicated on the same record, as will be final decision.

(l) *Decisions.* (1) The Hearing Examiner shall render the initial decision in all debarment proceedings before him. The same Hearing Examiner who presides at the hearing shall render the initial decision except when such Examiner becomes unavailable to the Department of Commerce. In such case, another Hearing Examiner will be designated by the Secretary or Director to render the initial decision. Briefs, or other documents, to be submitted after the hearing must be received not later than twenty (20) days after the hearing, unless otherwise extended by the Hearing Examiner upon motion by a party. The initial decision shall be made within sixty (60) days after the receipt of all briefs. If no appeals from the initial decision is served upon the Director within ten (10) days of the date of the initial decision, it will become the final decision on the 20th day following the date of the initial decision. If an appeal is received, the appeal will be transmitted to the Secretary who will render the final decision after considering the record and the appeal.

(2) All initial and final decisions shall include a statement of findings and conclusions, as well as the reasons or bases therefore, upon the material

issues presented. A copy of each decision shall be served on the parties to the proceeding, and furnished to interested persons upon request.

(3) It shall be the duty of the Hearing Examiner, and the Secretary where there is an appeal, to determine whether the person has engaged in one or more of the acts or activities described in paragraph (a) of this section, and, if there is a finding that the person has engaged in such acts or activities, the length of time the person shall be debarred, and the plants to which the debarment shall apply.

[31 FR 16052, Dec. 15, 1966, as amended at 36 FR 18738, Sept. 21, 1971]

REQUIREMENTS FOR PLANTS OPERATING UNDER CONTINUOUS INSPECTION ON A CONTRACT BASIS [1]

### § 260.96 Application for fishery products inspection service on a contract basis at official establishments.

Any person desiring to process and pack products in an establishment under fishery products inspection service on a contract basis, must receive approval of such buildings and facilities as an official establishment prior to the inauguration of such service. An application for inspection service to be rendered in an establishment shall be approved according to the following procedure:

(a) Initial survey: When application has been filed for inspection service as aforesaid, NMFS inspector(s) shall examine the buildings, premises, and facilities according to the requirements of the fishery products inspection service and shall specify any additional facilities required for the service.

(b) Final survey and establishment approval: Prior to the inauguration of the fishery products inspection service, a final survey of the buildings, premises, and facilities shall be made to verify that the buildings are constructed and facilities are in accordance with the approved drawings and the regulations in this part.

(c) Drawings and specifications of new construction or proposed alterations of existing official establishments shall be furnished to the Director in advance of actual construction for prior approval with regard to compliance with requirements for facilities.

[36 FR 21039, Nov. 3, 1971]

### § 260.97 Conditions for providing fishery products inspection service at official establishments.

(a) The determination as to the inspection effort required to adequately provide inspection service at any establishment will be made by NMFS. The man-hours required may vary at different official establishments due to factors such as, but not limited to, size and complexity of operations, volume and variety of products produced, and adequacy of control systems and cooperation. The inspection effort requirement may be reevaluated when the contracting party or NMFS deems there is sufficient change in production, equipment and change of quality control input to warrant reevaluation. Inspectors will not be available to perform any of employee or management duties, however, they will be available for consultation purposes. NMFS reserves the right to reassign inspectors as it deems necessary.

(b) NMFS shall not be held responsible:

(1) For damages occurring through any act of commission or omission on the part of its inspectors when engaged in performing services; or

(2) For production errors, such as processing temperatures, length of process, or misbranding of products; or

(3) For failure to supply enough inspection effort during any period of service.

(c) The contracting party will:

(1) Use only wholesome raw material which has been handled or stored under sanitary conditions and is suitable for processings; maintain the official establishment(s), designated on the contract in such sanitary condition and to employ such methods of handling raw

[1] Compliance with the above requirements does not excuse failure to comply with all applicable sanitary rules and regulations of city, county, State, Federal, or other agencies having jursidiction over such establishments and operations.

materials for processing as may be necessary to conform to the sanitary requirements precribed or approved by NMFS;

(2) Adequately code each primary container and master case of products sold or otherwise distributed from a manufacturing, processing, packing, or repackaging activity to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use;

(3) Not permit any labels on which reference is made to Federal inspection, to be used on any product which is not packed under fishery products inspection service nor permit any labels on which reference is made to any U.S. Grade to be used on any product which has not been officially certified as meeting the requirements of such grade; nor supply labels bearing reference to Federal inspection to another establishment unless the products to which such labels are to be applied have been packed under Federal inspection at an official establishment;

(4) Not affix any label on which reference is made to Federal inspection to any container of processed foods, produced in any designated official establishment, with respect to which the grade of such product is not certified because of adulteration due to the presence of contaminants in excess of limits established in accordance with the regulations or guidelines issued pursuant to the Food, Drug, and Cosmetic Act, as amended;

(5) Not, with respect to any product for which U.S. Grade Standards are in effect, affix any label on which reference is made to Federal inspection to any container of processed food which is substandard: *Provided*, That such label may be affixed to any container of such substandard quality product if such label bears a statement to indicate the substandard quality;

(6) Not, with respect to any product for which U.S. Grade Standard are not in effect, affix any label on which reference is made to the Federal inspection to containers of processed foods, except with the approval of NMFS;

(7) Furnish such reports of processing, packaging, grading, laboratory analyses, and output of products inspected, processed, and packaged at the designated official establish-ment(s) as may be requested by NMFS, subject to the approval of the Bureau of the Budget in accordance with the Federal Reports Act of 1942;

(8) Make available for use by inspectors, adequate office space in the designated official establishment(s) and furnish suitable desks, office equipment, and files for the proper care and storage of inspection records;

(9) Make laboratory facilities and necessary equipment available for the use of inspectors to inspect samples of processed foods and/or components thereof;

(10) Furnish and provide laundry service, as required by NMFS, for coats, trousers, smocks, and towels used by inspectors during performance of duty in official establishment(s);

(11) Furnish stenographic and clerical assistance as may be necessary in the typing of certificates and reports and the handling of official correspondence, as well as furnish the labor incident to the drawing and grading of samples and other work required to facilitate adequate inspection procedures whenever necessary;

(12) Submit to NMFS, three (3) copies of new product specifications in a manner prescribed by NMFS, and three (3) end-product samples for evaluation and/or laboratory analysis on all products for approval, for which U.S. Grade Standards are not available, when inspection is to be applied to such products. If requested of NMFS, such new specifications and end-product samples shall be considered confidential;

(13) Submit, as required by NMFS, for approval, proofs prior to printing and thereafter four (4) copies of any finished label which may or may not bear official identification marks, when such products are packed under Federal inspection on a contract basis;

(14) Not make deceptive, fraudulent, or unauthorized use in advertising, or otherwise, of the fishery products inspection service, the inspection certificates or reports issued, or the containers on which official identification marks are embossed or otherwise identified, in connection with the sale of any processed products;

(15) Submit to NMFS, four (4) copies of each label which may or may not bear official identification marks, when such labels are to be withdrawn from inspection or when approved labels are disapproved for further use under inspection;

(16) Notify NMFS in advance of the proposed use of any labels which require obliteration of any official identification marks, and all reference to the inspection service on approved labels which have been withdrawn or disapproved for use;

(17) Accord representatives of NMFS at all reasonable times free and immediate access to establishment(s) and official establishment(s) under applicant's control for the purpose of checking codes, coded products, coding devices, coding procedures, official identification marks obliteration, and use of withdrawn or disapproved labels.

(d) Termination of inspection services:

(1) The fishery products inspection service, including the issuance of inspection reports, shall be rendered from the date of the commencement specified in the contract and continue until suspended or terminated:

(i) By mutual consent;

(ii) by either party giving the other party sixty (60) days' written notice specifying the date of suspension or termination;

(iii) by one (1) day's written notice by NMFS in the event the applicant fails to honor any invoice within ten (10) days after date of receipt of such invoice covering the full costs of the inspection service provided, or in the event the applicant fails to maintain its designated plants in a sanitary condition or to use wholesome raw materials for processing as required by NMFS, or in the event the applicant fails to comply with any provisions of the regulations contained in this part;

(iv) by automatic termination in case of bankruptcy, closing out of business, or change in controlling ownership.

(2) In case the contracting party wishes to terminate the fishery products inspection service under the terms of paragraph (d)(1)(i) or (ii) of this section, either the service must be continued until all unused containers, labels, and advertising material on hand or in possession of his supplier bearing official identification marks, or reference to fishery products inspection service have been used, or said containers, labels, and advertising material must be destroyed, or official identification marks, and all other reference to the fishery products inspection service on said containers, labels, advertising material must be obliterated, or assurance satisfactory to NMFS must be furnished that such containers, labels, and advertising material will not be used in violation of any of the provisions of the regulations in the part.

(3) In case the fishery products inspection service is terminated for cause by NMFS under the terms of paragraph (d)(1)(iii) of this section, or in case of automatic termination under terms of paragraph (d)(1)(iv) of this section, the contracting party must destroy all unused containers, labels, and advertising material on hand bearing official identification marks, or reference to fishery products inspection service, or must obliterate official identification marks, and all reference to the fishery products inspection service on said containers, labels and advertising material.

After termination of the fishery products inspection service, NMFS may, at such time or times as it may determine to be necessary, during regular business hours, enter the establishment(s) or other facilities in order to ascertain that the containers, labels, and advertising material have been altered or disposed of in the manner provided herein, to the satisfaction of NMFS.

[36 FR 21039, Nov. 3, 1971]

### § 260.98 Premises.

The premises about an official establishment shall be free from conditions which may result in the contamination of food including, but not limited to, the following:

(a) Strong offensive odors;

(b) Improperly stored equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests;

(c) Excessively dusty roads, yards, or parking lots that may constitute a

source of contamination in areas where food is exposed;

(d) Inadequately drained areas that may contribute contamination to food products through seepage or foot-borne filth and by providing a breeding place for insects or micro-organisms;

If the grounds of an official establishment are bordered by grounds not under the official establishment operator's control of the kind described in paragraphs (b) through (d) of this section, care must be exercised in the official establishment by inspection, extermination, or other means to effect exclusion of pests, dirt, and other filth that may be a source of food contamination.

[36 FR 21040, Nov. 3, 1971]

### § 260.99 Buildings and structures.

The buildings and structures shall be properly constructed and maintained in a sanitary condition, including, but not limited to the following requirements:

(a) *Lighting.* There shall be sufficient light (1) consistent with the use to which the particular portion of the building is devoted, and (2) to provide for efficient cleaning. Belts and tables on which picking, sorting, or trimming operations are carried on shall be provided with sufficient nonglaring light to insure adequacy of the respective operation. Light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation shall be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(b) *Ventilation.* There shall be sufficient ventilation in each room and compartment thereof to prevent excessive condensation of moisture and to insure sanitary and suitable processing and operating conditions. If such ventilation does not prevent excessive condensation, the Director may require that suitable facilities be provided to prevent the condensate from coming in contact with equipment used in processing operations and with any ingredient used in the manufacture or production of a processed product.

(c) *Drains and gutters.* All drains and gutters shall be properly installed with approved traps and vents. The drainage and plumbing system must permit the quick runoff of all water from official establishment buildings, and surface water around buildings and on the premises; and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard. Tanks or other equipment whose drains are connected to the waste system must have such screens and vacuum breaking devices affixed so as to prevent the entrance of waste water, material, and the entrance of vermin to the processing tanks or equipment.

(d) *Water supply.* There shall be ample supply of both hot and cold water; and the water shall be of safe and sanitary quality with adequate facilities for its (1) distribution throughout buildings, and (2) protection against contamination and pollution.

Sea water of safe suitable and sanitary quality may be used in the processing of various fishery products when approved by NMFS prior to use.

(e) *Construction.* Roofs shall be weathertight. The walls, ceilings, partitions, posts, doors, and other parts of all buildings and structures shall be of such materials, construction, and finish as to permit their efficient and thorough cleaning. The floors shall be constructed of tile, cement, or other equally impervious material, shall have good surface drainage, and shall be free from openings or rough surfaces which would interfere with maintaining the floors in a clean condition.

(f) *Processing rooms.* Each room and each compartment in which any processed products are handled, processed, or stored (1) shall be so designed and constructed as to insure processing and operating conditions of a clean and orderly character; (2) shall be free from objectional odors and vapors; and (3) shall be maintained in a clean and sanitary condition.

(g) *Prevention of animals and insects in official establishment(s).* Dogs, cats, birds, and other animals (including, but not being limited to rodents and insects) shall be excluded from the rooms from which processed products are being prepared, handled, or stored and from any rooms from which ingredients (including, but not being limited to salt, sugar, spices, flour, batter, breading, and fishery products) are handled and stored. Screens, or other

devices, adequate to prevent the passage of insects shall, where practical, be provided for all outside doors and openings. The use of chemical compounds such as cleaning agents, insecticides, bactericides, or rodent poisons shall not be permitted except under such precautions and restrictions as will prevent any possibility of their contamination of the processed product. The use of such compounds shall be limited to those circumstances and conditions as approved by NMFS.

(h) *Inspector's office.* Furnished suitable and adequate office space, including, but not being limited to, light, heat, and janitor service shall be provided rent free in official establishments for use for official purposes by the inspector and NMFS representatives. The room or rooms designated for this purpose shall meet with the approval of NMFS and shall be conveniently located, properly ventilated, and provided with lockers or cabinets suitable for the protection and storage of inspection equipment and supplies and with facilities suitable for inspectors to change clothing.

(i) Adequate parking space, conveniently located, for private or official vehicles used in connection with providing inspection services shall be provided.

[36 FR 21040, Nov. 3, 1971]

### § 260.100 Facilities.

Each official establishment shall be equipped with adequate sanitary facilities and accommodations, including, but not being limited to, the following:

(a) Containers approved for use as containers for processed products shall not be used for any other purpose.

(b) No product or material not intended for human food or which creates an objectionable condition shall be processed, handled, or stored in any room, compartment, or place where any fishery product is manufactured, processed, handled, or stored.

(c) Suitable facilities for cleaning and sanitizing equipment (e.g., brooms, brushes, mops, clean cloths, hose, nozzles, soaps, detergent, sprayers) shall be provided at convenient locations throughout the plant.

[36 FR 21040, Nov. 3, 1971]

### § 260.101 Lavatory accommodations.

Modern lavatory accommodations, and properly located facilities for cleaning and sanitizing utensils and hands, shall be provided.

(a) Adequate lavatory and toilet accommodations, including, but not being limited to, running hot water (135 °F. or more) and cold water, soap, and single service towels, shall be provided. Such accommodations shall be in or near toilet and locker rooms and also at such other places as may be essential to the cleanliness of all personnel handling products.

(b) Sufficient containers with covers shall be provided for used towels and other wastes.

(c) An adequate number of hand washing facilities serving areas where edible products are prepared shall be operated by other than hand-operated controls, or shall be of a continuous flow type which provides an adequate flow of water for washing hands.

(d) Durable signs shall be posted conspicuously in each toilet room and locker room directing employees to wash hands before returning to work.

(e) Toilet facilities shall be provided according to the following formula:

| Number of persons | Toilet bowls required |
|---|---|
| 1 to 15, inclusive | 1 |
| 16 to 35, inclusive | 2 |
| 36 to 55, inclusive | [1] 3 |
| 56 to 80, inclusive | [1] 4 |
| For each additional 30 persons in excess of 80 | [1] 1 |

[1] Urinals may be substituted for toilet bowls but only to the extent of one-third of the total number of bowls required.

All toilet equipment shall be kept operative, in good repair, and in a sanitary condition.

[36 FR 21041, Nov. 3, 1971]

### § 260.102 Equipment.

All equipment used for receiving, washing, segregating, picking, processing, packaging, or storing any processed products or any ingredients used in the manufacture or production thereof, shall be of such design, material, and construction as will:

(a) Enable the examination, segregation, preparation, packaging, and other processing operations applicable to

processed products, in an efficient, clean, and sanitary manner, and

(b) Permit easy access to all parts to insure thorough cleaning and effective bactericidal treatment. Insofar as is practicable, all such equipment shall be made of smooth impermeable corrosion-resistant material that will not adversely affect the processed product by chemical action or physical contact. Such equipment shall be kept in good repair and sanitary condition. Such equipment shall be cleaned and sanitized at a frequency as is necessary or required in accordance with Good Manufacturing Practice Regulations, 21 CFR part 128.

[36 FR 21041, Nov. 3, 1971]

### § 260.103 Operations and operating procedures shall be in accordance with an effective sanitation program.

(a) All operators in the receiving transporting, holdings, segregating, preparing, processing, packaging, and storing of processed products and ingredients, used as aforesaid, shall be strictly in accord with clean and sanitary methods and shall be conducted as rapidly as possible and at temperatures that will inhibit and retard the growth of bacterial and other micro-organisms and prevent any deterioration or contamination of such processed products or ingredients thereof. Mechanical adjustments or practices which may cause contamination of foods by oil, dust, paint, scale, fumes, grinding materials, decomposed food, filth, chemicals, or other foreign materials shall not be conducted during any manufacturing or processing operation.

(b) All processed products, raw materials, ingredients, and components thereof shall be subject to inspection during each manufacturing or processing operation. To assure a safe, wholesome finished product, changes in processing methods and procedures as may be required by the Director shall be effectuated as soon as practicable. All processed products which are not manufactured or prepared in accordance with the requirements contained in § 260.96 to § 260.104 or are unwholesome or otherwise not fit for human food shall be removed and segregated prior to any further processing operation.

(c) Official establishments operating under Federal inspection should have an effective quality control program as appropriate for the nature of the products and processing operations.

(d) All ingredients used in the manufacture or processing of any processed product shall be wholesome and fit for human food.

(e) The methods and procedures employed in the receiving, segregating, handling, transporting, and processing of ingredients in official estab lishment(s) shall be adequate to result in a satisfactory processed product. Such methods and procedures include, but are not limited to, the following requirements:

(1) Containers, utensils, pans, and buckets used for the storage or transporting of partially processed food ingredients shall not be nested unless rewashed and sanitized before each use;

(2) Containers which are used for holding partially processed food ingredients shall not be stacked in such manner as to permit contamination of the partially processed food ingredients;

(3) Packages or containers for processed products shall be clean when being filled with such products; and all reasonable precautions shall be taken to avoid soiling or contaminating the surface of any package or container liner which is, or will be, in direct contact with such products.

(f) Retention tags: (1) Any equipment such as, but not limited to, conveyors, tillers, sorters, choppers, and containers which fail to meet appropriate and adequate sanitation requirements will be identified by the inspector in an appropriate and conspicuous manner with the word ''RETAINED.'' Following such identification, the equipment shall not be used until the discrepancy has been resolved, the equipment reinspected and approved by the inspector and the ''RETAINED'' identification removed by the inspector.

(2) Lot(s) of processed products that may be considered to be mislabeled and/or unwholesome by reason of contaminants or which may otherwise be in such condition as to require further evaluation or testing to determine that

the product properly labeled and/or wholesome will be identified by the inspector in an appropriate and conspicuous manner with the word ''RETAINED.'' Such lot(s) of product shall be held for reinspection or testing. Final disposition of the lot(s) shall be determined by NMFS and the removal of the ''RETAINED'' identification shall be performed by the inspector.

[36 FR 21041, Nov. 3, 1971]

### § 260.104 Personnel.

The establishment management shall be responsible for taking all precautions to assure the following:

(a) *Disease control.* No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.

(b) *Cleanliness.* All persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:

(1) Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygenic practices while on duty, to the extent necessary to prevent contamination of food products.

(2) Wash and sanitize their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(3) Remove all insecure jewelry and, when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

(4) If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

(5) Wear hair nets, caps, masks, or other effective hair restraints. Other persons that may incidentally enter the processing areas shall comply with this requirement.

(6) Not store clothing or other personal belongings, eat food, drink beverages, chew gum, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.

(7) Take any other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean wholesome food. Food handlers and supervisors should receive appropriate training in proper food-handling techniques and food-protection principles and should be cognizant of the danger of poor personal hygiene and unsanitary practices, and other vectors of contamination.

[36 FR 21041, Nov. 3, 1971]

LABELING REQUIREMENTS

### §§ 260.200–260.201 [Reserved]

## PART 261—UNITED STATES STANDARDS FOR GRADES

Sec.

261.101 Standard description.
261.102 Publication and removal of U.S. Grade Standards.
261.103 Basis for determination of a U.S. Standard for Grades.

AUTHORITY: 7 U.S.C. 1621–1630.

SOURCE: 61 FR 9369, Mar. 8, 1996, unless otherwise noted.

### § 261.101 Standard description.

A U.S. Standard for Grades authorized under this part is a standard for a fish or fishery product that has been developed and adopted by the voluntary seafood inspection program pursuant to the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*) and

other authorities delegated to the U.S. Department of Commerce.

### § 261.102 Publication and removal of U.S. Grade Standards.

(a) The voluntary U.S. Standards for Grades adopted pursuant to this part shall be issued as Program policies and contained within the NMFS Fishery Products Inspection Manual. Compliance with voluntary standards issued as Program policies within the manual shall satisfy the requirements of this part. Compliance with a voluntary standard issued as a Program policy does not relieve any party from the responsibility to comply with the provisions of the Federal Food, Drug, and Cosmetic Act; or other Federal laws and regulations.

(b) Notification of an application for a new grade standard shall be published in the FEDERAL REGISTER. If adopted, the grade standard shall be issued as a Program policy and contained in the NMFS Fishery Products Inspection Manual.

(c) Recision and revision of a U.S. Standard for Grades will be made a Program policy amendment and contained in the NMFS Fishery Products Inspection Manual.

(d) The NMFS Fishery Products Inspection Manual is available to interested parties.

### § 261.103 Basis for determination of a U.S. Standard for Grades.

(a) To address the inherently distinct and dissimilar attributes found in the fishery product groups, each standard for grades should have a different scope and product description, product forms, sample sizes, definition of defects, etc. The Secretary will make the final determination regarding the content of a U.S. Standard for Grades.

(b) A proposal for a new or revised U.S. grade standard may include the following:

(1) *Scope and product description,* which describes the products that are eligible for grading using the standard (e.g., fish portion, fish fillet).

(2) *Product forms,* which describe the types, styles and market forms covered by the standard (e.g., skin-off, tail-on, headless).

(3) *Grade and inspection marks,* which describe the grades and inspection mark criteria for each grade category (e.g., Grade A ≤ 15 points).

(4) *Grade determination,* which describes the means by which the grade is determined (i.e., the factors rated by score points and those that are not). Standards may contain defect grouping limiting rules that contain additional provisions that must be met.

(5) *Sampling,* which describes the method of sampling and sample unit sizes (e.g., 10 portions, 8 ounces, etc.).

(6) *Procedures* that describe the process used to determine the product grade (e.g., label declarations, sensory evaluation).

(7) *Definitions of defects,* which outline the defects associated with the products covered by the standard, defines them, and describes the method of counting or measuring the defects. This section may provide associated defect points or reference a defect table (e.g., bruises, blood spots, bones, black spots, coating defects, 1–inch squares, percent by weight, ratios).

(8) *Defect point assessment,* which describes how to assess points and provides any special guidance that may be necessary to the particular standard (e.g., defect points for certain categories are added together and divided by the weight of the sample unit; the number of instances are counted to determine if it is slight, moderate, or excessive defect).

(9) *Tolerances for lot certification,* which provide the sections from Title 50 CFR that regulate lot certification.

(10) *Hygiene,* which specifies the sections of applicable Federal regulations regulating the safe, wholesome production of food for human consumption.

(11) *Methods of analysis,* which describe the methods of analysis that will be used in the evaluation of the products covered by the standard for grades (e.g., net weight, deglazing, debreading).

(12) *Defect table,* which is the table of defects and associated points to be assessed for each defect.

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2007]
[CITE: 21CFR123]

# TITLE 21--FOOD AND DRUGS
# CHAPTER I--FOOD AND DRUG ADMINISTRATION
# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION PART 123 FISH AND FISHERY PRODUCTS

**Subpart A--General Provisions**

Sec. 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) *Critical control point* means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

(c) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(d) *Fish* means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) *Fishery product* means any human food product in which fish is a characterizing ingredient.

(f) *Food safety hazard* means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(g) *Importer* means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h) *Molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) *Preventive measure* means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) *Process-monitoring instrument* means an instrument or device used to indicate conditions during processing at a critical control point.

(k)(1) *Processing* means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) *Processor* means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) *Scombroid toxin-forming species* means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) *Shall* is used to state mandatory requirements.

(o) *Shellfish control authority* means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) *Shellstock* means raw, in-shell molluscan shellfish.

(q) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(r) *Shucked shellfish* means molluscan shellfish that have one or both shells removed.

(s) *Smoked or smoke-flavored fishery products* means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Sec. 123.5 Current good manufacturing practice.

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

Sec. 123.6 Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan.

(a) *Hazard analysis.* Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) *The HACCP plan.* Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with 123.7(b), to be followed in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) *Signing and dating the HACCP plan.*

(1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with 123.8(a)(1).

(e) *Products subject to other regulations.* For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with 123.11 (b) they need not be included in the HACCP plan, and vice versa.

(g) *Legal basis.* Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

Sec. 123.7 Corrective actions.

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with 123.8(a)(3)(ii) and the recordkeeping requirements of 123.9.

Sec. 123.8 Verification.

(a) *Overall verification.* Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) *Reassessment of the HACCP plan.* A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of 123.6(c).

(2) *Ongoing verification activities.* Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine

whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic endproduct or in-process testing.

(3) *Records review.* A review, including signing and dating, by an individual who has been trained in accordance with 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) *Corrective actions.* Processors shall immediately follow the procedures in 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) *Reassessment of the hazard analysis.* Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with 123.10.

(d) *Recordkeeping.* The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of 123.9.

Sec. 123.9 Records.

(a) *General requirements.* All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) *Record retention.* (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) *Public disclosure.* (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) *Tags.* Tags as defined in 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of 123.28 (c) .

(f) *Records maintained on computers.* The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Sec. 123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in 123.8(c); and

(c) Performing the record review required by 123.8(a)(3); The trained individual need not be an employee of the processor.

Sec. 123.11 Sanitation control procedures.

(a) *Sanitation SOP.* Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) *Sanitation monitoring.* Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) *Sanitation control records.* Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of 123.9.

(d) *Relationship to HACCP plan.* Sanitation controls may be included in the HACCP plan, required by 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

Sec. 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a) *Importer verification.* Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of 123.9.

(d) *Determination of compliance.* There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

**Subpart B--Smoked and Smoke-Flavored Fishery Products**

Sec. 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

Sec. 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

**Subpart C--Raw Molluscan Shellfish**

Sec. 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

Sec. 123.28 Source controls.

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority.

In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;

(2) The location of harvest by State and site;

(3) The quantity and type of shellfish;

(4) The date of receipt by the processor; and

(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with 1240.60 (c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;

(2) The quantity and type of shellfish; and

(3) The name and certification number of the packer or repacker of the product.

**Authority:** 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 241l, 264.

**Source:** 60 FR 65197, Dec. 18, 1995, unless otherwise noted.

Database Updated April 1, 2007

# THE FREEDOM OF INFORMATION ACT
## 5 U.S.C. § 552
As Amended in 2002

§ 552. Public information; agency rules, opinions, orders, records, and proceedings (a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public--

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying--

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register;

(C) administrative staff manuals and instructions to staff that affect a member of the public;

(D) copies of all records, regardless of form or format, which have been released to any person under paragraph (3) and which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; and (E) a general index of the records referred to under subparagraph (D);

unless the materials are promptly published and copies offered for sale. For records created on or after November 1, 1996, within one year after such date, each agency shall make such records available, including by computer telecommunications or, if computer telecommunications means have not been established by the agency, by other electronic means. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, staff manual, instruction, or copies of records referred to in subparagraph (D). However, in each case the justification for the deletion shall be explained fully in writing, and the extent of such deletion shall be indicated on the portion of the record which is made available or published, unless including that indication would harm an interest protected by the exemption in subsection (b) under which the deletion is made. If technically feasible, the extent of the deletion shall be indicated at the place in the record where the deletion was made. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of an index on request at a cost not to exceed the direct cost of duplication. Each agency shall make the index referred to in subparagraph (E) available by computer telecommunications by December 31, 1999. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if--

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3)(A) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(B) In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format. Each agency shall make reasonable efforts to maintain its records in forms or formats that are reproducible for purposes of this section.

(C) In responding under this paragraph to a request for records, an agency shall make reasonable efforts to search for the records in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information system.

(D) For purposes of this paragraph, the term "search" means to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request.

(E) An agency, or part of an agency, that is an element of the intelligence community (as that term is defined in section 3(4) of the National Security Act of 1947 (50 U.S.C. 401 a(4))) shall not make any record available under this paragraph to--

(i) any government entity, other than a State, territory, commonwealth, or district of the United States, or any subdivision thereof; or

(ii) a representative of a government entity described in clause (i).

(4)(A)(i) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying the schedule of fees applicable to the processing of requests under this section and establishing procedures and guidelines for determining when such fees should be waived or reduced. Such schedule shall conform to the guidelines which shall be promulgated, pursuant to notice and receipt of public comment, by the Director of the Office of Management and Budget and which shall provide for a uniform schedule of fees for all agencies.

(ii) Such agency regulations shall provide that--

(I) fees shall be limited to reasonable standard charges for document search, duplication, and review, when records are requested for commercial use;

(II) fees shall be limited to reasonable standard charges for document duplication when records are not sought for commercial use and the request is made by an educational or noncommercial scientific institution, whose purpose is scholarly or scientific research; or a representative of the news media; and

(III) for any request not described in (I) or (II), fees shall be limited to reasonable standard charges for document search and duplication.

(iii) Documents shall be furnished without any charge or at a charge reduced below the fees established under clause (ii) if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(iv) Fee schedules shall provide for the recovery of only the direct costs of search, duplication, or review. Review costs shall include only the direct costs incurred during the initial examination of a document for the purposes of determining whether the documents must be disclosed under this section and for the purposes of withholding any portions exempt from disclosure under this section. Review costs may not include any costs incurred in resolving issues of law or policy that may be raised in the course of processing a request under this section. No fee may be charged by any agency under this section--

(I) if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee; or

(II) for any request described in clause (ii)(II) or (III) of this subparagraph for the first two hours of search time or for the first one hundred pages of duplication.

(v) No agency may require advance payment of any fee unless the requester has previously failed to pay fees in a timely fashion, or the

agency has determined that the fee will exceed $250.

(vi) Nothing in this subparagraph shall supersede fees chargeable under a statute specifically providing for setting the level of fees for particular types of records.

(vii) In any action by a requester regarding the waiver of fees under this section, the court shall determine the matter de novo, provided that the court's review of the matter shall be limited to the record before the agency.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action. In addition to any other matters to which a court accords substantial weight, a court shall accord substantial weight to an affidavit of an agency concerning the agency's determination as to technical feasibility under paragraph (2) and subsection (b) and reproducibility under paragraph (3)(B).

(C) Notwithstanding any other provision of law, the defendant shall serve an answer or otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court other wise directs for good cause is shown.

(C) Repealed by Pub. L. 98-620, Title IV, 402(2), Nov. 8, 1984, 98 Stat. 3335, 3357.

(D) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(E) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Special Counsel shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Special Counsel, after investigation and consideration of the evidence submitted, shall submit his findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Special Counsel recommends.

(F) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefore, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B)(i) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days, except as provided in clause (ii) of this subparagraph.

(ii) With respect to a request for which a written notice under clause (i) extends the time limits prescribed under clause (i) of subparagraph (A), the agency shall notify the person making the request if the request cannot be processed within the time limit specified in that clause and shall provide the person an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request. Refusal by the person to reasonably modify the request or arrange such an alternative time frame shall be considered as a factor in determining whether exceptional circumstances exist for purposes of subparagraph (C).

(iii) As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular requests--

(I) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(II) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(III) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject matter interest therein.

(iv) Each agency may promulgate regulations, pursuant to notice and receipt of public comment, providing for the aggregation of certain requests by the same requestor, or by a group of requestors acting in concert, if the agency reasonably believes that such requests actually constitute a single request, which would otherwise satisfy the unusual circumstances specified in this subparagraph, and the requests involve clearly related matters. Multiple requests involving unrelated matters shall not be aggregated.

(C)(i) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(ii) For purposes of this subparagraph, the term "exceptional circumstances" does not include a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

(iii) Refusal by a person to reasonably modify the scope of a request or arrange an alternative time frame for processing the request (or a modified request) under clause (ii) after being given an opportunity to do so by the agency to whom the person made the request shall be considered as a factor in determining whether exceptional circumstances exist for purposes of this subparagraph.

(D)(i) Each agency may promulgate regulations, pursuant to notice and receipt of public comment, providing for multitrack processing of requests for records based on the amount of work or time (or both) involved in processing requests.

(ii) Regulations under this subparagraph may provide a person making a request that does not qualify for the fastest multitrack processing an opportunity to limit the scope of the request in order to qualify for faster processing.

(iii) This subparagraph shall not be considered to affect the requirement under subparagraph (C) to exercise due diligence.

(E)(i) Each agency shall promulgate regulations, pursuant to notice and receipt of public comment, providing for expedited processing of requests for records--

(I) in cases in which the person requesting the records demonstrates a compelling need; and

(II) in other cases determined by the agency.

(ii) Notwithstanding clause (i), regulations under this subparagraph must ensure--

(I) that a determination of whether to provide expedited processing shall be made, and notice of the determination shall be provided to the person making the request, within 10 days after the date of the request; and

(II) expeditious consideration of administrative appeals of such determinations of whether to provide expedited processing.

(iii) An agency shall process as soon as practicable any request for records to which the agency has granted expedited processing under this subparagraph. Agency action to deny or affirm denial of a request for expedited processing pursuant to this subparagraph, and failure by an agency to respond in a timely manner to such a request shall be subject to judicial review under paragraph (4), except that the judicial review shall be based on the record before the agency at the time of the determination.

(iv) A district court of the United States shall not have jurisdiction to review an agency denial of expedited

processing of a request for records after the agency has provided a complete response to the request.

(v) For purposes of this subparagraph, the term "compelling need" means--

(I) that a failure to obtain requested records on an expedited basis under this paragraph could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(II) with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity.

(vi) A demonstration of a compelling need by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief.

(F) In denying a request for records, in whole or in part, an agency shall make a reasonable effort to estimate the volume of any requested matter the provision of which is denied, and shall provide any such estimate to the person making the request, unless providing such estimate would harm an interest protected by the exemption in subsection (b) pursuant to which the denial is made.

(b) This section does not apply to matters that are--

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection. The amount of information deleted shall be indicated on the released portion of the record, unless including that indication would harm an interest protected by the exemption in this subsection under which the deletion is made. If technically feasible, the amount of the information deleted shall be indicated at the place in the record where such deletion is made.

(c)(1) Whenever a request is made which involves access to records described in subsection (b)(7)(A) and--

(A) the investigation or proceeding involves a possible violation of criminal law; and

(B) there is reason to believe that (i) the subject of the investigation or proceeding is not aware of its pendency, and (ii) disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, the agency may, during only such time as that circumstance continues, treat the records as not subject to the requirements of this section.

(2) Whenever informant records maintained by a criminal law enforcement agency under an informant's name or personal identifier are requested by a third party according to the informant's name or personal identifier, the agency may treat the records as not subject to the requirements of this section unless the informant's status as an informant has been officially confirmed.

(3) Whenever a request is made which involves access to records maintained by the Federal Bureau of Investigation pertaining to foreign intelligence or counterintelligence, or international terrorism, and the existence of the records is classified information as provided in subsection (b) (1), the Bureau may, as long as the existence of the records remains classified information, treat the records as not subject to the requirements of this section.

(d) This section does not authorize the withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(e)(1) On or before February 1 of each year, each agency shall submit to the Attorney General of the United States a report which shall cover the preceding fiscal year and which shall include--

(A) the number of determinations made by the agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(B)(i) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information; and

(ii) a complete list of all statutes that the agency relies upon to authorize the agency to withhold information

under subsection (b)(3), a description of whether a court has upheld the decision of the agency to withhold information under each such statute, and a concise description of the scope of any information withheld;

(C) the number of requests for records pending before the agency as of September 30 of the preceding year, and the median number of days that such requests had been pending before the agency as of that date;

(D) the number of requests for records received by the agency and the number of requests which the agency processed;

(E) the median number of days taken by the agency to process different types of requests;

(F) the total amount of fees collected by the agency for processing requests; and

(G) the number of full-time staff of the agency devoted to processing requests for records under this section, and the total amount expended by the agency for processing such requests.

(2) Each agency shall make each such report available to the public including by computer telecommunications, or if computer telecommunications means have not been established by the agency, by other electronic means.

(3) The Attorney General of the United States shall make each report which has been made available by electronic means available at a single electronic access point. The Attorney General of the United States shall notify the Chairman and ranking minority member of the Committee on Government Reform and Oversight of the House of Representatives and the Chairman and ranking minority member of the Committees on Governmental Affairs and the Judiciary of the Senate, no later than April 1 of the year in which each such report is issued, that such reports are available by electronic means.

(4) The Attorney General of the United States, in consultation with the Director of the Office of Management and Budget, shall develop reporting and performance guidelines in connection with reports required by this subsection by October 1, 1997, and may establish additional requirements for such reports as the Attorney General determines may be useful.

(5) The Attorney General of the United States shall submit an annual report on or before April 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subparagraphs (E), (F), and (G) of subsection (a)(4). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(f) For purposes of this section, the term--

(1) "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency; and

(2) "record" and any other term used in this section in reference to information includes any information that would be an agency record subject to the requirements of this section when maintained by an agency in any format, including an electronic format.

(g) The head of each agency shall prepare and make publicly available upon request, reference material or a guide for requesting records or information from the agency, subject to the exemptions in subsection (b), including--

(1) an index of all major information systems of the agency;

(2) a description of major information and record locator systems maintained by the agency; and

(3) a handbook for obtaining various types and categories of public information from the agency pursuant to chapter 35 of title 44, and under this section.

Last Updated December 23, 2002

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Proposed Information Collection; Comment Request; National Marine Sanctuary Permits

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before April 14, 2008.

**ADDRESSES:** Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Ave., NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to David Bizot, 301–713–7268 or *David.Bizot@noaa.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Abstract

National Marine Sanctuary Program (NMSP) regulations at 15 CFR part 922 list specific activities that are prohibited in national marine sanctuaries. These regulations also state that otherwise prohibited activities are permissible if a permit is issued by the NMSP. The persons desiring a permit must submit an application, and anyone obtaining a permit is generally required to submit one or more reports on the activity allowed under the permit.

The recordkeeping and reporting requirements at 15 CFR part 922 form the basis for this collection of information. This information is required by NMSP to protect and manage sanctuary resources as required by the National Marine Sanctuaries Act (16 U.S.C. 1431 et seq.)

#### II. Method of Collection

Depending on the permit being requested, various applications, reports, and telephone calls may be required from applicants. Applications and reports can be submitted via e-mail, fax, or traditional mail. Applicants are encouraged to use electronic means to apply for permits and submit reports whenever possible.

#### III. Data

*OMB Number:* 0648–0141.

*Form Number:* None.

*Type of Review:* Regular submission.

*Affected Public:* Business or other for-profit organizations; individuals or households; not-for-profit institutions; Federal government; state, local or tribal government.

*Estimated Number of Respondents:* 424.

*Estimated Time per Response:* General permits, 1 hour, 30 minutes; special use permits, 8 hours; historical resources permits, 13 hours; baitfish permits, certifications and permit amendments, 30 minutes; voluntary registrations, 15 minutes; appeals, 24 hours; Tortugas access permits, 6 minutes.

*Estimated Total Annual Burden Hours:* 1,437.

*Estimated Total Annual Cost to Public:* $949 in reporting/recordkeeping costs.

#### IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 7, 2008.

**Gwellnar Banks,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. E8–2582 Filed 2–12–08; 8:45 am]

**BILLING CODE 3510–NK–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Proposed Information Collection; Comment Request; Seafood Inspection and Certification Requirements

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

**ACTION:** Notice.

**SUMMARY:** The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted on or before April 14, 2008.

**ADDRESSES:** Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the information collection instrument and instructions should be directed to James Appel, (301) 713–2355 or *James.Appel@noaa.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Abstract

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program (Program) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and the Reorganization Plan No. 4 of 1970.

The regulations for the Program are contained in 50 CFR part 260. The Program offers inspection grading and certification services, including the use of official quality grade marks which indicate that specific products have been Federally inspected. Qualified participants are permitted to use the Program's official quality grade marks on their products to facilitate trade of fishery products.

The participants in the inspection program are requested to submit specific information pertaining to the type of inspection services requested [Section 260.15]. In all cases, applicants provide information regarding the type of products to be inspected, the quantity, and location of the product. There are also application requirements if there is

an appeal of previous inspection results [Section 260.36]. Participants requesting regular inspection services on a contractual basis also submit a contract [Section 260.96]. The participants interested in using official grade marks are required to submit product labels and specifications for review and approval to ensure compliance with mandatory labeling regulations established by the U.S. Food and Drug Administration as well as proper use of the Program's marks [Section 260.97 (12) and (13)].

Current regulations require approval of drawings and specifications prior to approval of facilities [Section 260.96 (b) and (c)]. There are no respondents under this section. The Program will amend this part of the regulations in a future action.

In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under Section 260.15 of the regulations. These guidelines required that a facility's quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as identified personnel responsible for oversight of the system. The HACCP requires continuing monitoring and recordkeeping by the facility's personnel.

Although HACCP involves substantial self-monitoring by the industry, the HACCP-based program is not a self-certification program. It relies on unannounced system audits by NMFS. The frequency of audits is determined by the ability of the firm to monitor its operation. By means of these audits, NMFS reviews the records produced through the Program participant's self-monitoring. The audits determine whether the participant's HACCP-based system is in compliance by checking for overall sanitation, accordance with good manufacturing practices, labeling, and other requirements. In addition, in-process reviews, end-product sampling, and laboratory analyses are performed by NMFS at frequencies based on the potential consumer risk associated with the product and/or the firm's history of compliance with the Program's criteria.

The information collected is used to determine a participant's compliance with the program. The reported information, a HACCP plan, is needed only once. Other information is collected and kept by the participant as part of its routine monitoring activities. NMFS audits the participant's records on unannounced frequencies to further determine compliance.

## II. Method of Collection

Information will be obtained via telephone, fax, hard-copy submission, or audit conducted by NMFS personnel.

## III. Data

*OMB Number:* 0648–0266.

*Form Number:* NOAA Forms 89–800, 89–814, and 89–819.

*Type of Review:* Regular submission.

*Affected Public:* Business or other for-profit organizations.

*Estimated Number of Respondents:* 7,082.

*Estimated Time per Response:* 5 minutes for an application of inspection services; 5 minutes for an application for an appeal; 5 minutes for submitting a contract; 30 minutes to submit a label and specification; 105 hours for a Hazard Analysis Critical Control Point (HACCP) plan; and 80 hours for HACCP monitoring and recordkeeping.

*Estimated Total Annual Burden Hours:* 13,065.

*Estimated Total Annual Cost to Public:* $3,579.

## IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 7, 2008.

**Gwellnar Banks,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. E8–2583 Filed 2–12–08; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XF51**

### Marine Mammals; File No. 727–1915

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; issuance of permit.

**SUMMARY:** Notice is hereby given that the Scripps Institute of Oceanography [Responsible Party/Principal Investigator: John Hildebrand, Ph.D.] has been issued a permit to conduct scientific research on marine mammals.

**ADDRESSES:** The permit and related documents are available for review upon written request or by appointment (See **SUPPLEMENTARY INFORMATION**).

**FOR FURTHER INFORMATION CONTACT:** Jaclyn Daly or Kate Swails, (301)713–2289.

**SUPPLEMENTARY INFORMATION:** On May 3, 2007, notice was published in the **Federal Register** (72 FR 24564) that a request for a scientific research permit to take 31 species of cetaceans, including ESA-listed species, had been submitted by the above-named organization. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The permit authorizes close approach, biopsy sampling, suction-cup tagging, fecal sampling, skin collection, and passive acoustic recording of cetaceans in the Northern and Central Pacific Ocean. The purpose of the research is to improve baseline data on marine mammal status, abundance, stock structure, life history, seasonal distribution, and acoustic communication and behavior of non-ESA and ESA listed species. The permit is issued for five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an environmental assessment was prepared analyzing the effects of the permitted activities. After a Finding of No Significant Impact, the determination was made that it was not necessary to prepare an environmental impact statement.