QUALITY CONTROL & QUALITY ASSURANCE FOR SEAFOOD

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Controlling and improving seafood quality is one of the foremost challenges confronting the world’s seafood industries. Seafoods can be considered delicate and highly perishable "commodities" like other foods, but many complex quality issues result from conditions unique to this industry. For example, most seafoods aren’t raised under controlled conditions from a few cultivated breeds, but are hunted and captured from thousands of publicly managed wild stocks and species. These conditions complicate efforts to standardize product quality, particularly in comparison to competing industries that use animal husbandry techniques (including aquaculture). Commercially harvested seafoods are also captured at long distances from processing and distribution centers. Variability in supply and quality due to natural variation in these wild creatures, and problems arising from public management of the resource, complicate quality problems. The risk and uncertainty associated with this variability often make it unprofitable to invest in the capital and human resources necessary to improve product quality. Providing products that consistently satisfy consumer demand and enhance market opportunities is therefore a difficult and daunting task for many sectors of the industry.

Many of the firms that process products from the assemblage of codlike fish known as hakes and whittings are particularly vulnerable to these problems. Although these species are spread across every major ocean and have diverse life histories, they share two intrinsic characteristics that significantly affect final product quality: a relatively soft flesh and infestation of parasites, including myxosporidean parasites. These parasites are not only unsightly, but are often associated with high levels of protease enzymes. These enzymes can result in a soft texture and contribute to bruised or mushy flesh, rapid rancidity, and reduced shelf life.

Among all species of hakes and whittings, none may be characterized by a greater combination of preharvest product quality problems than Pacific whiting (Merluccius productus), found off the west coast of the United States and Canada. Until recently, poor final product quality resulted, and market prices were too low to generate profits. Prior to 1991, the vast majority of the stock was harvested by foreign and joint-venture vessels delivering to processing ships from Europe and Asia. Domestic use of whiting grew from 20,000 metric tons (mt) in 1990 to over 200,000 mt in 1991 because of increased prices for various product forms and an expanding west coast fishing and processing fleet. Pacific whiting, with potential allowable biological harvests of 200,000 to 500,000 mt, is now considered “fully utilized.” The 1992 season showed a dramatic increase in shore-based investment in processing facilities; it is estimated that 75,000 to 100,000 mt of Pacific whiting will be processed shoreside in 1994 (the remaining 140,000 mt will be processed at sea).

This rapid transformation to domestic processing has compounded difficulties in understanding and controlling the quality attributes that critically affect the value of whiting products. A better understanding of the inherent characteristics of Pacific whiting and how they affect final product quality and market development is crucial for the development of a sustainable, profitable industry.

Given the size of the resource and its product quality problems, a considerable amount of private and public effort has been expended to understand biological, technical, and marketing problems. Conferences on Pacific whiting were held in Astoria, Oregon, in 1990 and again in Newport in 1992. In late 1992, Oregon fishers and seafood processors joined together to form the Pacific Northwest Seafood Association (PNSA). One of the primary objectives of the association was to establish guidelines for controlling and improving Pacific whiting quality. Association members recognized that there were a number of organizations, seafood marketing associations, and government agencies that had established seafood quality standards. They also understood that "official" programs such as HACCP, ISO 9000, and TQM were being proposed for implementation at regional, national, and international levels. The association believed that it would be beneficial to learn from the individuals, firms, industry groups, and regional or national governments that had spent years wrestling with the problem of managing seafood quality. The PNSA therefore asked the organizers to plan a conference that would gather U.S. and international...
experts to share their experiences and knowledge, in order to guide the Pacific whiting industry in developing its own successful quality assurance programs.

The conference was designed to cover a range of topics and to highlight the relationships between production, marketing, and quality management strategies. Topics covered were (1) the status and evolution of national and international seafood quality standards, (2) the “buyer’s” perspective on quality assurance, (3) seafood associations and the role of quality standards, (4) measuring and controlling seafood quality, (5) designing and managing quality assurance programs, and (6) quality assurance as a tool in marketing management programs.

As conference organizers, we were extremely pleased by the quality of the speakers and their active participation in round table discussions as well as question and answer sessions. We were also gratified to see the commitment to seafood quality demonstrated by many of our colleagues, including fishers, processors, marketers, and researchers. We felt fortunate to have so many experts from regional, national, and international arenas who could provide us with insights from their experience and research.

One of the missions of both Oregon State University’s Coastal Oregon Experiment Station and the International Institute of Fisheries Economics and Trade is to transfer information on managing marine resources and marine resource-based industries to the public and private sectors where it can be used. We feel that this conference and its proceedings serve this purpose and provide the industry with some unique insights into quality control and quality assurance programs for seafood.

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Several organizations, government agencies, and individuals made significant contributions to the success of the conference and the publication of the proceedings. The Pacific Northwest Seafood Association and the Oregon Economic Development Department (as part of its Key Industries Program) were the primary conference sponsors. We would like to thank the other contributors, which included the International Institute of Fisheries Economics and Trade, the National Security Bank, the Oregon Coastal Zone Management Association, the Oregon Department of Agriculture, the Oregon Sea Grant Program, Oregon State University's Coastal Oregon Marine Experiment Station, the Oregon State University Seafood Laboratory, the Oregon Trawl Commission, Pacificorp, and the U.S. Department of Agriculture.

We would especially like to thank those individuals who contributed significant amounts of time and effort in support of the conference. They include Jay Rasmussen (Oregon Coastal Zone Management Association), Tom Libbey (Pt. Adams Packing Co.), Mark Cooper (Midwater Trawlers Cooperative), Barry Fisher (Yankee Fisheries), and Joe Easley (Oregon Trawl Commission). A special thanks to Susan Mills and Maureen Collson (Coastal Oregon Marine Experiment Station), Nancy Chamberlain (OSU Seafood Laboratory), and Georgia York (Oregon Coastal Zone Management Association) for helping in conference organization and overseeing the myriad details that collectively make the difference between success and failure. Graduate students Michael Murphy, Maurice McCarthy, Liz Brown, Finley Anderson, Greg Peters, and Sherry Larkin did yeomen's work transporting speakers and editing various conference sessions. A round of applause from the editors goes out to Sandy Ridlington who edited the manuscripts and who took on the responsibility of getting the proceedings to print. We also thank Bob Malouf, Director of Oregon Sea Grant, for financial support for the publication. Finally, a heartfelt thanks to Lavern Weber, who, as Director of the Coastal Oregon Marine Experiment Station, has engendered among his researchers a strong sense of responsibility for communicating and working with the coastal community to effectively address coastal concerns.
ABBREVIATIONS

AFAQ-Association Francaise pour l'Assurance Qualite (the French Quality Assurance Association)
ANSI-American National Standards Institute
AOC-Appellation d'Origine Controlee (specified origin label, France)
ASMI-Alaska Seafood Marketing Institute
ASP-amnesic shellfish poison
ASQC-American Society for Quality Control
ATP-adenosine triphosphate
CAC-Codex Alimentarius Commission
CCP-critical control point
CFR-Code of Federal Regulations
CP-control point
DFO-Department of Fisheries and Oceans (Canada)
DSP-Division of Seafood Programs (OS)
EC-European Community
EEC-European Economic Community
ESOP-employee stock ownership plan
FAO-Food and Agriculture Organization (UN)
FD&C-Food Drug and Cosmetic Act of 1938 (U.S.)
FDA-Food and Drug Administration (U.S.-HHS)
FSIS-Food Safety and Inspection Services (USDA)
FTA-Free Trade Agreement (U.S.-Canada)
FWF-Fish and Wildlife Service (U.S.)
GATT-General Agreement on Tariffs and Trade
GMP-good manufacturing practice
HACCP-hazard analysis and critical control points
HHS-Department of Health and Human Services (U.S.)
IQF-individually quick frozen
ISO-International Standards Organization
MF-Ministry of Fisheries (Norway)
MOU-memorandum of understanding
MSSP-Model Seafood Surveillance Program (NOAA)
NACMCF-National Advisory Committee Microbiological Criteria for Foods
NAS-National Academy of Science (U.S.)
NFFSO-Norwegian Fish Farmers' Sales Organization
NFI-National Fisheries Institute (U.S.)
NMFS-National Marine Fisheries Service (U.S.)
NOAA-National Oceanic and Atmospheric Administration (U.S.)
NSIP-National Seafood Inspection Program (U.S.)
OIE-Office of Epizootics-health and sanitary requirements for the import and export of animals (U.S.)
OS-Office of Seafood (U.S.-FDA)
PC-production capacity
PO-producer organizations
PSP-paralytic shellfish poison
PUFI-packed under federal inspection
P-production
QA-quality assurance
QMP-Quality Management Program (Canada)
RAB-Registrar Accreditation Board
RNE-Reseau National d'Essais (National Testing Network, France)
SIFE-Sanitarily Inspected Fish Establishment
SPC-statistical process control
STP-sodium tripolyphosphate
TQM-total quality management
TRQ-Tariff Rate Quota
UN-United Nations
USDA-U.S. Department of Agriculture
USDC-U.S. Department of Commerce
WHO-World Health Organization
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GLOBAL PICTURE
In the United States, consumers eat about 1,000 commercial species and spend about $30 billion annually on seafood. Every year the U.S. exports approximately $3 billion of its harvest and imports approximately 200,000 seafood entries from 135 countries, worth about $5 billion.

Nutritionally, seafood contributes to a healthful diet as a source of high-quality protein, certain vitamins and minerals, and essential fatty acids. Consumers have come to depend on seafood as a protein source in their quest for low-fat, low-cholesterol diets: consumption has increased in the last decade to almost 15 pounds a person. It is evident, then, that seafood is an important commodity in the U.S. diet and a significant contributor to the GNP and world trade.

OFFICE OF SEAFOOD
The Food and Drug Administration's (FDA) Office of Seafood is a little over two years old and in that brief period has accomplished much that will serve as the springboard to improving and assuring the safety of seafood.

In remarks at the March 22, 1993 National Food Policy Conference, David Kessler, Commissioner of Food and Drugs, said that if we food regulators are going to ensure the safety and wholesomeness of the U.S. food supply, we can’t do the job the same way we were doing it 25- or even 10- years ago. We cannot afford to march in place.

We need to recognize that the food industry and consumption patterns have changed dramatically. The Pacific whiting surimi industry is a good example.

FDA SEAFOOD PROGRAM
In the face of these changes in the production and consumption of food, consumers continue to ask the same two simple and legitimate questions: “Is the food safe to eat?” and “What are you doing to make it safe?”

It is not that the public expects assurance that food is absolutely safe. But it does expect that a system is in place to ensure that food is as safe as we can possibly make it—a system that is responsive to today’s realities, today’s risks, and today’s consumer expectations.

Seafood, like many other foods, poses a wide array of potential health problems, most of which never occur. Data indicate that the rate of illness from seafood is extremely low and, on a per pound consumed basis, is declining.

Some problems, however, do arise because of pathogenic bacteria and viruses: natural toxins, like domoic acid along the Oregon coast; chemical contaminants; parasites; decomposition; and drug residues.

The changing conditions and increasing technological advances in the seafood industry are typified by the areas of aquaculture, engineered seafood (surimi) and vacuum and modified atmospheric packaging. These changes and resultant demands are not unique to the seafood industry. The fundamental ways in how we produce, distribute, and consume food have changed since the basic elements of today’s food safety system were put in place. The Office of Seafood is in the forefront of FDA efforts to respond to these new issues and challenges which it sees not as obstacles, but as opportunities.

STRATEGIC PLAN FY 93-98
The Office of Seafood has recognized that conducting inspections, gathering samples, and running laboratory analyses and research were not sufficient to protect the consumer from all potential hazards. This recognition has resulted in a different perspective on seafood safety. The new perspective is reflected in a draft strategic plan that is in its final formative stages and that will reflect suggestions from the industry, state and local agencies, scientists and consumers. Our intention with this plan is to create complete consumer confidence in all seafood.

The strategic plan sets four strategic goals. They are to ensure the following:
1) that seafood products are safe
2) that seafood is wholesome and properly labeled
3) that the FDA, industry, and consumers have accurate information concerning seafood
4) that the infrastructure exists to accomplish 1, 2, and 3 above

We are achieving these goals, as I will show, through specific activities and new initiatives in the seafood arena.

ECONOMIC FRAUD

Economic fraud is of sufficient complexity that it can occur even among members of the seafood industry who are most knowledgeable about the products and trade practices. This problem has been targeted as a major concern by Commissioner Kessler, who has been applauded by the industry for his efforts. First, the FDA's budget for work in this area has been doubled. Second, over 1,000 letters have been sent to the industry warning against overglazing. Third, a number of actions have been taken against species substitution, including Pacific rockfish substituted for red snapper, pollock for cod, oreo dory for orange roughy, and some freshwater species for saltwater species. The FDA has been much more active in this area over the past two years, and it intends to continue to vigorously pursue action against these and other types of economic fraud.

SCALLOPS AND PHOSPHATES

Fresh sea scallops are 75 to 79 percent water. They may lose considerable moisture after shucking; however, this loss may be prevented by treatment with sodium tripolyphosphate (STP). There is even some indication that STP may help preserve desirable eating characteristics.

However, it turns out that prolonged soaking of scallops in STP solutions results in the scallops' taking up excess water. And unfortunately, some scallop processors have been taking advantage of this to enhance product weight and their profits. Selling this excess water at the price of scallops constitutes economic fraud.

INTERIM LABELING POLICY

After some people in industry expressed their frustration and concern to the FDA, we responded by setting an interim labeling policy for scallops based on water content. This policy was designed to ensure fair play within the industry and a fair product for the consumer.

Specifically, the policy is that scallops that have been treated with STP and have picked up water must be labeled with the identity statement, “X percent of water-added scallop product.” This labeling must be used with any scallop with 80 to 84 percent water. In addition, the statement “Processed with Sodium Tripolyphosphate” or any other phosphate that might be used must appear on the label; and the phosphate(s) and added water must be in the ingredients statement. No scallops containing greater than 84 percent water will be allowed on the market.

In other words, untreated scallops with 79 percent water or less are to be labeled “scallops.” Any product with 80 to 84 percent moisture should be labeled as scallop product, and anything over 84 percent moisture cannot be marketed.

This policy will remain in effect until the agency completes an evaluation of the additional data recently provided by industry. The data concern the relationship between the normal moisture content of freshly shucked scallops and their treatment, as well as the possible loss of key nutrients.

PROBLEMS WITH CRAB

Blue Crab

It has been FDA policy for decades that product labeled “crab meat,” with no qualifications, must be derived from the blue crab. There have been some complaints from the blue crab industry, however, that imported, less valuable crab meat from other species is being substituted for blue crab and labeled as “crab meat,” with no regard for our policy and requirements. In addition, some companies are ignoring the U.S. Customs Service’s labeling requirement for country of origin. We are working closely with the U.S. Customs Service and other agencies on this problem. One firm has already been prosecuted for this illegal practice in the State of Maryland.

Dungeness Crab

The west coast has certainly had more than its share of problems in the last few years with domoic acid and the saxitoxins, associated with amnesic shellfish poison (ASP) and paralytic shellfish poison (PSP), found in the vis-
cera of Dungeness crab. Again, the FDA has established a policy and is taking action against crabs found to have 30 or more parts per million (ppm) domoic acid in the viscera; or 80 or more micrograms per 100 grams saxitoxin in the viscera. This 30 ppm is a recent revision upward from a previous level of 20 ppm, based upon new data provided to our Health Hazards Evaluation Board. These toxins also have affected the harvest of west coast razor clams. PSP in razor clams must be below 80 micrograms per 100 grams; domoic acid must be below 20 ppm, or the beds are closed to harvest.

CONTAMINANTS

Chemical Contaminants

The presence of chemical contaminants in seafood—both marine and freshwater species—is often a regional issue. The FDA’s role is to determine allowable levels for products entering interstate commerce. Because we recognize that regional concerns may not be effectively addressed by national controls, we have been working on guidance documents that local health authorities can use to issue advisories or close areas to both commercial and recreational fisheries.

Contaminant Limits for Shellfish

Four of these guidance documents have been issued for contaminants of shellfish (including molluscan and crustacean shellfish). The contaminants are arsenic, nickel, chromium, and cadmium. Documents for other contaminants are under development and, following review by a subcommittee of the Association of Food and Drug Officials, will be issued.

National Conference

In April 1993, the FDA hosted a two-day conference in Washington, D.C., on chemical contaminants in seafood. The purpose was to draw together state regulatory agencies, industry, scientists, other federal agencies, and interested consumer groups to share information on current and planned efforts to assess the risk of chemical contaminants in seafood. Participants also discussed how to manage these risks and how to go about communicating to the world what the risks really are. Our meeting was hailed as a new paradigm in risk communication. This meeting will go a long way in helping us in FDA to focus our resources.

Color Additives

When canthaxanthin was approved for coloring food directly and through chicken feed, it was not the agency’s intent to permit its use as an additive to fish feed, although we did not explicitly prohibit it. This ambiguity has led to some confusion in the aquaculture industry and in the agency.

Petitions for the use of canthaxanthin and astaxanthin are in varying stages of submission and review. These and other color additives may be present in fish products, and regardless of whether they are added directly or through the fish feed, or whether they are of natural or synthetic origins, they are artificial colors and any labeling must state that color has been added.

Listeria

The problem with Listeria in seafood remains difficult. Our current policy is that if we detect it, we take action. The focus here is with ready-to-eat products such as smoked fish and surimi that will not be cooked sufficiently by the consumer.

Inspections of High-Risk Products

As a follow-up to limited inspections of virtually the entire domestic seafood processing industry completed over a year ago, we have conducted more in-depth inspections of producers of

1) ready-to-eat products
2) products in modified atmosphere packaging
3) products from scombrotoxic species, such as tuna, mahi mahi, and amberjack
4) some specialty products likely to have high microbial loads

These inspection surveys have been a great help in providing us with an overview and understanding of the latest industry practices and in targeting for future activities.

Firms processing these types of products, often referred to as “high-risk” products, are now inspected on an annual basis.

HACCP Initiative

I mentioned earlier that both the food industry and consumption patterns have changed drastically in the last decade. The American consumer relies now on foods produced in high-tech, centralized processing facilities, shipped
over long distances, and packaged and stored in new ways. For a number of reasons, the opportunities for food-borne illness have increased. The consumption of prepared foods sold ready-to-eat at retail outlets is expanding rapidly. There are more steps between the harvest site and the kitchen table, more steps in processing, and greater distances of transport. As a result, there is more opportunity for food to be contaminated. Furthermore, new pathogens have appeared, there has been an increase in the incidence of industrial chemicals and environmental contaminants, and certain human subpopulations are now at higher risk than others.

Unfortunately, the FDA's current system of monitoring the food supply has not kept up with the technology. As Commissioner Kessler has said, our current system of food safety regulation is piecemeal and reactive. What we need now is a system built on preventing problems. That system is HACCP.

HACCP stands for hazard analysis critical control points. It was adopted for mandatory federal control over the processing of low-acid canned foods over 20 years ago and has been an unqualified success in an industry sector that was fraught with problems. HACCP has been endorsed by the World Health Organization, the Food and Agriculture Organization's Codex Alimentarius, and the National Academy of Sciences (NAS). The 1991 NAS report, Seafood Safety, recommended that HACCP be applied to the seafood industry.

**HACCP DEFINITION**

HACCP is a system of preventive controls by which food processors and handlers evaluate the kinds of hazards that could affect their products, institute controls to prevent those hazards, monitor the performance of these controls, and maintain records of this monitoring of routine practice. It puts industry squarely into the driver's seat of preventing public health hazards.

Government's role, of course, is one of verification-through inspection, examination of records, sampling and analysis, if necessary, to make sure industry has done its part.

The FDA has developed a draft regulation requiring that industry apply the kinds of controls that will enhance consumer confidence in seafood. The draft is currently under review by our general counsel. We hope to publish soon.

**FDA/NOAA VOLUNTARY SEAFOOD PROGRAM**

In cooperation with the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration (NOAA), we have designed a voluntary, fee-for-service inspection program, based on HACCP concepts. It may serve as an adjunct to our already existing inspection programs, both of which are being transformed to a HACCP-based approach. We have conducted pilots for domestic seafood processors, foreign processors, and retailers. We are currently piloting one for food service facilities. Publication of the proposed regulation on this program has been delayed pending completion of my agency's mandatory HACCP initiative. In the meantime, NOAA is shifting its program for processors to a HACCP-based approach as well.

**IMPORTS**

We have recently adopted a new strategy for dealing with imported seafood. This strategy includes:

1) much closer cooperation with state and local authorities to identify imports that reach the retail market
2) the initiation of civil and criminal actions against consistent and flagrant violators
3) short-term inspection surveys targeting specific products categories
4) education of importers, brokers, and foreign processors

At the same time, we think that importers must do a better job, they must be more responsible to make sure the products they import meet our requirements.

Another aspect of the new import strategy that holds great promise is to give priority to the establishment of memoranda of understanding (MOUs) with countries that, because of their own inspection systems, consistently ship acceptable products to the U.S. This philosophy will facilitate the entry of products from countries that export safe, wholesome, properly labeled products and will permit us to direct our resources to the inspection of products of concern from other countries.

**IRRADIATION**

Irradiation of seafood to reduce microorganisms is approved for use in 35 countries. If
properly used, it can give the consumer a higher quality, as well as a safer, product. The FDA is reviewing petitions to permit application of this technology to U.S. seafood products.

We are already receiving inquiries about the technology from consumers. Clearly, there is a need for greater consumer education to achieve acceptance and understanding. Industry and government must work together to prevent misuse of the technology and to promote public understanding. We believe the petition process is the key.

DECOMPOSITION

Decomposition is a leading cause of complaints about seafood. Besides its aesthetic effects, decomposition may also be a direct health threat; scombrotoxins are a prime example. We have been putting much effort into this area. Analyses for decomposition in seafood—fresh, frozen, and canned products, domestic and imported—have been increased significantly. We're trying to improve the consistency of detection of decomposition, through both microbiological and chemical indicators. To date, the microbiological indicators have not panned out as well as the chemical indicators.

We are putting together a plan to set a defect action level for histamine in all scombroid fish, and a 1 ppm cadaverine action level for mahi mahi, tuna, and other fishery products. We are also looking at the implementation of a pass-fail system rather than the current three-class system for organoleptic assessment of decomposition.

RESEARCH

I can't describe the activities of the Office of Safety without talking about our research program. The FDA's seafood research is directed toward understanding the nature and severity of risks in seafood and finding the means to control those risks. We believe we need a solid scientific base from which to make sound regulatory decisions, address new problems, and perform inspection activities.

Our scientists develop or evaluate the tests or methods used to determine if seafood has been prepared, packed, or held under unsanitary conditions and to ensure that it is not contaminated with filth or rendered injurious to health. The scientists design these tests not only to determine the presence of biological and chemical contaminants in seafood, but also to assess what effects chemical contaminants and toxins have on biological systems, how specific pathogens cause disease, and whether economic fraud has occurred.

A recently completed inventory indicates that there are over 180 ongoing seafood research projects directly related to safety. They fall into three general areas:

1) biological hazards, including the natural toxins—algal toxins and toxins arising from decomposition
2) microbiological hazards—bacteria, viruses, and parasites
3) chemical hazards

Research is also being done in the areas of economic fraud, exposure, consumption patterns, and occurrence of illness.

The FDA wants to lead the nation in coordinating seafood research; it also intends to work hand-in-hand with industry, other federal agencies, state and local authorities, private groups, and the international community to ensure and promote seafood safety.

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In its first six months, the hotline received almost 10,000 calls. Inquiries have ranged from purchasing, storing, and handling, to safety, labeling, and preparation.
over long distances, and packaged and stored in new ways. For a number of reasons, the opportunities for food-borne illness have increased. The consumption of prepared foods sold ready-to-eat at retail outlets is expanding rapidly. There are more steps between the harvest site and the kitchen table, more steps in processing, and greater distances of transport. As a result, there is more opportunity for food to be contaminated. Furthermore, new pathogens have appeared, there has been an increase in the incidence of industrial chemicals and environmental contaminants, and certain human subpopulations are now at higher risk than others.

Unfortunately, the FDA's current system of monitoring the food supply has not kept up with the technology. As Commissioner Kessler has said, our current system of food safety regulation is piecemeal and reactive. What we need now is a system built on preventing problems. That system is HACCP.

HACCP stands for hazard analysis critical control points. It was adopted for mandatory federal control over the processing of low-acid canned foods over 20 years ago and has been an unqualified success in an industry sector that was fraught with problems. HACCP has been endorsed by the World Health Organization, the Food and Agriculture Organization's Codex Alimentarius, and the National Academy of Sciences (NAS). The 1991 NAS report, *Seafood Safety*, recommended that HACCP be applied to the seafood industry.

**HACCP DEFINITION**

HACCP is a system of preventive controls by which food processors and handlers evaluate the kinds of hazards that could affect their products, institute controls to prevent those hazards, monitor the performance of these controls, and maintain records of this monitoring of routine practice. It puts industry squarely into the driver's seat of preventing public health hazards.

Government's role, of course, is one of verification-through inspection, examination of records, sampling and analysis, if necessary-to make sure industry has done its part.

The FDA has developed a draft regulation requiring that industry apply the kinds of controls that will enhance consumer confidence in seafood. The draft is currently under review by our general counsel. We hope to publish soon.

**FDA/NOAA VOLUNTARY SEAFOOD PROGRAM**

In cooperation with the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration (NOAA), we have designed a voluntary, fee-for-service inspection program, based on HACCP concepts. It may serve as an adjunct to our already existing inspection programs, both of which are being transformed to a HACCP-based approach. We have conducted pilots for domestic seafood processors, foreign processors, and retailers. We are currently piloting one for food service facilities. Publication of the proposed regulation on this program has been delayed pending completion of my agency's mandatory HACCP initiative. In the meantime, NOAA is shifting its program for processors to a HACCP-based approach as well.

**IMPORTS**

We have recently adopted a new strategy for dealing with imported seafood. This strategy includes

1) much closer cooperation with state and local authorities to identify imports that reach the retail market
2) the initiation of civil and criminal actions against consistent and flagrant violators
3) short-term inspection surveys targeting specific products categories
4) education of importers, brokers, and foreign processors

At the same time, we think that importers must do a better job; they must be more responsible to make sure the products they import meet our requirements.

Another aspect of the new import strategy that holds great promise is to give priority to the establishment of memoranda of understanding (MOUs) with countries that, because of their own inspection systems, consistently ship acceptable products to the U.S. This philosophy will facilitate the entry of products from countries that export safe, wholesome, properly labeled products and will permit us to direct our resources to the inspection of products of concern from other countries.

**IRRADIATION**

Irradiation of seafood to reduce microorganisms is approved for use in 35 countries. If
properly used, it can give the consumer a higher quality, as well as a safer, product. The FDA is reviewing petitions to permit application of this technology to U.S. seafood products.

We are already receiving inquiries about the technology from consumers. Clearly, there is a need for greater consumer education to achieve acceptance and understanding. Industry and government must work together to prevent misuse of the technology and to promote public understanding. We believe the petition process is the key.

DECOMPOSITION

Decomposition is a leading cause of complaints about seafood. Besides its aesthetic effects, decomposition may also be a direct health threat; scombrotoxins are a prime example. We have been putting much effort into this area. Analyses for decomposition in seafood-fresh, frozen, and canned products, domestic and imported-have been increased significantly. We're trying to improve the consistency of detection of decomposition, through both microbiological and chemical indicators. To date, the microbiological indicators have not panned out as well as the chemical indicators.

We are putting together a plan to set a defect action level for histamine in all scombroid fish, and a 1 ppm cadaverine action level for mahi mahi, tuna, and other fishery products. We are also looking at the implementation of a pass-fail system rather than the current three-class system for organoleptic assessment of decomposition.

RESEARCH

I can't describe the activities of the Office of Safety without talking about our research program. The FDA's seafood research is directed toward understanding the nature and severity of risks in seafood and finding the means to control those risks. We believe we need a solid scientific base from which to make sound regulatory decisions, address new problems, and perform inspection activities.

Our scientists develop or evaluate the tests or methods used to determine if seafood has been prepared, packed, or held under unsanitary conditions and to ensure that it is not contaminated with filth or rendered injurious to health. The scientists design these tests not only to determine the presence of biological and chemical contaminants in seafood, but also to assess what effects chemical contaminants and toxins have on biological systems, how specific pathogens cause disease, and whether economic fraud has occurred.

A recently completed inventory indicates that there are over 180 ongoing seafood research projects directly related to safety. They fall into three general areas:

1) biological hazards, including the natural toxins--algal toxins and toxins arising from decomposition
2) microbiological hazards-bacteria, viruses, and parasites
3) chemical hazards

Research is also being done in the areas of economic fraud, exposure, consumption patterns, and occurrence of illness.

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GET HOOKED ON SEAFOOD SAFETY

There is a lot on our plate at the Office of Seafood, but with the help and cooperation of groups such as this, we have every confidence that together we can face the challenges and develop new ways of thinking, new approaches, and a new dedication to food safety.
National and International Perspectives on Seafood Quality
INTRODUCTION

The issue of seafood quality is becoming increasingly complex. Consumers want more than safe and wholesome food—they want consistent and high quality. Fishers and processors must meet these changing demands and realize that harvesting and processing using traditional practices or simple “rules of thumb” are inadequate to meet evolving international standards for seafood quality. Every country incorporates minimum safety standards into import regulations, which processors routinely meet and generally exceed. The problem lies in knowing the level of quality beyond simple “safety” that must be met to improve profits and create new market opportunities. Contemporary consumers demand quality that is costly to produce. However, depending on the market, “excess” quality will increase costs and decrease profits. Both exceeding and not meeting optimal quality will lead to lower profits.

Seafood producers are familiar with the technical aspects of quality control and are accustomed to adapting to technical problems as they arise. Today, however, quality assurance means more than identifying belly burn and tearing down seams. To succeed in the highly competitive food protein market, the seafood industry must address a wide range of issues related to public regulations, consumer behavior, and product quality. Adaptability is a necessary element of good management. The objectives of this paper are to summarize the latest trends and issues in seafood safety and quality in the United States and internationally. The first sections of the paper describe U.S. programs and agency responsibilities. The remaining sections outline international programs, particularly those being developed by the European Community (EC). The paper concludes with a discussion of implications for the U.S. industry.

SEAFOOD INSPECTION

American seafood producers are routinely inspected by the government for food safety issues. Plants are also regularly visited by various buyers, each with individual needs and specifications.

A prominent topic in the seafood industry is whether inspections will become “mandatory.” This is somewhat misleading because the U.S. Food and Drug Administration (FDA) has had a mandatory inspection program for many years. Where confusion lies is that the inspections for seafood are periodic, unlike those for beef and poultry, which require the continuous presence of a U.S. Department of Agriculture (USDA) inspector in the plant.

The newest plan of the FDA is to continue its periodic inspection with modifications, including the incorporation of the hazard analysis and critical control points (HACCP) program, as discussed below. The broad outline for this plan was announced March 22, 1993 by FDA Commissioner David Kessler. The periodic plant inspection has always included certain records and will now add a HACCP plan. HACCP training workshops are available through the National Marine Fisheries Service (NMFS) and various industry groups. These workshops should provide adequate training for designing a HACCP plan, but each plan will be individually reviewed by the FDA. The FDA plan has been drafted and is under review by the Department of Health and Human Services (HHS). After leaving HHS, the plan will be reviewed by the Office of Management and Budget, then published for public comment. A publication date of late 1993 is predicted. There will be a substantial period of up to a year for implementing the FDA-mandated HACCP program (Billy 1993; Lowell, personal communication).
HACCP

Hazard analysis and critical control points is a method of proactive and preventative inspection. The traditional system of inspecting only the final product can be extremely wasteful of both materials and labor. In contrast, the HACCP system is designed to identify critical areas in the plant and monitor those points during processing, which allows the quality assurance personnel to find problems where and when they occur. This technique has been used successfully in many industries, notably low-acid canning of seafood. The function of the HACCP program primarily is safety rather than quality (Pierson 1992).

Producing a HACCP program requires familiarity with the workings of the plant and then tailoring a plan on the basis of that information. Many agencies have their own versions of HACCP checklists. For example, the USDA uses the checklist of the National Advisory Committee on Microbiological Criteria for Food, and the Codex Commission has its own list. With slight variations, each list consists of

1. the personnel to be involved with the procedure
2. construction of a product flow diagram for the plant
3. the control points, potential preventative measures, and establishment of target levels and tolerances at each critical control point ("critical" referring to possible consumer health hazards resulting from loss of control at this point)
4. the monitoring system, documentation systems and procedures to address process deviation
5. the review system

The FDA and the National Oceanic and Atmospheric Administration (NOAA) have been collaborating on developing regulations and a manual for a HACCP-based inspection program targeting (1) food safety, (2) food hygiene, and (3) economic fraud. According to Lu Cano of the FDA, this was to be accomplished by the end of 1993, but as of August the project had been halted to reconsider its necessity as an addition to the other programs (Cano, personal communication).

NOAA began operating a HACCP-based inspection system in July 1992, which is a fee-for-service program. NOAA administers three types of inspection programs: heavy inspection, occasional inspection, and HACCP-based self-inspection. The three vary in cost. The NOAA programs result in inspection certification which, according to Thomas Moreau of NMFS Technical Services, will be adequate for export of product to the EC. The certificates will be available in nine languages to expedite exportation procedures (Moreau 1993).

Over the years many mandatory seafood inspection bills have been introduced in Congress but have not been passed. The 1992 Congress examined two bills, neither of which made it out of committee. No new seafood inspection bills have been submitted to the 1993 Congress, although there is a shellfish water bill-HR1412-sponsored by Jolene Unsoeld, a Democrat from Washington. The interest in creating seafood inspection legislation has been decreasing because of difficulties in developing congressional consensus on (1) the choice of agency to administer the new law, (2) protection of whistle blowers, (3) a new definition of "adulteration" in the federal Food, Drug, and Cosmetic Act of 1938, and (4) the origin of the funding.

The FDA predicts that their HACCP-based inspection will be a sufficient program for meeting safety and export needs. The FDA believes that the program will require minimal additional effort from industry and incur no extra cost to the FDA.

UNITED STATES AGENCIES

There are three U.S. Executive Branch cabinet posts directly responsible for dealing with contaminants in seafood: the Department of Health and Human Services, which houses the FDA, the Department of Commerce, within which NOAA administers NMFS; and the Department of the Interior, which contains the Fish and Wildlife Service.

FDA-Office of Seafood

The U.S. FDA administers the Food, Drug, and Cosmetic Act through the use of random inspections.

In February 1991, David Kessler created the first product-specific office in the FDA: the Office of Seafood (OS), contained in the FDA’s Center for Food Safety and Applied Nutrition. The OS attempts to address the most serious problems associated with seafood consumption, which it defines as water quality, exports, imports, retail, and consumer concerns. The OS comprises two divisions:

1. The Division of Seafood Research, which plans and conducts research on (a) seafood harvesting and processing and (b) storage and
distribution of wild and farmed sources that may be affected by chemical and biological contamination.

2. The Division of Seafood Programs, which is responsible for agency policies, planning and coordinating all seafood inspection, and enforcement. The Division of Seafood Protection is further broken down into (a) policy guidance, (b) program and enforcement, and (c) shellfish sanitation.

The current strategy of the FDA is to become more effective by aiming for prevention. However, there are two problems with this more aggressive strategy: the difficulty of identifying future problems and the tendency to undertake a wider scope of responsibility than was originally intended - for example, the monitoring for ocean contaminants that could affect seafood safety. The FDA justifies this broadening of responsibility as necessary for the protection of consumers against the production and trade of adulterated goods. The FDA uses several methods of protection:

1. creating minimum tolerance levels
2. monitoring water quality in shellfish harvest areas
3. developing simple field tests for toxins
4. compiling data from other organizations on chemical contaminants
5. analyzing species susceptibility to pesticides and chemicals
6. requiring the incorporation of a HACCP program for seafood processing plants

NOAA-NMFS

The National Oceanic and Atmospheric Administration is a branch of the U.S. Department of Commerce. The National Marine Fisheries Service, under the directorship of NOAA, offers several fee-for-service inspection programs. These inspections may be used to supplement the FDA-required inspection either when buyers require an independent grading system or when an inspection is needed sooner than the regularly scheduled FDA inspection.

There are several different auditing frequencies that lead to different approval marks. "U.S. grade A," required by some buyers, is achieved through a heavy inspection system. "Packed Under Federal Inspection" (PUFI) is the general NOAA inspection mark. "Sanitarily Inspected Fish Establishment" (SIFE) inspection focuses only on plant sanitation and includes no product qualifications. "Lot Inspected" is an inspection of samples of entire lots.

NMFS has written Model Seafood Surveillance Programs (MSSP) for various seafood businesses. MSSP is a guideline for building a HACCP program. MSSP subjects covered are aquaculture, breaded and specialty items, food service/consumers, imported products, plan of operations, raw fish, retail, smoked and cured products, and wholesale distributors.

In July 1992 the U.S. Department of Commerce announced the incorporation of HACCP into its inspection program. Completing a HACCP workshop is mandatory by at least one employee in a company wishing to use the NMFS inspection service. Training is provided through NOAA workshops and several industry groups. Along with the inspection services, NMFS is working on joint training between the FDA and the Department of Fisheries and Oceans of Canada, in a move to harmonize trade between Canada and the U.S.

U.S. Department of Agriculture - FSIS

The USDA oversees other protein foods besides seafood through the Food Safety and Inspection Service (FSIS), which uses a comprehensive continuous inspection program in all meat and poultry plants.

The National Fisheries Institute (NFI) preference for administrator of a continuous seafood inspection is the FSIS (Richard Gutting, personal communication). At the suggestion of the National Academy of Science, the current continuous inspection in the meat and poultry industries would be changed to a HACCP random inspection program that would free up some of the program's labor to include seafood. The reason the NFI prefers the USDA is that the cooperative international inspections are already in place for meat and poultry importation. However, this preference may be reconsidered in light of the recent E. coli outbreaks in the Western United States.

The United States, along with Guam, Puerto Rico, and the Virgin Islands, falls under the jurisdiction of the Code of Federal Regulations Part 21 when dealing with the transportation and inspection of seafood and CFR 50 when dealing with fishery products. Many states have additional regulations, tailored to regional production, that are slightly more restrictive than the Federal regulations.
ISO 9000

With increasing international trade in seafood and other goods, the need for uniformity among quality systems has also increased. This need has been addressed by the International Organization for Standardization (ISO), Geneva, with the creation of the ISO 9000 series of standards. The object of ISO is to "promote the development of standardization and related world activities with a view to facilitating international exchange of goods and services and to developing cooperation in the sphere of intellectual, scientific, technological and economic activity" (ANSI/ASQC, 1990).

In the United States, certification is achieved through an audit by a third party approved by the Registrar Accreditation Board (RAB). RAB is an affiliate of the American Society for Quality Control, and the registrar program is part of the American National Standards Institute’s (ANSI) accreditation program. ANSI is the U.S. member to the ISO. A current list of third-party auditors can be obtained from:

Registrar Accreditation Board
611 E. Wisconsin Ave.
P.O. Box 3005
Milwaukee, WI 53201-3005
(414) 272-8575
fax (414) 765-8661

The ISO standards are not specific to any one industry or process but are broadly defined to encompass all areas. The five standards are:

- ISO 9000: Selection of the right standard
- ISO 9001: Product development, production, delivery, and follow-up
- ISO 9002: Production and delivery
- ISO 9003: Final inspections and testing
- ISO 9004: Guidelines

Seafood processing is covered under ISO 9002 or 9001, depending on the function of the company. If carried out as planned, the standardization should help international trade. The responsibility for guaranteeing quality is shifted from the buyer to the producer. However, the certification process may be expensive and difficult to standardize (Chynoweth and Mullin, 1992).

ISO registration may prove unnecessary to American seafood companies. If a company already has a comfortable trade relationship, its European buyer may be willing to continue to send over inspectors to be sure of the existence of a competent program instead of requiring ISO certification. Both the FDA and MFS inspection programs result in certificates suitable to existing EC needs. The consolidation of the EC and evolving standards may change future needs and requirements. If the standards address only microbial safety, then the U.S. HACCP as it is now constituted will meet EC requirements. If, however, the EC requirements extend to price and general quality, then U.S. HACCP programs may be inadequate to meet European standards.

EUROPEAN COMMUNITY

The new, unified European Community has shifted its inspection focus to the point of origin, a strategy which reinforces the value of programs such as ISO 9000. The regulations are published in the *Official Journal of the European Communities*, volume 34, September 24, 1991. EC Directive 91/493 sets standards for both European and foreign producers. The quality assurance requirements of the directive are listed in article 6 and incorporate HACCP principles.

The purpose of the EC is to form an economically powerful union of its 12 member countries: Belgium, Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, and Spain. From a tariff perspective, the EC is also a customs union. A common tariff is applied on imports to the EC, and all products are free of duty within the 12 member nations.

The following directives in the *Official Journal* pertain to seafood:

- 91/67, of 28 January 1991, concerning the animal health conditions governing the placing on the market of aquaculture animals and products
- 91/492, of 15 July 1991, laying down the health conditions for the production and the placing on the market of live bivalve mollusks
- 91/493, of 22 July 1991, laying down the health conditions for the production and the placing on the market of fishery products
- 91/2587, of 26 July 1991, chapter 3, amending 87/2658 on the tariff and statistical nomenclature and on the Common Customs Tariff
- 91/3865, of 16 December 1991, fixing the reference prices for fishery products for the 1992 fishing year

Directive 91/493 concerns imports of seafood into the EC, but, as EC fisheries consultant, Peter Howgate puts it, “[It’s] no big deal for the
United States" in terms of microbiological safety. The directive does not require any action that exceeds HACCP requirements. The purpose of the directive is to define how fishery products will be regulated in the EC based on equivalency of quality standards and control. The directive places more emphasis on control during processing than on final inspections. Although HACCP is not specifically mentioned, the four steps on which the directive is based are consistent with HACCP concepts: identification and monitoring of critical points, keeping records, and sampling. The sample analysis must be performed by a competent authority. ("Competent authority" is a nebulous term that will be more completely defined in the upcoming annexes [Howgate 1993]).

The EC is protective in its stance towards its agricultural industry. "The U.S. proposed during the Uruguay round of the General Agreement on Tariffs and Trade (GATT) a zero-for-zero measure where the U.S. would remove all tariffs on certain goods in exchange for reciprocal action on the part of other nations. Seafood is included in this zero-for-zero proposal. This rather strong proposal has been met with resistance on the part of many GATT members, particularly the EC, and prospects for its adoption appear slim. The outcome of the Uruguay round is unclear" (AIPCEE 1992).

**CODEX ALIMENTARIUS**

International guidelines for seafood safety essentially lie under the auspices of the United Nations, whose Codex Alimentarius (Food Code) sets international standards for minimum safety. In practice, major importing countries have their own standards, which exceed Codex standards.

The Codex Alimentarius is a joint project of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). It is the compilation of all the standards, codes of practice, guidelines, and recommendations of various world governments by the Codex Alimentarius Commission (CAC). The CAC is a subsidiary body of the FAO and WHO and is funded by these two groups and open to all of their members.

The purpose of Codex is to facilitate the world trade in food by means of international standards incorporating the goals of fair trade and consumer protection. Codex balances the removal of trade barriers with an emphasis on the ethical aspects of food supply. The standards imposed by Codex address safety assurance and are generally exceeded by U.S. products. The Codex Commission meets every two years to consider revision of standards. Some current concerns are codes of practice for surimi, addition of sensory techniques to other evaluation practices, and questions about aquaculture. NMFS represents the U.S.; the FDA is the alternate delegate.

**CONCLUSION**

The goal of the NFI is to increase U.S. seafood consumption to 20 pounds per person by the year 2000. To realize even a portion of this objective, the seafood industry will need to develop seafood programs that are part of greater efforts to promote seafood consumption. It currently appears that HACCP programs will be mandated for each U.S. processing plant as well as some vessels. Although such programs are ostensibly designed for controlling microbiological contamination of seafood, their development has much broader use and implications: a program and management structure for controlling other aspects of seafood safety and quality; an important promotional device for assuring the public of seafood safety; and a way to meet evolving international standards for seafood safety and quality.

While HACCP-based seafood programs have been traditionally designed to cost effectively reduce seafood contamination, the structure of the programs may be flexible enough to accommodate future firm and industry needs. Evolving European standards may require programs that assure seafood quality and integrity beyond microbiological contamination. It is recommended that as the U.S. seafood industry adopts HACCP, it consider how this program will fit within a longer-term commitment to seafood quality control. The general design of HACCP may prove to be a flexible and economically effective structure for incorporating other quality control objectives and programs.

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IMPORT STANDARDS AND REGULATIONS FOR SEAFOOD SOLD IN THE EEC, AND IN-PLANT QUALITY ASSURANCE

Peter Howgate
Aberdeen, United Kingdom

INTRODUCTION
The single European market came into effect January 1, 1993. In preparation for this event, a wealth of legislation over many fields of activity had to be harmonized to become EC legislation. Food laws were included in this harmonization program with the aim that member states could have confidence in the safety of foods produced anywhere within the EC. In principle, and ultimately in practice, foods produced in any member state can be traded throughout the Community without any hygiene and safety checks at borders, although there will be a brief period while member states introduce national legislation when some foods might still be subject to checks. The harmonized regulations also impose a single set of criteria for the entry of imported products, and once a food product has entered a country within the EC, it can be distributed without further checks at internal borders.

Broad classes of food commodities are the subject of separate legislation, and two directives apply to fishery products. They are the council directive of 22 July 1991, laying down the health conditions for producing and marketing fishery products (91/493/EEC), and the council directive of 15 July 1991, laying down the health conditions for producing and marketing live bivalve molluscs (91/492/EEC) (Council of the European Community 1991a & b). As only a very small amount of live bivalve molluscs enters international trade, this article will not discuss the latter directive. Community law requires that member states enact national legislation to put into effect the requirements of a council directive.

Harmonizing food laws within the Community has also formalized a shift in approaches to ensuring the safety and quality of foods. There will be less reliance on inspecting products; rather, the basic principle is that the safety of food should be assured by control and inspection primarily at the point of production. This is in accord with current thinking on quality assurance and inspection of food products. The directive also establishes in legislation the principle of "equivalency" with regard to imported fishery products-products imported into the Community must be produced under conditions equivalent to those applicable in the Community and subjected to equivalent controls. The directive, then, is worth studying by anyone interested in quality assurance and inspection of fishery products because it lays down a framework of principle and practice for regulating safety and quality of fishery products.

PROVISIONS OF THE DIRECTIVE

General
Quotations in this paper are from the English edition, but versions are available in the other official languages of the Community.

The July 22, 1991 directive consists of three parts: a preamble of 2 pages, which states the reasons for the directive and its principles; 5 pages of provisions of the directive, which define the legislation; and 13 pages of a technical annex laying down conditions for handling, processing, and storing fishery products.

Some Definitions
Article 2 of chapter I, General Provisions, defines terms used in the directive. Some, like "chilling," are general technological terms and have no special meaning in the context of the directive, but some terms are worth picking out for their importance in the application of the directive.

Fishery products--all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs, and aquatic animals covered by other Community acts.
Competent authority-the central authority of a member state competent to carry out veterinary checks, or any authority to which
it has delegated that competence. (Note: it is common in many European countries for meat foods and premises where meat foods are handled and stored to be controlled by persons with veterinary qualifications. Hence the reference to “veterinary” checks.) Establishment - any premises where fishery products are prepared, processed, chilled, frozen, packaged, or stored. Auction and wholesale markets in which only display and sale by wholesale takes place are not deemed to be establishments. Placing on the market - holding or displaying for sale, offering for sale, selling, delivering, or any other form of placing on the market in the Community, excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or customers, which must be subject to the health check laid down by national rules for checking the retail trade. Factory vessel - any vessel on which fishery products undergo one or more of the following operations followed by packaging: filleting, slicing, skinning, mincing, freezing, or processing. The following are not deemed to be factory vessels: • fishing vessels in which only shrimps and molluscs are cooked on board • fishing vessels on board which only freezing is carried out

The Competent Authority
The directive places certain responsibilities on the “competent authority” defined above. This is in effect the inspection agency in the country, but how it is organized for fishery products differs among member states. Only one country, Denmark, has a dedicated fish inspection service. In other states the requirements of the directive will be enforced by the national or local government body responsible for the safety of foods generally, or more specifically, meat foods. In the United Kingdom, food laws are enforced by environmental health officers employed by local government.

Approval of Establishments
A central requirement of the directive is that fish placed on the market must have been handled, processed, packed, and stored in approved establishments. An approved establishment must meet the technical requirements for construction, equipment, and operation specified in the annex to the directive. An approved establishment is given a registration number, and the competent authority must submit a list of approved establishments to the commission. Only products from approved and registered premises may be marketed.

The competent authority is also required to “register” auction and wholesale markets, which must comply with the appropriate standards specified in the annex to the directive.

Monitoring by the Commission
The directive allows for monitoring of application of the directive by “experts” from the commission. These experts will be employed by the commission and will have the power to make on-the-spot checks to verify that establishments are complying with the provisions of the directive. For this purpose, the commission will recruit a small force of inspectors.

APPLICATION TO_EXPORTING COUNTRIES
Though the primary objective of the directive is to harmonize practices within the Community, it is a principle of the directive that its provisions should apply equally to imports from “third countries” and that there should be a common import control system applied by all member states of the Community. Article 10 of the directive is quite clear:

Provisions applied to imports of fishery products from third countries shall be equivalent to those governing the placing on the market of Community products.

What this means is that the EC requires fishery products intended for export to the Community to be processed under conditions equivalent to those prevailing in the Community and to have been subjected to inspection and control equivalent to that applied in the Community. This principle of equivalence is being applied to imports by other countries importing fishery products, particularly by authorities in the U.S. and Canada.

Before the introduction of the single market, each member state controlled the safety of imported fishery products according to the legislation in force in that state. Fishery products imported into a country, or for that matter, produced in a country, could be further inspected when they crossed a border. Control was exercised by sampling and inspecting a sample from a consignment. The directive now establishes a completely different principle - control will be at the point of production, and
though inspectors at the ports of entry of imports still have the right to inspect consignments, such action is expected to be the exception. Clearly this approach will work only if there is effective control over the safety of products during production and effective monitoring by the competent authority.

In order to apply the principle of equivalency, the commission reserves the right to carry out inspections of the situation concerning hygiene and inspection in the exporting country by experts from the commission and the member states. Article 11, section 2 states

In order to allow the import conditions to be fixed, and in order to verify the conditions of production, storage and dispatch of fishery products for consignment to the Community, inspections may be carried out on the spot by experts from the Commission and the member states.

The experts will be appointed by, and working for, the commission, and the commission will bear all costs of the inspection.

Though the commission reserves the right to carry out inspections in the exporting country, this does not necessarily mean it will do so. Each country will be considered of itself, and specific import conditions will be fixed, depending on what the directive refers to as the hygiene situation in that country. When fixing these import conditions, the commission will take into account the situation with regard to the existence and competence of an inspection service and the hygiene standards prevailing in the industry.

When fixing the import conditions of fishery products referred to in paragraph 1, particular account shall be taken of:

(a) the legislation of the third country;
(b) the organization of the competent authority of the third country and of its inspection services, the powers of such services, and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force.

The commission's own team of inspectors is expected to be in place in mid-1993, but clearly it will be some time before it can consider or survey the situation in all countries exporting to the Community. In the meantime it is up to each member state to ensure the safety of fishery products entering that country.

**PRODUCT STANDARDS**

The thrust of the directive is control over the safety of fishery products by control over conditions for processing, storage, and distribution, not by control of the quality of end products. The directive, though, does have some requirements for testing products.

**Freshness**

Fitness for human consumption is tested by sensory evaluation for freshness. There is a separate council regulation, 103/76, which requires that fish must be inspected at first sale, essentially when landed, and classified into grades of freshness and size (Howgate 1987). Three grades of freshness, E, A, and B, are defined by sensory attributes for fish considered suitable for human consumption, and fish which is not fresh enough to be classified into one of these grades is deemed unfit for consumption. The directive under discussion here refers back to this regulation and further allows for products to be checked at any point in
the processing, storage, and distribution chain for compliance with the minimum freshness standards defined in the regulation.

The sensory evaluation for freshness may be supplemented by chemical or microbiological tests. Total volatile basic nitrogen and trimethylamine are included as tests for freshness, though limits have not yet been set.

**Histamine**

The directive specifies a sampling scheme and limits for histamine that can be applied to fish of the Scombridae or Clupeidae families. A sample of nine units are taken and analyzed individually. The following criteria are specified:

- the mean value must not exceed 100 ppm
- two samples may have a value of more than 100 ppm but less than 200 ppm
- no sample may have a value exceeding 200 ppm

**Contaminants**

The directive requires that “fishery products must not contain in their edible parts contaminants, such as heavy metals and organochlorines, present in the aquatic environment at such a level that the calculated dietary intake exceeds the acceptable daily or weekly intake for humans.” This principle has still to be translated into concentration limits.

**Microbiological Criteria**

The commission may lay down microbiological criteria for products, including sampling plans and methods of analysis, where there is a need to protect public health. One set of criteria, for cooked crustaceans and molluscs, has been issued (Commission of the European Communities 1992).

**THE ANNEX**

The annex contains the detailed conditions and requirements for handling, processing, storing, and dispatching fishery products from landing at ports to packaging and transport. The separate chapters and sections include the following:

- Conditions applicable to factory vessels
- Requirements during and after landing
- General conditions for establishments on land
- General conditions relating to premises and equipment
- General conditions of hygiene
  - Premises and equipment
  - Staff
- Special conditions for handling fishery products on shore
  - Conditions for fresh products
  - Conditions for frozen products
  - Conditions for thawing products
  - Conditions for processed products
  - Canning
  - Smoking
  - Salting
  - Cooked crustacean and molluscan shellfish products
  - Mechanically recovered fish flesh
- Conditions concerning parasites
- Health control and monitoring of production conditions
- Packaging
- Identification marks
- Storage and transport

The various chapters are written as brief codes of practice for the operation under consideration, and any factory vessel, market, or establishment that is already operating to good manufacturing practices will meet the requirements of the annex.

**IN-PLANT QUALITY ASSURANCE AND HACCP**

An approved establishment must meet the requirements specified in the general provisions of the directive which, in article 6, explicitly lays a responsibility on “persons responsible for establishments” to have effective quality assurance systems in place in the plant.

Member states shall ensure that persons responsible for establishments take all necessary measures, so that, at all stages of the production of fishery products, the specifications of this directive are complied with.

To that end, the said persons responsible must carry out their own checks based on the following principles:

- identification of critical points in their establishment on the basis of the manufacturing processes used;
- establishment and implementation of methods for monitoring and checking such critical points;
- taking samples for analysis in a laboratory approved by the competent
authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by the directive;

- keeping a written record or a record registered in an indelible fashion of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests will in particular be kept for a period of at least two years.

All this reads very much like the principles of hazard analysis and critical control points (HACCP) (ICMSF 1988), but HACCP is not referred to as such in the directive.

Throughout the food industry in general in Europe, including the fish processing industry, there is an increasing use of the HACCP approach for controlling microbiological hazards of foods. Generally seafoods are not common sources of food poisoning, and where they are implicated, most outbreaks are associated with bacteria, viruses, or toxins present in the food when caught or harvested. Examples are various forms of food poisoning from bivalve shellfish throughout the world and ciguatera poisoning in some countries (Ahmed 1991; Bryan 1987; Gibson 1992). The EEC directive on marketing of live bivalves controls the intrinsic safety of bivalve mollusc, and the directive on fish products forbids the marketing of fish from specified families (Molidae, Diodontidae, Canthigasteridae), which are associated with intrinsic toxins, and products containing ciguatera toxin. Food poisoning resulting from contamination of fish products during processing or from poor handling and storage practices are quite rare, the most common being scombrototoxin poisoning. Criteria for histamine content referred to earlier are intended to control this hazard.

There have been considerable changes in the marketing of fish in Britain over the last couple of decades, changes which have had a major impact on quality assurance practices in the processing industry. The number of fishmonger shops and similar specialist outlets for fish has declined over this period, and more fish is being sold through multiple retail outlets-supermarkets and similar stores. These outlets are now responsible for about two-thirds of retail sales of frozen fish and about one-third of retail sales of “wet” fish in Britain. Of the wet fish, about half are sold at fish counters and half as prepacked products. Sales of ready-to-eat fish products and of “recipe” dishes, that is, complete meals incorporating fish, are increasing markedly. Multiple retailers set high standards for both the safety and the consumer acceptability of the products they market, and as they have considerable buying power and consequently an ability to dictate conditions, they have had a significant impact on improving quality assurance practices in the fish-processing industry. In addition, trade associations, like the Sea Fish Industry Association, the Scottish Salmon Growers Association, and the Shetland Seafood Quality Company, set standards for products or guidelines for the manufacture of products marketed by their members.

There is a general worldwide shortage of fish. Natural stocks throughout the world are fully exploited, if not overexploited, and though farmed products are making an increasing contribution to supplies, they are still only a small proportion of the total. At the same time demand for seafood is increasing. Fish is recognized as being a nutritious food, and, if of good quality, very pleasant to eat. As a result of restricted supplies and increasing demand, the price of fish has increased over the years more than that of other meat foods. Some species of fish, particularly shellfish, have long been considered luxury foods, but there is a tendency now for almost all varieties of fish to be considered expensive foodstuffs. Naturally, the consumer is expecting high quality for a high-priced product.

Regulatory authorities have been tightening up their control over the safety of foods, including fish products. I think it has to be accepted that fish processing has not led the field in standards of hygiene and sanitation, but the tightened regulations of the last few years are improving the situation. Certainly the EC directive on hygiene in fish processing has markedly changed attitudes in the fish processing industry in Britain. It might not be possible to get an exact figure for Britain or the EC, but in Aberdeen alone some tens of millions of pounds has been spent on new or refurbished processing plants to meet the requirements of the directive.

These pressures, from the marketers of fish products, from consumers, and from regulatory authorities, have resulted in a marked improvement in the quality of fish available to the consumer at all types of outlets and in a marked improvement in quality assurance practices in the industry. Control over hygiene and safety is accepted as a basic and essential requirement in fish processing, but consumer
satisfaction and at least maintenance of, if not increasing, market share in a competitive environment are seen as important objectives of quality assurance. Fish processors, certainly those selling under their own brand names or supplying the multiple retailers, view the provisions of the EC directive for hygiene, sanitation, and product quality as minimum requirements and in practice will work to higher standards. For example, the minimum freshness standard required in the directive, equivalent to around 15 days in ice for typical demersal species like cod, would not be acceptable to a processor with any pretensions towards supplying good quality products. The specifications for freshness typically imposed by multiples or by secondary processors for either prepacked wet fish or frozen products are equivalent to about five days in ice. Prepacked wet fish of this quality, in air, MAP, or vacuum pack, would be date stamped with a three-day storage life from the time of packing.

HACCP methodology is adopted as part of a total quality management (TQM) system (Shaw 1992) in a company. TQM is seen as the means of achieving consumer satisfaction through consistently high quality and safety. TQM can be seen as an extended HACCP approach. The same principles of defining hazards and identifying and monitoring critical points are adopted, but a hazard is any circumstance that could affect any aspect of the quality of the product, including safety.

Many food-processing companies in Britain, including those manufacturing fish products, use BS 5750, part 2 (British Standards Institution 1987, identical to ISO 9002-1987 and EN 29002-1987), as a model for their quality assurance systems, even if they do not seek accreditation as complying. It must be remembered that meeting the provisions of ISO 9002 is no guarantee that the product is of good quality, only that the quality assurance systems will consistently achieve the standards of quality, good or bad, set by the company.

REFERENCES


INTERNAL MARKETING OF QUALITY AND MARKETING ORIENTATION AT THE NATIONAL LEVEL: COOPERATION BETWEEN THE NORWEGIAN GOVERNMENT AND THE INDUSTRY

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INCREASED FOCUS ON QUALITY
During the 1980s, various internal and external factors had an important impact on the attitudes towards quality in the fishery sector in Norway.

The fishery industry entered into a period of reduced quotas and subsequently reduced supply to the fish-processing industry. At the same time, competition in the market became stronger and more difficult and thus made it clear that there had to be strategies other than increased volume through which profit could be made.

Norway's main competitors in the seafood market, like Canada and Iceland, have been improving the quality of seafood through various means, and Norway's status as the number one quality seafood producer has therefore in some markets been challenged. Although markets for less expensive products can be found, it is more and more obvious that an increasing number of companies and sectors are competing on quality and with brand products. In this situation it is important to be in the market to sell to the best paying, quality-conscious customers, who demand safe products and specified quality at the correct price.

Furthermore, the Norwegian system of subsidizing the fisheries sector has changed dramatically, from a system of a general income guarantee to a general improvement of the framework of the fisheries sector. This latter policy, it is believed, results in an industry that has more efficient units of production. The most important factor in the increasingly significant role of quality is the process of establishing a single market within the European Economic Community (EEC). The Norwegian industry also heeded U.S. talk about a mandatory fish inspection program on all imports.

The Single Market
Europe is Norway's most important market, importing some 60 percent of our total export of fishery products. In Europe efforts have been underway for many years to establish the EEC as one single market as of 1 January 1993. The single market will be a community wherein goods, money, and people can move freely. Existing technical obstacles to intra-Community trade will be removed and replaced by common rules affecting marketing of goods and standardization of production.

Whereas an EEC council directive (directive 91/493/EEC, of July 1991) lays down the health conditions for the production and the general admission of fish to the market, the EEC council requests the different entrepreneurs in the market to strive for higher standards and thereby increase competition and efficiency within the community. As a result of this policy, there is a growing tendency for customers to ask Norwegian exporters to produce certificates of quality assurance according to principles in the International Standard's ISO 9000 and ISO 45000 series.1 In March 1993, the company NORFRA became the first exporter in Norway to receive the ISO 9002 certificate.

National Regulations
So that Norway's regulations will be consistent with those of the EEC, the Government has proposed an amendment to our national regulations. Because the technical and hygienic standards are very high in Norway, the new EEC regulations will have only limited

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1International Standard ISO 9000 and ISO 45 000 have been adopted as European Standard EN 29 000 and EN 45 000 and as Norwegian Standard NS-ISO 9000 and NS-ISO 45 000.
impact as far as investments are concerned. The seafood industry in other countries, including member countries, is facing massive investments in order to comply with the new technical standards set forward by the council. The major change in Norway will be the question of a compulsory monitoring system for all establishments to ensure that the production of fishery products complies with the directive. Such a monitoring system will be based on the principles of hazard analysis and critical control points (HACCP).

FROM A NATIONAL SEAFOOD INSPECTION SYSTEM TOWARDS AN INDIVIDUAL QUALITY ASSURANCE SYSTEM

The fisheries sector has previously been the most important sector of the Norwegian economy. The industry is fragmented, with numerous fishers and a large number of small- and medium-sized fish-processing companies spread along the Norwegian coastline. Today we have a register of about 21,000 full-time and part-time fishers, about 12,000 employed in the processing industry, and 6,000-7,000 employed in the fish farming industry. Recurring problems in such a fragmented structure are to assure a consistently high quality of goods from the many suppliers and to coordinate efforts to maintain and achieve the high quality of the products.

It is well known that the existence of a large group with a common interest (high quality) does not automatically give rise to collective action. There must be an individual incentive to join in, or there must be compulsion (Olsen 1977).

National Seafood Inspection System

In Norway there has always been strong governmental involvement in the fisheries sector to secure the national economic interest. The first governmental intervention occurred in 1444, with regard to the inspection of stockfish. The first national act on “quality control of fish handling and processing” was implemented in 1937. The act has since been mended, in 1958, and reviewed, in 1986. It is still a major instrument in national efforts to secure a high standard of quality within the sector.

The law, which lies under the jurisdiction of the Directorate of Fisheries, is implemented through a system of regional fish inspectors and laboratories. The main task of the inspectors is to undertake quality inspection of fish as they are landed, processed, and stored. Issuing different certificates (health, grading, and so on) on consignments of seafood ready for export to certain countries occupies a significant part of their time. It is also the duty of the fish inspectors to control the hygienic standard of all fishing vessels and processing units to monitor conformity with the specified requirements. During the 1980s the department was also involved in the national resource control.

The quality inspection of fish and other foodstuff at the point of retailing is, however, monitored by the Norwegian Food Control Authority.

Quality Inspection

The focus of the fish inspection authorities in Norway has been on quality inspection. Those who are not following the rules will get a fine, get an improvement order, or even lose their license. However, more serious fraud cases are taken to court.

Because of the way the fish inspection system has been operating, with emphases on controlling quality, issuing certificates, and monitoring resources, there has been less time left for giving advice to the industry on quality matters. Therefore, to a large extent, fish inspectors have been recognized as “quality police.” At the same time there have been few incentives for the industry to produce a higher quality than that required by the regulations; as a result, the national standard has become a maximum standard.

However, through this national system for mandatory fish inspection, the government has been able to “guarantee” the quality of consignments of fishery products. Producers in other countries have thus recognized our national inspection system as a significant competitive force in the market.

Quality Assurance Systems

Through the ongoing process of establishing a general market standard in the EEC, we have faced a process in which the responsibility for monitoring and assuring a certain production standard gradually is being transferred from the governmental to the private sphere. The greater responsibility put on

2Testing the freshness of the fish through sensory and biochemical tests. The tests are carried out by random sampling
the processors to ensure the health and safety of the consumers implies that safeguarding quality, including monitoring internal quality, has to be an integrated part of the processing activities of any successful company.

We therefore believe that in the near future, Norway will have a system where the national fish inspection system will continue to play a vital role as a system for securing a "minimum (high) quality standard" through inspection and monitoring of processing establishments. In addition, the National Seafood Inspection System will possibly be accredited as a competent body for issuing health certificates for fishery products to be exported. It is urgent that we strengthen the advisory part of the service to facilitate improved systems for quality assurance in the industry.

Above this "minimum level," the fishers and processors who have a policy of supplying seafood to quality-conscious buyers paying the highest prices will have to introduce systems through which quality control and quality assurance can be ensured within the company. Such quality systems will most likely be based on the principles of quality assurance rather than on those of quality inspection. To some extent such systems have to be approved through ISO certificates or through certified laboratory tests by an independent third party (the global approach).

DIFFERENT LEVELS OF STANDARD

As a consequence of the new marketing trends that have been discussed, a certain minimum standard has to be adopted in the industry before a processor can obtain an official registration number and be allowed to enter the market. The next step will be that some customers will ask the industry to certify that it is able to manufacture goods according to an ISO standard for quality assurance. These certificates are issued by certain private enterprises that are accredited in one of the EEC member countries. Those who think an ISO certificate will be the ultimate solution will have to reconsider their opinion. The most quality-conscious customers, like brand owners and supermarket chains, will, however, ask for a quality certificate before any processor is invited to negotiate a contract. In addition, processors will have to demonstrate their ability to manufacture a certain product on the basis of strict guidelines and process specifications from the customer.

NATIONAL CAMPAIGN FOR IMPROVED QUALITY

The Ministry of Fisheries (MF) is fully aware of these challenging market trends among quality-conscious consumers and has taken the initiative to maintain and strengthen our position as the leading quality seafood producer. The Government designated 1990 "the Quality and Marketing Year" in the fisheries sector. To accomplish this, the Government approved and launched a national campaign for improved quality on all seafood. The campaign continued the following years but was due to be terminated by the end of 1993.

Organization

The campaign-called "Kvalitetsbølgen" (the "Wave of Quality") has been planned and implemented as a joint program between the MF and major fisheries and the aquaculture organizations. The Norwegian Institute for Fisheries and Aquaculture was given the secretarial functions for the coordination of the program. A professional public relation agency is assisting in the preparation and presentation of the necessary material and brochures. The different activities have been agreed upon by the Steering Committee and executed either by the Norwegian Institute of Fisheries and Aquaculture or by one of the organizations involved.

The campaign has thus become a collaboration among three main parties:

1. the Government
2. the producers and the processors
3. research and development institutions

Objective

"Quality" means different things to different people. The main objective of the first phase of the campaign was to motivate and influence the fishers' and industry workers' awareness of and attitude to quality in all Norwegian seafood. An objective of the campaign was to teach people to recognize "quality" as meaning that a product has characteristics that correspond "to specifications from identified customers."

According to NS ISO 8402 the definition is "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs."
A further objective of the campaign was to increase the total market value of the fishery products and the profitability in the Norwegian seafood industry. Finally, for nutritional and health reasons, it was an objective to increase the domestic consumption of seafood in Norway.

**Target Groups**

The target groups of this campaign are the fishing industry, the fish-processing industry, and all involved in marine aquaculture. But people engaged in related activities in the fishery sector, such as research, education, and administration, also have been included.

**The First Phase-Awareness and Attitude**

During the first phase, the campaign focused on awareness, attitude, and knowledge. In this connection, different kinds of informational material were developed; some material was made specific to a particular group, and some was made general for the entire target population.

**Seminars**

Initially a press conference was held to brief invited journalists about the campaign soon to be launched. As a result, many articles focusing on quality in the fisheries were printed.

At the beginning of the campaign, another seminar was held at which various topics related to quality were discussed. A concluding seminar is planned by the end of this year to review the achievements during the campaign period.

Seminars focusing on quality and quality assurance were held in 12 of the main fishing municipalities. Much local initiative has been noticed in the wake of these seminars, and subsequently, many companies are now implementing quality assurance programs.

**Brochures**

The Norwegian Institute of Fisheries and Aquaculture wrote the text for each publication, which was then reformulated by the public relations agency. The text and drawings were reviewed by all members of the Steering Committee before the brochures were published. These publications highlight a number of activities:

- The importance of having support from highly motivated and dedicated managers who need to understand and participate in all quality matters. A pamphlet was distributed to about 8,000 managers, skippers, boat owners, and fish farmers.
- The importance of informing everybody involved in fish production and processing about the need for improved quality and to discuss quality not only as “freshness” but also in terms of “just in time” and “according to specifications.” A brochure on this topic was distributed to 45,000 persons.
- The importance of identifying improvement areas and to learn what people in the sector understand by quality. The Norwegian Institute of Fisheries and Aquaculture (Olsen 1991) conducted a survey, asking fishers and those who work in the processing industry their opinion of the present quality standards in the handling and processing operations. Everybody seems to be aware of major shortcomings in relation to quality, but nobody is willing or able to take the responsibility for the situation. These are the main conclusions we were able to draw:
  - Support from top management is necessary.
  - Quality can be improved at many stages of the processing line.
  - The supplier and the customer, external and internal, should establish a good relationship to achieve a higher quality end product.

We determined which activities to highlight in the second brochure by asking the people involved rather than referring to the common literature on quality assurance systems.

- The importance of identifying the needs of our main customers. How do consumers in our major markets recognize the quality of Norwegian seafood, and how does this information correspond with our own opinion?

On the basis of a survey conducted by the Norwegian Institute of Fisheries and Aquaculture in the U.S. (Olsen 1991), along with conclusions from various marketing reports, a third brochure was distributed. These are the main conclusion that could be drawn:
Norwegian exporters are considered to be reliable and professional. Norwegian brands are hardly recognized at all. The quality of Norway’s salmon is considered to be on top, whereas the quality of its cod is considered to be inferior to products from Iceland and Canada.

Advertisements
During the campaign we took out nine different advertisements in main fisheries newspapers and magazines. Our intention was to give facts and announcements of important messages in the brochures.

Newsletters
We printed monthly newsletters in the two main fisheries newspapers, intending to give information about people who had responded to the campaign and had started implementing different “quality projects.” The newsletters were also open to questions from the readers. However, we stopped the activity after one year, as it was rather demanding to follow up given the resources available and given the fact that the industry did not inform us about ongoing activities.

Also we printed a series of six posters and distributed them to the processing industry.

Scholarship for Journalists
As a follow up to the newsletters, we introduced five traveling scholarships for journalists. By giving these fellowships, we managed to get a lot of articles on quality printed in fishing newspapers and locally based newspapers. Various articles covered the Norwegian position in the Spanish market for salted fish as well as the position in the German wet fish market. Other articles are still to be printed. We believe this has been a worthwhile strategy to get journalists aware of the quality issue.

The Second Phase-Learning by Doing
In the second phase of the campaign, the strategy was to continue the efforts for changing attitudes and to support various ongoing activities and initiatives in the industry.

Guidelines for Handling of Fresh Fish
The Norwegian Institute of Fisheries and Aquaculture is the preparation of guidelines and instructions on handling and grading fresh fish (groundfish). The guidelines are not revolutionary, but rather a comprehensive and systematic presentation of the somewhat boring rules and regulations given in “the blue book.”

Other Activities
Because information and motivation are considered important parts of the campaign, different projects within these areas have been supported. In this regard, activities carried out by the fish industry associations have been given some financial support. The secretariat has also been giving advice to the industry on implementing quality systems.

The Role of the Norwegian Institute of Fisheries and Aquaculture
The Norwegian Institute of Fisheries and Aquaculture was designated in 1973 as an independent research institute under the Norwegian Fisheries Research Council and was reorganized in 1992. The institute has the following obligations:
The Norwegian Institute of Fisheries and Aquaculture was designated to be the secretariat of this campaign because our institute already had taken several initiatives to get more emphasis on quality aspects. We had responsibility for writing all background information for the brochures. Two of the brochures were based on results from ongoing research projects in the Center of Economics and Marketing. We have also been responsible for carrying out the different activities under the program.

In addition, the institute has played a major role in designing and implementing quality assurance programs in the industry, and we have tested different approaches. There has been a special need for extrapolating the requirements in the ISO standard to practical procedures in the industry. The nature of this work has been partly research and partly basic consulting. With regard to consulting, our work has been taken further than our policy intends, but it was necessary at an early stage before the traditional consultants had obtained the necessary training and experience. In the next stage, we will undertake training, monitor the program, and assist in the certification of new companies. We shall not be practically involved in any enterprise.

The Norwegian Institute of Fisheries and Aquaculture has been highly involved in the planning and execution of an education program under the University of Tromsoe. The Fisheries Research Council has stressed quality in its research program, and the Norwegian Institute of Fisheries and Aquaculture has carried out research on subjects like methods for sorting fish alive, processing of prerigor fish, methods for measuring the fat content in farmed salmon, and important quality attributes for the processing of salted fish.

We have also been involved in different committees to formulate strategies for different development programs (financed 50-50) and establish priorities among applications from the industry.

**INDUSTRY INITIATIVES ON QUALITY ASSURANCE**

During the campaign, quality has been put on the agenda in fisheries as never before, and there has been an increased focus on the need for quality assurance and quality improvements. Several projects are being implemented, with the associations in a key role. These efforts have also identified the need for better education and training of the employees.

**Quality Prizes**

The Norwegian Fishermen's Association and the Directorate of Fisheries have introduced quality prizes for the fishing fleet and the processing industry, respectively. Though these prizes are not based on the principles of the more famous prizes, like the Deminger prize or the Malcolm Baldrige Award, they constitute important rewards for those who have shown an above-average interest in quality.

**Quality Assurance Systems**

At the beginning of this campaign, the Norwegian Institute of Fisheries and Aquaculture, in cooperation with some consultants, planned a program for implementing a quality management system in 10 companies in northern Norway. The Federation of Norwegian Fishing Industry has responsibility for implementing and coordinating the program, whereas the Norwegian Institute of Fisheries and Aquaculture has been giving professional support. This program will terminate in July; by that time most of the companies will be at the level of NS ISO 9002. The program is considered to be very successful, and another group of 26 companies have already joined a two-year program at a total cost of about U.S. $7 million. Another important quality program has been implemented in the Lofoten and Vesteraalen area.

The Norwegian Institute of Fisheries and Aquaculture, in cooperation with trained teachers, has been responsible for the professional support. This program was implemented in two separate phases. The first phase covered all 26 companies, with emphasis on motivation and education of shop floor people in order to organize and generate improvement activities. In the second phase, 19 of the factories continued and worked out system documentation.

This program was implemented in two separate phases. The first phase covered all 26 companies, with emphasis on motivation and education of shop floor people in order to organize and generate improvement activities. In the second phase, 19 of the factories continued and worked out system documentation.

A third program in which the Norwegian Institute of Fisheries and Aquaculture has been involved is a quality program for five
shrimp factories. The shrimp processing industry in Norway has a high level of quality and is familiar with strict requirements from customers like Marks & Spencer and the legal authorities. Therefore, there is a market-driven quality culture in the shrimp industry and consequently less need for motivation than in the fish-processing industry.

The marine aquaculture sector had been focusing on quality long before the campaign was launched and had, at the time we started, already made a plan—"Quality Fish Project" ("Prosjekt God Fisk")—for implementing quality assurance in the whole sector.

Through this program, they have worked systematically towards awareness of quality and practical information on the handling and processing of farmed salmon to maintain the highest degree of freshness and quality. They planned a second phase to prepare the companies for the process of being certified according to international standards of quality. For two to three years it was expected that most companies in the aquaculture sector should introduce quality management. However, the bankruptcy of the Norwegian Fish Farmers' Sales Organization was a setback to this plan. (Unlike the fishing industry, the aquaculture sector planned to implement a strict quality assurance program giving priority not so much to education and training, but to establishing a quality system documentation).

Education

Fish processing remains a relatively labor-intensive industry. One of the keys to improving performances in this industry is to find ways of helping employees do a better job. As we have implemented quality systems, we have identified the need for improved education and training of managers and employees. This need for education cannot possibly be met by the sector alone, and so some financial and professional support is given by the Government. The training and education of workers is basically given as (1) training program for specialized workers or (2) "internal training," thus using both public and private funds for education. The Directorate of Labor has made funds available for companies that want to offer the employees internal training programs as an alternative to unemployment and expenditures on unemployment pensions. As a fund of this nature has been made available, a more comprehensive effort for implementing quality in the fish-processing industry in Norway could be made possible.

Several projects of this nature are being implemented, something that seems propitious for the future of the fisheries sector in Norway. A weak point, however, is that the fishing industry is not given the same training opportunities as the processing industry. Because the fishing industry is an important part of an interdependent production chain, its training needs should be given a higher priority.

At university level, a training program in quality management has been introduced. In connection with "the Lofoten and Vesteraalen program," the Finnmark Regional College has started an integrated one-year program on "education and development" of teachers and of key personnel in the factories.

Research and Development

The research institutes and the universities have also focused on quality, which has been given priority through special research programs administered under the Fisheries Research Council. Quality (in the handling of marine resources) has also been emphasized in development programs in connection with the annual agreement between the MF and the Norwegian Fishermen’s Association.

Grading System for Codfish

Another important decision related to improving quality in the fisheries sector in Norway was the introduction of new principles for determining the minimum prices of raw fish by the Norwegian Fishermen’s Sales Organization in May 1989.

Prices were previously determined on the basis of the various product categories; the new system determines prices on the basis of specific criteria of quality. The new system grades the fish into Extra, A (ordinary), and Rejection. Grade A is based on the standard described in

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4 The training program for the processing industry and the marine aquaculture industry was approved in 1989; a similar program for the fishing fleet is still to be approved by the Government.

5 The Government covers 50 percent of the labor cost if people are given internal training programs as an alternative to unemployment.

6 In the case of nonconformity with the standard, the price can be reduced up to 30% on the basic price for the A grade.
the guidelines of the quality regulation, whereas Extra requires careful and professional handling similar to that for the grade Superior salmon. The price of grade E is about 10 percent above grade A.

The effect of this change in price regime is evident. During the first two years of the new system, the quality of the landed fish increased significantly and the rejection rate due to poor quality of raw fish was reduced. However, when practicing the new system, it has been difficult to distinguish between matters such as the objective quality of the fish and the question of fixing a reasonable price for the fish.

CONCLUDING REMARKS

The underlying message of this campaign has been that people are the most important factor when we want to achieve higher quality. Internal marketing has thus become the key strategy of this campaign. In this context we have emphasized identifying internal customers through the processing line of any company. Do the products we supply to the next customer comply with expectations or specifications? Have the employees received the necessary training and qualifications for the job they are going to perform? And finally, who is responsible for the quality level in an establishment?

The final goal should not be to establish a system only to ensure quality assurance, but also to encourage quality improvement activities in line with the Total Quality Management concept.

Today, we feel that the wave of quality that was introduced by the Ministry of Fisheries and the organizations of the sector was launched at the right moment, as the campaign for improved quality supports ongoing and planned efforts. We certainly believe that such a massive quality effort in the coming years will increase the total value of Norwegian fish resources.

REFERENCES


NATIONAL AND INTERNATIONAL PERSPECTIVES ON SEAFOOD QUALITY
INTRODUCTION
Evolving international standards will likely have an impact on seafood trade for the United States in both exports and imports. The U.S. was the number one exporting nation in the world in 1990, with over $3 billion in seafood exports, and the number two importing nation in the world, with over $5.5 billion in seafood imports (Fisheries of the United States 1991).

The international requirements will evolve from activities that are in progress in the Codex Alimentarius, negotiations under the U.S./Canada Free Trade Agreement, the North American Free Trade Agreement, and negotiations with the European Community (EC).

It is in the best interests of the United States to continue to actively participate in these activities.

CODEX ALIMENTARIUS

The Codex Alimentarius Commission is a subsidiary body of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The Latin words *codex alimentarius* mean "food code." In the present context it is the compilation of all the standards, codes of practice, guidelines, and recommendations of the Codex Alimentarius Commission.

The Codex Alimentarius Commission was established in 1962. The Codex system was set up because of a widely perceived need to facilitate world trade in foods, and internationally accepted standards were seen as the means. At the same time it was realized that if such internationally acceptable standards could be developed, then these standards must be based on added protection for consumers' health. Such standards would also promote fair practices in the food trade. The objectives of freer trade and better consumer protection are mutually dependent and mutually supportive.

Membership in the Codex Alimentarius Commission is open to all member nations and associate members of FAO and WHO; some 137 countries were codex members by the end of 1989.

Codex work is divided between committees dealing with "vertical" measures and those with "horizontal" measures, that is, committees on commodities and those dealing with general subjects such as food labeling. Each standard is considered in both kinds of committee as necessary.

A Codex standard sets out the required qualities of the food commodity, as sold, in objective terms. The elaboration of Codex standards follows eight different steps to completion. Degrees of acceptance by member countries are "full acceptance," "target acceptance," and "acceptance with specified deviations."

Codex also develops recommended international codes of hygienic practice for various commodities. Their purpose is to provide guidance for good manufacturing practices, and they are advisory in nature. The Codex contact point in the United States is the Executive Officer for Codex, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.

The Codex Committee on Fish and Fishery Products is responsible for the elaboration of worldwide standards for fishery products. The United States delegate is from the National Marine Fisheries Service (NMFS). The delegation consists of technical advisors from government - that is, NMFS and the Food and Drug Administration (FDA) - and industry.

The host government for this committee is Norway. The committee, which had its first session in 1966, now meets every two years.

There are currently 15 Codex standards that are approved or in draft form for frozen, canned, dried, and salted fishery products. All standards are in the process of being revised. The purpose of the revision process is to identify baseline acceptability criteria, which, if not met, would result in governments' taking action against the product.

The aesthetic characteristics would be retained and placed in appropriate documents as advisories to be used by buyers and sellers in establishing trading specifications.

There are currently 17 recommended international codes of practice for fish and fishery products either approved or under elaboration. The committee has been requested to consider a review of the codes of practice for possible
revision and to consider incorporating hazard analysis and critical control points (HACCP) principles into the documents.

The National Standards and Specifications Branch, Technical Services Unit, Inspection Services Division, NMFS, is responsible for coordinating all work to be done to establish U.S. positions that are presented to the committee at each session. This work includes developing protocols, field testing data collection sheets, analyzing data, and soliciting comments on appropriate documents for consideration by the U.S. delegation.

It is extremely important that government and industry work in harmony to provide accurate and precise information to the U.S. delegation in order to protect the U.S. interests for trading fishery products.

CANADA - U.S. FREE TRADE AGREEMENT

A Bilateral Technical Working Group on Fish and Fishery Product Inspection was organized and the first meeting held in January 1990 in Ottawa, Canada. The objective of the working group is to harmonize inspection systems by eliminating technical trade barriers between both countries. Meetings take place approximately every six months and alternate between the United States and Canada.

The Technical Working Group consists of a U.S. cochair from the FDA, a cochair from the NMFS for trade matters and those matters where NMFS assumes responsibility, and technical representatives from the FDA, NMFS and the U.S. Fish and Wildlife Service (USFWS). The Canadian representatives include a cochair from the Department of Fisheries and Oceans (DFO), Inspection and Enforcement Directorate; and technical representatives from the Directorate, International Directorate, and from the National Health and Welfare, Canada Health Protection Branch.

There are eight subworking groups under the direction of the Technical Working Group to deal with specific areas and issues:

1. Comparison of Regulatory Measures
2. Training and Education
3. Notification and Information Sharing
4. Essential Composition and Quality
5. Facilities/Imports and Exports Inspection
6. Molluscan Shellfish
7. Aquaculture
8. Reciprocal/International Activities

Each subworking group is under the direction of a U.S. and Canadian cochair.

The major activity in harmonizing inspection systems is taking place in sensory evaluation, analytical procedures and requirements, and evaluation of the equivalency of inspection systems.

Recent sensory harmonization workshops were conducted using the latest criteria from internationally recognized sensory scientists. Expert analysts from the FDA, NMFS, and the DFO Inspection Directorate participated. An in-depth analysis of the workshops clearly indicated that use of the appropriate sensory analysis applications resulted in expert assessor harmonization. These workshops will lead to diminished technical trade barriers and enhance the trading of fish and fishery products.

Analytical procedures and requirements for microorganisms, biotoxins, and food additives are being evaluated by both countries to harmonize procedures, requirements, and action levels. Of particular interest are *Listeria* in cooked, ready-to-eat fishery products, domoic acid levels, paralytic shellfish poisoning, methyl mercury, and polyphosphates. A protocol for a collaborative study on the use of cadaverine and putrescine as spoilage indicators has been submitted to the Association of Official Analytical Chemists for approval. The study will include collaborators from the FDA, NMFS, and the DFO.

In regard to the examination for equivalency of existing inspection systems in the United States and Canada, NMFS has submitted its voluntary HACCP-based inspection program to Canada for review. This program was developed using the Canadian Quality Management Program (QMP) as a model. The program was published in the *Federal Register* of July 29, 1992 for use. It is expected that a delegation from Canada will perform an on-site visit to the United States to evaluate the program for equivalency in the near future. The United States has visited Canada to observe and review the Quality Management Program.

Other activities include arrangements for joint training, the development of a cooperative study on fish parasites by both governments and industry, and close coordination of all the activities in Codex Alimentarius.

NORTH AMERICAN FREE TRADE AGREEMENT

There is currently little activity concerning progress under the North American Free Trade Agreement (NAFTA) as it relates to fish and fishery products. Based on the most recent