

**U.S. FDA
Seafood HACCP
Regulatory
Workshop**

Technical Report No. 12



**Regional Agribusiness Project
7250 Woodmont Avenue, Suite 200, Bethesda, Maryland 20814**

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U.S. FDA Seafood HACCP Regulatory Workshop

by

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with the support of the
Office of International Cooperation and Development
of the U.S. Department of Agriculture's Foreign Agricultural Service
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SECTION ONE

INTRODUCTION

This project involved the holding of a series of workshops/seminars on the new United States Food and Drug Administration's (FDA) Seafood Hazard Analysis and Critical Control Point (HACCP) regulations. These regulations will, effectively, put into place a new approach to ensuring the safety of seafood products. The new regulations will become effective December 18, 1997. The program is equally applicable to both U.S. domestic and imported product. Thus, foreign seafood processors must adhere to the new regulations. Since a new approach to ensuring seafood safety is involved, substantial changes to the way in which processor's food safety and quality assurance programs operate are needed. These changes are particularly challenging to seafood processors in developing countries where current programs in these areas are often limited. This workshop was specifically designed to provide countries served by the Asia Regional Agribusiness Project with early information on the nature, scope and extent of the new regulations to assist them in beginning the process of preparing for the new regulations. The workshop was not designed to be a HACCP training workshop; such an effort requires substantially more time and resources. However, clear follow-up needs were identified in the HACCP training area that are identified in this report.

In addition to providing information on the new U.S. FDA Seafood HACCP regulations, information was also provided on current seafood marketing trends, both internationally and for the United States.

While each workshop was conducted somewhat differently (see country sections below), the basic information provided was the same. The subject matter covered and the technical team presenting the workshop was the following.

HACCP: An Overview and Its Role in International Food Safety Regulation. Dr. H. Michael Wehr, Ph.D., Director, International Food Standards, TAS, Incorporated, Washington, D.C..

The New U.S. FDA Seafood HACCP Regulations. Dr. Frank MacKeith, Consumer Safety Officer, Center for Food Safety and Applied Nutrition, Office of Constituent Operations, International Program, U.S. Food and Drug Administration, Washington, D.C..

Food Safety Hazards of Regional Fish Species and Their Management Under FDA Seafood HACCP. Mr. Richard Dees, Consultant, Seafood Export Assistance, Rockville, MD.

Practical Information on Importing. Mr. Jonathan Little, Consultant, Surefish Company, Seattle, WA.

U.S. and World Seafood Market Trends. Mr. Howard Johnson, President, H.M. Johnson and Associates, Bellevue, WA.

The participation of Mr. Little and Mr. Johnson was made possible by USAID's SUSTAIN Program (sharing United States technology to AID in the Improvement of Nutrition). SUSTAIN assistance in this project is gratefully acknowledged.

Attached in Appendix 5 to this report are presentation materials covering the presentations of the various team members documenting their presentations.

Venues for the workshop were Cochin, India, Jakarta, Indonesia, and Manila, Philippines. Dhaka, Bangladesh was originally scheduled as a presentation location but was canceled due to civil disturbances within the country during the scheduled time for the workshop. Because of the Bangladesh cancellation, additional time was spent in Singapore; advantage was taken of this change to visit the Southeast ASEAN Fisheries Development Center (SEAFDEC).

The following report summarizes the key findings for each venue including sponsoring organizations and key contact individuals, attendance, findings from each workshop including concerns/questions raised by attendees (and responses given as appropriate), visits undertaken (if any), and published information obtained (if any). Since the recommended follow-on activities are regional and apply to all countries visited, they are given in a separate section.

Short reports were requested from all workshop team members. These are provided in Appendix 1.

Note: Questions on seafood embargoes to the U.S. due to environmental concerns, specifically the entrapment of sea turtles, were raised by participants at each workshop. At the request of the U.S. Government, the team directed inquiries to the Commercial Section of the U.S. Embassies.

SECTION TWO

COUNTRY REPORTS

INDIA

This workshop was held in Cochin, India on March 19, 1996. Visits to government agencies involved with fishery products and visit to a frozen shrimp processor were undertaken at the request of the sponsoring organizations. These visits were requested to provide the team with the necessary background on the Indian fisheries industry.

Sponsors for the workshop were U.S. AID India, Department of Energy and the Environment, the Export Inspection Council, the Export Inspection Agency, and the Marine Products Export Development. Co-sponsors included the Seafood Exporters Association of India, the Central Institute of Fisheries Technology, and the Confederation of Indian Food Trade and Industry.

Copies of the technical team's itinerary, the Workshop Inaugural Program and the actual Seminar Program are provided in Appendix 2.

Key contact individuals are given in Appendix 3.

Workshop attendance was approximately 70 individuals. A small registration fee was charged.

The Workshop and Inauguration Program occupied one day. At the request of the sponsoring organizations, approximately two days equivalent time was spent visiting various organizations to obtain an understanding of the fisheries situation in India.

Findings

It was apparent from the discussions at the various government agencies and organizations visited (see below), the number of workshop participants, and the side discussions and networking that occurred with team members during the workshop that there clearly is a significant interest and awareness of HACCP and the new U.S. FDA Seafood HACCP Regulations. Based primarily on discussion with industry representatives attending the workshop (visits were too few to provide extensive information) and on discussions with the Export Inspection Agency, it appears that HACCP capability within the Indian seafood industry is, however, very limited. A representative of the Export Inspection Agency indicated that, of some 120 processing facilities establishments in the Cochin area, none are currently HACCP ready and only 10% are "getting further along". Discussion with several workshop attendees indicated their technical confusion between quality control programs and HACCP. There is no doubt, however, of the seriousness with which India is addressing the need for HACCP; this appears to be particularly noticeable with the efforts of the Export Inspection Council and the Export Inspection Agency to bring a HACCP awareness and capability to the industry.

Several key points of inquiry/interest arose from the seminar participants. Please refer to Appendix 1 for additional items provided by the individual team members.

- The need and interest for detailed HACCP plans (effectively HACCP "recipes") for use by the industry to implement HACCP. Questions were asked re: where and when will model HACCP plans be available.
- Does qualification under the FDA Seafood HACCP program remove a firm from the FDA's automatic detention list. Answer (from MacKeith): No, the two areas are separate; a firm must still complete five successive acceptable shipments to be removed from the automatic detention list. But the proper operation of HACCP should, in principle, result in a product acceptable to FDA. Thus, a properly operating HACCP program should lead to a firm's eventual removal from the automatic detention list.
- What is the difference between HACCP and ISO 9000? Answer (from Wehr): HACCP is solely a food safety program; ISO 9000 is a comprehensive quality assurance program that will normally ensure a given level of quality specified by the manufacturer. Properly designed, an ISO 9000 program may incorporate HACCP but it need not do so.
- Several related questions.
 - Where does HACCP begin and end?
 - What are examples of sanitation begin and end.
 - What is the role of the transporter?
 - What is the role of the consumer?

Answer (from Dees, Wehr): Depends on the specific product and process. Normally, HACCP extends from the time a firm assumes responsibility for an ingredient of a product until it relinquishes control of the product; however, it may extend beyond these limits if safety demands it. HACCP often incorporates product specifications which effectively extend HACCP.

Consumer activities (storage, preparation, etc.) is normally not a part of HACCP but may be part of a manufacturer's educational program to ensure the safe use of a product.

- Can you have a separate HACCP plan for a fish pre-processing center? Answer (from Dees): yes.
- FDA Seafood HACCP regulations state that where there is no identified hazard, there is no need for a HACCP plan. Is there ever such a situation? Answer (from Dees): There may be but it will be very rare (Processing Atlantic Cod was an example given where a HACCP plan may not be required.
- Questions regarding information resources, including:
 - How can copies of FDA regulations be obtained?
 - How can a copy of the FDA Seafood Hazard and Control guide be obtained?
 - What is the Internet addresses for FDA?
 - How can we access additional training resources for HACCP?

- Questions regarding further HACCP preparation and training.
 - What should a processor be doing now in preparation for HACCP?
 - When can the U.S. industry training acceptable to the U.S. be made available to India?
 - Will previous HACCP training or training in HACCP be sufficient to be in compliance with this regulation?
 - How does India's government and seafood industry obtain continued interactions with experts such as those on this team?

It should also be noted that, during the team's visit to the Export Inspection Agency (EIA) Laboratory in Cochin, an inquiry was addressed to the team relating to Salmonella testing on shrimp. This area has been the subject of extensive previous discussions with the U.S. Food and Drug Administration. FDA has expressed concern with the occurrence of false negative findings by the Cochin EIA Laboratory (i.e., negative salmonella tests by the EIA and positive findings by the U.S. FDA on the same lot). EIA representatives requested a review of their methodology to help ascertain the reasons for the discrepancy. The team did not provide this review, but noted the need and suggested that a good first step would be to have the EIA laboratory participate in that portion of FDA's food microbiology proficiency program that deals with salmonella. On-site review and training in this technical area may also be helpful.

Summaries of Organizations Visited

Export Inspection Authority (EIA)

The EIA is under the India Ministry of Commerce and is organized into five regions (Bombay, Calcutta, Cochin, Delhi, Madras). The Agency provides product grades and standards inspection certification for food and agricultural products.

The Cochin region consists of the southern two states of India. Primary products involved are fish, cashews and spices. 90% of the district's work is with fishery products. All work is done on a fee for service basis. Sixteen inspection stations comprise the Cochin district. EIA inspects only those products involved with export.

Currently, all fishery products are under mandatory export inspection. In order to gain approval to export, minimum process facilities and laboratory and product specifications must be met.

Cochin EIA is heavily involved in working with the fisheries industry to implement HACCP. Efforts are coordinated through the Export Inspection Quality Control Laboratory. There is an assigned HACCP point person for the processing industry. There is an active (and apparently cooperative) effort to inspect, assess, and improve facilities, equipment, water/ice quality, quality assurance programs as well as to implement HACCP. Routine monthly inspections are made of all 120 fishery processing establishments for which the region is responsible; these inspections normally include product and water/ice sampling; testing includes that for total bacterial count, coliforms, salmonella, listeria, vibrio cholera, heavy metals (e.g., mercury), antibiotic residues (e.g., tetracyclines) and pesticide residues (e.g., chlorinated hydrocarbons). The actual extent to which all programs are actually carried out needs to be verified. A walk through tour of the laboratory indicated apparent adequate competency (although the

laboratory has had and still has a problem with the U.S. FDA regarding false negative salmonella findings (see above). The work force, particularly the management, appeared capable.

Marine Products Export Development Authority (MPEDA)

MPEDA is a part of the India Ministry of Commerce with a responsibility to assist the seafood industry in developing its export markets including providing guidance on foreign regulations and quality standards requirements. Note: the horticultural equivalent organization is the Agricultural Products Export Development Authority (APEDA) which was visited by RAP on a previous mission. MPEDA is government funded and has 22 field offices throughout India. The role of MPEDA is six fold.

- Coordinate federal and state government activities related to the development of the fishery industry.
- Implement development activities in both capture and culture fisheries.
- Assist in the introduction of new technologies.
- Upgrade quality and safety standards through extension activities.
- Conduct overseas market promotion
- Gather overseas market intelligence including new regulatory requirements for fishery products.

The current focus of MPEDA is threefold with activities in seven (7) areas.

Focus Areas

- A. Development of aquaculture.
- B. Development of value added fishery products.
- C. Improvement of product quality and safety.

Activity Areas

1. Conservation management
2. Registration of exporters and processors.
3. Assisting with the development of product standards and specifications.
4. Regulation of marine product exports.
5. Providing technical extension assistance in seafood harvesting.
6. Providing market intelligence for industry.
7. Assisting industry with technical training needs.

Central Institute of Fisheries Technology (CIFT)

CIFT is a research and training organization for the Indian seafood industry, operating in seven broad areas: fishing technology, fish processing, biochemistry and nutrition, engineering, microbiology

and fermentation, biotechnology, and extension/information/statistics. Specifics on both areas are provided in references obtained (see below).

CAP Seafoods (Division of ABAD Fisheries)

CAP Seafoods is a frozen shrimp processor exporting frozen product to developed countries, primarily the EU. Eight plants are operated by CAP. The plant toured is very new, approximately 1 year in operation. Construction was done by a UK firm with plant design, construction and equipment world class in nature.

CAP is in the process of implementing HACCP; it is clearly one of the 10% Cochin area plants that are on the way to HACCP readiness although a brief review of quality control records indicated some discrepancies between stated and actual practices.

The team did not have the opportunity to tour other processors; we believe this plant is substantially better than most, if not all, others in the area and is not typical of the average processing establishment.

Information Obtained

The following published material was provided to the team. Copies are on file for reference.

- Export of Fresh, Frozen and Processed Fish and Fishery Products (Quality Control, Inspection and Monitoring). Order and Rules, 1995 (Govt. of India, Ministry of Commerce).
- Export Inspection Agency, Assessment Report (a listing of inspection points for food processing establishments), undated.
- MPEDA- An overview; the Marine Products Export Development Authority (Ministry of Commerce, Govt. of India). August, 1995.
- Central Institute of Fisheries Technology, Indian Council of Agricultural Research, Annual Report, 1994-95.
- Central Institute of Fisheries Technology, Research Highlights, 1994-95.
- Central Institute of Fisheries Technology, Training Programmes in CIFT, April, 1995.

INDONESIA

This workshop was held March 25 and 26, 1996 in Jakarta.

Sponsors for the workshop were the Gabungan Pengusaha Perikanan Indonesia (GAPPINDO), a federation of Indonesian seafood industry associations, and the U.S. AID Agribusiness Development Project (ADP).

A copy of the workshop agenda is given in Appendix 2.

Total workshop attendance was approximately 75 individuals. Average workshop session attendance was approximately 50 individuals. No registration fee was charged.

The workshop occupied two full days. Each formal presentation was followed by a summary given in Indonesia by the session moderator. A significant number of questions arose from the floor and from networking during the meeting. Time was provided for one-on-one discussions but only a few consultations (5-6) were requested.

Key contact individuals are given in Appendix 3.

Workshop participants indicated the following in regards to their involvement in the fisheries business.

Involved with:

| | |
|--|------|
| ● Industry fishery processing | 30% |
| ● Industry fishery management | 15% |
| ● Government fishery inspection | 10% |
| ● Government fishery management | < 5% |
| ● Quality control/quality assurance | 30% |
| ● Shrimp processing (capture on aquaculture) | 30% |
| ● Finfish processing | 10% |
| ● Shellfish processing | < 5% |
| ● Value added product processing | < 5% |

Findings

A survey of workshop attendees indicated that only 20% were involved in implementing HACCP and that only 10% felt that their firms were HACCP ready.

There was a clear underlying feeling that the U.S. Government policy (particularly that of the FDA) was the cause for the inability of Indonesia seafood industry to expand their imports into the United States. This was evidenced by several comments that were made during the sessions; e.g.;

- Is there a direct relationship between U.S. government policies and the declining importation of seafood into the U.S.? Response: no- strength of U.S. economy is the primary reason.

- Why can Indonesia get product into Japan (a stringent quality market) and not the U.S.? Response: price and product selection are primary factors for success to Japan.
- A direct comment that FDA is a technical trade barrier.

Many of the technical questions raised in India also arose in Indonesia. Additional areas for comment/inquiry were the following.

- Interest was expressed regarding memoranda of understanding between the FDA and specific companies. Questions were asked as to how such agreements can be obtained. Response from MacKeith: Agreements are made between governments; firms interested in obtaining MOU approval with FDA must work through their government and convince all parties of their long term capability to meet U.S. import standards.
- What is relationship between HACCP and product detention? Response from MacKeith: Product detention is separate from HACCP. The "five clean lot" rule still applies. Effective HACCP should, however, provide a non-violative product.
- Questions were raised regarding personal hygiene related to religious practices, specifically the lack of certain individuals to use towels or tissue to cleanse themselves after bathroom usage. The response provided focused for the need for any system, under the HACCP program, to ensure proper personal hygiene, regardless of specific cultural or religious practices.
- Country of origin product sampling and use of private laboratories. An inquiry was raised as to whether FDA accepted samples obtained by official bodies in the country of origin apart from an MOU. Response from MacKeith: No. The use of private laboratories in testing exported product destined for the U.S. was reviewed (i.e., FDA guidelines for the use of private laboratories).
- Abuse of HACCP. Concern was expressed regarding the potential for importers to use the HACCP system to bargain for lower prices. Specifically, the concern was on importers using the perceived inability of a country to adequately produce a product under HACCP, even if a formal HACCP program were in place in a country, to bargain for a lower price. A recognition of this issue was made but no resolution was provided.
- Status of HACCP in the U.S. A question was raised as to the true status of HACCP in the U.S. Response: at the beginning.
- Why do some U.S. ports take longer to process a import than others? Response from MacKeith: They shouldn't but workloads and resources vary.
- What will FDA do if product is rejected from a plant operating under an acceptable HACCP plan. Response from MacKeith: FDA will re-review the HACCP plan and HACCP plan product documentation.

There were, additionally, multiple questions on training, including a request identical to that made in India as to when can HACCP training acceptable to the FDA be brought to Indonesia.

There were also multiple questions relating to technical information access, specifically to U.S. seafood regulations and regulatory product standards (e.g., allowable histamine, drug residue, and formalin levels).

Please refer to Appendix 1 for additional areas of concern and inquiry identified in reports of the individual team members.

No agency or plant visits were undertaken in Jakarta. Additionally, no information materials were provided on Indonesian organizations or industrial firms.

PHILIPPINES

This workshop was held March 28 and 29, 1996 in Manila.

The sponsor for the workshop was the Foundation for Resource Linkage and Development, a private non-profit organization providing information and training services to the Philippine food and agriculture industry. FRLD was originally funded through U.S. AID but is now self-supporting.

A copy of the workshop agenda and an agenda for a brief follow up HACCP Planning Session is given in Appendix 2.

Total workshop attendance was approximately 25. A substantial registration fee (P5500, US \$215) was charged to cover all meeting costs (promotion, hotel and meals). While the registration fee likely affected attendance levels, the organization of the workshop was excellent and the amount of pre-meeting workshop effort required by RAP was minimal.

The workshop occupied two full days. Each formal presentation was followed by a question and answer session. While the questions from the floor were relatively few, the number of one-on-one consultations held was substantial- approximately 25 short individual consultations were held with all five of the workshop team. There was a clear and successful effort by FRLD to motivate attendees to use the one-on-one consultations.

Key contact individuals and a listing of attendees is given in Appendix 3.

Workshop participants indicated the following in regards to their involvement in the fisheries business.

Involved with:

- Private sector fishery operations 80%
- Government agencies 20%

A specific breakout of individuals associated with various activities was the following.

| | | |
|--|---|-------------|
| ● Tuna canners | 2 | individuals |
| ● Tuna-fresh/frozen processors | 3 | " |
| ● Fish sauce/paste manufacturers | 1 | " |
| ● Third party certifying organizations | 2 | " |
| ● Other processor | 3 | " |
| ● Trading Companies | 2 | " |
| ● Regulatory Agency | 6 | " |
| ● Port shipper/operator | 2 | " |
| ● Research Organization | 2 | " |
| ● Miscellaneous | 2 | " |

Findings

A survey of workshop attendees that eight individuals had prior experience with HACCP and 8 companies indicated they were developing HACCP plans.

Much of the interaction with participants in this workshop venue took place in the one-on-one consultations. Please refer to Appendix 1 for more detail on these meetings.

To a significant extent, issues brought forward in discussion were similar in nature to those arising from the other two workshop venues, including those dealing with: HACCP training; details of HACCP implementation; the relationship between automatic detention and implementation of HACCP; the use of private laboratories for export product testing; and the establishment of Memoranda of Understanding between FDA and countries. Additional areas of discussion included the following.

- How will FDA operate between now and the implementation of Seafood HACCP? Response from MacKeith: business as usual.
- How will MOU's between countries be influenced by Seafood HACCP? Response from MacKeith: too early to tell.
- What criteria are used by FDA in selecting product for inspection? Response from MacKeith: compliance history of product, country, exporter, shipper, and importer.
- How can a continuing dialogue be set up to facilitate the implementation of the provisions of this regulation?
- How can Codex help to resolve differences between differences between countries (specifically the U.S., Canada, and the EU) in histamine maximum residue limits? Referral was made to the Codex Committee on Fish and Fish Products through the Philippine Codex Contact Point.

An additional topic regarding laboratory analytical capability for extraneous material testing arose in the one-on-one discussions; this subject arose in a previous visit to the Philippines under RAP. Interest was expressed by both government laboratory representatives, and third party certifiers for assistance in training laboratory analysts in extraneous material testing. As indicated in a previous trip

report, and as described in a previous technical assistance proposal, such assistance could be very beneficial to both the Philippines and other developing countries.

Planning Session

A post workshop planning session was held to evaluate the next steps needed to be taken to assist the Philippine Seafood Industry in meeting the FDA Seafood HACCP regulations. Attending the meeting, in addition to the technical team, were representatives of the Philippine Chamber of Commerce and Industry, the Philippine Food and Drug Administration, the Philippine National Food Authority Food Development Center and FRLD. The recommendations arising from this session were similar in nature to those brought forward in other countries and are outlined in the Recommendation Section below. Minutes of this planning session are given in Appendix 4.

SINGAPORE

As a result of the cancellation of the Bangladesh venue of the workshop due to civil unrest, the technical team spent an extra day in Singapore. This time was used to visit the Southeast Asian Seafood Fishery Development Center or SEAFDEC. Also included in the visit to the ASEAN-Canada Fisheries Post Harvest Technology Project; this project is an integral part of SEAFDEC.

This visit was carried out on March 22, 1995.

Key individuals with whom visitations occurred are given in Appendix 3.

Findings

SEAFDEC is an ASEAN focused provider of technical and quality control information. SEAFDEC is funded by Japan with Canada and Japan providing the primary technical guidance. Countries involved include Singapore (headquarters location), Indonesia, Malaysia, Thailand, Japan, Brunei, and the Philippines. Each country has a different center of focus although they can all participate in the various projects of the center. These specialties, all related to fishery products are the following:

- Indonesia: Quality control for fresh and frozen shrimp.
- Brunei: Quality control for small and medium processing plants and developing technologies for processing underutilized species into value added products.
- Malaysia: Production of information and training resources.
- Philippines: Development and improvement of value added shrimp products.
- Singapore: Development of surimi based products. Development of analytical methods, especially those related to histamines, drug residues, and heavy metals. Development of packaging materials.

Thailand: Improving shrimp aquaculture farm practices. Controlling tuna/tuna product decomposition.

A primary and key role of SEAFDEC is in the training area. The current training focus includes HACCP.

SEAFDEC should be a major resource to RAP in future HACCP related activities.

SEAFDEC has or is developing training materials for the following.

- Fish plant inspection.
- Fish plant design (includes floors, ceilings, water supply, etc.).
- Plant hygiene and Good Manufacturing Practices.
- Personal hygiene.
- Equipment design.

Most of the material is in written form (we were provided an example: Hygiene for Food Processing Plants). However, videos are under development.

Key points to note:

1. SEAFDEC information is publicly available to all, including non-ASEAN countries such as India and Bangladesh.
2. SEAFDEC is in the process of developing a regional seafood HACCP training curriculum, incorporating components for of both the EU and U.S. programs).
3. This center clearly knows the SE Asian fisheries business and is an excellent technical resource with materials that are readily available at little or no cost.
4. SEAFDEC is on-line on the internet with a ASEAN SEAFDEC home page.
5. SEAFDEC representatives clearly stated that the impact of HACCP will be to restructure the ASEAN seafood industry, essentially a survival of the fittest situation. SEAFDEC's current assessment of HACCP readiness of the region is that "some plants are ready".

Materials Obtained

Role of SEAFDEC in Fisheries Development in Southeast Asia, Southeast ASEAN Fisheries Development Center, July, 1991.

ASEAN Canada Fisheries Post-Harvest Technology Project, Phase II; an information brochure.

List of MFRD Publications, Marine Fisheries Research Department, SEAFDEC, 22 Dec., 1995.

Hygiene for Fish Processing Plants, ASEAN-Canada Fisheries Post-Harvest Technology Project Program, Phase II. Compiled by Leonard Limpus, Program Manager, undated.

SECTION THREE

RECOMMENDED FOLLOW-ON ACTIVITIES

It is very clear from the discussions and visitations that occurred during this series of workshops that substantial effort is needed to permit seafood processors in the countries visited (and in Bangladesh) to be prepared for the requirements of the U.S. Food and Drug Administration's mandatory seafood HACCP program planned for implementation in December, 1997. Few, if any, plants are HACCP ready and there appears to still be a lack of understanding of HACCP among many seafood processors. SEAFDEC representatives clearly stated that the impact of HACCP will likely be a restructuring of the industry, essentially a survival of the fittest situation. If seafood processors are to be prepared for implementation of the U.S. FDA Seafood HACCP program, it is important that efforts begin now.

There was a clear consistency of need shown in all countries visited regarding preparation for the implementation of HACCP, including training, plant audits, and remediation efforts. While much of this activity is beyond the resources available to U.S. government funding sources, there are clear next-step activities that are possible through the support of U.S. AID, its projects, missions and ancillary organizations, particularly if coupled with support from the individual country seafood industries and their trade and/or government support organizations. It is the judgment of this report that support from a country's industry or government is important to provide the incentives necessary to achieve meaningful improvement of the seafood industry.

Based on the information obtained during this project, we recommend that U.S. AID (and its RAP Project Component) and USDA Foreign Agricultural Service International Cooperation Division consider the following next steps.

1. Support the attendance of 2-3 individuals from each country at "train the trainer" Seafood HACCP Alliance Training Courses held in the United States. The U.S. Seafood HACCP Alliance is a consortium of government (FDA), university (Sea Grant Institutions) and industry (particularly the National Fisheries Institute) interests that have developed a comprehensive seafood HACCP training course. The U.S. Food and Drug Administration will not conduct training in seafood HACCP itself, but is recognizing courses using the Seafood HACCP Alliance Training Curriculum conducted by qualified organizations as meeting the training requirement of the Seafood HACCP regulations.

The individuals sponsored for attending a Seafood HACCP Alliance course should be individuals with broad responsibility for HACCP training (e.g, government, institute, or association representatives).

2. Support Seafood HACCP Alliance courses at 2-3 venues within the Asian region. There is such a great need for HACCP training in the region, that recommendation 1 cannot provide training sufficient to meet the needs of the region in time to meet the requirements of the FDA Seafood HACCP December, 1997 deadline. It is important to get Seafood HACCP Alliance courses into the region.

However, the level of HACCP readiness is marginal in all countries. For this reason, the course should extend its instruction to plant sanitation and good manufacturing practices. This can be done as a 1 day workshop in front of the Seafood Alliance Course.

3. Conduct a series of HACCP readiness audits (reviews) of representative seafood processing plants. The purpose of this exercise is to provide a clear understanding of the precise level of readiness of processors with respect to implementing HACCP, including costs associated with upgrading plants and personnel. Plants selected should be representative of the industry as a whole, excluding those plants that already do have the potential to become HACCP ready. It may be advisable to conduct the HACCP readiness audits prior to the in-country Seafood HACCP Alliance course to better relate the course to the needs of the regional seafood industry.

We also suggest the following.

1. The HACCP readiness audits be paid for entirely by the regional seafood industry, their trade association and/or national governments. It is important that an investment be made by the local industry re: HACCP in recognition that HACCP is a normal cost of doing business.
2. That SEAFDEC expertise be incorporated into the workshops. Since Asian fisheries must meet not only U.S., but also EU and Japanese HACCP requirements, any training done should include this component in the curriculum. SEAFDEC has this information and can bring it into the workshop. Additionally, SEAFDEC is very HACCP knowledgeable generally and has a strong working relationship with at least some of the countries that could be involved in this program; their assistance will be particularly valuable.

Since time is of the essence to permit countries to meet the December, 1997 FDA Seafood HACCP implementation deadline, we recommend that the above next steps be undertaken in the Fall of 1996. This schedule will provide for at least one year for processors to carry out the necessary activity to meet the FDA requirements.

APPENDIX 1

**Issues of Concern for Southeast Asia Workshop
Prepared by Richard Dees**

Issues of Concern
to
India

During the March 1996 Workshop in India, I was asked questions by participants about various issues and I brought up others of interest to myself. Those issues brought up by the participants from India industry and government are as follows:

(a * indicates a topic brought up more than once)

*What should a processor be doing now in preparation for HACCP?

Can FDA assist in obtaining clean containers in which to ship finished product?

*Where can a copy of the Seafood HACCP Regulation be obtained?

*Where and when can a copy of the Hazards and Controls Guide be obtained?

*When can the US industry training acceptable to FDA be made available to the industry and government in India?

Will previous HACCP training or training in HACCP be sufficient to be in compliance with this regulation?

*What types of organizations did FDA have in mind when they provided for third parties?

*Obtaining good raw material is a problem, why did FDA not include harvest vessels?

When will model HACCP plans be available and how can they be obtained?

How will FDA determine compliance of processors in India?

*How does a country or company get off of automatic detention?

Can examples of likely Hazard Analysis and HACCP Plan forms be obtained now?

*What are the hazards to watch out for in seafood?

Where can information on sanitation and Part 110 be obtained?

What are examples of Sanitation SOP's?

What is the U.S. methodology for S. Aureus and its enterotoxin?

*The FDA finds salmonella but samples run in India and by private laboratories often do not find salmonella. What is causing this?

*What does the Seafood HACCP Regulation do to prevent in-transit contamination of finished product to market?

What seafood parasites are considered human health hazards?

*What are the internet addresses of FDA, Canada, and Australia?

What is the address for obtaining the Texas A&M Aquaculture guide?

What are the steps in HACCP plan development?

*How does the Indian government obtain continued interactions with someone like me? With FDA directly?

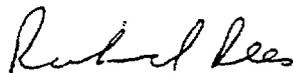
*How does someone obtain a copy of the manual such as I have prepared?

Can a critical control point (hazard that is likely to occur) be eliminated by process or plant design?

Can there be a fishery product without a hazard?

Is the NLEA in effect and what are its provisions?

Will an ISO certified plant need to perform a hazard analysis and implement HACCP and sanitation monitoring?



Richard Dees

Issues of Concern
to
Indonesia

During the March 1996 Workshop in Indonesia, I was asked questions by participants about various topics and I brought up others of interest to myself. Those issues brought up by the participants from Indonesian industry and government are as follows:

(a * indicates a topic brought up more than once)

What are the Seafood HACCP Regulation provisions that cover importers?

*How can a copy of the Regulation and of the Hazards and Controls Guide be obtained?

What is recommended as a response to employees, who as a result of religious requirements, cleanse themselves with bare fingers and water after a bowel movement?

Am confused over Corrective Actions and whether they need to be prepared in advance.

*When can the training acceptable to FDA be provided in Indonesia?

How does a person in Indonesia obtain the FDA training?

*Will training previously obtained in HACCP satisfy the requirements of this regulation?

What are the limits allowed by FDA for formalin, listeria and salmonella in seafood?

Why is there a zero tolerance for salmonella in uncooked shrimp?

*What are the internet addresses of FDA, Canada and Australia?

How will MOU's be done and what will the process be?

Will generic HACCP courses satisfy the requirements of this regulation?

Will compliance with the HACCP regulation get my company off of the automatic detention?

How does a processor in Indonesia get help with a hazard analysis and HACCP plan?

*How can a copy of my reference manual be obtained?

Will FDA inspect foreign processors?

*What is an acceptable third party?

*Can I come back again?

Is the NFI conference in May 1996 for governments or industry?

What port in the US is most lenient?

Why do some ports take longer than others to get product in?

Why do some ports sample more products than others?

How do the HACCP programs of EU/Canada/US compare?

*What will FDA do if product shipped from a plant using a HACCP plan is found to contain a hazard?

What is my fee?

Why do I insist it necessary to visit a plant if helping them prepare a hazard analysis and HACCP plan? Since others do not and are offering to send a plan from the US for a fee without the cost of a visit to their tuna cannery why do I need to see their plant and process and raw materials and procedures?

Is it necessary to send the HACCP plan to the US?

What can be done to improve the condition of delivery vehicles that carry finished product?

Will following the ASEAN Hygiene handbook guidance satisfy the sanitation requirements of the regulation?



Richard Dees

Issues of Concern
to
Philippines

During the March 1996 Workshop in the Philippines, I was asked questions by participants about various topics and I brought up others of interest to myself. Those issues brought up by the participants from the Philippine industry and government are as follows:

(a * indicates a topic brought up more than once)

*How can a continuing dialog be set up to facilitate the implementation of the provisions of this regulation?

How can assistance in providing HACCP training be obtained for commodities beyond seafood?

*What should processors start doing now?

How does a person obtain detention information from FDA?

How will FDA verify foreign processor HACCP plans?

*When will the course acceptable to FDA be available and how will it be made available to the Philippine processors and government?

Why does FDA not plan to pre-approve HACCP plans?

What are the internet addresses of FDA, Canada and Australia?

*What is the relationship between the US, Canada and EU requirements?

When will model HACCP plans be available and how?

How can Risk Assessment guidance be obtained?

How much will the course acceptable to FDA cost?

Who will MOU's be with (industry or government) and what is the procedure?

What is the address of Texas A&M for the aquaculture guide?

*What is the address of the ASEAN Post Harvest Technology Project?

Can someone from the Philippines come to the US, take the course acceptable to FDA, then return to the Philippines and provide the course to others?

How can processors get help in having harvest vessels be better maintained and have their handling procedures improved?

What drugs are allowed for use in aquaculture in the US?

Who will ck on foreign processor HACCP plans?

What are the requirements for smoked fish in the US?

What is the relationship of histamine, cadaverine and putracine to organoleptic analysis?

What are the specifications that importers will send to processors?

Will the course acceptable to FDA be given in the Philippines?

Who is considered to be an acceptable third party?

Will fish fillets be sampled by FDA? For what? How?

For Blue Crab Meat being packed in Philippines, what is the requirement for nutritional labeling?

Why does FDA have a zero level allowed of pathogens in raw seafood?

What is the methodology for examining seafood for decomposition?

*How can a list of FDA accredited laboratories be obtained?

How does FDA select what and how much to collect as a sample?

What are the hazards to be reasonably expected in processing shrimp?

What is the method currently used for canned tuna (drained wt or pressed wt)?

For histamines, why do US, Canada, and EU have different standards?

Does heat lower the level of histamine present?



Richard Dees

**Final Report for Southeast Asia Workshop
Prepared by Jonathan Little**

24

Surefish

Seafood Quality Specialists

Pier 91, Box C120
Seattle, Washington 98119

Delta Western Dock - Dutch Harbor, Alaska Phone 907-581-4904 Fax 907-581-3459

Telephone 206-284-2686

Fax 206-284-2667

FAX TRANSMISSION

To: Michael Wehr, TAS
From: Jonathan Little
Date: April 5, 1996
Subject: Final report for SE Asia Workshop
Pages sent: 2

The following is a summary report on the U.S. Seafood HACCP Regulatory Workshop as requested. A 'team' of five individuals from the U.S., spent two weeks in Southeast Asia giving three workshops on the new U.S. Seafood HACCP regulations, importation requirements and seafood marketing trends in the United States.

My contribution to the workshop was to provide practical information on importing seafood products into the U.S., and meeting the new HACCP requirements for importers.

India:

Of the three workshops given on this trip, the workshop in India was the only one day event. This shortened venue necessitated an abbreviated presentation by all the members of the 'team'. As a result, I thought the participants were given a lot of good concise information in a full day of presentations. While many questions were asked, I thought there might be more questions asked had time allowed. Unfortunately, there was not enough time for a formal one-on-one session afterwards. I think that the participants would have benefited from a one-on-one session had there been the time.

While in India we were accompanied by and visited the following people: P. Bhaskaran Nair with Export Inspection Agency, K.B. Pillai with the Marine Products Export Development Authority, Felipe Manteiga with U.S.AID. We had the pleasure of visiting a shrimp farm to the south of Cochin, and a shrimp processor (CAP Seafoods) on Vypeen Island.

Singapore:

Because of political unrest it was decided to not participate in the planned workshop in Dhaka, Bangladesh. As a result we traveled directly to Singapore instead. While in Singapore, we had the opportunity to visit the Southeast Asian Fisheries Development Center (ASEAN) Post Harvest Technology Project - Phase II and meet with the Project Manager Leonard Limpus and others. We toured their food technology labs and observed some of their materials that they are developing. The ASEAN group have created some informative materials to help the seafood industry (primarily processors) develop HACCP plans and Good Manufacturing Practices in Southeast Asia.



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Indonesia:

This workshop was a two day event. We had more time than in India to give our entire presentation, and allowed for sufficient time for questions afterward. There was an one-on-one opportunity between attendees and the 'team' at the end of the presentations. Unfortunately I was not able to attend this one-on-one session, so I can not comment to its success.

There were no outside tours of processing facilities while in Indonesia.

Philippines:

Similar to Indonesia this was a two day venue with plenty of time for our presentations and discussion afterwards. While there weren't many questions asked after each presentation, the one-on-one discussions proved to be very good chance for exchange of information and ideas between attendees and the 'team'.

My one-on-one discussions consisted of quickly reviewing two HACCP plans that participants had brought with them and reviewing the sources (telephone/FAX/internet addresses) for regulations, Import Alerts/Detentions, and Govt. Printing Office material. One individual requested information on Laboratory Guidelines on analyzing seafood products.



**Final Report for Southeast Asia Workshop
Prepared by Howard Johnson**

H. M. JOHNSON & ASSOCIATES*Information and Analysis for Decision-Makers*

MARKETING
 MARKET RESEARCH
 NEW PRODUCT DEVELOPMENT

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 BELLEVUE, WA 98015-3146
 (206) 747-2757
 FAX (206) 747-2672

April 15, 1996

Elizabeth Turner
 Executive Director
 SUSTAIN
 1400 16th Street NW, Suite 241
 Washington, DC 20036

Dear Elizabeth:

Thank you for your letter of April 10 and my apologies for not responding sooner regarding the HACCP workshops. Upon returning from the Asian trip I had to go to central Mexico on business.

I am enclosing a copy of the slides I presented as well as a handout that was made available to all attendees. In addition, I am attaching a copy of the cards I picked up along the way. I hope this letter will suffice as a "report" in that my presentation did not deal specifically with HACCP. However, I did feel that the participants in all countries were interested in my remarks and I fielded a number of marketing-related questions. Since the audience for the workshops consisted of government representatives and quality control individuals the subject of seafood marketing may have been outside their area of expertise or interest.

My general view of the countries we visited is that they are not ready for the imposition of HACCP and most likely many will not be ready by the December 1997 deadline. While the various government entities we met with were interested in letting us know where they stood, we learned little of the actual preparedness of industry. The only processing plant we visited on the entire trip was in India. My sense is that the impetus for HACCP will come from concerned U.S. importers wanting to insure continued sources of supply. These importers will try and identify technical assistance which can get these companies HACCP certified. I don't believe the individual governments will be in a position to provide the certification....to the satisfaction of FDA.

India

In India we were hosted by the Export Inspection Agency and met also with officials from the Marine Products Export Development Authority and the Central Institute of Fisheries Technology. India has no shortage of government agencies involved in fisheries. Still, the problems facing the Indian seafood industry, particularly shrimp, are many. For openers, the about-to-be-imposed embargo on shrimp from countries without turtle-exclusion devices will have a tremendous impact on India. The HACCP team was instructed not to discuss

this subject but many individuals had questions and concerns on this issue. Also, the main problem for Indian shrimp is that much of the product is initially handled on unsanitary vessels, then pre-processed in "peeling sheds" which are wide open to contamination.

Indonesia

Participants in Indonesia seemed only moderately concerned about HACCP. This may be because most of Indonesia's shrimp currently goes to Japan and the tuna operations in the country are most likely closer to HACCP certification. Of the 60 attendees in Jakarta 21 indicated their company had some form of HACCP program underway (although only 5 indicated they had personally had some HACCP training).

Some of the HACCP-related problems noted in Indonesia were the problem with infrastructure (transportation) and conflicts between religious practices and personal hygiene requirements for food handlers.

Marketing questions which came up following the formal presentation focused on the tuna market in the United States, the turtle-exclusion issue and the potential for marketing milkfish in the U.S. (see attached letter).

Philippines

The workshop in Manila was the smallest in attendance and "energy," although the participants seemed to be more technically oriented. I got the feeling the workshop attendees were looking for more specifics regarding HACCP and less "chapter and verse" regarding regulations.

My overall impression is that if companies in Asia are going to become HACCP certified it will be through "one-on-one" interaction with experts from the U.S. and not through local government mandates. On the other hand, my own research indicates that more and more countries are starting to look at internal and regional markets for seafood. In some cases, these markets may become more viable not only because of perceived difficulty in complying with U.S. regulations, but also because of developing economies in the region. Also, some countries, such as the Philippines, are now experiencing seafood "shortfalls." In such cases, what is needed is more aquaculture training in addition of moving toward sustainable fisheries rather than exploitative harvest programs.

Again, my apologies for the brevity of this "report." I can assure you I thoroughly enjoyed participating in this program and trust that I was able to convey some useful information to the participants.

Sincerely,

Howard M. Johnson
H.M. Johnson & Associates

cc: Mike Wehr, TAS, Inc.

APPENDIX 2

India Itinerary and Workshop Agenda

Itinerary of local visits

| | | | | |
|------------|---------------------|-----------------------------------|---------------|------|
| 11.03.1996 | Arr. | Cochin Airport (I/C 467) | 13.45 | hrs. |
| | Dep. | Cochin Airport | 14.00 | " |
| | Arr. | Taj Malabar | 14.15 | " |
| | Dep. | Taj Malabar | 15.00 | " |
| | Arr. | EIA-Lab, Thoppumpady | 15.15 | " |
| | | Laboratory visit | 15.15 - 17.15 | hrs. |
| | Dep. | EIA-Lab. | 17.15 | " |
| | Arr. | Taj Malabar | 17.30 | " |
| 17.03.1996 | Dep. | Taj Malabar | 12.00 | " |
| | Arr. | Abad Plaza | 12.30 | " |
| | | Lunch | 12.30 - 14.00 | hrs. |
| | Dep. | Abad Plaza | 14.00 | " |
| | Arr. | Fine Arts Hall Jetty | 14.15 | " |
| | Dep. | Fine Arts Hall Jetty | 14.20 | " |
| | Arr. | Taj Malabar Jetty | 14.30 | " |
| | Dep. | Taj Malabar Jetty | 14.35 | " |
| | Arr. | Fish processing facility | 14.45 | " |
| | | Visit to fish processing facility | 14.45 - 16.45 | hrs. |
| | Dep. | Fish processing facility | 16.50 | " |
| | Boating | 16.50 - 19.00 | hrs. | |
| | Back to Taj Malabar | 19.00 | " | |
| 18.03.1996 | Dep. | Taj Malabar | 11.00 | " |
| | Arr. | MPEDA | 11.30 | " |
| | | Discussion with MPEDA Officials | 11.30 - 13.00 | hrs. |
| | | Lunch | 13.00 - 14.30 | hrs. |
| | | Shopping (if required) | 14.30 - 16.30 | " |
| | Dep. | To Taj Malabar | 16.30 | " |
| | Arr. | Taj Malabar | 17.00 | " |
| | Dep. | Taj Malabar | 17.30 | " |
| | Arr. | Chandiroor | 18.30 | " |
| | | Visit to fish farm and dinner | 18.30 - 20.30 | hrs. |
| | Dep. | Chandiroor | 20.30 | " |
| Arr. | Taj Malabar | 21.30 | " | |

(Dr. Frank MacKeith-
joins)

--: 2 :--

| | | | |
|------------|-------------------------|---------------|------|
| 19.03.1996 | Dep. Taj Malabar | 08.30 | hrs. |
| | Arr. Abad Plaza | 09.00 | " |
| | Seminar | 09.30 - 17.30 | hrs. |
| | Dep. Abad Plaza | 18.00 | " |
| | Arr. Taj Malabar | 18.30 | " |
| | Dep. Taj Malabar | 19.00 | " |
| | Arr. Abad Plaza | 19.30 | " |
| | Dinner | 19.30 - 21.00 | hrs. |
| | Dep. Abad Plaza | 21.00 | " |
| | Arr. Taj Malabar | 21.30 | " |
| 20.03.1996 | Dep. Taj Malabar | 11.00 | " |
| | Arr. Cochin Airport | 11.15 | " |
| | Leave Cochin by I/C 468 | | |

Cochin - IndiaATTENDANCE: APPROX 70 paid REGISTRANTS
+ U.I.P.S.SEMINAR ON HACCP

Date : 19 March 1996

Venue : Grand Ball Room
Hotel Abad Plaza
Cochin - 682 035

Time : 09.30 Hours

INAUGURAL PROGRAMME

Invocation

Welcome Address

Mr. S. Lakshmikanthan
Acting Director (Insp. & Q/C)
Export Inspection Council of India
New Delhi

Presidential Address

Mr. K.B. Pillai, IAS
Chairman
Marine Products Export Development Authority
Cochin

Address by

- (1) Mr. C. Cherian - absent.
President
Seafood Exporters' Association of India
Cochin
2. Dr. K. Gopakumar
Director
Central Institute of Fisheries Technology
Cochin
3. Dr. Pai Panandikar
Confederation of Indian Food Trade &
Industry, New Delhi
4. Mr. Filipe Manteiga
U.S. Agency for International
Development, New Delhi

Inaugural Address

Dr. K.G. Adiyodi
Vice Chancellor
Cochin University of Science & Technology
Cochin

Vote of thanks

Mr. P. Bhaskaran Nair
Joint Director
Export Inspection Agency-Cochin
Cochin

BEST AVAILABLE COPYSEMINAR ON HACCP

Date : 19 March 1996

Venue : Grand Ball Room
Abad Plaza
Cochin, IndiaProgramme

| <u>Time (hours)</u> | <u>Session</u> | <u>Presenter</u> |
|---------------------|---|---|
| 08.30-09.30 | Registration | |
| 09.30-10.15 | Inaugural Ceremony | |
| 10.15-10.45 | Tea | |
| 10.45-11.30 | HACCP : An overview and its role in international food safety regulation | Dr. H. Michael Wehr, Director, International Food Standards, TMS, Inc, Washington, D.C. |
| 11.30-12.30 | The new US-FDA Seafood HACCP regulations | Dr. Frank Mackeith, International Programs, Center for Food Safety & Applied Nutrition, Food & Drug Administration, Washington, D.C. |
| 12.30-13.15 | LUNCH | |
| 13.15-14.15 | Food Safety Hazards of Regional Fish Species and their management under FDA Seafood HACCP | Mr. Richard Dees, President, Seafood Export Assistance (SEA), Washington, D.C. |
| 14.15-15.15 | Practical Information on Importing | Mr. Jonathan Little, Seafood Consultant, Surefish Company, Seattle, Washington. |
| 15.15-15.30 | Tea | |
| 15.30-16.15 | U.S. Seafood Market Trends | Mr. Howard Johnson, President, H.J. Johnson & Associates, Seattle, Washington. |
| 16.15-17.30 | Discussion & closing | |

Indonesia Workshop Agenda

SEAFOOD HACCP WORKSHOP, JAKARTA, Indonesia, March 25, 26, 1996.

WORKSHOP AGENDA

1st day

| | |
|---------------|--|
| 08.30 - 09.00 | <i>Registration</i> |
| 09.00 - 09.20 | Opening ceremonies - Key Note : President of Gappindo - Opening Address : Director General of Fisheries |
| 09.20 - 10.20 | Overview of HACCP Speaker : Dr. H. Michael Wehr Moderator : Dr. Josephine Wiryanti |
| 10.20 - 10.40 | <i>Break</i> |
| 10.40 - 12.10 | The New U.S FDA Sea Food HACCP Regulations Speaker : Dr. Frank MacKeith Moderator : Dr. Josephine Wiryanti |
| 12.10 - 13.00 | <i>Lunch</i> |
| 13.00 - 14.00 | Question and Answer |
| 14.00 - 15.30 | Food Safety Hazard of Regional Fish Species Speaker : Mr. Richard Deas Moderator : Dr. Sunarya |
| 15.30 - 16.00 | <i>Break.</i> |
| 16.00 - 17.00 | Question and Answer |

2nd day

| | |
|---------------|--|
| 09.00 - 10.00 | Current US Market Information and Trends for Fishery Product Speaker : Mr. Howard Johnson Moderator : Burhanudin Lubis, MSc. |
| 10.00 - 11.00 | Practical Information on Importing Fishery Product Speaker : Mr. Jonathan Little Moderator : Burhanudin Lubis, MSc. |
| 11.00 - 11.15 | <i>Break</i> |
| 11.15 - 12.45 | Open Discussion and Wrap-up Moderator : Burhanudin Lubis, MSc. |
| 12.45 - 13.45 | <i>Lunch</i> |
| 13.45 - 14.45 | One on One Discussion Between Attendees and Expert Presenters |
| 14.45 - 15.00 | Break and Closing Ceremonies |

2-11

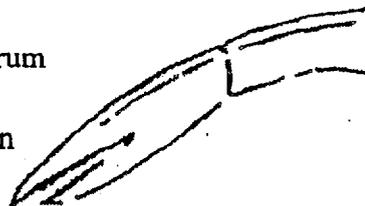
Philippines Workshop Agenda

program



5:00 pm - 5:15 pm
5:15 pm - 5:45 pm
5:45 pm - 6:45 pm
6:45 pm - 7:30 pm
7:30 pm - 8:30 pm

Open Forum
Recap
Reception
Dinner



Current U.S. Market Information
and Trends for Fishery Products
Mr. Howard Johnson
President
H.M. Johnson & Associates

8:30 pm - 9:00 pm

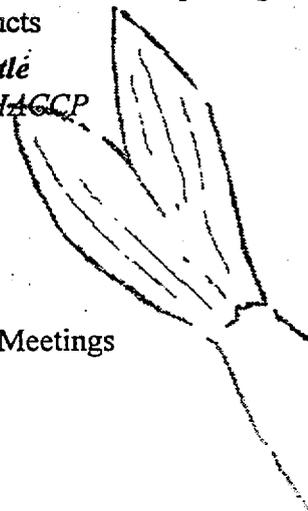
Open Forum

March 29, 1996

8:00 am - 9:00 am
9:00 am - 10:30 am

Registration
Practical Information on Importing
Fishery Products

Mr. John Little
Consultant, HACCP



10:30 am - 10:45 am
10:45 am - 11:00 am
11:00 am - 12:00 nn

Break
Open Forum
Lunch

Afternoon

One-on-One Meetings

New HACCP Regulations Planning Session
29 March 1996
Traders Hotel Manila

A G E N D A

1. Rationale / Objective of the Planning Session
2. Review of US FDA Seafood HACCP Workshop
3. Brainstorming on Plan of Action for Local Implementation of the New HACCP Regulations
 - 3.1 Information Needs
 - 3.2 Resource Needs
 - 3.3 Timetable
4. Others

APPENDIX 3

Primary Contacts: India

Gram : SHIPMENTQUALITY PHONE : 361465 PMBX
 Telex : 0885-6277 : 353210 DIRECT
 Fax : 091-0484-366375 : 315564 RESIDENCE

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P. BHASKARAN NAIR
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Dr. P.U. VERGHESE
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US - FDA SEAFOOD HACCP REGULATIONS WORKSHOP

March 28-29, 1996

Traders Hotel Manila

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APPENDIX 4

**Minutes of the Meeting for the
USFDA HACCP Seafood Regulations Planning Session
29 March 1996, Manila**

BEST AVAILABLE COPY

PRLD Form No.

FOUNDATION FOR RESOURCE LINKAGE & DEVELOPMENT, INC.
5th Floor Agustin I Bldg., Emerald Ave., Ortigas Center, Pasig, MM

FACSIMILE TRANSMITTAL

DATE April 8, 1996 NO. OF PAGES INCLUDING THIS PAGE 7
 TO DR. MICHAEL WEHR
 COMPANY TAS
 ADDRESS WASHINGTON D.C., USA
 FAX NO. (001) 202-387-FMIL TEL NO. _____
 FROM MR. SALVADOR SALACUD
 COMPANY FALD
 ADDRESS PASIG CITY, PHIL.
 FAX NO. (0663) 2-633-4627 TEL NO. _____
 REFERENCE minutes of the meeting



FOUNDATION FOR RESOURCE
LINKAGE AND DEVELOPMENT, INC.

5th Floor, Agustin I Building
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Tel. Nos.: (632) 631-3354 to 56
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08 April 1996

H. MICHAEL WEHR, Ph.D.
Director
International Food Standards
Technical Assessment Systems, Inc.
The Flour Mill
1000 Potomac St., N.W.
Washington, D.C. 20007

Dear Dr. Wehr:

Thank you for your letter dated 05 April. In behalf of the Foundation, I would like to extend our appreciation to your group for the experience and expertise you have shared with the participants.

Meanwhile, as agreed during the planning session, we are forwarding herewith a copy of the minutes of the meeting for your information.

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We trust that this will only be the start of a fruitful business relationship with you. We look forward to working with you again in the future.

Thank you very much.

Very truly yours,

Salvador S. Salacup
SALVADOR S.M. SALACUP
 General Manager

Projects:

MARTLINK
 MARKET LINKAGE DEVELOPMENT

MARID
 MARKET INFORMATION DISEMINATION

MARTPROM
 MARKET PROMOTION

**USFDA HACCP SEAFOOD REGULATIONS
 PLANNING SESSION**

**Minutes of the Meeting
 Traders Hotel Manila
 29 March 1996**

ATTENDANCE :

- | | | |
|-----|-----------------------|---|
| 1. | Ms. Carmina Parce | Bureau of Food and Drug |
| 2. | Dr. Alicia Lustre | Food Development Corporation |
| 3. | Mr. Vicente Lim Jr. | Phil. Chamber of Food Manufacturers |
| 4. | Mr. Salvador Salacup | Foundation for Resource Linkage & Devt. |
| 5. | Dr. Michael Wehr | Technical Assessment Systems |
| 6. | Dr. Franklin MacKeith | US Food and Drug Administration |
| 7. | Mr. Jonathan Little | Surefish |
| 8. | Mr. Antonio Roces | Foundation for Resource Linkage & Devt. |
| 9. | Mr. Howard Johnson | H.M. Johnson and Associates |
| 10. | Mr. Richard Dees | SEA |
| 11. | Ms. Gerrah Aquino | Foundation for Resource Linkage & Devt. |
| 12. | Ms. Myra Moral | Foundation for Resource Linkage & Devt. |

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MINUTES

I. Call to Order

The meeting was called to order by Mr. Vicente Lim, presiding officer, at 7:00 PM.

II. Approval of the Agenda

The agenda was presented and duly approved. The agenda was as follows:

1. Rationale/Objective of the Planning Session
2. Review of US FDA Seafood HACCP Workshop
3. Brainstorming on Plan of Action for Local Implementation of the New HACCP Regulations
 - 3.1 Information Needs
 - 3.2 Resource Needs
 - 3.3 Timetable
4. Other Matters

III. Matters for Discussion

As a start, *Mr. Lim* asked *Dr. Wehr* to give his evaluation of the workshop. According to *Dr. Wehr*, the workshop was a success in terms of attaining its objective of imparting to the local participants the need for a HACCP plan. He also commended the interest and enthusiasm of the participants during the one-on-one discussion. Lastly, he appreciated the preparation and organization done for the workshop.

Mr. Lim questioned the body as to whether the group would like to have the private sector or a government regulatory body as lead party in the local implementation of the HACCP program.

Dr. Wehr mentioned that in order to answer the above, the group should realize that, presently, there are limited local resources available and that the implementation would require budgets. Hence, he suggested that there might be a need for co-sharing between the FDA and the Philippine government.

He also brought up the possible need to bring to Manila the Seafood Alliance Course or a Trainor's Training which could be done in conjunction with SEAFDEC.

Dr. MacKeith, on the other hand, suggested that, as an alternative, the Philippines could also send trainees to the US to be trained on the above courses.

medium processors were not represented in the workshop.

Mr. Dees is of the opinion that the industry alone cannot do it. While the processors/exporters should understand the need for sanitation, it is either the market or the government who should "push" them to adopt the HACCP program. The government should provide technical assistance and establish it standard.

Dr. Wehr added that if a local processor/exporter would like to enter the foreign market, particularly the US, then he should be HACCP-ready. Thus, he suggested that an assessment might be necessary to evaluate the readiness of the industry to adopt the HACCP program.

Ms. Parce volunteered the information that the big companies, like San Miguel, have already started with their own HACCP plan. However, for it to be practiced widely, both the government and the industry should be trained.

Mr. Lim pointed out that, at present SMEs put their resources on product development, rather than on good GMP (Good Manufacturing Practice).

Dr. Lustre referred to a previous situation wherein the "shotgun" did not come from the government, but from the market (buyers). Another form of "shotgun" is forced implementation which would come from the government.

Thus, she stressed that there are two tasks ahead of the industry: 1) to get the "shotgun" felt by the industry, and 2) to get the training needed.

Mr. Dees mentioned that one of the questions also raised during the one-on-one consultation is how to get good raw materials.

Mr. Little opined that in order to have good raw materials, quality control should start from the source.

However, *Dr. Wehr* also mentioned that quality control should also be supported by infrastructures (roads, etc.). Hence, support from ADB and WB might be needed along these areas.

Going back to the issue on "shotgun", *Mr. Roces* re-affirmed that the best "shotgun" is the market. He further cited a situation in tuna before wherein producers were forced to put their acts together when the importers enforced the ruling on histamine content. He believes that this is something that will happen again; this time, the "shotgun" is the December 18, 1997 target of FIDA to enforce the new HACCP regulations. He also mentioned that one strategy that can be adopted is the use of comparable scenarios for

the profit and loss effect on a company whose imports were accepted, and on a company whose imports were detained).

Mr. Lim agreed that the big companies can influence the small-medium ones, as well as, supply.

At this point, *Mr. Roces* posed the question as to which agency or unit of government should take the lead.

Dr. Wehr agreed that this matter should be settled, and in particular, the following: 1) get a consensus on what actions to take, and 2) who makes the proposal to whom.

In addition, the repository of all these information should be identified, according to *Mr. Lim* and he suggested the Food Development Center. He elaborated that the FDC has done it in the past and has an existing MOU with the US FDA. Further, FDC is more accessible to the private sector. This arrangement, as mentioned by *Mr. Lim*, would get the endorsement of the Food Chamber.

In support of the above, *Dr. Wehr* mentioned that he, on their end, can work out something along the lines of an aid.

In this, *Mr. Lim* volunteered that both FRLD and PCFMI could serve as links to the private sector.

At this point, *Dr. Wehr* brought up again the Seafood Alliance Course. His idea is for it to be a 3 to 4 day course with lectures and workshop. He also suggested that it might be a good idea for the government to select key individuals, both from private companies and government agencies, to form a core group to be trained as trainers.

Further, *Mr. Dees* noted that each company has a different need and within the company, there are different levels of HACCP needs. Henceforth, the course should address these needs.

Mr. Johnson gave his analysis of the situation from a marketing point of view. For him, it is a "push-pull" scenario. The "push" is the "shotgun" coming from the government side, while the "pull" is the one coming from the importers side, ie. importers inquiring on the HACCP-readiness of the exporters.

Dr. Lustre inquired if an audit on HACCP-ready companies is conducted, is it possible to issue certificates (similar to ISO).

As a follow-up, *Mr. Dees* inquired whether a third party accreditation would help the importers.

To which, *Dr. Wehr* answered that there should be a certified, credible and independent third party accreditation.

Mr. Lim also broached the idea of involving the academe in future plans and strategies.

As a recap, the group agreed on the following:

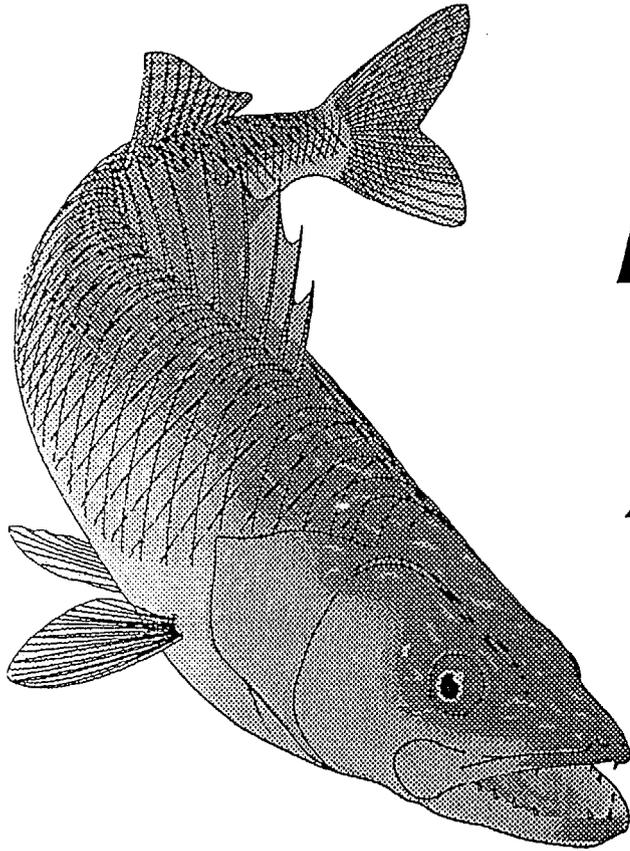
1. FRLD to send minutes of the meeting to Dr. Wehr by 1st week of April
2. Dr. Wehr to inform FRLD to whom to address the proposal for strategies and action plans
3. FRLD and FDC to come up with strategic plans to gain backing for funds

The meeting was adjourned by *Mr. Lim* resolving that a meeting with FDC be set in the 3rd week of April.

SB

APPENDIX 5

Selected Presentation Materials: H. Michael Wehr



U.S. Seafood HACCP Regulatory Workshop

***Asia Regional Agribusiness Project
U.S. Agency for International
Development***

In Cooperation With:

- *U.S. Food and Drug Administration*
- *SUSTAIN (Sharing United States Technology to AID in the Improvement of Nutrition)*
- *USDA FAS International Cooperation and Development*
- *Development Alternatives, Inc.*
- *TAS, Inc.*

TAS

Hazard Analysis and Critical Control Point (HACCP) (1)

- Systematic approach used in food production to ensure food safety
- Involves a systematic study of the ingredients, the food product, the conditions of processing, handling, storage, packaging, distribution and consumer use to see:
 - *where the potential hazards are that could lead to an unsafe product;*

Hazard Analysis and Critical Control Point (HACCP) (2)

- (Continued)
 - *where the points are that must be controlled to prevent a problem;*
 - *what the limits are for these points;*
 - *what is the monitoring, documentation and follow-up that must be done to keep the system working properly.*

HACCP Principles (1)

- Conduct a hazard analysis
- Identify the critical control points (CCPs) in the process
- Establish critical limits for preventative measures for each CCP
- Establish CCP monitoring requirements and procedures for using the results of monitoring to adjust process and maintain control

HACCP Principles (2)

- Establish corrective action to be taken when monitoring indicates that there is a deviation from a critical limit
- Establish recordkeeping procedures to document the HACCP system
- Establish procedures for verification that HACCP is working correctly

HACCP

Prerequisite Program Elements (1)

- Premises - outside property, buildings, sanitary facilities, water quality
- Receiving and storage - raw materials, ingredients, packaging materials
- Equipment performance - design, installation, maintenance

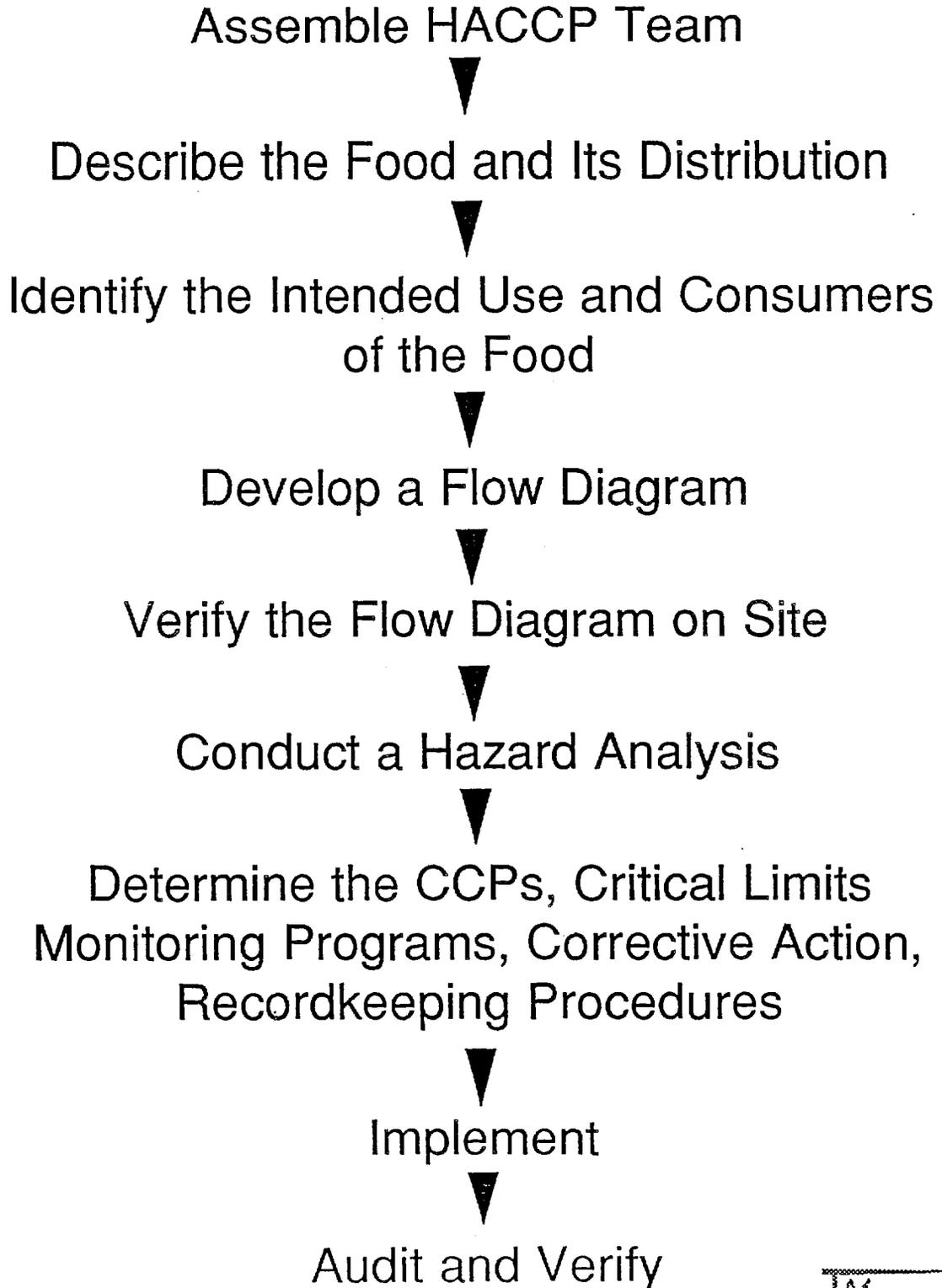
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HACCP

Prerequisite Program Elements (2)

- Personnel training
- Sanitation and pest control
- Health and safety recall
- Vendor, contract packer, manufacturer specifications
- Food safety associated with good manufacturing practices

HACCP Process



TAS

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HACCP Step 1: Assemble HACCP Team

- Representatives from:
 - *Production*
 - *Sanitation*
 - *Quality Assurance*
 - *Engineering*
- HACCP expert

HACCP Step 2: Describe Product

- Name
- Ingredients
- End-product characteristics (pH, water activity)
- How it will be used (ready-to-eat, cooked)
- Type of packaging
- Shelf life
- Where it will be sold
- Labeling
- Shipping, distribution controls

HACCP Step 3: Identify Intended Use

- Normal consumption
- Consumed by sensitive groups
(infants, elderly, immunologically compromised)

HACCP Step 4: Create Flow Diagram

- Ingredient, packaging material flow
- Product flow
- Employee movement/traffic flow

HACCP Step 5:

Verify Flow Diagram on Site

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HACCP Step 6: List Hazards Associated With Each Step (Principle No. 1)

- Hazards are biological, chemical, physical properties that may cause a product to be unsafe for consumption
- Process:
 - *Review each incoming material/ingredient*
 - *Review each and every step of the processing, storage and distribution*
 - *Observe actual practices*
 - *Take measurements*

HACCP Step 6: List Hazards Associated With Each Step (Principle No. 1)

- (Continued)

- *Ask questions*

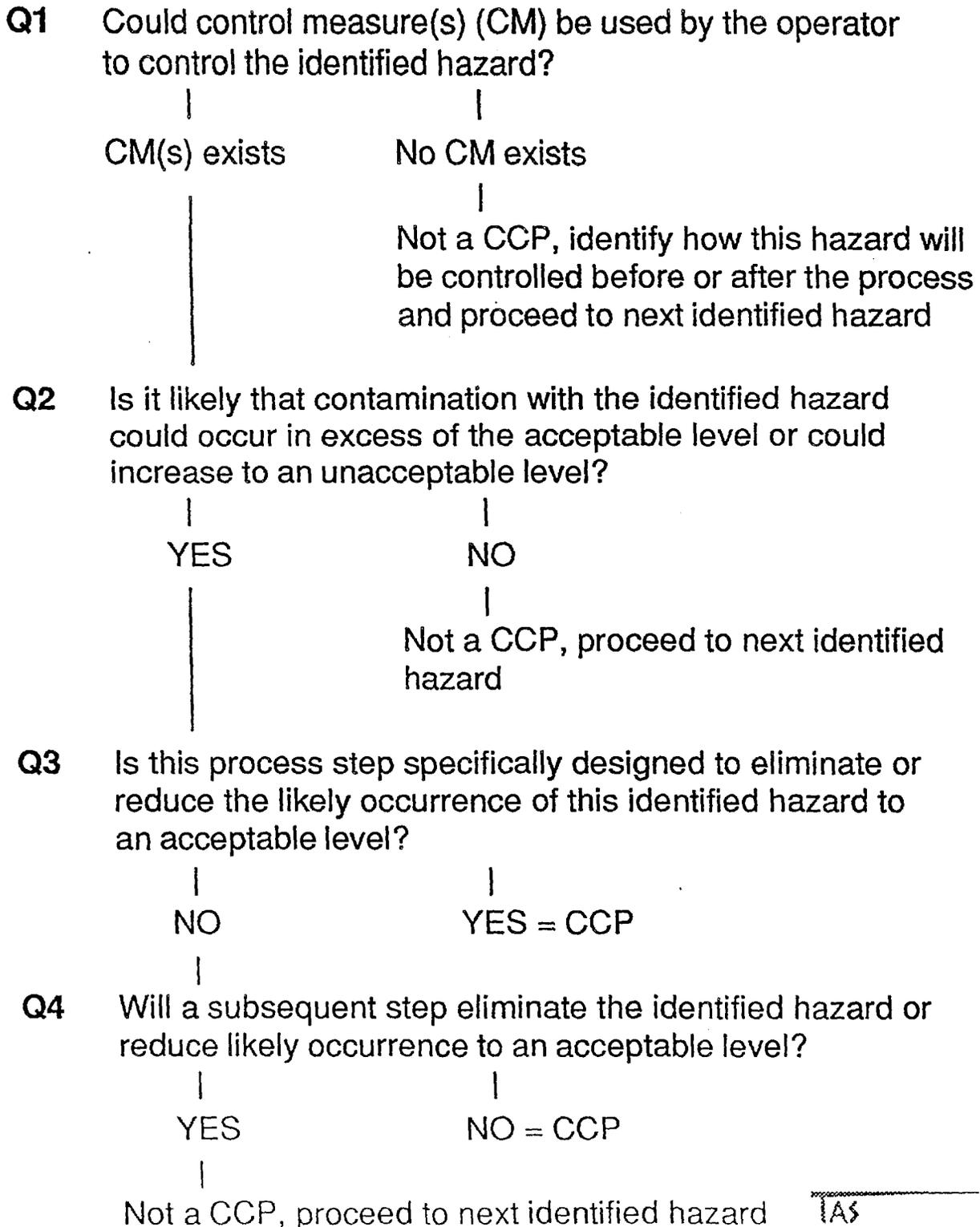
- Could pathogenic microorganisms, toxins, chemicals or physical objects be present?
 - Are returned/reworked products used as ingredients?
If yes, is there a hazard associated with that practice?
 - Are preservatives or additives used to kill microorganisms or inhibit their growth?

HACCP Step 7:

**Determine the Critical Control Points
Through a Decision-tree Process
(Principle 2)**

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Decision Tree



HACCP Step 8: Establish the Critical Limits (Principle No. 3)

- Establish limits for each CCP
- Limits may be governmental requirements or internal specifications

HACCP Step 9: Establish Monitoring Procedures (Principle No. 4)

- Planned sequence of observations or measurements to assess whether a CCP is under control and within established critical limits.
- Monitoring procedures should be rapid; preferably in-line:
 - *Temperatures*
 - *Time*
 - *pH*
 - *Moisture*
 - *Metal detection*

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HACCP Step 10: Establish Corrective Action Procedures (Principle No. 5)

- Deviation is a failure to meet specified critical limits
- Written procedures must be in place specifying the corrective action that will be taken when a critical limit is exceeded
- Immediate action taken by the operator, according to written plan, when critical limit is exceeded during processing

HACCP Step 11: Establish Verification Procedures (Principle No. 6)

- Procedures used to verify HACCP plan are correct and functioning properly
- Involves:
 - *Actual observation of defined procedures*
 - *Product sampling/Testing*
 - *Internal or external audits*
 - External audit may include compliance audits by regulatory authorities
 - *Periodic review of entire HACCP plan by HACCP team*

IAS

HACCP Step 12: Establish Recordkeeping Documentation (Principle No. 7)

HACCP records include:

- HACCP plan itself
- Plant records done at each CCP to ensure that HACCP plan is followed and critical limits are met
- Records of corrective actions

Recommendations of FAO Technical Meeting on HACCP (1)

- The use of HACCP serves to improve food safety control and should be applied on that basis.
- . . . food safety policies by governments and international agencies should use risk analysis as the basis for establishing food safety priorities.
- Governments should provide leadership in implementing HACCP, provide an infrastructure for its uniform application by industry (to include appropriate regulations and verifications of compliance, research, training, industry guidelines . . . and the assessment of pilot programs.

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Recommendations of FAO Technical Meeting on HACCP (2)

- . . . Governments should accept the challenge of eliminating any constraints associated with the implementation of HACCP in all segments and sectors of the food chain, particularly, statutory and regulatory requirements, administrative procedures, and other requirements which negatively impact on HACCP implementation.
- The ability of an industry segment . . . to support or implement HACCP must be considered in terms of . . . prerequisite programs. If . . . prerequisite programs are inadequate, they must be addressed first.

Recommendations of FAO Technical Meeting on HACCP (3)

- While recognizing that HACCP is applicable to all segments . . . of the food chain, governments should accept that HACCP implementation should be guided by scientific evidence of unacceptable public health risk.
- In the post-Uruguay round of GATT, Codex should recognize the importance of its role in harmonizing and establishing food standards, guidelines and recommendations, particularly, as they relate to safety of food in international trade.

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Selected Presentation Materials: Frank MacKeith

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U. S. Food and Drug Administration
Press Handout: December 5, 1995

THE PROVISIONS OF THE REGULATION THE SEAFOOD HACCP REGULATIONS

1. Coverage

a. All "processors"

- All seafood-related entities in our establishment inventory. All foreign processors that export to U.S.
- Exempt:
 - Fishing vessels
 - Common carriers
 - Retail

b. All importers

2. Hazard Analysis (HACCP PRINCIPLE #1)

a. Every "processor" must conduct a hazard analysis to determine whether they have likely food safety hazards that they must control.

- If no: they do not need a HACCP Plan for the time being (assuming they're right). They must reassess, however, whenever a significant change occurs.
 - If yes: they must have and implement a HACCP plan.
-

3. The HACCP plan

a. Where hazard analysis reveals need, every "processor" must have a written HACCP plan that's specific to location and kind of product.

b. HACCP plan must ID:

i. Food safety *hazards* that are reasonably likely to occur.

- These include anything that causes a food to be unsafe under the act, e.g., toxins, micro, chemicals, pesticides, drug residues, physical hazards, decomposition.

ii. *Critical control points* to control hazards that can occur both inside & outside the processing plant. (HACCP PRINCIPLE #2)

iii. *Critical limits* (i.e., safe operating parameters) for the ccp's. (HACCP PRINCIPLE #3)

iv. *Monitoring procedures*. (HACCP PRINCIPLE #4)

v. *Corrective action plans*, if any. (HACCP PRINCIPLE #5)

vi. *Verification procedures* to: (HACCP PRINCIPLE #6)

Two purposes:

- Ensure HACCP plan is up to date, at least annually.
- Ensure ongoing implementation is OK.

vii. *Recordkeeping* system to document monitoring, corrective actions, certain verification procedures. (HACCP PRINCIPLE #7)

c. *Signing/dating*: Plan must be signed/dated by a senior firm official. This must occur initially, upon modification, and at least annually.

4. Corrective Actions

Processors may either...

a. Follow *corrective action plans* they have developed in advance,

or

b. Do the following:

- Segregate & hold product while determining acceptability of product for distribution. (Must use person with adequate training or experience.)
 - Take necessary corrective action;
 - Check the plan to see if it needs to be modified; modify as necessary. (Must use trained individual.)
-

5. Verification

a. *Verifying the HACCP plan*: Processors must reassess adequacy of their HACCP plan at least annually or whenever a significant change occurs.

b. *Verifying ongoing activities*:

- i. Processors must follow written verification procedures that are in their HACCP plans for reviewing consumer complains, calibrating their monitoring devices, engaging in any end-product testing.
 - ii. Processors must review monitoring & corrective action records within one week of the creation of the records, and must review calibration & end-product testing records within a reasonable time.
 - iii. Processors must check whether their consumer complaints that allege safety problems reveal any problems with their HACCP systems that must be fixed.
-

6. Records

a. Monitoring and similar records must state the name & location of the processor, date & date, signature/initials of person making the record.

b. Records retention: processors must store records for 1 to 2 years, depending on type of record and type of product (i.e., shelf-life).

c. Plans, HACCP records, & sanitation records, must be available to FDA inspectors for review and copying. Consumer complaints are not available, but the consumer complaint SOP is available.

d. All plans & records in possession of FDA are deemed to be not available for public disclosure per FOIA regulations. Exceptions: 1) previously disclosed or abandoned materials; 2) discretionary disclosure in accordance with FDA's FOIA regulations.

7. Training

a. For each processor, certain enumerated HACCP functions must be performed by an individual who has been trained in HACCP through course materials or who through job experience that has provided knowledge equivalent to a course. The course must be at least equivalent to a standard curriculum recognized as adequate by FDA.

b. The enumerated functions are:

- Developing the HACCP plan or adopting a generic-type HACCP plan to fit the specific needs of a processor.
- Reassessing/modifying the HACCP plan as a result of verification activities and any corrective actions that occur.
- Reviewing HACCP records for adequacy.

c. Processors have a choice: they may either obtain training for one or more of their own employees, or they may hire trained independent contractors to perform these functions.

8. Sanitation

a. *Monitoring/Recordkeeping.* Processors must monitor and keep records in 8 enumerated areas of sanitation. Processors may establish their own monitoring frequencies. This monitoring and recordkeeping may be part of the processor's HACCP system or in a parallel system outside the HACCP plan. FDA has access to these records. The regulations recommend that processors have a sanitation SOP for the 8 enumerated areas, but it is not required.

9. Special Requirements for Imports

a. Importers must verify that their overseas suppliers follow HACCP. There are two ways to verify:

- i. Obtain product from a country with which the U.S. has a HACCP-based agreement re the equivalency of inspection programs.
 - ii. Implement verification procedures:
 - product specifications for safety.
 - affirmative steps to ensure that HACCP was actually practiced. Any of the following:
 - going overseas and checking;
 - obtaining processor's HACCP records;
 - obtaining processor's HACCP plan & a guarantee that it is being followed;
 - end-product testing & guarantee that plan is being followed
-

10. Special Requirement for Molluscan Shellfish

a. Controlling the origin of molluscan shellfish (i.e., properly classified waters) is most important preventive control for most hazards. Thus, the HACCP plans of processors of molluscan shellfish must include how this control is being performed, including how processor are only obtaining shellfish:

- From waters approved by a "shellfish control authority."
 - From harvesters who are in compliance with local licensure requirements.
 - If properly "tagged."
-

11. Special Requirement for Smoked Fish

a. Botulism is a significant likely hazard for this type of product if not sufficiently controlled. Thus, the HACCP plans of processors of smoked fish must include how they are controlling this hazard to ensure zero toxin production in the product for a time slightly beyond the shelf life of the product.

12. Time Frame for Implementation

a. The industry has two years to obtain training, write HACCP plans, install HACCP systems, engage in sanitation monitoring, etc. FDA is preparing to conduct voluntary, "dry run" HACCP inspections during this two year period. Full, mandatory implementation must occur by the end of this period.

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222. Kraemer, D., memorandum, "Unique Configuration of HACCP Plans," August 17, 1995.

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229. Final Regulatory Impact Analysis.

List of Subjects

21 CFR Part 123

Fish, Fishery products, Imports, Reporting and recordkeeping requirements, Seafood.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, title 21 CFR chapter I is amended as follows:

1. New part 123 is added to read as follows:

PART 123—FISH AND FISHERY PRODUCTS

Subpart A—General Provisions

Sec.

- 123.3 Definitions.
- 123.5 Current good manufacturing practice.
- 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.
- 123.7 Corrective actions.
- 123.8 Verification

123.9 Records.

123.10 Training.

123.11 Sanitation control procedures.

123.12 Special requirements for imported products.

Subpart B—Smoked and Smoke-Flavored Fishery Products

123.15 General.

123.16 Process controls.

Subpart C—Raw Molluscan Shellfish

123.20 General.

123.28 Source controls.

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379a, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 2421, 264).

Subpart A—General Provisions

§ 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) *Scombrotoxin-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

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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.

§ 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.

§ 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.

§ 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

§ 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 end-product 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.

§ 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

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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.

§ 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.

§ 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.

§ 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

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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

§ 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

§ 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

§ 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.

§ 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.

PART 1240—CONTROL OF COMMUNICABLE DISEASES

2. The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

3. Section 1240.3 is amended by revising paragraph (r), and by adding new paragraphs (s), (t), and (u) to read as follows:

§ 1240.3 General definitions.

(r) *Molluscan shellfish.* Any edible species of fresh or frozen oysters, clam mussels, and scallops or edible portion thereof, except when the product consists entirely of the shucked adductor muscle.

(s) *Certification number* means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) *Shellfish control authority* means 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 control and certification of molluscan shellfish processors.

(u) *Tag* means a record of harvesting information attached to a container of shellstock by the harvester or processor.

4. Section 1240.60 is amended by revising the section heading, to

redesignating the existing text as paragraph (a) and adding the word "molluscan" before the word "shellfish" the two times that it appears, and by adding new paragraphs (b), (c), and (d) to read as follows:

§ 1240.60 Molluscan shellfish.

* * * * *

(b) All shellstock shall bear a tag that discloses the date and place they were harvested (by State and site), type and quantity of shellfish, and by whom they were harvested (i.e., the identification number assigned to the harvester by the shellfish control authority, where

applicable or, if such identification numbers are not assigned, the name of the harvester or the name or registration number of the harvester's vessel). In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the same information.

(c) All containers of shucked molluscan shellfish shall bear a label that identifies the name, address, and certification number of the packer or repacker of the molluscan shellfish.

(d) Any molluscan shellfish without such a tag, shipping document, or label,

or with a tag, shipping document, or label that does not bear all the information required by paragraphs (b) and (c) of this section, shall be subject to seizure or refusal of entry, and destruction.

Dated: October 3, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc 95-30332 Filed 12-11-95; 10:40 am]

BILLING CODE 4160-01-P

Selected Presentation Materials: Richard Dees

Lists of
IMPORT ALERTS IN EFFECT
February 1996

Covering products entering U.S.

By type of Hazard or defect .

Shows product or species covered.

SEAFOOD



Lists of
IMPORT ALERTS IN EFFECT
February 1996

Covering products entering U.S.

By type of Hazard or defect .

Shows product or species covered.

Import Alerts February 1996

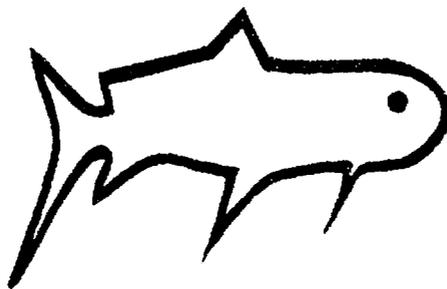
HISTAMINES

16-05

Mahi Mahi

16-105

Seafood



IMPORT ALERTS

FEBRUARY 1996

Salmonella



| | |
|--------|---------------------|
| 16-114 | Shrimp |
| 16-12 | Frog Legs |
| 16-17 | Raw Fish |
| 16-18 | Shrimp |
| 16-19 | Shrimp |
| 16-35 | Shrimp |
| 16-50 | Molluscan Shellfish |
| 16-81 | Seafood |

IMPORT ALERTS

FEBRUARY 1996

V. CHOLERA

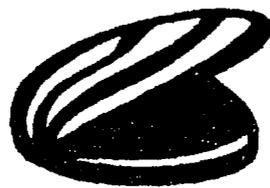
16-50 Molluscan Shellfish

Botulism

16-74 Cured Uneviscerated Fish

Listeria Mono.

16-39 Processed Seafood and Surimi



IMPORT ALERTS



February 1996

| | | |
|----------|--------|-------------|
| Sulfites | 99-21 | All Foods |
| Mercury | 16-08 | Swordfish |
| | 16-66 | Shark |
| Colors | 45-02 | All Foods |
| Borates | 16-94 | Seafood |
| | 16-108 | Caviar |
| Toxin | 16-20 | Puffer Fish |
| Label | 16-04 | Species |
| | 16-47 | Snapper |
| Lead | 99-12 | All Foods |
| Stevia | 45-06 | All Foods |
| Importer | 16-90 | All Foods |

IMPORT ALERTS

FEBRUARY 1996



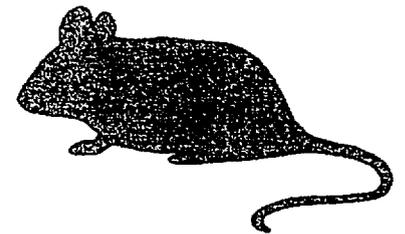
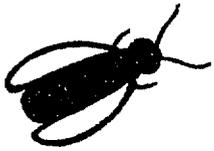
Decomposition

| | |
|--------|--------------------|
| 16-05 | Mahi Mahi |
| 16-09 | Kingfish |
| 16-105 | Seafood |
| 16-114 | Shrimp |
| 16-13 | Bagoong or Anchovy |
| 16-18 | Shrimp |
| 16-22 | Canned Shrimp |
| 16-23 | Lobster |
| 16-35 | Shrimp |
| 16-95 | Tuna |
| 37-03 | Shrimp Sauce |

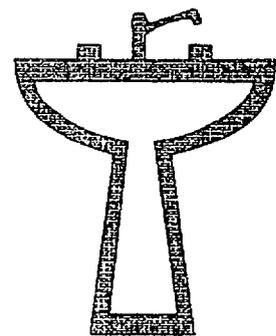
IMPORT ALERTS

FEBRUARY 1996

Filth



| | |
|-------|------------------------|
| 16-02 | Dried Shark Fins |
| 16-07 | Dried and Pickled Fish |
| 16-13 | Anchovy and Bagoong |
| 16-18 | Shrimp |
| 16-19 | Shrimp |
| 16-21 | Shrimp |
| 16-25 | Crabmeat |
| 16-35 | Shrimp |
| 99-03 | Importer |
| 99-06 | Company |



Lists of IMPORT ALERTS AND DETENTIONS

Showing product and Hazard or defect

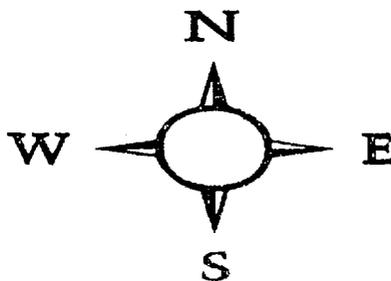
1. Import Alerts that apply to seafood from all source countries. (Feb 1996)
2. By specified country, those import alerts that apply by direction to product of that country.
3. By specified country, detentions of seafood from those countries that took place in January 1996 and June 1995.

105

IMPORT ALERTS ALL COUNTRIES

Feb 1996

- 16-02 Dr. Shark Fins and Maws
Automatic Detention Filth
- 16-04 All Seafood Guidance Sp. Substitution
- 16-05 Mahi Mahi Detain Histamines/Decomp
- 16-08 Swordfish Detain Mercury
- 16-19 Shrimp Guidance Salmonella/Decomp
- 16-20 Puffer Fish Detain Toxin
- 16-21 Raw Shrimp Guidance Filth
- 16-39 Surimi/Processed Guidance Listeria
- 16-74 Cured Unev. Fish Detain C. Botulism
- 16-90 Fz. Seafood Detain/Importer Salmonella
- 16-108 Caviar Guidance Borates
- 16-114 Fz. Shrimp Detain/Importer Salmonella
-
- 45-02 All Foods Detain/Guidance
Illegal/Undeclared Colors
- 45-06 All Foods Detain Stevia
-
- 99-12 All Foods Detain/Guidance Lead
- 99-21 All Foods Detain/Guidance Sulfites



BANGLADESH

Import Alerts

Feb. 1996

- 16-12 Frog Legs Detain Salmonella
1 firm exempt
- 16-18 Shrimp Detain Salmonella
Listed firms exempt Decomp.
Filth
- 16-81 Seafood Detain 2 firms Salmonella

DETENTIONS

Jan 1996 and June 1995

- 3 of Fz. Shrimp Salmonella
- 2 of Fz. Shrimp Salmonella/Decomp.

CHINA

IMPORT ALERTS

Feb 1996

- 16-12 Frog Legs Detain 2 firms Salmonella
 16-18 Shrimp Detain Except Listed Firms
 Decomposition
 16-81 Seafood Detain 5 Firms Salmonella
 45-02 All Food Detain 1 firm Color

DETENTIONS

Jan 1996 and June 1995

| | |
|--------------------------|--------------------|
| 1 of Imitation Crab | Labeling |
| 1 of Fried Fish Maw | Filth |
| 10 of Fz. Shrimp | Salmonella/Decomp. |
| 1 of Fz. Scallops | Additive |
| 9 of Fz. Shrimp | salmonella |
| 1 of Fz. Dace | Salmonella/Decomp |
| 1 of Fz. Scallop/Shrimp | Salmonella/Decom |
| 1 of Fz. Scallops | Other |
| 2 of Jellyfish | Filth |
| 1 of Oysters | Unfit |
| 2 of Shark Cartilage | Filth |
| 1 of Fz. Scallops | Filth |
| 4 of Fz. Scallops | Salmonella |
| 1 of Fz. Croaker | Decomposition |
| 1 of Fz. Mahi Mani | Histamine/Decomp |
| 7 of Fz. Scallops Shrimp | Decomposition |

FR. POLYNESIA

DETENTIONS

Jan. 1996 and June 1995

1 of Dr. Shark Fin

Filth

HONG KONG IMPORT ALERTS

Feb 1996

- 16-18 Shrimp Detain Except Listed Firms
Salmonella/Decomp/Filth
- 16-81 Seafood Detain 8 Firms Salmonella
- 37-03 Shrimp Sauce Detain 1 Firm Filth
- 99-21 Lobster Detain Sulfites

DETENTIONS

Jan 1996 and June 1995

| | |
|-----------------------|------------------|
| 1 of Fz. Shrimp | Decomposition |
| 1 of Perch Fillets | Decomposition |
| 2 of Salted Jellyfish | Filth |
| 2 of Shark Fins | Filth |
| 1 of Shrimp Sauce | Filth |
| 1 of Dr. Fish Lips | Filth |
| 2 of Dr. Fish Maw | Filth |
| 1 of Dr. Fried Pike | Filth |
| 1 of Dr. Sea Cucumber | Filth |
| 3 of Dr. Fish | Filth |
| 1 of Fz. Abalone | Decomposition |
| 1 of Fz. Catfish | Decomposition |
| 1 of Shark Fin Soup | Filth |
| 2 of Shrimp Sauce | Unfiled LACF |
| 1 of Fz. Shrimp | Salmonella/Filth |
| 2 of Fz. Shrimp | Salmonella |

INDIA

IMPORT ALERTS

FEB 1996

| | | | |
|-------|---------------------|-----------------------|-------------------|
| 16-09 | Fz. Kingfish | Detain 1 Firm | Decompositior |
| 16-12 | Frog Legs | Detain 1 Firm | Salmonella |
| 16-23 | Lobster | Detain Except 9 Firms | Decomp. |
| 16-35 | Raw & Cooked Shrimp | Detain | Filth |
| | | Except 69 Firms | Salmonella/Decomp |
| 16-81 | Seafood | Detain 7 Firms | Salmonella |

DETENTIONS

JAN 1996 AND JUNE 1995

| | |
|----------------------|--------------------|
| 1 of Fish Waste | Decomposed |
| 1 of Fz. Squid | Decomposed |
| 82 of Fz. Shrimp | Salmonella/Decomp. |
| 1 of Fz. Shrimp | Filth |
| 3 of Kingfish | Decomposed |
| 6 of Fz. Shrimp | Decomposed |
| 1 of Fz. Shrimp | Decomp/Filth |
| 1 of Grouper Fillets | Decomposed |
| 1 of Makerel | Labeling |

INDONESIA IMPORT ALERTS

Feb 1996

- 16-12 Frog Legs Detain 2 Firms Salmonella
- 16-18 Shrimp Detain Except Listed Firms
Salmonella/Decomposition/Filth
- 16-95 Canned Tuna Detain 1 Firm Decomp.

DETENTIONS

Jan 1996 and June 1995

- | | |
|----------------------|--------------------|
| 7 of Canned Tuna | Decomposition |
| 4 of Dr. Shark Bones | Filth |
| 1 of Fz. Shrimp | Decompositon |
| 4 of Fz. Shrimp | Salmonella/Decomp. |
| 1 of Swordfish | Mercury |
| 1 of Chunks Tuna | Decomposition |

JAPAN

IMPORT ALERTS

July 1996

16-39 Processed Seafood and Analogs
 Detain 5 Firms Listeria M.

DETENTIONS

Jan. 1996 and June 1996

| | |
|----------------------|-----------------|
| 1 of Dr. Scallops | Filth |
| 1 of Dr. Squid | Filth |
| 1 of Fz. Smelt Roe | Labeling |
| 1 of Fz. Dr. Fish | Listeria/Others |
| 1 of Canned Tuna | Unfiled/Unreg. |
| 7 of Dr. Fishes | Filth |
| 1 of Dr. Sardine | Labeling |
| 1 of Fz. Halibut | Decomp/Lblg |
| 1 of Dr. Mussel | Filth |
| 1 of Roasted Bonito | Labeling |
| 3 of Shark Cartilage | Filth |
| 1 of Shark Fins | Filth |

KOREA

IMPORT ALERTS

Feb 1996

- 16-39 Processed Seafood and Analogs
 Detain 15 Firms Listeria M.
- 16-81 Seafood Detain 2 Firms Salmonella
- 99-06 All Foods Guidance 1 Firm Filth

DETENTIONS

Jan 1996 and June 1995

- | | |
|--------------------|----------------|
| 1 of Fz. Shrimp | Decomposition |
| 1 of Fz. Snow Crab | Listeria/other |
| 1 of Baby Yellow | Filth |
| 1 of Dr. Alaska | Labeling |
| 1 of Dr. File Fish | Listeria |

MACAO

DETENTIONS

Jan 1996 and June 1995

1 of Fish Maw
1 of Fz. Shrimp

Filth
Salmonella

MALAYSIA

IMPORT ALERTS

Feb 1996

16-81 Seafood Detain 2 Firms Salmonella

DETENTIONS

Jan 1996 and June 1995

1 of Dr. Gouramy
2 of Salted Jellyfish

C. Botulinum
Filth

PHILIPPINES IMPORT ALERTS

Feb 1996

- 16-12 Frog Legs Detain 1 Firm Salmonella
- 16-13 Anchovy or Bagoong Detain
Decomp/E. Coli
- 16-81 Seafood Detain 6 Firms Salmonella
- 99-03 All Foods Guidance 1 Firm Filth

PHILIPPINES

IMPORT DETENTIONS

Jan 1997 and June 1995

| | |
|-------------------------|------------------|
| 1 of Tuna Bicol | Labeling |
| 2 of Sardines in Tom. | Unfiled LACF |
| 1 of Span. Sardines | Unfiled LACF |
| 1 of Sm. Herring | Listeria/Other |
| 1 of Sm. Round Scad | Listeria/Other |
| 4 of Canned Tuna | Decomposition |
| 1 of Shrimp Paste | Colors |
| 4 of Crispy Anchovies | Filth |
| 1 of Dr. Nemipterids | Filth |
| 1 of Fz. Baby Milkfish | Filth |
| 3 of Fz. Baby Milkfish | Labeling |
| 1 of Octopus | Salmonella |
| 1 of Patsi (Fish Sauce) | Labeling |
| 2 of Salted Shrimp Fry | Filth |
| 2 of Fz. Shrimp | Salmonella/Filth |
| 1 of Sm. Fish | Filth |
| 1 of Sm Milkish | Filth/Labe |
| 1 of Dr. Anchovies | C. Botulinum |
| 1 of Dr. Herring | Listeria/Other |
| 1 of Dr. Herring | C. Botulinum |
| 1 of Dr. Makerel | Filth |
| 1 of Dr. Tiny | Filth |
| 1 of Fish Sauce | Filth |
| 1 of Fz. Crevelle | Filth |
| 1 of Fz. Mudfish | Labeling |
| 1 of Salted Ziganid | Filth |

SINGAPORE IMPORT ALERTS

Feb 1996

16-81 Seafood Detain 5 Firms Salmonella

99-21 Fz. Shrimp Detain 1 Firm Sulfites

DETENTIONS

Jan 1996 and June 1995

3 of Sharkfin

4 of Swordfish Fillets

Filth

Mercury

TAIWAN

IMPORT ALERTS

July 1994

- 16-12 Frog Legs Detain 1 Firm Salmonella
 16-18 Shrimp Detain Except Listed Firms
 Salmonells/Decomp./Filth
 16-39 Processed Seafood & Analogs
 Detain 3 Firms Listeria M.
 16-81 Seafood Detain 4 Firms Salmonella
 16-95 Canned Tuna Detain 1 Firm Decomp.

DETENTIONS

July 1994 and June 1995

- 1 of Fish Paste Filth
 1 of Fz. Frog Legs Salmonella
 1 of Fz. Monkfish Labeling
 1 of Fz. Squid Decomposition
 1 of Dr. Fish Slice Filth
 1 of Fish Snack Labeling
 1 of Fried Fish Labeling
 21 of Fz. Mahi Mahi Salmonella
 and Decomp.
 4 of Fz. Mahi Mahi Decomposition

THAILAND

IMPORT ALERTS

Feb 1996

- 16-07 Dried & Pickled Fish Detain Filth
- 16-12 Frog Legs Detain 1 Firm Salmonella
- 16-17 Fz. Raw Fish Detain 18 Firms Salmonella
- 16-18 Shrimp Detain Except Listed Firms Filth
Salmonella/Decomposition
- 16-22 Canned Shrimp Detain except 6 firms
Decomposition
- 16-25 Canned Crabmeat Detain Except
9 Firms Filth
- 16-47 Red Snapper Detain Sp. Substitution
- 16-50 Molluscan Shellfish Detain 1 Firm
Salmonella/V. Cholera/Other
- 16-81 Seafood Detain 9 Firmss Salmonella
- 16-95 Canned Tuna Detain 1 Firm Decomp.
- 99-21 Fz. Shrimp Detain 1 Firm Sulfites

THAILAND DETENTIONS

Jan 1996 and June 1995

| | |
|----------------------------|-------------------|
| 1 of Seasoned Red Clams | Labeling |
| 1 of Sardines in Hot Sauce | Unfiled LACF |
| 3 of Canned Crabmeat | Decomp. |
| 2 of Canned Crabmeat | Filth |
| 16 of Canned Shrimp | Decomp. |
| 12 of Fz. Shrimp | Salmonella/Decomp |
| 8 of Fz. Shrimp | Salmonella |
| 5 of Canned Tuna | Decomp. |
| 2 of Topl Shell | Decomp. |
| 9 of Fz. Fish | Salmonella |
| 1 of Shrimp Paste | Filth/Labeling |
| 2 of Mackerel in Tom. | Unfiled/Unreg. |
| 1 of Salted Gouramy | Filth |
| 1 of Saba Fish in Chili | Unfiled/Unreg. |
| 1 of Snapper | Decomp. |
| 1 canned Abalone | Unfiled/Unreg. |
| 1 canned Calamari | Unfiled/Unreg. |
| 2 of Fish | Filth |
| 1 of Canned Fish Maw | Decomp./Filth |
| 1 of Canned Fish Maw | Unfiled/Unreg. |
| 1 of Fish Sauce | Labeling |
| 1 of Fz. Snapper | Substitution |
| 1 of Pickled Fish | Filth |
| 1 of Fz. Pilot Fish | C. Botulinum |

VIETNAM IMPORT ALERTS

Feb. 1996

16-81 Seafood Detain 14 Firms Salmonella

DETENTIONS

Jan 1996 and June 1995

| | |
|----------------------|--------------------|
| 1 of Fz. Salted Fish | Filth |
| 4 of Fz. Shrimp | Salmonella |
| 4 of Fz. Fish | Salmonella |
| 1 of Fz. Crabmeat | Unfit |
| 1 of Fz. Dr. Squid | Filth |
| 1 of Thread Fin Fish | Salmonella/Decomp. |
| 1 of Fish Sauce | Filth |
| 1 of Fz. Octopus | Filth |
| 1 of Fz. Shrimp | Decomposition |
| 1 of Fz. Lobster | Salmonella |

Selected Presentation Materials: Jonathan Little

Importation of Seafood Products into the US

Presented by Jonathan Little, HACCP Specialist

Surefish
Seafood Quality Specialists



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Importation of Seafood Products into the US

The Regulators

1. US Customs

- a) **Tariff Act of 1930 -- duties include: assessment and collection of all duties, taxes, and fees on imported merchandise, enforcement of customs and related laws, and the administration of certain navigation laws and treaties.**

2. Food and Drug Administration

- a) **Food, Drug, and Cosmetic Act -- requires that food be prepared, packed, and held under sanitary conditions; the food be safe, clean, and wholesome article; and its labeling to be honest and informative.**
- b) **Fair Packaging and Labeling Act -- prescribe the manner in which mandatory label information must appear on the label of food intended for retail sale**
- c) **Nutrition Labeling and Education Act of 1990 -- similar to the Fair Packaging and Labeling Act**

Requirements for the importer

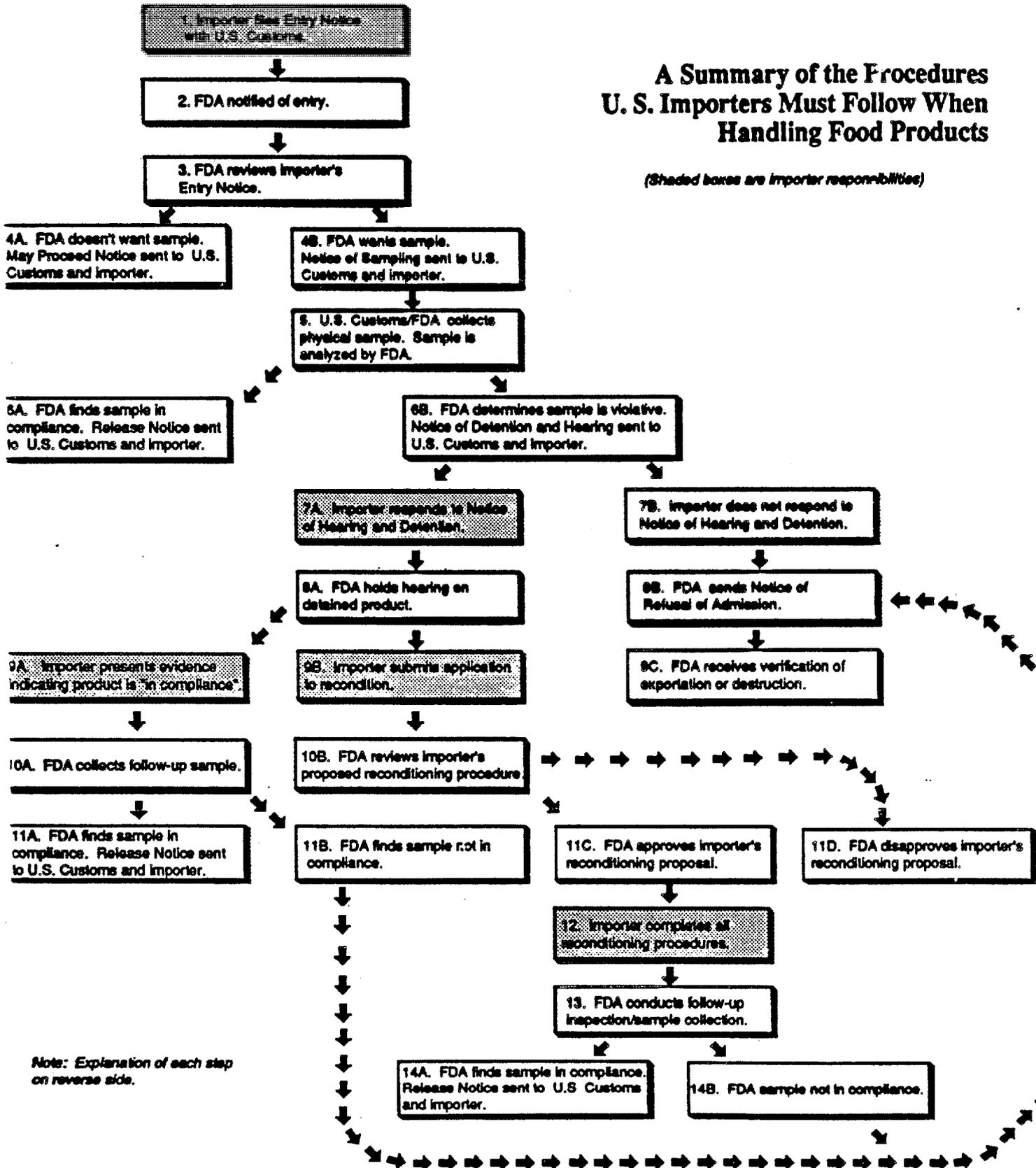
1. Have confidence in your product's quality and condition
2. Proper labeling
 - a) mark and number each case - corresponding with marks & numbers on invoice
 - b) mark conspicuously & legibly
 - i) country of origin - i.e. Product of ____, Made in _____.
 - ii) contents, additives
 - iii) quantity, size,
3. US Customs:
 - a) entry document- entry manifest (Customs Form 7533), Summary Sheet for Consumption Entry (Form 7501), or Application and Special Permit for Immediate Delivery (Form 3461). Entry needs to be done within five days of arrival.
 - b) Evidence of right to make entry (bill of lading, air waybill, shipping receipt)
 - c) Commercial Invoice or pro forma invoice
 - i) must be in English
 - ii) port of entry, country of origin
 - iii) contain information that would be shown on a well-prepared packing list
 - iv) case markings correspond with invoice
 - v) detailed description of each item of goods in each individual package
 - vi) invoice goods in a systematic manner
 - vii) kind of currency, weights, measures
 - d) Packing list (if appropriate)
 - e) Surety Bond - covers any potential duties, taxes, and penalties that might accrue

1000 200 0000 0000

IMPORTING FOODS INTO THE UNITED STATES

A Summary of the Procedures U. S. Importers Must Follow When Handling Food Products

(Shaded boxes are importer responsibilities)



Note: Explanation of each step on reverse side.

Requirements for the Importer (continued)

4. FDA requirements Internet address : www.fda.gov.com

- a) File entry with U.S. Customs**

- b) HACCP requirements (mandatory after December 18, 1997)**
 - i) MOU**
 - ii) Product specifications, any of the following:**
 - a) copy of HACCP & sanitation monitoring records**
 - b) export health document for the lot or competent 3rd party certifying product process**
 - c) regularly inspecting foreign processor's facilities**
 - d) maintain on file (in English) processor's HACCP plan, and written guarantee**
 - e) periodic testing of imported products**
 - f) other verifications measures**
 - iii) The importer may hire a competent 3rd party to assist with verification activities, including writing the importer's verification procedures.**
 - iv) The importer shall maintain records (in English) that document the performance.**
 - v) There must be evidence that products imported comply with the regulations.**

Requirements for the Importer (continued)

c) Other FDA issues

- i) Automatic Detention - based on past volatile history. Aka "Blocklist"**
 - a) Issued through Import Alerts. Shifts the burden of proof of compliance**
 - b) for products, processors, or countries**
 - c) removal from detention by petition - individual, firm, or country**
 - d) Import detention Reports**

- ii) Specific product regulations:**
 - a) bisulfate residues & labeling in shrimp**
 - b) indole, mercury, histamine testing**
 - c) low- acid can requirements - register process with FDA**

Import Alerts

Importation of Seafood Products into the US

| Alert Revised | Title/Description |
|-----------------|--|
| 16-04 03/24/95 | MISBRANDED SEAFOOD |
| 16-05 12/22/94 | AUTOMATIC DETENTION OF MAHIMAHU BECAUSE OF HISTAMINE AND DECOMPOSITION |
| 16-08 04/06/90 | AUTO DET OF SWORDFISH FOR METHYL MERCURY (REV) |
| 16-09 06/05/89 | AUTOMATIC DETENTION OF FROZEN KINGFISH FROM TRI-TEE SEAFOOD COMPANY |
| 16-12 02/17/95 | AUTOMATIC DETENTION OF FROG LEGS |
| 16-13 10/05/84 | AUTO DET OF ANCHOVY OR BAGOONG PRODUCTS FROM PHILIPPINES (REV) |
| 16-18 07/21/95 | AUTO DETENTION OF SHRIMP (REV) |
| 16-21 08/16/94 | FILTH IN IMPORTED FRESH OR FROZEN RAW SHRIMP |
| 16-23 05/01/92 | AUTO DET OF FRESH & FROZEN LOBSTER/LOBSTER TAILS FROM INDIA (REV) |
| 16-35 07/06/95 | AUTOMATIC DETENTION OF FRESH RAW FRESH FROZEN AND COOKED SHRIMP FROM INDIA |
| 16-50 07/31/89 | AUTOMATIC DETENTION OF MOLLUSCAN SHELLFISH |
| 16-66 03/10/95 | AUTOMATIC DETENTION OF SHARK FOR METHYL MERCURY |
| 16-81 09/22/92 | AUTOMATIC DETENTION OF SEAFOOD PRODUCTS DUE TO THE PRESENCE OF SALMONELLA |
| 16-95 03/05/93 | AUTOMATIC DETENTION OF CANNED TUNA DUE TO DECOMPOSITION |
| 16-105 12/18/95 | AUTOMATIC DETENTION OF SEAFOOD AND SEAFOOD PRODUCTS FROM SPECIFIC MFRS/SHIPPERS DUE TO DECOMPOSITION AND/OR HISTAMINES |

Import Detention Report

January '96

SEAFOOD DETENTIONS FOR PHILIPPINES

| | |
|---|-------------------------|
| DEL MAR FOODS, GEN SANTOS CITY 3039183 SAN D DECOMPOSED 96/01/10 | CANNED CHUNK LIGHT TUNA |
| DEL MAR FOODS DIV OF NAUTICA, PASIGM.M. 1985430 NYK D DECOMPOSED 96/01/19 | CHUNK LIGHT TUNA |
| PACIFIC ISLES INTL TRADING, QUEZON CITY 3039340 SAN D UNS.COL.ADD.-N.E.C. 96/01/08 | COOKED SHRIMP PASTE |
| ALEIS PRODUCTS, QUEZON CITY 3066701 LOS A E.COLI/COLIFORMS 96/01/09 16013 INSECT FILTH/DAM. | CRISPY ANCHOVIES |
| CABANILLA ENTERPRISES, MANILA 3038452 SAN D RODENT FILTH/DAM. 96/01/08 INSECT FILTH/DAM. | DRIED NEMIPTERIDS |
| SEASKY FOOD EXPORT INC., CALOOCAN CITY 3022613 LOS D RODENT FILTH/DAM. 96/01/16 ANIMAL FILTH/DAM.-NEC | FRESH FRZ BABY MILKFISH |
| SEASKY FOOD EXPORT INC., KALOOKAN CITY 3067010 LOS D MAND. LBLING. OMIT. 96/01/24 | FROZEN BABY MILKFISH |
| SEASKY FOOD EXPORT INC., CALOOCAN CITY 3066435 LOS D MAND. LBLING. OMIT. 96/01/25 | FRZ BABY MILKFISH |
| SEASKY FOOD EXPORT INC., CALOOCAN CITY 3066442 LOS D MAND. LBLING. OMIT. 96/01/25 | FRZ BABY MILKFISH |
| SMI FISH INDUSTRIES, INC., MAKATI CITY 1626118 SJN D SALMONELLA-ARIZ. 96/01/30 | OCTOPUS (BALL PACK) |
| SEASKY FOOD EXPORT INC., CALOOCAN CITY 3066443 LOS D MAND. LBLING. OMIT. 96/01/18 FAL./MISLEAD.LBLING | PATSI (FISH SAUCE) |
| SEASKY FOOD EXPORT INC., KALOOKAN CITY 3064259 LOS A INSECT FILTH/DAM. 96/01/26 16013 RODENT FILTH/DAM. | SALTED SHRIMP FRY |
| SEASKY FOOD EXPORT INC., CALOOCAN CITY 3066436 LOS A INSECT FILTH/DAM. 96/01/11 16013 RODENT FILTH/DAM. | SALTED SHRIMP FRY |

Importation of Seafood Products into the US

How to expedite shipments - the tricks of the trade

1. Insurance
 - a) all-risk insurance for reefer break-down
 - b) little or no FDA-clearance insurance written
2. Temperature recorders - inexpensive insurance
3. Customs brokers
 - a) Automated Broker Interface (ABI) - can speed-up entry making and response time when clearing Customs/FDA. Hard copies still have to be created.
 - b) Automated Manifest System - speed-up clearance response for steamship industry
4. Work with, know, and understand U.S. Customs/FDA regulations
 - a) comply with any special law pertaining to your commodity
 - b) develop packing standards for your commodity
 - c) organized documentation - complete, matching paperwork
 - d) include all information on paperwork
 - e) type clearly
 - f) data/information within columns

5. **Have a private laboratory analyze product before shipment**
 - a) **Test especially for mercury, histamines, E. Coli, Salmonella, filth, decomposition. While not conclusive, these analyses might serve as an indicator of processor's ability to produce acceptable, passable product.**
 - b) **Keep results until cleared.**
 - c) **Laboratory Guidelines -- sampling & analytical procedures**
6. **Pack proper weights, sizes, quality - think long-term customer**
7. **Have a contingency plan in case product is rejected by Customs or FDA .**
 - a) **Recondition/re-label the product**
 - b) **Re-export the product**
 - c) **Destroy product**
8. **Have confidence in your product's quality and condition - have all the necessary steps taken place to insure optimum quality in your process ??**

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Selected Presentation Materials: Howard Johnson

H. M. JOHNSON & ASSOCIATES

Information and Analysis for Decision-Makers

MARKETING
MARKET RESEARCH
NEW PRODUCT DEVELOPMENT

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The U.S. Seafood Market: Trends and Opportunities

Howard M. Johnson, H.M. Johnson & Associates

U.S. Seafood Market Overview

U.S. per capita seafood consumption has increased 29 percent since 1970, peaking in 1987 at 7.35 kg per capita (edible weight). Since 1987 U.S. consumption has remained steady at approximately 6.81 kg (edible weight) each year. However, the total volume of seafood sold in the U.S. is still increasing due to population growth. In 1994 United States domestic seafood sales totaled \$18.6 billion at the wholesale level and \$39 billion at the consumer level. The total volume of the edible U.S. seafood supply, landings and imports, was 6.2 million tons round weight and 1994 consumption totaled 1.8 million tons edible weight, an increase of 40 thousand tons over 1993.

The overall volume of fresh and frozen seafood sold in the U.S. continues to increase as the population grows. Over the past 10 years, the volume of fresh and frozen seafood consumed annually has increased 16.1 percent, rising from 1.05 million tons (edible weight) in 1984 to 1.22 million tons in 1994. Shrimp consumption has increased faster than any other seafood species in the U.S.

World Supply Trends

The world seafood supply increased rapidly through the 1980's and now stands at approximately 100 million tons. Aquaculture accounts for 16 million tons and is expected to grow substantially into the future. Wild catches are not expected to increase beyond current levels.

As world per capita seafood supply decreases (as the population increases) competition for seafood can be expected to grow. China is already increasing seafood imports and, with a population of 1.2 billion, will put tremendous pressure on seafood supplies world wide. Because the United States is a net importer of seafood, but also a major exporter, the issue of world seafood supply is vital to the future of the U.S. industry.

U.S. Seafood Supply Trends

U.S. Seafood Imports

Over the past ten years, the U.S. has imported between 40 percent and 60 percent of its seafood supply. In 1994, edible fresh and frozen seafood imports in the U.S. market consisted of just over 1.1 million metric tons of product valued at \$5.9 billion, an increase of \$800 million over 1993. Canned seafood imports added an additional \$542 million, and increase of \$48 million over 1993. Shrimp remains the most important seafood item imported in the U.S. although actual imports for 1995 were slightly below 1994 levels.

Table 1. Top 10 1994 U.S. Seafood Imports - Product Weight and Value

| Item | Tons | \$Million | vs 1993 | Item | MT | \$Million | vs 1993 |
|--------------------------|---------|-----------|---------|----------------------|--------|-----------|---------|
| 1. Shrimp | 284,828 | \$2,700 | +4.9% | 6. Salmon | 53,229 | \$253 | 2.3% |
| 2. Lobster | 28,720 | 448 | +7.0% | 7. Scallops | 25,708 | 216 | 9.0% |
| 3. Tuna (uncanned) | 207,921 | 426 | +5.2% | 8. Blocks/Slabs | 90,541 | 184 | -5.7% |
| 4. Groundfish Fillet/Stk | 85,774 | 337 | +1.3% | 9. Crabmeat | 13,938 | 103 | +12.9% |
| 5. Canned Tuna | 112,965 | 286 | +11.0 | 10. Flatfish Fillets | 17,914 | 96 | -19.6% |

U.S. Seafood Catch

With the transfer of the Bering Sea pollock fishery to American boats in the late 1980's, the U.S. entered a period where domestic landings exceeded imports. While that situation remains, the reality is that we tend to export lower value products, such as surimi and pollock, and import higher value items, such as shrimp and crab.

Although the United States has domestic resources of almost all major species of fish and shellfish, supplies are not usually adequate to meet demand. This trend can only be expected to continue, particularly for those higher-value species that are best suited to aquaculture in warm water areas not found in the continuous United States. A good example is the U.S. shrimp industry. While the country has major shrimp fisheries in many areas, and a small domestic shrimp-farming industry, shrimp still represents the leading product imported into the U.S. in both volume and value.

U.S. domestic seafood production is now heavily dependent upon production from Alaska, which currently accounts for 68 percent of seafood production (by weight) from U.S. waters. Catches of pollock, Pacific cod and salmon are at or near record levels in Alaska. While these stocks all seem to be capable of sustaining current harvest levels, further increases are unlikely. The implementation of more conservative resource management and the use of individually transferable quotas in U.S. fisheries will most likely insure stability of seafood species which have not already suffered from over-utilization.

C. U.S. Seafood Consumption Trends

Seafood consumption patterns in the United States, reflect not only changes in product form preferences, as indicated by declines in canned and breaded products, but also shifts in species availability. For example, demand for mild, white-fleshed, fish remains strong, and major declines in Atlantic cod landings along the Northeast United States and Canada have been offset by increases in the use of Alaska pollock and cod from Russia and Alaska--a large percentage of which is reprocessed into blocks and fillets in China. Increased consumption of some species, particularly shrimp, salmon and catfish, has resulted from increased production through aquaculture. Tilapia consumption is expected to increase in the U.S. because the fish, in fillet form, is light colored, boneless and mild tasting.

Table 3. U.S. Per Capita Seafood Consumption 1988-1994

| 1987 Rank | Grams Per Capita | | | | | | | 1994 Rank |
|----------------|------------------|------|------|------|------|------|------|-----------|
| | 1988 | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | |
| 1. Canned Tuna | 1633 | 1769 | 1678 | 1633 | 1588 | 1588 | 1497 | 1 |
| 2. Shrimp | 1089 | 1043 | 998 | 1089 | 1134 | 1134 | 1179 | 2 |
| 3. Cod | 776 | 767 | 626 | 508 | 488 | 467 | 421 | 5 |
| 4. AK Pollock | 535 | 656 | 576 | 449 | 558 | 544 | 689 | 3 |
| 5. Flatfish | 281 | 260 | 259 | 172 | 230 | 283 | 164 | 8 |
| 6. Clams | 278 | 278 | 277 | 263 | 279 | 267 | 247 | 7 |
| 7. Catfish | 272 | 314 | 318 | 349 | 411 | 448 | 388 | 6 |
| 8. Salmon | 201 | 214 | 331 | 440 | 395 | 451 | 505 | 4 |
| 9. Crabs | 148 | 132 | 132 | 145 | 151 | 170 | 142 | 9 |
| 10. Scallops | 142 | 149 | 136 | 113 | 123 | 117 | 132 | 10 |
| Total (Kg) | 6.9 | 7.08 | 6.8 | 6.76 | 6.72 | 6.8 | 6.9 | |

There are a number of reasons why U.S. seafood consumption, which increased approximately 25 percent during the early and mid 1980's, has declined or remained flat in the 1990's. During the 1980's, U.S. consumers became more health conscious and began to reduce their intake of red meat. As red meat consumption decreased from 56.9 kg per person in 1980 to 51.3 kg by 1990 (a decline of 11.4 percent), demand for poultry and seafood increased. However, poultry benefitted the most from the decline in red meat consumption, with chicken and turkey consumption increasing by over 9 kg per person since 1980. It is estimated that 1995 per capita consumption of seafood in the United States will be down slightly from the previous year with shrimp consumption at or slightly below 1994 levels. Beef and poultry prices remain low and many seafood items remain high (at least by comparison).

Today, U.S. consumers, while still health conscious, are more concerned about getting good food value for their money, and seafood is increasingly perceived as an expensive, "special occasion" purchase. In addition, U.S. consumers now want seafood that is more convenient and "user friendly." Consumers want "value-added" seafood with greater convenience, less waste and easier to prepare and store.

D. Value-Added Seafood, What is it?

To the Producer: Further processing of a product that provides revenue greater than the cost of additional processing. And/or: Further processing that increases sales volume without a decrease in profit margin. Examples: peeling, cooking, breading.

To the Importer/Wholesaler: Products which: reduce labor, decrease waste, have longer shelf-life, are easier to store or distribute, offer increased profit or result in increased sales.

To the Consumer: Products which: offer greater convenience, are easier to prepare, taste good, are efficiently packaged, are healthy, have good storage life and are priced fairly.

The U.S. Seafood Market Trends and Opportunities

Howard M. Johnson
H.M. Johnson & Associates

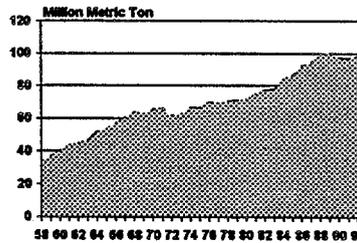
U.S. Market Overview

- Per capita consumption 21kg (live wt.)
- 2.6 million tons of imports
- 3.6 million tons of exports
- Domestic sales \$18.6 billion (wholesale)

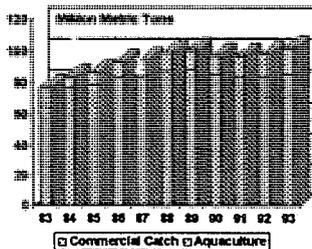
Major U.S. Seafood Trends World Supply

- Rapid increase in wild catch through 1980's
- Annual world supply now 100 million tons
- Aquaculture contributing 16 million tons
- World per capita supply declining
- Future increases must come from aquaculture
- Seafood demand in China increasing

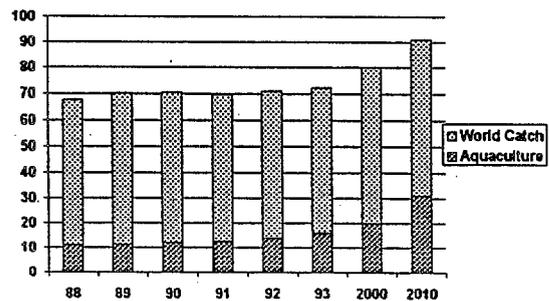
World Seafood Supply 1958-1993 Rapid Growth in 1960's and 1970's



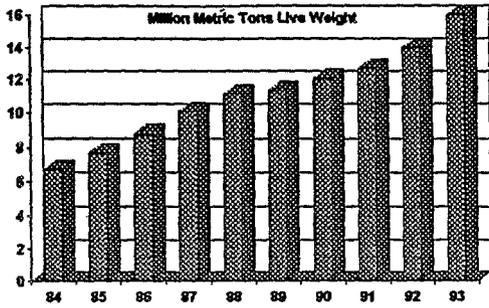
World Seafood Supply 1983-1993 Commercial Catch Peaked in 1989



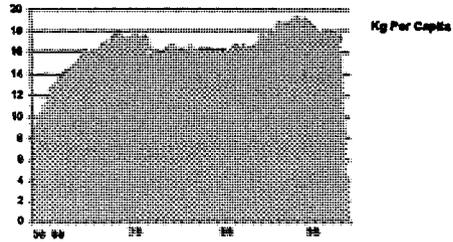
World Food Fish Supply Aquaculture Drives Future Increases



World Aquaculture Production Steady Increase in Past Decade



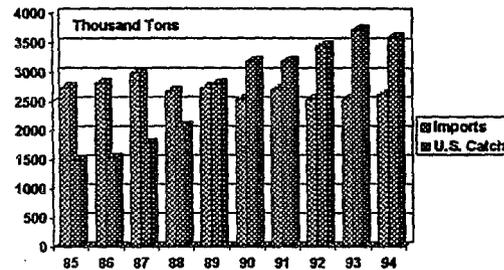
World Fish Catch Per Capita 1988 Peak Unlikely to Be Reached Again



Major U.S. Seafood Trends U.S. Supply

- Domestic catch steady and well-managed
- Imports level but value increasing
- Shrimp imports total \$2.6 billion
- Aquaculture an important supply source

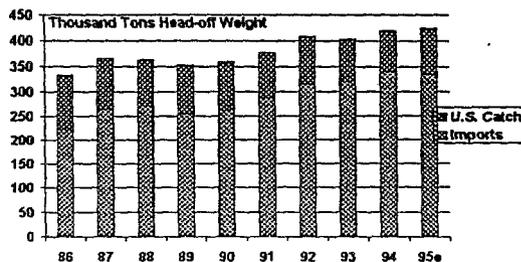
U.S. Seafood Supply



Major U.S. Seafood Imports

1. Shrimp \$2,654 million
2. Lobster \$ 448 million
3. Whole Tuna \$ 426 million
4. Groundfish Fillets \$ 337 million
5. Canned Tuna \$ 286 million

U.S. Shrimp Supply



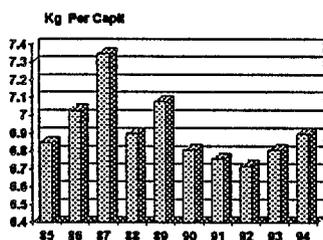
1995 U.S. Shrimp Imports - Asia

| Country | '000 MT | Import Rank |
|-------------|---------|-------------|
| Thailand | 77.8 | 1. |
| India | 17.8 | 4. |
| China | 14.6 | 5. |
| Indonesia | 5.3 | 9. |
| Bangladesh | 5.0 | 10. |
| Pakistan | 2.3 | 18. |
| Philippines | 2.1 | 19. |
| Singapore | 1.7 | 20. |
| Vietnam | 1.3 | 21. |
| Malaysia | 1.2 | 23. |

Major U.S. Seafood Trends Consumer Issues

- Per capita consumption level at 6.8kg
- Low poultry/beef prices put pressure on seafood
- Supermarkets changing seafood departments
- Growth in value-added seafood products

U.S. Per Capita Seafood Consumption Little Increase in the Future

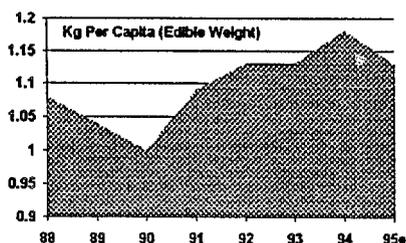


U.S. Seafood Consumption Trends

| Species | Consumption | Trend |
|----------------|-------------|-------------|
| 1. Canned Tuna | 1497 grams | Down |
| 2. Whitefish* | 1275 grams | Steady/Up |
| 3. Shrimp | 1180 grams | Steady/Down |
| 4. Salmon | 505 grams | Up |
| 5. Catfish | 388 grams | Up |
| 6. Clams | 247 grams | Steady |
| 7. Crabs | 142 grams | Down |
| 8. Scallops | 132 grams | Up |

* Pollock, Cod and Flatfish

U.S. Shrimp Consumption



Key Species Trends: Tilapia

- World production tops 650,000 tons in 1993
- Strong U.S. market developing
- U.S. imports exceed 7,000 MT in 1995
- Frozen fillets may be best U.S. market
- U.S. wholesale price \$2.75 for frozen fillets
- Price will drop as supply increases
- Quality is key

What is Value-Added? To the Producer

- Further processing of a product that provides revenue greater than the cost of the additional processing.
- Further processing that increases sales volume without a decrease in profit margin.

What is Value-Added? To the Importer/Wholesaler

- Reduced labor
- Less waste
- Easier stocking/storage/distribution
- Increased profit
- Increased sales
- Longer shelf-life

What is Value-Added? To the Consumer

- Greater convenience
- Easier to prepare
- Tastes good
- Efficiently packaged
- Healthy
- Good storage life