meetings, it appears that evolving international standards will be used as a basis for trade. There is a committee on sanitary and phytosanitary measures that directs its attention to those areas that protect human, animal, and plant life or health. There are no subcommittees or working groups. Joint Canadian-U.S. working groups continue to coordinate with the NAFTA Sanitary/Phytosanitary Committee.

There is also a committee on standards-related measures to consider quality, nomenclature, packaging, and labeling issues.

EUROPEAN COMMUNITY (EC)

NMFS is aware that the EC directives regarding the inspection and certification requirements to be implemented July 1, 1993 are a matter of concern to exporters of fishery products.

Our meetings with industry across the country during the past several months attempted to provide the industry with as much advance notice of the EC's intentions as possible so that plans could be made to meet these new requirements. It is important to note that the EC has adopted import requirements. Once the requirements are fully implemented, all countries must comply with them if their products are to be accepted into the EC.

Officials from NMFS, the FDA, and the USFWS have met with representatives of the EC to discuss the impending directives, explain the various controls and programs in the U.S., and seek clarification on a number of items described in the respective directives. These and other efforts have been undertaken to assure that there will be minimal disruption to U.S. export trade in seafood with the EC.

As an official U.S. Government agency responsible for inspecting and certifying fishery products, NMFS cannot ignore the EC import requirements. It must assure that products it certifies for export to the EC comply with appropriate requirements. In the event that a requirement is not being uniformly applied, to the detriment of the U.S., it will be viewed as a nontariff trade barrier and the U.S. Government will take appropriate trade actions.

Three EC directives have a major impact on fishery products:

1. Council directive 91/493, "laying down the health conditions for the production and the placing on the market of live bivalve molluscs."

2. Council directive 91/67, "concerning the animal health conditions governing the placing on the market of aquaculture animals and products."

Council directive 91/493 requires that third countries (for example, the United States) have a system at least equivalent to the system described in the directive. The general provisions of the system are delineated under Article 6 with additional requirements that would be applicable in the annex of the directive in chapters 2-7, which covers sanitation of the facility, handling and storage practices, and product requirements.

Article 6 outlines the principles of the HACCP-based system. The value of such a system has been widely acknowledged by food control authorities internationally (for example, Codex Alimentarius) as well as in the United States (for example, various reports issued by the National Academy of Sciences regarding meat, poultry, and seafood products). The United States, in particular, has recognized the advantages of adopting a HACCP-based inspection system.

EC representatives have acknowledged that traditional NMFS in-plant inspection techniques (such as continuous inspection) would also be considered equivalent to the HACCP-based inspection system. They have acknowledged that a lot inspection without knowledge of the handling and processing conditions would not be considered adequate.

The forthcoming system under the EC directives contains significant changes from previous experiences:

1. The establishment must be approved by a competent authority of the third country for compliance with requirements equivalent to those laid down in directive 91/493.

2. The establishment must be on a list of officially approved establishments that is submitted to the EC by the competent authority.

3. The product must bear a mark containing the approval number of the establishment.

4. The shipment must be accompanied by a health certificate.

The United States has identified NMFS the FDA, and the FWS as competent authorities for the inspection and certification of fishery products and has submitted all the required
material pertaining to laws, regulations, procedures, and so on, to the EC for evaluation. The United States has been informed that the EC will perform on-site visits between July 15 and October 1993.

Commission decision 93/185/EEC, "laying down certain transitional measures concerning the certification of fishery products from third countries in order to facilitate the switchover to the arrangements laid down in council directive 91/493/EEC," is to be implemented July 1, 1993. We have been informed that these transitional measures for certification have been taken to provide the EC with sufficient time to conduct site evaluations of the inspection systems of third countries exporting products to the EC. The decision will apply from July 1, 1993 to December 31, 1994. NMFS is in the process of translating the model certificate into the nine official languages of the EC. All certificates will be bilingual.

Council directive 91/492, requirements for live bivalve molluscs, is being discussed by the FDA and the EC. The major difference between the U.S. and the EC systems is the method of control. The EC relies on testing of the meats whereas the U.S. FDA system relies on testing the waters in the growing areas for control purposes. The United States continues to pursue EC approval for equivalency of our system.

Council directive 91/67, deals with aquaculture animals and products. The USFWS is discussing its programs with the EC to determine equivalency. The measures in this directive address matters pertaining to health and disease control.

The United States will continue to pursue clarification of language and areas in all of the EC directive that are unclear or left to interpretation. The industry will be kept informed of the status of the ongoing negotiations.

OTHER ISSUES

NMFS has received inquiries from several countries - Canada, Iceland, Chile, Indonesia and Ecuador - expressing interest in the development of memorandums of understanding to recognize each others inspection systems for equivalency.

Initial meetings to discuss protocol for the development of a memorandum of understanding have taken place with officials from Iceland.

Any development of a memorandum of understanding will be discussed and coordinated with the FDA for mutual agreement before approval.

INTERNATIONAL TRAINING BY NMFS

The FAO, Rome, Italy, has requested that NMFS provide training assistance at workshops and seminars conducted in South and Central America over the past 18 months. The requests have originated from the Food and Agriculture Organization of the United Nations, Rome. The training has focused on quality assurance and HACCP inspection systems. All of these seminars and workshops have been conducted in Spanish, and U.S. participation has been from the National Training Branch of NMFS. The host countries have been Chile, Panama, Costa Rica, El Salvador, Honduras, Brazil, and Guatemala.

There were 790 participants in the various workshops and seminars, from 40 different countries.

NEW NMFS HACCP-BASED INSPECTION SERVICE

On July 29, 1992, NMFS published in the Federal Register the new NMFS inspection service based on HACCP principles. This inspection service is in addition to the existing traditional NMFS inspection services available to industry. As is the case with the traditional inspection services, participation is voluntary, on a fee-for-service basis, the scope being safety, wholesomeness, and economic integrity. The service is available to all interested parties.

As of May 14, 1992, three firms at four locations have been participating in the NMFS HACCP-based inspection program. NMFS has received twelve HACCP plans for review. There continues to be interest from the retail sector.

NMFS provides HACCP certification by administering a test. Interested parties can arrange for a test to be given at a NMFS facility, following an NMFS training workshop, or following an industry training workshop. This certification is recognized by the FDA.

REFERENCES

THE CANADIAN QUALITY MANAGEMENT PROGRAM

Ian Devlin
Department of Fisheries and Oceans, British Columbia

INTRODUCTION

During the past five years, the Department of Fisheries and Oceans and the Canadian fish-processing industry have worked together to develop the Quality Management Program (QMP). On February 1, 1992 it became mandatory and is now a condition of federal registration for fish-processing plants.

In this paper I explain the rationale for developing the QMP by providing you with some background information on the Canadian fish inspection program and identifying the challenges that we were facing in delivering our inspection program and that prompted the re-examination of the way industry was being regulated. I then briefly explain the basic principles of our new QMP and clarify the Government’s and industry’s roles under the QMP.

THE CANADIAN FISH INSPECTION PROGRAM

The Inspection Services Directorate Mandate

The Inspection Services Branch of the Department of Fisheries and Oceans is mandated through federal legislation to inspect all fish and fish products intended for export from Canada or for interprovincial trade, and all fish and fish products imported into Canada. Through this mandate, we assure that both domestic production and imported products meet Canadian and foreign standards for grade, handling, identity, process, quality, and safety. In simpler terms, the Canadian Fish Inspection Program ensures that fish products produced in Canada or imported and sold in Canada are safe and wholesome and are fairly traded.

For fish and fish products produced in Canada, we have a dual concern: the health and safety of Canadian consumers and the overall quality of Canadian fish and fish products and their acceptability in international markets. Eighty-four percent of the fish caught and processed in Canada is exported. The Inspection Services Branch plays an important role in facilitating the trade of these Canadian fishery products through its product inspection and certification programs.

To achieve its mandate, the Inspection Services Branch has developed over the years a multifaceted national fish inspection program that focuses on the strategic steps of the fish-processing industry to ensure safe and acceptable fish products. This program involves a variety of inspection activities that include the inspection of:

- domestically produced fish products to determine the acceptability of these products for sale in Canada or on foreign markets
- domestic fish-processing establishments to determine the degree of compliance with regulatory requirements for construction, equipment, and operation
- domestic fishing vessels, unloading sites, and transport vehicles to determine compliance with the applicable construction and operating requirements
- imported product and the offshore processing operations to determine the acceptability of these products for sale in Canada and the monitoring of shellfish-growing waters through the Canadian Shellfish Sanitation Program.

Traditionally, many of the decisions made under the Fish Inspection Program relied on final product analysis and the results of single independent inspections of fish-processing plants. Implementing the QMP will expand the sources of information used in making decisions. A new decision-making process based on interrelated inspection data, gathered over time by both government inspectors and the processor, will be established.

Future Challenges

Before I focus on the specifics of our new approach, I would like to comment briefly on the changing nature of the commercial environment of the 1990s, which is making innovative approaches to food inspection so necessary.

One of the key challenges will be to endure the scrutiny of the informed consumer and
public media. Because of the increase in contaminants, pollution, and threats to the environment, there has been an increase in media and public concern regarding the safety of the food supply in general and fish products in particular. International trends lead us to believe that there will be no letup in media attention in the next decade. Today's consumers are better educated, better informed, and concerned about the safety of the food they eat. In all probability the workload of all food inspection agencies will continue to grow.

The rapid pace of changing technologies presents an additional challenge to industry and food inspection agencies. As the Canadian fish-processing industry develops new products and processes, the Fish Inspection Program must adapt its inspection methods to continue to meet its mandate.

Another major challenge for the 1990s will be responding to trade issues. The movement towards HACCP in the United States and the developments in the European Community are already indicating additional demands on the Canadian fish processors and the Fish Inspection Program. These countries and others are requiring more assurances from the Canadian Government that standards are being met. The factors I have mentioned are all external factors that will affect both the Inspection Services Branch and the Canadian fish-processing industry; but there is another key factor internal to government that will have an impact on all of the Canadian food inspection agencies. That is the question of resources.

The Canadian Government, as well as other western governments, is under constant pressure to limit spending and inspection programs such as the Department of Fisheries and Oceans and the Department of Agriculture. Canada cannot expect to have ever increasing resources to meet the challenges of the future. We must find smarter and more cost-effective ways to carry out our mandate.

The challenges of the 1990s make it necessary for government and the food processing industries to find, develop, and implement innovative and cost-effective approaches to food inspection. These new approaches must be flexible and sensitive to the needs of the industry and permit industry to adapt and remain competitive in the changing markets.

The Department of Fisheries and Oceans' QMP is a key component of our strategy for responding to the demands of future marketplace and addressing both industry concerns. The QMP has been developed jointly by the Canadian fish-processing industry and the Department of Fisheries and Oceans. The QMP that the Canadian fish-processing industry will be required to establish in their plants is based on the HACCP philosophy. The QMP is, like HACCP, a system designed to prevent instances of public health significance. However, the QMP has been designed to also prevent instances of unacceptable quality and economic fraud.

The development of an individual QMP for a fish-processing operation incorporates all of the basic steps involved in developing a HACCP system for a specific food product. A hazard assessment of the process operation is performed. Critical control points are identified. Defect definitions and tolerances, monitoring procedures, record-keeping criteria, corrective action systems, and company verification measures are established for each critical control point.

The QMP is not however purely a HACCP system. It could be better described as a regulatory compliance program as it is closely linked to the Canadian Fish Inspection Regulations. During the initial stages of the development of the QMP, the industry-government working group decided that the QMP would be based on existing regulations, which are designed to ensure that fish and fish products are safe, wholesome, of acceptable quality, and fairly traded.

The QMP is designed for the fish-processing industry to control their processing operations within the compliance boundaries of the regulations governing the production of fish products. By implementing the QMP, the fish-processing industry will be able to demonstrate that it is operating on a day-to-day basis with controls that ensure compliance with the regulations.

Let’s look a little closer at our QMP and how it fits into increasing industry’s responsibility and accountability.

As of February 1, 1992, each fish-processing plant is required to have in place and be operating under a QMP specific to its fish-processing operations. The department has developed the QMP Submission Guide to assist the industry in developing their programs. The guide helps the processor identify the critical control points in the process and the associated hazards and sets out for the fish-processing industry the minimum requirements for a plant’s QMP.

The QMP of a fish-processing plant will be required to address each of the 12 critical con-
control points that are applicable to their operation. Potential hazards should be prevented through the monitoring of these 12 points:

1. incoming fish
2. other ingredients
3. packaging material
4. labeling
5. chemicals (cleaning agents, sanitizers, lubricants, and pesticides)
6. construction and equipment
7. operation and sanitation
8. process control
9. storage
10. final product
11. recall procedures
12. employee qualifications

"Critical control point" is defined as a point in time or a physical location in the process at which failure of preventative measures will expose the customer to unacceptable risks related to tainted, decomposed, or unwholesome fish or to economic fraud.

At each critical control point the fish plant must

- identify the standard that is being applied to ensure compliance with regulatory requirements
- identify the monitoring procedures and inspection frequencies that will be followed to ensure that the standard is being met during production
- identify the reporting mechanism that will be used at each critical control point to document the results of the inspections. The fish plant will be required to develop contingency plans or corrective action plans that will be followed if and when the monitoring procedures identify an instance where the standard is not being met.

The fish-processing plant will be required to have available for inspection their documented QMP that provides a written description of the program being implemented in the processing plant. The fish-processing plant will also be required to retain records of all inspections performed as part of their QMP for three years. These records must be made available when requested to inspectors from the Department of Fisheries and Oceans.

In summary, a fish-processing plant's responsibilities under QMP will be

- to develop its own in-plant QMP specific to its operation
- to implement the in-plant QMP
- to maintain the QMP records of the QMP inspections
- to correct all problems identified during the QMP inspections.

**QMP Inspection**

The Department of Fisheries and Oceans will inspect the fish-processing plant against the QMP requirements.

Individual inspectors will perform QMP inspections that will entail the following:

- verification of the written QMP to ensure that the documented standards, monitoring procedures, record-keeping systems, and guidelines for corrective action meet the minimum requirements as set by the Department of Fisheries and Oceans
- confirmation that the written QMP is being followed in the plant. This will require the inspector to observe the processor's QMP activities at each critical control point in the plant
- verification that the processor's records are accurate. This will require the inspector to withdraw and inspect parallel samples of the processor's products and compare the results with those of the company.

The completion of the QMP inspection will result in the process operation's being rated "excellent," "good," "satisfactory," or "fail." These QMP ratings represent the degree of confidence the Department of Fisheries and Oceans has in the company's ability to operate within compliance of the regulations and will determine the inspection coverage to be directed at the operation in subsequent weeks.

Fail-rated plants will be asked to voluntarily correct the deficiencies and improve their rating to at least a "satisfactory." Refusal to deal with the problems voluntarily will jeopardize the federal certificate of registration and therefore the ability of the processing plant to export its products. Plants which receive a "satisfactory" rating will be inspected on a frequent basis until they gain greater control over their process and obtain a higher rating.

Processing operations that are successful in meeting all but a few of the QMP requirements will receive an "excellent" or "good" rating. These plants will be qualified to apply for the use of the "CANADA INSPECTED" logo on their product labels. Also the product certification process will be streamlined and provided...
without delay, and the company will have more autonomy in its day-to-day processing operation.

The QMP will provide added assurances that problems are identified early in the process before value is added to the product and before the product reaches the market. The QMP will also allow the department to measure the level of compliance of the industry in a uniform manner and direct its resources to those areas where problems have been identified.

The Quality Management Program—
Industry’s Role

The major change for industry under the QMP is that it must accept more responsibility and accountability in monitoring its performance. The processing plants will be required to perform inspections of the plant and products and initiate corrective actions when they identify a problem. And records of all these QMP activities must be maintained so that they are able to demonstrate that they consistently operate in compliance with the regulations.

The Role of Government in Regulating Under QMP

The implementation of the QMP will mean a change in the relationship between the fish-processing industry and the department. Under the QMP, the Department of Fisheries and Oceans’ role will shift from solely an inspection function to include an auditing function.

The inspector will continue to perform random inspections of the process operation and products, but the focus will not be on individual lots of product or on a day of plant operation, as now is the case, but rather on the overall QMP system. The inspector’s decisions will be based upon a compilation of interrelated inspection results gathered over time by both the inspector and the processor.

CONCLUSION

We feel the QMP will provide the Canadian fish-processing industry and the Department of Fisheries and Oceans with an effective mechanism to ensure the protection and assurance needed in today’s demanding markets. The price of this assurance is change.

We will have to change. Industry will have to change. But this approach should realize more impact from each inspection. The number of inspections we do may be somewhat reduced for some plants, but each inspection will count for more. We will be able to focus our effort on areas of higher risk and apply our resources in a more cost-effective manner.

In summary, the Department of Fisheries and Oceans’ new approach to quality management is a joint industry-government system that is aimed at preventing problems before they occur. Working together through the QMP, the Canadian fish-processing industry and the Federal Government will be able to provide Canadian and international customers even better assurance than in the past so that the high standards Canadian fish products have been known for will be met in the future.
Sometimes the impression from the media is that the Food and Drug Administration (FDA) doesn't have a mandatory seafood inspection program in this country or that we have no seafood inspection program at all. I take issue with this position, and in this paper, I'll show some statistics for the inspectional work that is done. I'll also give some insight into what a district office looks like and how it works.

The main FDA office for the Pacific region is in Seattle (figure 1), which also houses the seafood products research laboratory for FDA's field organization. Seattle has an investigations branch and a compliance branch. Most of the people that you see are from the inspection branch of the FDA, where Jim Davis is chief inspector. If you have questions about what is going on in your plant and I am not available, Jim Davis is the person to contact. Under the chief inspector, there are eight supervisors, each responsible for various programs. Chris Rezendes is a seafood monitor for the whole Pacific region. He is the most knowledgeable person in the district when it comes to seafood issues.

The Pacific Northwest should have a great deal of power in terms of the seafood industry, as shown in table 1. It can be frustrating to deal with the Washington office because of the influence that the east coast industry has on FDA decisions. The west coast, and in particular the Pacific Northwest, accounts for over 50 percent of the domestic seafood production and nearly the same amount of exports in this country. Yet, I don't believe our voice is well heard. If you look at dollar values of landings on the various ports for the United States, you see that the west coast dominates the list.

<table>
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<th>State</th>
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<tr>
<td>America Samoa</td>
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When it comes to seafood regulations, our voice needs to be heard along with the voices of public opinion, the bureaucracy, and the law.
The Pacific Region, Seattle district, has 1,070 of the 1,392 firms that are registered with the FDA. The official Establishment Inventory lists firm names by a central file number. The Seattle district has a great deal to say about what happens in seafood in the FDA.

Seafood firms are listed by state, with Washington leading and Alaska and California following. We can break down seafood use into establishment types as shown in table 2: (1) manufacturers (people who do something with the seafood); (2) repackers (people who take something that someone else has put together, break it into smaller entities, and repack it for retail); (3) shellfish shippers; and (4) growers (who include people in aquaculture). To put the Pacific Region Seattle district into national perspective, we can talk about the number of inspections that have been made and the percent of the national total accounted for out of this region. We account for a good share of what happens in seafood out of this region. The FDA has six regions; we are simply one of them. Our region accounts for 27 percent of the nation’s inspections, 26 percent of the hours spent making those inspections, and 40 percent of the samples collected from both import status and domestic status. We do wharf exams for imports, which are just short of sampling that product. The exam is usually for labeling, but it could also be for seams on cans or other characteristics that an investigator can look at right on the dock without bringing a sample back to our laboratory.

Inspection classifications are assigned to firms we have inspected (figure 2). NAI means “No Action Indicated,” which doesn’t mean that you don’t have some problem; it simply means that we are not going to take legal action against your firm. VAI-2 stands for “Voluntary Action Indicated.” It indicates to us that there were more serious problems, but we anticipate that you are going to fix them. VAI-3, or “Voluntary Action Indicated,” and OAI, which is “Official Action Indicated,” entail receiving official written notice from us that you have a problem and that we’re going to take action if you don’t remedy the situation. First, we give you a warning letter describing actions you must take and requiring a response in 10 or 15 days telling us what you’ve

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Figure 2. Pacific Region inspection classification.
done. If we don't get an adequate response, we are prepared to take FDA legal actions, such as seizing product, or injunctive action against moving your product in interstate commerce, or our last resort, to prosecute. We don't have many firms in that last category, but we do have some.

Sample classifications are listed as classes 1, 2, and 3. Classes 1 and 2 are what we consider mostly in compliance. Class 3 samples are considered out of compliance. These are not surveillance samples: they do not indicate the condition of the industry. Frequently, the media and other people will pick up on our sample results and claim that 20 percent of what the FDA looks at in the seafood industry is contaminated. Where the misinformation occurs is in not understanding that these samples are targeted. We do not have enough resources to do a strict surveillance-based sampling program to show the amount of compliance in the industry. Our samples, both domestic and imported, are focused where we think there are problems. Therefore, when people look at our sample results, they can get a false image of what seafood looks like in the country.

We have a higher level of samples that we consider violative in imports. I must emphasize that these are targeted samples. We target our samples with nationwide alerts. If a sample hits New York from a particular country with something wrong, when that same product from the same country hits Seattle, I sample it. That also includes automatic detention, where a country has a reputation of giving us bad products.

Because there is often confusion over what the FDA does, I'll describe the steps of an FDA inspection. First, inspectors show up in your plant and make an inspection. At the end of the inspection, they give you the 483 form, which is a list of observations. The law mandates that we give you this list before we leave. Next, the inspector writes a report, which is reviewed by a supervisor, so it is not the inspector's opinion that is going to affect you. There are several further steps before you get in trouble. The report is given to the supervisor, and the chief inspector, Jim Davis, takes it to the compliance branch. Our compliance officers review it with national policy to see if there is a case. The compliance branch director reviews it and then I, as district director, review any action. Only the OAI violations leave our district and go to headquarters for the Office of Enforcement review, in Washington, D.C. The general counsel are not Food and Drug employees, but employees of the Department of Health and Human Services. The next step is to the U.S. Attorney. The FDA does not have police powers; we can't lock your doors. The FDA goes through the Justice Department to the federal courts before any actions are taken. There are many steps and reviews before FDA takes action against a firm.

The prohibited acts section of the Food and Drug Law is what applies to your products and the acts are mandatory. You don't have a choice in complying with these rules. The law talks about the introduction, adulteration, receipt, and interstate commerce of adulterated products. Good manufacturing practices (GMPs) are always going to be here because they are a part of the law. The hazard analysis and critical control points program (HACCP) is simply an augment to those GMPs to make them tighter. I agree that we tend to focus on HACCP, but you can't forget about GMPs. They are a part of the Food and Drug regulations. They are not being replaced by HACCP, they are simply being added.

The seafood complaints that the Seattle district gets today are the same complaints I heard 20 years ago. We still see poor employee practices, especially in moving raw material through finished product areas; that can contribute to cross contamination. Employees move from one area to another without changing clothes or sanitizing themselves before switching from handling raw product to handling finished product. This is especially important when you deal with ready-to-eat products where there is potentially Listeria or other pathogens.

Listeria is still a problem, especially in cold smoked fish. The east coast is enmeshed in Listeria from smoked fish. The district director in New York is preparing many injunctions against firms back there. Dr. Ecklund of the National Marine Fisheries is on the east coast working with the east coast industry. Listeria is not going to go away. People keep asking if we are going to abolish the zero tolerance level. As Tom Billy said, I do not see our changing the tolerance on Listeria at all.

Two years ago, we started with the incident of domoic acid in razor clams. The season was essentially closed for the entire year. Now everyone is out happily harvesting the largest razor clams they've ever seen, so maybe there was a good side to that. The next incident was finding domoic acid in crab viscera. We never did find any crab in interstate commerce from Washington and Oregon that exceeded the tolerance of 20 parts per million. We got close and had some problems especially with exports to...
Japan The result of that was a meeting in San Pedro regional. The region hired a regional coordinator for domoic acid; actually, for all marine toxins, to try to coordinate what the states were doing. We awarded state contracts to California, Washington, and Oregon to set up a more intricate monitoring system for domoic acid, but it didn't show up this year. Our hope for these systems is that we can close the season if domoic acid shows up rather than harvest the resource, or delay the opening of the season until the toxic levels go down. Through the work of the states and our seafood coordinator, we raised the tolerance for domoic acid in Dungeness crab viscera from 20 to 30 parts per million. That same request is being made for paralytic shellfish poisoning in crab viscera.

Paralytic shellfish poisoning is the next issue. Alaska had a great deal of trouble with paralytic shellfish poisoning in Dungeness crab viscera again this year. We had production that had to be eviscerated and sold as sections rather than as whole crab because of the toxin levels in the viscera. Alaska has drafted a monitoring program whose goal is to monitor that area and open and close the crab harvesting season to prevent crab with problems from even being harvested.

Last, I'd like to discuss the European Community (EC). The FDA intends to issue certificates to firms wishing to export to the EC. The protocol is being written and will be reviewed and distributed to industry and others for comments. You will apply to us to be placed on a list for exports to the EC. We will then review your firm's inspection records and, if applicable, the records of your state agency or of the National Marine Fisheries Service (NMFS). If necessary, we may have to reinspect your plant to update our information. If you pass these steps, other than the VAI-3 or OAI category, we will put you on a list.

When You deal with the EC, you've got to have a firm number, which you've always had from the FDA, called a central file number. We can give that list of numbers to the EC. If you are on that list, you can submit filled-out certificates to us. You are going to have to give me an English version so that I can understand what I am signing. After I sign, the certificate is returned to you to accompany that shipment. I will not inspect those lots. I will sign that certificate based on the fact that you are on our list as an acceptable firm. If your buyer wants additional quality attributes or you need to have additional inspections, you are going to have to arrange for them in the same way you always have, typically, by going to NMFS and getting their lot certification for the value added part. If you fail to make our list, your choice is probably to go to NMFS, sign up for their program, and pay for the service. Once you get upgraded, you can always come back to us and ask to be reinstated.

This FDA program has to be resource neutral. I have no additional resources to run the program. If the inspection of your firm is not routinely scheduled for six to eight months from now, then I will not visit your firm until I have it regularly scheduled. If you want to get on to EC, you are going to have to have some other authority come to me and show me that your firm is in compliance. That could be the Alaska Department of Environmental Conservation, the Oregon State Department of Agriculture, the Washington State Department of Agriculture, or NOAA, but if I have to make an inspection to get you on the list, it will be done only when I'm on my routine inspection.

You need to provide specific information. You should be able to describe the HACCP program for your firm. You must be site specific. If you're a company that has five firms, I have to have a letter for each one of your sites because that is the way your firms appear in our files right now. You also have to be product specific. You must provide a contact person for each program. If you have five different plants, you can give me one contact person, but that contact person should be knowledgeable about those five sites. I also need to know what other government agencies are inspecting you, like your state's Department of Agriculture or NOAA, and when those inspections are made and who is doing that in your plant. I don't need to know about the Occupational Safety and Health Administration or the EPA. I simply need to know about those that would be germane to shipping to the EC. I need permission to look at those other records. This especially applies to NMFS. When NMFS does an inspection in your plant, that is a contract between you and them. Those records are between you and them. They are not available to me unless you tell NMFS that I can look at them.

Canned salmon has had the "canned salmon control plan" for over 70 years. This is an agreement between industry, the FDA, the Alaska Department of Environmental Conservation and the National Food Processors Association with their lab in Seattle. Everything that has been done under that plan is a
HACCP program, and we will sign certificates for shipments of firms in good standing under that plan right now. That includes the past year's production and current production. As long as you’re in good standing under that plan, your canned salmon will get a certificate from the FDA.
Industry Standards in National and International Markets
The Use of Total Quality Product and Total Quality Management Programs in Meeting New EEC Regulations

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In this paper I discuss the current status of quality certification in the French and European markets. I focus on the organization of French markets, using examples from the seafood industry.

BACKGROUND

The French Market in Europe

The French market has a dominant position in Europe for all food products, whether destined for at-home or away-from-home consumption, for three main reasons:

1. French cuisine sets the international standard for food preparation and presentation.
2. France has developed a high level of technical knowledge of both innovation and tradition in human nutrition, of which the invention of vacuum cooking by a student of the famous chef Troisgros is the best illustration.
3. The German market strongly prefers "French quality," and Germany, in all matters concerning the organization of European markets for food products, is very receptive to French proposals.

Treaties, Directives, and Regulations

The European Common Market is organized around three levels of agreements with very distinct functions:

1. The Treaty of Rome. This provides the constitution. All regulations must be in strict conformity with the Rome Treaty. As with other constitutions, the treaty text is unknown to most of those in the business world. Its real significance is revealed in the legal decisions of the European Law Court, which constantly refer to it.
2. Directives. Directives are the directions or positions established by the European Commission. These directions are not optional; each member state must set its national legislation in conformity with them. But in practice, national laws demonstrate a strong passive resistance to these directives. In addition, it is very often the jurisprudence of the European Law Court which must determine precisely which modifications will be required. For instance, a member state is not permitted to advertise the national origin of its products; thus, France is not allowed to build an advertising campaign with and about "qualité France."

The passive resistance of national law, everyday practice, and the threats and sanctions of the EC Commission combine to provide the context within which the directives become regulations.

3. Regulations. These are laws. Member states are given only the time period set by the regulation itself in which to make their own laws conform to these regulations. For this reason regulations encounter much less passive resistance from national law and practice than do directives.

The Use of Standards

The primary function of a standard is to provide security to transactions made over a distance. It is the industrial world that has contributed the most to the definition and propagation of the standards that support and guarantee contractual relationships between firms placing orders and those that carry them out, or their subcontractors. Inherent in a standard is reference to a sale contract, that is, the given commercial practice at a given time concerning the exchange of merchandise. The merchandise itself functions as a support for the system which allows the individuals concerned with the exchange to make the necessary profits.

In regard to human nutrition, the development of standards is much more recent, for two main reasons. First, the definition of what constitutes human food is complex, with a strong cultural component. The constant change that characterizes technology and culture presents an ongoing challenge to this definition. Second, tradition is efficient, which is to say that expectations of "fair and customary use" provide the main guarantee, at the national level, of the success of food products sales.
I should emphasize that the safety of a food (the first priority of every regulation) is only the first step toward consumer satisfaction, which is the real driving force behind every exchange involving food products. Safety is an implicit expectation of consumers. But consumer expectations are evolving and vary from one country to another, as do the methods of satisfying them. Since each market can refer, in good faith, to its own tradition of “fair and customary use,” a preoccupation with legal protections has arisen in the competition between EC members. In the hope of improving credibility and protection, economic partners will demand more and more sophisticated proof of facts that support the fairness of allegations and the safety of common food uses.

Fundamental to understanding the current evolution of the EC regulations concerning quality certification are the specific requirements of human nutrition. It is equally important to keep in mind the essential function of a standard, whatever this standard might be: to provide security to an economic transaction from a distance.

The "New Approach" and the Cassis de Dijon Case

The requirement of free circulation of goods between member states of the EC affects every product. When the unifying act was signed, it was technically impossible to define a full set of regulations guaranteeing free trade within a short period. This is why the “New Approach” directives were adopted. These directives are limited to the essentials, leaving the working out of technical details to the standardization process (or, as we shall discuss further, the “professional approach”). The object of having these directives come into force simultaneously in each national legal system is to set up an “automatic” harmonization process among these systems. The application schedule of these New Approach directives is determined by the goods’ complexity, to allow time for concerned firms to gather correct information and to adapt their production processes to EC standards.

The directive of 22 July 1991 (see appendix), fixing the sanitation regulations for production and trade of seafood products, is typical of the "New Approach." To make it easier for readers to understand the following discussion, I advise them to take a break for a careful reading of this directive, integrating the information provided above before going on. (This advice is in fact a directive, since the contents of the July 22 1991 directive will be referred to below without further citation than the article number).

At the same time as the New Approach was defining a method of harmonizing various types of “fair and customary uses,” the outcome of the Cassis de Dijon case nipped in the bud the protectionist tendencies embodied within various national legal interpretations of "fair and customary use." This case merits further examination in order to elucidate the essential common rights it established.

In the 1970s a German importer was refused authorization to import Cassis de Dijon into Germany. The reason: the alcoholic content of Cassis de Dijon is 18%, and only alcoholic beverages with a minimum alcoholic content of 32% are allowed to be called "Cassis" for sale in Germany. This national law conformed to what was considered “fair and customary use” in the German market. German authorities took the position commonly held by all member states at that time in cases not covered by EEC regulations: a national law that forbids the trade of a product, whether processed locally or imported, concerns EC products too, as there should be no discrimination between the treatment of domestic and community goods. The European Law Court refuted this position by affirming that any product legally processed and traded in one of the member states, must, in principle, be allowed in trade in every other member state.

This case set a precedent confirming one of the fundamental principles of the Rome Treaty: free circulation of goods. It further introduced an equivalence between the “fair and customary uses” of different member states. In so doing it established an initial practice that is the basis of the lowest common denominator of the food trade: the less demanding “usage” must be allowed in as far as the relevant authority allows it.

The New Approach and the Cassis de Dijon case established also, as a corollary, a clear responsibility on the part of the processor as a prerequisite to any transaction. It is the establishment of the processor's credibility which is the goal of the development of quality certification systems.

Defining Concepts: Competent Authority

The dictionary offers two different meanings for the term quality:

1. what it is that makes a thing what it is (with reference to final uses)
2. the excellence inherent in something (with reference to ethical considerations)

Food consumers’ expectations can be based on one or both of these concepts. Food technologists and industry concern themselves primarily with the first concept; consumers and traders with the second. The fact that the EC’s “competent authority” should be composed of veterinary technicians (article 2 directive 91/493) provides a clear indication of the kind of certification expected from a firm: it consists essentially of its capacity to organize and guarantee the processes within the competent authority’s charge (article 6 directive 91/493).

We now turn to the general context of firm certification, or a firm’s quality assurance systems, as an implicit element of the New Approach to the approval of firms (article 7 directive 91/493). As I will discuss later, the oversight of this implicit trend of European Community regulation is managed in France through applications initiated by AFAQ (Association Française pour l’Assurance Qualité). However, as a preamble, I must emphasize that this is a trend and not a legal obligation.

We have already mentioned the effect of the inertia of national laws on EC directives. This is even more important in cases of quality assurance applications. In such cases, the inertia is strengthened by the perverse effects of the Cassis de Dijon case, which concerns de facto the former French colonies in Africa (through the Lomé convention), thus allowing very low-quality goods into the EC. Some French processors actually seek trade in such goods or use them as inputs in their production processes to diversify their sources of profit. Several examples of such behavior are famous on the canned fish market, including sardines in oil, anchovy fillets, and canned tuna. A good part of the turnover of this sector comes from low-quality product imported by small French processors and sold under their own brand names.

At the opposite end of the scale, large processors such as SAUPIQUET anticipated the evolution of the regulations and have already certified their own quality assurance systems to ISO 9000 standards. In fact, there is currently a clear split between two categories of operators in France:

- firms that anticipated regulatory evolution and are involved in certification of their quality assurance processes
- firms that are unaware of this evolution or wish to profit from current regulatory distortions of free competition and free circulation of goods

Limits of the Current System: an Example of Regulatory Distortion

It is generally accepted that it is the large firms that will be most concerned with certifying their quality assurance systems. The following example concerns a large distribution firm with a quality assurance program that trades seafood products under its own brand name, imported from Denmark as fresh products with a nine-month shelf life. There is currently a strong demand in France for all seafood sold fresh, especially in the saurissonerie, or smoked foods, department: smoked fish, taramas, snack products, fish fritters, and so on.

For products or meals prepared in advance and sold as fresh, French regulations allow French processors to indicate, following precise procedures, a shelf life date of 21 days for vacuum cooked products and 42 days for pasteurized products. Processors are not allowed to claim a shelf life of over 42 days for fresh or processed seafood (article 2 directive 91/493), except for “semiconserves.” For these products, the minimum shelf life is over two weeks, due to the use of conservation techniques indicated on the label. Danish products imported and traded under this distributor’s brand name are effectively sold in the fresh department as “semiconserves,” with instructions to keep them at 8 degrees Celsius. Last year they were sold as canned.

This example and others are very well known among French processors, and some of them are actually trying to define new lines of “fresh canned products” for sale under the current regulatory loophole.

TOTAL QUALITY MANAGEMENT

ISO 9000 Standards

Certification of quality assurance systems originated mainly within the customer-supplier relationship. A customer, having certain specifications for a product, would seek out suppliers who could meet these specifications and purchase only from those suppliers. Certificates attesting to the suppliers’ ability to meet specifications could be granted either by an independent organization (third-party certification) or directly by the buyer or distributor (second-party certification). Various terms of reference can be used in
these two cases. In the case of third-party certification, ISO 9000 standards are usually used, for easier recognition both of the certifying body specializing in these standards and for the certified firm's use in communicating internationally known references.

The definition of quality assurance in ISO 9000 standards is as follows, roughly translated into English: “the combination of preestablished and systematic actions necessary to give appropriate confidence that a product or service will satisfy requirements related to quality,” these requirements being “the combination of properties and characteristics of a service or product which confer upon it the ability to satisfy expressed or implicit needs.”

It must be noted that the notion of quality is defined here in its wider sense, including all the expectations of the concerned public, without specifying a particular level of quality. It must be emphasized as well that it is the firm itself which selects the set of preestablished processes that are to be verified, processes that will be established through its own technical expertise in quality management. Also, it can only be a voluntary effort, indicative of both the firm’s management expertise and of the quality of production due to this management. The voluntary nature of this approach presumes a clarity of objectives within the firm necessary to mobilize the staff to realize these objectives.

Third-party certification of quality assurance systems under ISO 9000 thus functions as a management tool attesting to a highly effective level of management. It is this tool and this level that give the processor credibility, even from a distance. The function of ISO 9000 standards, like that of every set of standards, is effectively to give security to a transaction from a distance.

The Relationship Between Distributors and Processors: Competent Authority and Current Developments in France

At the moment, most distributors who want to distribute goods under their own brand name accord limited importance to third-party certification of their quality assurance systems, preferring their own controls to those of an independent organization. The current level of development of trade standards embodied in directive 91/493 allows distributors to impose commercial pressure in the guise of second-party certification “standards,” at very low cost to themselves. However, the inevitable trend is toward independently imposed standards originating with an international certification body that will ensure the independence of the manufacturer from the distributor of the manufacturer’s product. French processors know very well that without third-party ISO-9000 certification, they risk being submitted to arbitrary audits on the part of their foreign customers, which in some cases could be an ill-disguised effort to create barriers to free trade.

The best ally of the French processor, and those in the EC or other countries, is the competent authority in France that deals with community regulations: the state veterinary services. The veterinary services in charge of hygiene and food safety in France are powerful and efficient. Their actions are founded, according to “fair and customary use,” on allowing processors to be progressively more responsible for setting up and verifying quality-control processes. This means that overall, French authorities have responded positively to the increasing complexity of production techniques (for example, “4th range” and vacuum cooking) and the rising level of quality assurance requirements. From the beginning, the French have accepted the challenge of combining voluntary efforts and the legal obligations put upon them by France and the EC.

Indeed, everyone - firms, administrators, and experts-knows that at the beginning, the process of firm certification will be long and difficult, but that quality certification, though it is not a miracle drug, is the single best way to meet the managerial needs inextricably linked to the long-term satisfaction of consumers in developed nations.

The French Quality Assurance Association (AFAQ) and the National Testing Network (RNE)

Many industrial applications of quality assurance certification led to the creation, in 1988, of AFAQ, constituted by three “collèges”:

- collège A: AFNOR and professional sales organizations
- collège B: buyers
- collège C: technical controllers

AFAQ certification, like every standardization process, requires an interdisciplinary professional approach. AFAQ certification is based on international standard practices:

- standard 45012 for a firm’s own management
- ISO 9000 standards applied to firms
ISO 10011 standards for selection of experts

The final objective of this professional orthodoxy is to facilitate agreements between and partnerships with firms certified by other analogous certification centers, to improve the relationship between customers and suppliers. This kind of partnership already exists between German, Canadian, and Swiss bodies. Although AFAQ has no ambition to take control of international certification, it is clear that all significant firm certification programs currently being tested in France are aimed toward achieving AFAQ certification.

Created in 1979, the Réseau National d'Essais (National Testing Network) manages accreditation of laboratories to the EN 45001 standard according to detailed requirements for accredited laboratories and candidates for accreditation. Accreditation of a laboratory is the formal recognition of its ability to undertake specified tests and to ensure the quality of these tests. The political purpose of the RNE is to set up a network of similar organizations in other countries to establish more consistent standards between competent authorities.

Food Security

It is not by chance that the food security theme accompanied the complete set of common agricultural policy reforms. The entire policy was systematically linked to the establishment of professional strategies in quality certification, in all sectors. It is not possible to limit the free circulation of goods and services, but the increasing concern with health and safety by consumers in developed countries goes hand in hand with the increasing challenge to firms in developed countries to maintain their market positions. Certification of quality assurance systems is clearly the key to future access to EC markets for firms in developed countries.

TOTAL QUALITY PRODUCT

Specialty Foods

Certification systems for quality assurance mainly concern large industrial firms of the agro-food sector, producing goods for mass consumption. But many French producers famous for the quality of their product are very small firms, often "artisan" sized. This is particularly true for such products as wines, cheeses, poultry, red meat, pork specialties, and regional specialties such as Cassoulet de Castelnaudary.

At the national level, these specialty products are subject to a double set of consumer-recognized certifications:

- a certificate of higher quality indicated by the authorization to stamp the product Label Rouge (Label Rouge is a national collective brand name for higher quality foods; in French the word label connotes quality and not information requirements)
- a certificate of regional specialty attested to by the indication Appellation d'Origine Contrôlée (specified origin label or AOC).

Usually, certification by one of these methods precludes certification by the other, and thus products given the Appellation d'Origine Contrôlée would not also be certified with the Label Rouge. The Appellation d'Origine Contrôlée is reserved for products or processes giving proof of a strong historic tradition and precedence in setting a special or high-quality standard. The Appellation d'Origine Contrôlée concerns mainly wines and cheeses. Quality here refers essentially to bioclimatic conditions or traditional, often secret, technical knowledge.

Label Rouge concerns any superior-quality product. In order to be granted this label, a producer must adhere to precise terms of reference, explaining what differentiates it from generic products and justifying its higher price. Proof must be offered that this product of superior quality is produced in significant quantity (this was the main issue of contention in providing Scottish salmon with the Label Rouge).

The terms of reference for foods certified with the Label Rouge are public. The registration of these terms of reference is done by an independent certification organization using the 45011 standard. So, for products certified "Label Rouge," our general definition of quality is met: the following of preestablished procedures, with verification.

As this was not necessarily the case for Appellation d'Origine Contrôlée there has for a long time been a kind of philosophical opposition between the approaches followed by the Institut National des Appellations d'Origine (which focuses on tradition and French art de vivre) and the Commission Nationale des Labels (which focuses on consumer expectations). Each of these organizations has been lobbying Brussels for at least five years to publish...
directives or rules allowing it to determine the professional methods for certifying the quality of foods at the EEC level.

The Rule of 14 July 1992 on Agro-Food Specialties and the Rule of 14 July 1992 on Protection of Geographic Indications and Origin Appellations of Food Products

Rather than choose between the methods proposed by the two organizations, the EEC Commission permitted both, with these two closely related rules. The rule about food specialties is no more than the elevation to the EC level of the French Label Rouge. However “specialty,” in the rule, is not limited to superior quality for this type of product. Further, the harmonizing of the EEC register of recognized specialties between member states and producer groups has been difficult and complex, although the register has been adapted to changes in the terms of reference on which specialties are based. And, in order to maintain superior-quality levels, these changes are strictly necessary.

The rule about protected geographic indications mentions terms of reference as well (article 4 of the rule), explicitly the “description of the method of obtaining the agricultural or food product, and where relevant the fair and customary practices.”

These two rules have two points in common:

- the professional character of each method, managed by concerned professional groups
- the obligation of every member of the professional group to submit to the control of an independent certification body using the 45011 standard, valid to 1998 at the latest

Standard EN 45011 specifies criteria that must be met by a certification organization before the certification of products, in order to be recognized at the EC level as competent and reliable to set up such a certification system, whatever the concerned sector might be. The 1998 limit date on anything concerning the 45011 standard of certifying organizations for food specialties and origin appellations is connected with article 17 of directive 91/493

The Redeployment of Professional Organizations

These two rules will come into force next July and will certainly allow a new deployment of the largest French professional organizations, which have been crippled for a long time because of the illegal origin of their income (national obligatory parafiscal taxes). Indeed, there are strong similarities between the objectives of professional organizations and those of certification organizations.

In France, the goals of agro-food trade organizations are those which the individual firm cannot assume alone, including

- collective research and development
- collective promotion and advertising
- procedures and controls

These are also the goals of certification organizations dealing with producers who have already achieved the 45011 standards as well as those who have attained the “Label Rouge.”

The Challenge for “Peripheral” Agriculture

A few years ago, there was a clear distinction between the “agro-industrial,” or profit-making agricultural sector (milk, corn, and so on), and agricultural products from the peripheral regions, especially from the Mediterranean zone. At that time food security strategies concerned production only in these peripheral zones, while other producers had to compete in international markets around the world.

Recent developments show that this assumption was mistaken and that food security strategies concern the entire European agro-industrial sector. In this context it was imperative to immediately develop effective tools (rules) which would allow differential marketing for products from peripheral zones, while other producers had to compete in international markets around the world.

Perspectives for Other Countries

It is likely that the application of these two rules will be extended to agro-food products of non-EC states that are able to guarantee quality assurance practices equivalent to those in the EC and in which the competent certifying authority meets 45011 standards. These regulations could provide an excellent and useful tool for third-country professional groups to meet quality challenges, by furthering their understanding of the current evolution of EC food product quality management practices.
COUNCIL DIRECTIVE

of 22 July 1991

laying down the health conditions for the production and the placing
on the market of fishery products

(91/493/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposals from the Commission (1),

Having regard to the opinions of the European Parliament (2),

Having regard to the opinions of the Economic and Social Committee (3),

Whereas, with a view to achieving the internal market and more especially to ensuring the smooth operation of the common organization of the market in fishery products established by Regulation (EEC) No 3796/81 (4), as last amended by Regulation (EEC) No 2886/89 (5), it is essential that the marketing of fish and fish products should no longer be hindered by disparities existing in the Member States in respect of health requirements; whereas this will enable production and placing on the market to be better harmonized and bring about competition on equal terms, whilst ensuring quality products for the consumer;

Whereas the European Parliament in its legislative resolution of 17 March 1989 (6) requested the Commission to come forward with comprehensive proposals on the hygienic production and placing on the market of fishery products, including solutions for the problem of nematodes;

Whereas fishery products freshly caught are in principle free of contamination with microorganisms; whereas however contamination and subsequent decomposition may occur when handled and treated unhygienically;

Whereas therefore the essential requirements should be laid down for the correct hygienic handling of fresh and processed fishery products at all stages of production and during storage and transport;

Whereas it is appropriate to apply by analogy certain marketing standards which are laid down pursuant to Article 2 of Regulation (EEC) No 3796/81, in order to fix the health quality of these products;

Whereas it is the responsibility primarily of the fisheries industry to ensure that fishery products meet the health requirements laid down in this Directive;

Whereas the competent authorities of the Member States must, by carrying out checks and inspections, ensure that producers and manufacturers comply with the said requirements;

Whereas Community control measures should be introduced to guarantee the uniform

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(1) OJ No C 66, 11.3. 1988, p. 2;
OJ No C 282,8.11.1989, p. 7 and OJ No C 84, 2.4. 1990, p. 56.
(6) OJ No C 96, 17.4. 1989, p. 199.
application in all Member States of the standards laid down in this Directive;

Whereas, in order to ensure the smooth operation of the internal market, the measures should apply in an identical manner to trade within the Member States and to trade between the Member States;


Whereas fishery products from third countries intended to be placed on the market of the Community must not qualify for more favourable arrangements than those applied in the Community; whereas provision should therefore be made for a Community procedure for the inspection in third countries of the conditions of production and placing on the market in order to permit the application of a common import system based on conditions of equivalence;

Whereas the products in question are subject to the rules concerning checks and to safeguard measures covered by Council Directive 90/675/EEC of 10 December 1990 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries;

Whereas, so that account may be taken of particular circumstances, derogations should be granted to some establishments already operating before 1 January 1993 so as to allow them to adapt to all the requirements laid down in this Directive;

Whereas the Commission should be entrusted with the task of adopting certain measures for implementing this Directive; whereas, to that end, procedures should be laid down introducing close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas the essential requirements laid down in this Directive may need further specification,

HAS ADOPTED THIS DIRECTIVE

CHAPTER 1

General provisions

Article 1

This Directive lays down the health conditions for the production and the placing on the market of fishery products for human consumption.

Article 2

For the purposes of this Directive, the following definitions shall apply:

1. ‘fishery products’ means all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other Community acts;

2. ‘aquaculture products’ means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;

3. ‘chilling’ means the process of cooling fishery products to a temperature approaching that of melting ice;

4. ‘fresh products’ means any fishery product whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;

5. ‘prepared products’ means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc.;

6. ‘processed products’ means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, etc., of chilled or frozen products, whether or not associated with other foodstuffs, or a combination of these various processes;

7. ‘preserve’ means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any microorganisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

8. ‘frozen products’ means any fishery product which has undergone a freezing process to reach a core temperature of -18°C or lower after temperature stabilization;

9. ‘packaging’ means the procedure of protecting fishery products by a wrapper, a container or any other suitable device;

10. ‘batch’ means the quantity of fishery products obtained under practically identical circumstances;

11. ‘consignment’ means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;

12. ‘means of transport’ means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;

13. ‘competent authority’ means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;

14. ‘establishment’ means 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;

15. ‘placing on the market’ means the 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 consumers, which must be subject to the health checks laid down by national rules for checking the retail trade;

16. ‘importation’ means the introduction into the territory of the Community of fishery products from third countries;

17. ‘clean seawater’ means seawater or briny water which is free from microbiological contamination, harmful substances and/or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions laid down in this Directive;

18. ‘factory vessel’ means 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 cooled on board,
- fishing vessels on board which only freezing is carried out.

Article 3

1. The placing on the market of fishery products caught in their natural environment shall be subject to the following conditions:

(a) they must have:
(i) been caught and where appropriate handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, on board vessels in accordance with hygiene rules to be established by the Council acting by a qualified majority on a proposal from the Commission. The Commission shall submit proposals to that effect before 1 October 1992;

(ii) where appropriate, been handled in factory vessels approved in accordance with Article 7, and in accordance with the requirements of Chapter I of the Annex.

The cooking of shrimps and molluscs on board must comply with the provisions of Chapter III, section I(5), or Chapter IV, section IV(7), of the Annex. Such vessels shall be specifically registered by the competent authorities;

(b) during and after landing they must have been handled in accordance with Chapter II of the Annex;

(c) they must have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted or stored hygienically in establishments approved in accordance with Article 7, in compliance with the requirements of Chapters III and IV of the Annex.

The competent authority may, notwithstanding Chapter II, section 2 of the Annex, authorize the transfer of fishery products ex quay into containers for immediate delivery to an approved establishment or registered auction or wholesale market to be checked there;

(d) they must have undergone a health check in accordance with Chapter V of the Annex;

(e) they must have been appropriately packaged in accordance with Chapter VI of the Annex;

(f) they must have been given an identification mark in accordance with Chapter VII of the Annex;

(g) they must have been stored and transported under satisfactory conditions of hygiene, in accordance with Chapter VIII of the Annex.

2. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed.

3. The placing on the market of aquaculture products shall be subject to the following conditions:

(a) they must have been slaughtered under appropriate conditions of hygiene. They must not be soiled with earth, slime of faeces. If not processed immediately after having been slaughtered, they must be kept chilled;

(b) they must, in addition, comply with the requirements laid down under 1 (c) to (g).


(b) When processed, bivalve molluscs must, in addition to the requirements in point (a), satisfy those of paragraph 1 (c) to (g).

Article 4

Fishery products to be placed on the market alive shall at all times be kept under the most suitable survival conditions.

(1) See page 1 of this Official Journal.
Article 5

The placing on the market of the following products shall be forbidden:

- poisonous fish of the following families: *Tetraodontidae, Molidae, Diodontidae, Canthigasteridae*;

- fishery products containing biotoxins such as ciguatera toxins or muscle-paralysing toxins.

Detailed requirements concerning the species covered by this Article and concerning methods of analysis shall be laid down in accordance with the procedure prescribed in Article 15.

Article 6

1. Member States shall ensure that persons responsible for establishment 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 an approved laboratory 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 this 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.

2. If the results of own checks or any information at the disposal of the persons responsible referred to in paragraph 1 reveal the risk of a health risk or suggest one might exist and without prejudice to the measures laid down in the fourth subparagraph of Article 3 (1) of Directive 89/662/EEC, the appropriate measures shall be taken, under official supervision.

3. Rules for the application of the second subparagraph of paragraph 1 shall be established in accordance with the procedure laid down in Article 15.

Article 7

1. The competent authorities shall approve establishments once they have verified that these establishments meet the requirements of this Directive, with regard to the nature of the activities they carry out. The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval.

The competent authorities shall take the necessary measures if the requirements cease to be met. To this end, they shall take particular account of the conclusions of any check carried out in accordance with Article 8.

The competent authority shall register those auction and wholesale markets which are not subject to approval after verifying that such installations comply with the provisions of this Directive.

2. However, subject to the express condition that products coming from factory-vessels and establishments, auction and wholesale markets meet the hygiene standards set by this Directive, Member States may, for the requirements relating to equipment and structures laid down in Chapters I to IV to the Annex, grant to factory-vessels and establishments, auction and wholesale markets a further period expiring on 31 December 1995 within which to comply with the conditions of approval set out in Chapter IX. Such derogations may be granted only to factory-vessels and establishments, auction and wholesale markets, already operating on 31 December 1991, which have, before 1 July 1992, submitted a duly justified application for derogation to the competent national authority. This application must be accompanied by a work plan and programme indicating the period within which
it would be possible for them to comply with the requirements in question. Where financial assistance is requested from the Community, only requests in respect of projects complying with the requirements of this Directive can be accepted.

3. The competent authorities shall draw up a list of their approved establishments, each of which shall have an official number. Each Member State shall notify the Commission of its list of approved establishments and of any subsequent amendment thereof. The Commission shall forward this information to the other Member States.

4. The inspection and monitoring of establishments shall be carried out regularly under the responsibility of the competent authority, which shall at all times have free access to all parts of establishments, in order to ensure compliance with the requirements of this Directive. If such inspections and monitoring reveal that the requirements of this Directive are not being met, the competent authority shall take appropriate action.

5. Paragraphs 1, 3 and 4 shall also apply in respect of factory vessels.

6. Paragraphs 3 and 4 shall also apply to wholesale and auction markets.

**Article 8**

1. Experts from the Commission may, in cooperation with the competent authorities of the Member States, make on-the-spot checks insofar as this is necessary to ensure the uniform application of this Directive. They may in particular verify whether establishments are in effect complying with the requirements of this Directive. A Member State in whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The commission shall inform the Member States of the results of the investigations.

2. The arrangements for implementing paragraph 1 shall be adopted in accordance with the procedure laid down in Article 15.

**Article 9**

1. The rules laid down in Directive 89/662/EEC, as regards fishery products intended for human consumption, shall apply, in particular as regard the organization of and the action to be taken following the inspections to be carried out by the Member States of destination, and the protective measures to be implemented.

2. Directive 89/662/EEC shall be amended as follows:

   (a) in Annex A the following indent shall be added:


   (b) in Annex B the following indent shall be deleted:

   - fishery products intended for human consumption'.

**CHAPTER II**

Imports from third countries

**Article 10**

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

Fishery products caught in their natural environment by a fishing vessel flying the flag of a third country must undergo the checks laid down in Article 18 (3) of Directive 90/675/EEC.

**Article 11**

1. For each third country or group of third countries, fishery products must fulfill the specific import conditions fixed in accordance with the procedure laid down in Article 15, depending on the health situation in the third country concerned.
2. 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 of the Member States who are to be entrusted with these inspections shall be appointed by the Commission acting on a proposal from the Member States.

These inspections shall be made on behalf of the Community, which shall bear any expenditure incurred.

The frequency of and procedure for these inspections shall be determined in accordance with the procedure laid down in Article 15.

3. 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;

(c) the actual health conditions during the production, storage and dispatch of fishery products intended for the Community;

(d) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex.

4. The import conditions referred to in paragraph 1 shall include:

(a) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the Community;

(b) the placing of a mark identifying the fishery products, in particular with the approval number of the establishment of origin, except in the case of frozen fishery products, landed immediately for canning and bearing the certificate provided for under (a);

(c) drawing up a list of approved establishments and auction or wholesale markets registered and approved by the Commission in accordance with the procedure laid down in Article 15;

For that purpose, one or more lists of such establishments shall draw up on the basis of a communication from the competent authorities of the third country to the Commission. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

- compliance with requirements equivalent to those laid down in this Directive,

- monitoring by an official inspection service of the third country.

5. The conditions referred to in paragraph 4 (a) and (b) may be modified in accordance with the procedure laid down in Article 15.

The list referred to in paragraph 4 (c) may be amended by the Commission, in accordance with the rules established by Commission Decision 90/13/EEC (1).

6. To deal with specific situations and in accordance with the procedure laid down in Article 15, imports may be authorized direct from an establishment or factory vessel of a third country where the latter is unable to provide the guarantees laid down in paragraph 3, provided that the establishment or factory vessel in question has received special approval following an inspection carried out in accordance with paragraph (2). The authorization decision shall fix the specific import conditions to be followed for products coming from that establishment or factory vessel.

7. Pending the fixing of the import conditions referred to in paragraph 1, the Member States shall ensure that the conditions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of Community products.

(1) OJ No L 8, 1.1.1990, p. 70.
**Article 12**

1. The rules and principles laid down by Directive 90/675/EEC shall apply, notably as regards the organization of and follow up to the inspections to be carried out by the Member States.

2. Without prejudice to compliance with the rules and principles referred to in paragraph 1 of this Article and pending implementation of the decisions provided for in Article 8 (3) and Article 30 of Directive 90/675/EEC, and in Article 11 of this Directive the relevant national rules for applying Article 8 (1) and (2) of the said Directive shall continue to apply.

**CHAPTER III**

**Final Provisions**

**Article 13**

The Annexes shall be amended by the Council, acting by a qualified majority on a proposal from the Commission.

**Article 14**

The Commission, after consulting the Member States, shall by 1 July 1992 submit a report to the Council concerning the minimum structural and equipment requirements to be met by small establishments which distribute on the local market and are situated in regions subject to particular supply constraints, together with any proposals, on which the Council, acting under the voting procedure laid down in Article 43 of the Treaty, shall act before 31 December 1992.

**Article 15**

1. Where the procedure laid down in this Article is to be followed, the Chairman shall refer the matter to the Standing Veterinary Committee set up by Decision 68/361/EEC (2) hereafter referred to as the Committee, either on his own initiative or at the request of a Member State.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

**Article 16**

In order to take into account the possible failure to take a decision on the detailed rules for applying this Directive by 1 January 1993, necessary transitional measures may be adopted in accordance with the procedure laid down in Article 15 for a period of two years.

**Article 17**

The provisions of this Directive shall be re-examined before 1 January 1998 by the Council, acting on proposals from the Commission, on the basis of experience gained.

**Article 18**

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1993. They shall notify the

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(2) OJ No L 255, 18. 10. 1968, p. 23.
Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 19

This Directive is addressed to the Member states.


For the Council
The President
P. DANKERT
General Mills Restaurants Inc. is a division of General Mills. General Mills is the “Company of Champions.” Each division operates under the company goal statement, “To be the nation’s best food company in terms of product quality and shareholder value.”

Consumer Foods makes up 67 percent of company sales and earnings. Most of the major brands are common household items that you and your family use all the time.

The restaurant group makes up the other 33 percent of sales and earnings. The Red Lobster name is General Mills’ largest brand.

With sales of over $1.5 billion this year, Red Lobster will serve over 150 million guests. Red Lobster is the largest dinnerhouse chain in the world. The second largest is Olive Garden, with sales of over $900 million. The newest concept is China Coast Restaurant, with five units and ambitious goals to be as large as its sister companies. Asian food is the fastest growing segment of dining occasions in the U.S. By the year 2000, three out of the twenty-one meals you eat each week will be Asian.

Projected growth for all three chains is for over 50 units per concept in the next few years. General Mills believes that restaurants will be a critical part of its projected growth plans. By the year 2000, the goal is to have over 2000 restaurants worldwide.

The restaurant industry is very competitive. Currently, there is over 55 percent overcapacity in seating. The hardest hit segment is fine dining, but all segments are having trouble maintaining their market share and traffic.

General Mills restaurants will use over 85 million pounds of frozen seafood this year. Forty-two percent will be broiler products, 18 percent crab products, 17 percent fish fillets, 10 percent lobster, and 13 percent other shellfish and seafood products. We will also serve over 5 million pounds of fresh fish and 1.5 million pounds of live lobster. By the year 2000, our seafood needs will double to over 170 million pounds.

Not only are our seafood needs growing, but so are the needs of most dining segments. There has been a 4 percent increase in the number of restaurants serving seafood. This shows that America still prefers to eat seafood away from home. But even as U.S. consumption has turned down, so has consumption at restaurants. However, restaurants are using seafood to offer healthy alternatives to their guests. The American palate has changed in recent years. Variety sells, and people are more willing to experiment with different types of foods when dining out.

The history of the departments of Purchasing and Quality Control started at the same time. The founders of the company realized back in the early 1970s that the limiting factor to growing Red Lobster into a national chain the size it is today would be the supply of high-quality, value-priced seafood. The founders believed that these two traits, plus great service in a clean, efficient restaurant, would be the key to success.

In the early seventies we were buying through brokers and distributors. The quality of the products varied greatly. Supply was inconsistent and prices were unpredictable. So the decision was made to create a purchasing department. Today the purchasing department travels to over 40 countries a year. Our buyers spend over 50 percent of their time at the producing areas and production facilities where our products are harvested and packaged. Buyers spend time training in their products so that they can travel anywhere in the world and teach fishers, production workers, and plant quality control personnel how to produce Red Lobster quality. Over 70 percent of our seafood comes from overseas. One hundred percent of our shrimp now comes from aquaculture. No matter where the resource is, our buyers are willing to go and learn about what this area of the world can offer our guests. We continue to use some brokers and importers who understand our needs and philosophy of quality, value, and service.

Marketing supplies Purchasing with changing trends in dining patterns and guest expectations. Purchasing plays a large role in developing new products and species and introducing value added products to save on back of the house labor. Today every item is made at each restaurant daily to ensure that our food is fresh and that our guests receive only the
highest quality seafood they can buy. It is a constantly changing environment, and what was good enough yesterday will not meet the needs or standards of today. By having an internal purchasing and quality control function, it has been easier to communicate needed changes to industry so that we can maintain our competitive edge.

By having the buying team visit the world’s seafood-producing areas, we have been able to anticipate shortages, embargoes, and foreign competition that can drive price. Our menu and promotions are flexible, so we can work together with marketing to smooth out supply or price problems. Years ago when McDonalds put Pandalus shrimp on the menu and prices reached over $5.00 a pound, we were forced to reduce our usage from 3 million pounds to about 100,000 pounds. Now that the price has returned to a more stable level, our usage has increased to about 750,000 pounds. But it never gained its place completely back because the product we substituted continues to occupy that space and popularity. This year we substituted Dungeness crab for Opilio when supply and price became issues. On every trip we look for new ideas, products, or items. People forget that it was Red Lobster that introduced America to snow crab, popcorn shrimp, and orange roughy. This conference is an example of taking the opportunity to talk to industry about our company and to explore with this industry mutual areas of interest and potential business.

All our specifications are developed by our Purchasing Department with advice from industry. Before they are written up, Restaurant Operations and Test Kitchen approve them to make sure that our restaurants are receiving the correct product, properly packaged, and with maximum ease of use.

Once a specification is developed, products are shipped to one of our primary freezer locations (Atlanta, Los Angeles; Indianapolis; Trenton, Ontario). At each of these facilities, we have built quality control labs to inspect every shipment of seafood and other products. These labs are set up to evaluate packaging and physical characteristics and to check microlevels. No product ever is sent to one of our restaurants before it is inspected. Counts and weights are checked to ensure we pay for what we ordered and they meet our specifications.

Specifications address chemical additives, acceptable species, receiving temperatures, and other defects that could be seen with each individual product. Most of our specifications are stricter and more detailed than current government standards. They have been developed with industry so that what we inspect for is what industry can produce and package. We own our own shrimp processing plant, which enables us to understand that side of the business and teaches us what we should expect from other processing facilities. Our specifications are available for anyone to use.

During the late 1980s there were a number of seafood scares and bad publicity. To head off the issue that seafood was not government inspected, we worked with the U.S. Department of Commerce to have our inspection program certified. Our Integrated Lot Inspection Program has been very successful in that it is one more step to ensure that our guests receive only the best seafood. Red Lobster was one of the first companies to institute this program on a national level.

Training and continuing education programs are a key step to ensuring that the quality message is understood through all levels of the organization. Publications such as Lobster Tales and Expert’s Guide To Seafood are used to train our employees and keep them current on all changes. Brochures in our restaurants’ lobbies educate our guests to our quality programs, the health advantages of seafood, and nutritional levels of all our products.

All these programs together ensure that we deliver our goal: to provide a continuous supply of top quality seafood for our guests.

This translates into a pleasurable, safe, and confident dining experience for our guests every time they dine with us. If we do a poor job one percent of the time, over 1.5 million guests will have a bad experience. That is why we have always joined forces with industry and government to work together to create the best seafood dining experience for our guests.

It takes a complete understanding of all these areas to produce the quality story. For without a commitment to quality by all segments of our industry, consumers will find other ways to spend their food dollars.
THE NEED FOR DEVELOPING UNIFORM SURIMI STANDARDS

Jae Park and Michael T. Morrissey
Oregon State University Seafood Laboratory

INTRODUCTION

Surimi is washed, minced, fish flesh to which cryoprotectants have been added to maintain the functional properties of the proteins during frozen storage. More than any other seafood, it is relatively homogeneous in composition and physical attributes. Although there are a number of processing techniques, the end product (if made from the same species) will have similar characteristics whether it is made aboard a factory trawler or a shore-based surimi plant.

Japan has been the recognized leader in the global surimi industry. Surimi processing grew from a small traditional fisheries in Japan to large-scale operations during the 1950s. The initial phases of the industry depended on shore-based operations (Okada 1992). In 1965, the use of cryoprotectants allowed the production of surimi at sea, which greatly expanded the resource base for Japan (Zenkama 1987). The Americanization of the Alaska pollock fishery that began in the 1980s and was followed by the Pacific whiting fishery in the 1990s forced Japan to be more dependent on foreign harvests for their surimi. Nonetheless, Japan has dominated the world’s surimi processing technology for on-shore and at-sea operations. The total production of surimi in the world has fluctuated between 390,000 to 530,000 metric tons over the last five years (Kano 1992).

More than 100 types of surimi-based seafood products currently are produced in Japan. In the United States the majority of the surimi is processed into shellfish analogs, primarily imitation crab. The nature of the final product is such that gel strength and color are the most important attributes of surimi. Although a number of analog products are made in Japan and other Asian countries, gel strength and color continue to be critical characteristics of surimi sold overseas.

Surimi is one of the few seafood commodities that will receive a price differential based on a grading system. Understanding and manipulating the production to take advantage of this grading system is crucial in the marketing of surimi. For example, if company X makes three different grades of surimi - A, B, and C - for which there is a 10 percent price differential, it may be to the company’s advantage to produce the higher-grade surimi, depending on the market conditions. However, if the cost of making the higher-grade surimi (lower yields, added production costs) are such that the price differential is negated, it may be more economically beneficial to make grade B surimi. In either case, knowing how the grading system operates and how different factors can affect grading of surimi samples can mean substantial increases to profit margins.

Factors Affecting the Grading System

The grading system for surimi is based on a number of its characteristics, some more important than others. These include

- Gel strength
- Color
- Moisture content
- Impurities
- Microbiological count

Other properties of surimi that can influence the final grade are pH, protein content, fat content, cryoprotectants, and other ingredients such as protease inhibitors, gel enhancers, and whiteners. A number of factors will have an effect on these surimi characteristics and are taken into account during surimi production.

Gel strength depends on the functionality of the myofibrillar protein and its ability to form heat-set gels (Matsumoto 1979). The gel strength is affected by the species of fish, seasonality, and time and temperature factors during handling onboard the vessel as well as during the processing steps. Compositional factors will also affect the gel strength readings. Lower moisture content will improve gel strength as well as starches and gel enhancers (Hamann and MacDonald 1992; Lee 1986).

Color largely depends on the species of fish that are used for surimi products. The typical low-fat white fish species such as Alaska pollock and whiting will give a color that is slightly off-white but will turn a creamy white
during analog processing. Pelagic species such as sardine or mackerel will have a more grayish hue, while other species will take on the inherent color of the flesh. The degree of washing will greatly affect the final color as well. The washing away of pigments or impurities will generally lighten the color of the surimi.

As mentioned previously, the moisture content will affect gel strength: the lower the moisture, the higher the gel strength. However, a lower moisture content in surimi results in lower yields and decreased profit margins. Since analog manufacturers add water to their formulations, they prefer the moisture to be lower than 75 percent. This is within the manufacturing tolerances of present surimi producers.

Impurities are normal bits of skin or viscera that have not been washed out during processing. They have little affect on the gel strength of the surimi but do affect consumer acceptance of the product, especially, if the final product is a creamy white analog. Some species have a certain percentage of "black spotting" in the flesh. If these fish are not culled, they can cause a defect that appears like "pepper on snow" and will cause a reduction in the grade (Morrissey et al. 1992).

Microbiological levels of surimi are important for quality control and health standards. Standards may include total plate count and coliform count as well as specific pathogens such as Listeria. The initial bacterial load on the fish is the most important factor for final bacterial count of the surimi (Lee 1992). Researchers have found that the washing steps did not appreciably reduce the microbial count (Himelbloom et al. 1991). With the increasing use of HACCP in the surimi industry, there will be increasing reliance on good microbiological controls in the plant.

The pH of the final surimi can greatly affect its gel strength and should be monitored during processing (Chung et al. 1993). Other additives, such as calcium compounds, can affect gel strength while glycerides and hydrogenated vegetable oil will have an effect on color or the sheen of the final block. Protease inhibitors, such as beef plasma protein, used in Pacific whiting surimi, markedly improve gel strength but may cause an increase in yellow color if used in too great a concentration.

**Surimi Characteristics: Measurements and Additives**

Uniform surimi standards require a uniform methodology for testing surimi characteristics. Unfortunately, at present, this is not the case for surimi. There are a number of different instruments as well as methods for evaluating characteristics such as gel strength, color, and moisture. While the principles for measuring these characteristics may be similar among the instruments, there are a number of differences as well.

The measurement of gel strength is one of the more problematic. The traditional surimi method is the fold test by which a 3-mm-thick slice of surimi is folded several times and inspected for cracks resulting from the folding (Lee 1984). This procedure, although simple to use, can have a wide variation and is not very discriminatory among surimi samples with a high gel strength. Because of the subjective nature of the evaluation, it is difficult to standardize this type of test.

The punch test is currently the method of choice among surimi producers to measure gel strength. Recently, an electronic rheometer (Rheo Tex) has been commonly used to determine gel strength (NFI 1991). In this method, a plunger is driven at a constant speed into a surimi gel, and values are reported by measurements of force (force needed to penetrate the gel) and depth (the distance the plunger travels inside the gel). Gel strength (jelly strength) is expressed as the force (g) x depth (cm). While this method is more objective than the fold test, it still can give highly variable results that could lead to discrepancies between buyer and seller. Furthermore, there is no method to calibrate the instrument after extended use. Nonetheless, even with these shortcomings, the punch test is preferred because of its ease of use during at-sea processing.

A more accurate test of overall gel strength is the torsion test developed at North Carolina State University (Hamann and Lanier 1987). This procedure requires a standardized method of preparing the gel for testing such as bringing the moisture content of samples to 78 percent. The torsion test involves the twisting of an hourglass-shaped gel to failure. The resistance to the twisting is related to gel strength and is reported as stress while the degree of twisting that occurs before breaking is related to the elasticity of the gel and is reported as strain. The disadvantages of the instrument are that the accuracy of the results can depend on the technical expertise of the lab technician and that the instrument would be impractical on an at-sea factory trawler rolling in the Bering Sea.
Other researchers have used the compression test (most commonly performed with the Instron) as well as other instruments for analyzing texture. While these are good research tools, they are usually impractical for the typical surimi producer. The making of the cooked surimi gel to be measured is as much an art as a science. There are a number of factors, such as the type of sausage stuffer, and the use of a vacuum chopper, that will influence the results of the gel test (Babbitt and Reppond 1988).

The surimi paste is often prepared for testing by various methods that can lead to differences in the results. The surimi industry has been using three different formulas to prepare the surimi paste. One method uses 97 percent surimi and 3 percent salt, while another method uses 100 parts of surimi and 3 parts of salt. A third method uses 94 percent surimi, 3 percent salt, and 3 percent potato starch.

There are only minor differences in the first two methods, but by adding starch to measure surimi gel strength (third method), we are likely to observe increased gel-strength values due to starch gelatinization. Park (1993) found that the addition of starch up to a 6 percent level raised the gel strength by 15 to 45 percent, depending on its kind and modification. An addition of 3 percent potato starch in the surimi gel will upgrade the gel-strength of the surimi.

The surimi industry currently uses three different cooking methods for testing surimi gels. They are (a) a 90 C cook for 30-40 minutes, (b) 24-40 C preincubation for 2-6 hours followed by a 90 C cook for 30-40 minutes, and (c) a 5 C preincubation for 18-24 hours followed by a 90 C for 30-40 minutes. Preincubation is called suwari in Japanese. This technique is used in the industry to facilitate molding and forming products for kamaboko or crab analogs. The effects of preincubation have been studied by a number of investigators (Numakura et al. 1985; Kim 1987; Kamath 1990; Park et al. 1993). There is a minimum effect on gel elasticity, but preincubation can affect the gel stress (strength) by 15-60 percent, depending on the method and fish species. Because of these effects on gel strength, there is some confusion between buyers and sellers in surimi evaluation.

Surimi additives used in commercial processing are another important issue that we need to look at for the standardization of surimi. Cryoprotectants have been used in the processing of surimi since Japanese scientists found the combination of sugar and phosphates can extend the shelf life by inhibiting freeze-induced protein denaturation (Okada 1992). Different levels of sugar (4-5 percent), sorbitol (4-8 percent), phosphates (0.25-0.3 percent), and more recently glyceride (0.1-0.2 percent) for whiting surimi have been used by manufacturers. Manufacturers believe their recipe is specially blended with a patentable propriety.

With the processing of Pacific whiting for the last three years on the Pacific coast, the use of enzyme inhibitors is necessary to make quality surimi. In 1991-1992, several enzyme inhibitors such as beef plasma protein, egg white, and potato flour were evaluated by manufacturers and research institutes. In 1993, all manufacturers of Pacific whiting surimi used beef plasma protein (1.0-1.5 percent) as an enzyme inhibitor. With continuing efforts to make whiting surimi comparable to pollock surimi, calcium carriers (such as calcium lactate, calcium sulfate, and calcium caseinate), sodium bicarbonate, and canola oil have been used as a gel enhancer or a color-improving agent. Again, all manufacturers use different levels as well as different combinations in the name of proprietary blending.

There are some problems with the grades and specifications of surimi from the viewpoint of consumers and analog manufacturers. First, each manufacturing company has its own specification of grades and additives. Second, there are no uniform grades among companies. Third, there is no uniformity in compositional properties, because of the addition of different levels and kinds of additives. Fourth, there is not a universally accepted testing methodology. In 1991, the Technical Committee of Surimi and Surimi Seafoods through the National Fisheries Institute established the U.S. standard of surimi measurements (NFI 1991). However, none of the surimi manufacturers have shown their willingness to adopt it.

Current Practices in Surimi Industry

Technical systems for surimi processing have been developed by the five most important fisheries in Japan (Taiyo, Nisui, Hoko, Nichiro, and Kyokuyo) based upon their own interest and business involvement. These technical systems have been further modified by Korea and the United States, again because of their own interests.

To demonstrate the different grades, we have selected 11 major surimi manufacturers of Pacific whiting surimi (table 1). The grading systems vary from company to company, and
there are even differences between two factory
trawlers within the same company (I-1 and I-2).
The eleven companies use very similar
grades and specifications for Alaska pollock.
The only grade they all agree on is the SA
grade for their best surimi. Most of the com-
panies use the FA terminology for their second
best grades. Four different grades are avail-
able for their third best category. Five different
grade names are offered for the low-grade
surimi. Interestingly, company K offers only
two grades, SA and FA.

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<td>P</td>
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<tr>
<td>E</td>
<td>SA</td>
<td>FA</td>
<td>P</td>
</tr>
<tr>
<td>F</td>
<td>SA</td>
<td>FA</td>
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</tr>
<tr>
<td>G</td>
<td>SA</td>
<td>FA</td>
<td>A</td>
</tr>
<tr>
<td>H</td>
<td>SA</td>
<td>FA</td>
<td>A</td>
</tr>
<tr>
<td>I-1</td>
<td>SA</td>
<td>A</td>
<td>KA</td>
</tr>
<tr>
<td>I-2</td>
<td>SA</td>
<td>FA</td>
<td>A</td>
</tr>
<tr>
<td>J</td>
<td>SA</td>
<td>FA</td>
<td>AA</td>
</tr>
</tbody>
</table>

Table 1. Grades of commercial Pacific whiting surimi.

Specifications of each quality parameter
have been used as guidelines for grading. Five
major companies were selected to compare the
differences in their specifications. The mois-
ture level in surimi is important and is related
to whether or not the surimi-based seafood
manufacturers are buying water or fish pro-
tein. There is about a 1 percent difference
among companies for the top two grades. Most
of the companies set the same specifications for
all grades; company A and company D are ex-
ceptions. Four different heating elements may
be used to determine moisture. They are infra-
red, microwave heat/auto scale, electric heat/
auto scale, and oven methods. The first three
can give relatively good results within 10 to 15
minutes, whereas the oven method needs 16 to
20 hours. However, the oven method gives the
most accurate results.

For the measurement of skin bits or defects,
all manufacturers follow the guidelines of the
Japanese Surimi Association with various
degrees of modification. Sample size may vary,
being either 10 or 40 grams. The counting
scale may also vary when counting skin bits or
defects. Some companies assign 1 point to
lengths >2 mm and 1/3 of a point for lengths
<2 mm, while other companies give 1 point for
lengths >2 mm, 1/2 point for 1-2 mm, and 0
points for <1 mm. There are two systems used
in the industry for determining the impurity of
surimi. The most common method is to use de-
fect counts, while the other method uses a 1 to
10 scale purity point such as company B. The
numbers shown in table 2 are extremely differ-
tent among companies because of the sample
size and the counting method.

As previously mentioned, gel strength is one
of the most important factors in surimi quality
measurements. However, there is a large dif-
ference among the companies. Gel strength
(gm-cm) is calculated based on the force (gm)
required to break or tear the gel and on
deformation (cm), which indicates the degree of
the gel’s resistance to a penetration probe.
Most of the companies use the gel strength as
a force value multiplied by deformation, while
company H uses a force value only. The range
among the companies is between 850 and 1000
for the SA grade and between 900 and 750 for
FA grade. These differences may be due to the
type of gel preparation and whether starch is
used when making the sample gels. Preincu-
bating of the surimi will also affect the final gel
strength measurements (Kamath 1990). The
greatest difference between the different
companies is in the lower grade surimi (AA
and KA), where there is a 200-unit differ-
cence.

Color specifications for surimi are extremely
different among the companies, as shown in
table 2. The surimi industry has been using
three different brands of colorimeters: Minolta,
HunterLab, and Nippon Denshoku Kogyo.
Even though the principle of color measure-
ment is identical, there is still a small but sig-
nificant difference between the machines.
Table 2. Specifications of commercial Pacific whiting surimi. Companies A, B, D, and H are selected from table 1.

1. Moisture (± 0.3%)

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>D</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA</td>
<td>74.5</td>
<td>SA 74.1</td>
<td>SA 73.5</td>
<td>SA 74.3</td>
<td>SA 74.5</td>
</tr>
<tr>
<td>FA</td>
<td>74.5</td>
<td>FA 74.1</td>
<td>FA 73.5</td>
<td>FA 74.3</td>
<td>FA 74.5</td>
</tr>
<tr>
<td>AA</td>
<td>74.5</td>
<td>A  74.1</td>
<td>P  74</td>
<td>A  74.3</td>
<td>A  74.5</td>
</tr>
<tr>
<td>KA</td>
<td>74.5</td>
<td>KA 74.1</td>
<td>K  74.5</td>
<td>B  74.3</td>
<td>KA 74.5</td>
</tr>
<tr>
<td>RA</td>
<td>77</td>
<td>B   75</td>
<td></td>
<td>B   74.5</td>
<td></td>
</tr>
<tr>
<td>RB</td>
<td>77</td>
<td></td>
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<td></td>
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</tbody>
</table>

2. Skin and Defect Counts *Purity Score

<table>
<thead>
<tr>
<th></th>
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<th>B*</th>
<th>D</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA</td>
<td>15</td>
<td>SA 9</td>
<td>SA 10</td>
<td>SA 8</td>
<td>SA 15</td>
</tr>
<tr>
<td>FA</td>
<td>20</td>
<td>FA 8</td>
<td>FA 10</td>
<td>FA 14</td>
<td>FA 20</td>
</tr>
<tr>
<td>AA</td>
<td>20</td>
<td>A  7</td>
<td>P  10</td>
<td>A  14</td>
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</tr>
<tr>
<td>KA</td>
<td>20</td>
<td>KA 7</td>
<td>K  25</td>
<td>B  23</td>
<td>KA 80</td>
</tr>
<tr>
<td>RA</td>
<td>15</td>
<td>B   35</td>
<td></td>
<td>B   80</td>
<td></td>
</tr>
<tr>
<td>RB</td>
<td>30</td>
<td></td>
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</tbody>
</table>

3. Gel Strength (gram.cm) d*Force (Gram) Only

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<tr>
<th></th>
<th>A</th>
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<th>G</th>
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<tbody>
<tr>
<td>SA</td>
<td>1000</td>
<td>SA 900</td>
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<tr>
<td>FA</td>
<td>900</td>
<td>FA 750</td>
<td>FA 900</td>
<td>FA 750</td>
<td>FA 700</td>
</tr>
<tr>
<td>AA</td>
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<tr>
<td>KA</td>
<td>700</td>
<td>KA 450</td>
<td>K  500</td>
<td>B  450</td>
<td>KA 400</td>
</tr>
<tr>
<td>RA</td>
<td>300</td>
<td>B   300</td>
<td></td>
<td>B   &lt;400</td>
<td></td>
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<tr>
<td>RB</td>
<td></td>
<td></td>
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4. Color (L*/b*) *Nippon Denshoku Kogyo based on Whiteness Index

<table>
<thead>
<tr>
<th></th>
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<th>D</th>
<th>G</th>
<th>H</th>
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</thead>
<tbody>
<tr>
<td>SA</td>
<td>47</td>
<td>SA 7614.5</td>
<td>SA 74/12</td>
<td>SA 75/4.5</td>
<td>SA 46</td>
</tr>
<tr>
<td>FA</td>
<td>46</td>
<td>FA 75/5.0</td>
<td>FA 73/14</td>
<td>FA 75/5.0</td>
<td>FA 45</td>
</tr>
<tr>
<td>AA</td>
<td>45</td>
<td>A  74/5.5</td>
<td>P  72/15</td>
<td>A  74/5.5</td>
<td>A  44</td>
</tr>
<tr>
<td>KA</td>
<td>44</td>
<td>KA 72/8.5</td>
<td>K  71/15</td>
<td>B  74/8.5</td>
<td>KA 38</td>
</tr>
<tr>
<td>RA</td>
<td>38</td>
<td>B   70/17</td>
<td></td>
<td>B   &lt;38</td>
<td></td>
</tr>
<tr>
<td>RB</td>
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Companies A and H use a whiteness index based on an equation using X, Y, Z values; the other three use L* (lightness) and b* (yellowness). When L* and b* values are compared between companies (B, D) using the same equipment, a significant difference is observed, as shown on table 2.

Reasons for Establishing Surimi Standards

The setting of surimi grades has been a process that has evolved with each company over the years. In the past, when surimi was a small land-based industry concentrated in Japan, the traditional fold test was adequate to determine the gelling characteristics of the product made from the landed catch. As the industry has become more global and the production has grown to approximately 1 billion pounds per year of product being produced from at-sea factory trawlers and shore-based plants, these traditional methods are inadequate to define the product. There are, no doubt, advantages to individual companies in having their own grading system. If they are large producers, they can have a tighter control of their product and thus their markets. Ideally, they could have a complete understanding of their own surimi measurements and know how these measurements relate to harvest variables, yield, and protein content. They can lock in customers using their grading system and make it difficult for a customer to change to other brands.

However, the setting of different grading systems and values within the industry leads to high information costs. It becomes more difficult for a surimi-based seafood producer to change suppliers and fully know the characteristics of the surimi. How does a different grading system affect his formulation and final product quality? If there are differences, how does this affect consumer satisfaction? Does an FA grade of 900 gel strength from company A translate to the same protein quality of an FA grade of 750 gel strength for company B, if company A is using starch in its gel measurements?

These differences in measurements and grading can cause confusion in the marketing of surimi. Larkin (1993) states that different “firm-specific grades are not an efficient mechanism for conveying the key surimi characteristics for the following reasons:

1) Surimi is not an homogeneous product despite its appearance, i.e., laboratory tests are needed to determine levels of key characteristics;
2) External processors face unnecessarily high costs of gathering information about alternative supplier grades, i.e., search costs exist;
3) External processors may develop a dependency on a past supplier, i.e., buyer loyalty exists that may ensure product consistency while allowing suppliers to restrict substitution possibilities and monitor their potential rivals in the final surimi-based seafood market.”

Standards for any raw material help to define that commodity and promote fair trade practices. It is as important for buyers to know exactly what they are receiving as it is for sellers to receive a fair price for their product. Standards are beneficial to the industry as a whole and will encourage growth and promote stable markets. At present, the United States is the largest producer of surimi and Japan is the largest user. Any development of a surimi standard requires agreement between these two countries. A unilateral agreement by either one of the countries could cause greater confusion and mistrust in the surimi industry and uncertainty in world markets. Both countries need to fully agree on the standards and grading system.

A standard grading system requires the standardization of methodology and instrumentation. Preparation of samples, reagents, and calibration of instruments need to be accurately defined and followed. A start in the right direction has been the publication of the manual for measuring surimi quality by the National Fisheries Institute (NFI 1991). Although the manual does not establish a system of grades, it explains which compositional properties are important for measuring surimi quality and describes the methodology for measuring these properties. These standardized methods are suggested for in-house measurements to ensure quality control and accurate product formulation. Accurate measurements for surimi depends, in part, on whether a simple methodology can be followed by technicians at shore-based plants, on factory ships at sea, and in various counties. Cooking times, sample size, and ingredients for forming the test sample are important considerations. The salt concentration and moisture percentage are important variables that need to be held constant for a standardized testing regime. As noted previously, several companies add
starch. Since starch is an added variable in the testing and can exhibit its own gel-forming properties, it should be eliminated from the testing methods. These are some of the issues that should be decided by a standardization committee.

The standardization of testing equipment is also a necessary component of determining standards for surimi. The most commonly used methods for measuring gel strength are the punch test and the torsion method. There are limitations in correlating the punch test with the torsion test in surimi (NFI 1991). These correlations are weak for measuring the elasticity of the gels or for lower grade surimi. This could be especially true for some of the new species of fish that are being introduced into the surimi marketplace. It will be beneficial to the industry as a whole if only one type of instrument is used and the methodology is well described. This would require an accurate way to calibrate the instruments so that they would measure the same functions throughout the season. This should be true for the color measurement as well. The establishing of a color standard (or hitching tile) is necessary to accurately calibrate the instruments before taking color measurements.

CONCLUSIONS

The surimi industry has evolved rapidly over the last half century. It has changed from a small, traditional, shore-based industry in Japan to a billion dollar industry involving a number of countries and increasingly a number of species of fish. The grading system has evolved as well from a subjective analysis of texture and color to a more sophisticated objective system of analysis of gel strength, L value, moisture, and so on. Although there are several discrepancies in how these quality parameters are currently measured, there is a common goal for most companies to have a systematic way to evaluate surimi blocks. There are differences, at present, in the grading of the surimi. However, there are also a number of similarities, and the numbers almost beg for a committee to establish a standard grading system for measuring surimi. Any committee formed to establish standards and grades needs to include representatives from the Japanese and the U.S. surimi industry. The surimi industry should support the establishment of grading standards to help stabilize the industry. A uniform grading system would improve the efficiency of the industry and increase competitiveness across all sectors.

Reduced costs related to information gathering could be translated to decreased costs in final product form and to the consumer. This will allow surimi to be cost competitive against other seafood and nonseafood items and expand its marketing opportunities.

REFERENCES


Zenkama. 1987. Outline of All Japan Kamaboko Makers Association (Zenkama) and All Japan Surimi Users Committee. All Japan Kamaboko Makers Association. Tokyo, Japan.
IMPLEMENTING AN ISO 9000 QUALITY SYSTEM IN A
EUROPEAN SEAFOOD COMPANY OPERATING
INTERNATIONALLY

Sigurdur Bogason
Icelandic Freezing Plant Corporation

INTRODUCTION
In this paper I will discuss the various aspects of systematic quality management as presented in the ISO standards. Where appropriate, I will try to refer to my personal experience working with an ISO 9001-certified quality system. The focus of my discussion will be the following points.

- What is meant by the terms quality and quality assurance?
- What are the typical components of an ISO 9000 quality system?
- Why should a seafood company choose to work with a structured quality system?
- What are the benefits?
- How long does it take to integrate this kind of a system into an organization and how much might it cost?

I will discuss the general principles involved and use some practical examples that relate to the seafood industry.

QUALITY TERMS DEFINED
The international business world seems to be deeply concerned about quality. This concern may be only a new fad or the hope of salvation for every businessman and industry. My personal experience is that nobody with any sincerity can afford to look at this only as a fashionable idea. To compete successfully on the global food market, an industry like the seafood industry needs to take quality management very seriously. This recent interest in quality seems to arise mainly from the fact that the Western world has come to understand that the basis of Japan's industrial success in the last few decades is quality. Now we are all extremely busy trying to come to terms with this. Everybody wants to be saved by quality or at least use it somehow to achieve a competitive edge in the future.

The next logical question becomes, what is quality? The term has many meanings, depending on culture and type of industry. It is important to define quality before going any further. Many have said (Juran 1989; Surak and McAnelly 1992) that quality is the economical production of consistent products and services that meet or exceed customer requirements. We can add to this statement, and conformance to regulations. Furthermore, it is obvious that customer requirements are more than just meeting specifications.

To meet customer requirements, we need information from market research that lets us understand customers' needs and problems. Then we need to develop a process for producing goods and services that meet or exceed customer's needs or desires. Finally, we need to sell the products or services at appropriate prices. When any of these criteria can't be met, it is obvious that the product or services have not met the definition for quality. For example, rework, waste, or loss during production or distribution of seafood product means there is a decrease in quality. This is because the customer eventually will have to pay more for the product or the owners of the company will receive less return from their investment. To illustrate further the true meaning of quality, we can compare two automobiles. A Rolls-Royce, which meets the specifications for a Rolls-Royce, is a quality car. But it is equally true that a Russian-built Lada, which meets the specifications for a Lada, is a quality car. Quality is meeting the requirements.

Another term one comes across frequently (Surak and McAnelly 1992) is quality assurance, which is the planned and systematic actions necessary to provide adequate confidence that processes, products, and services satisfy the requirements of quality. This definition brings us back to the ISO 9000 standards since they are probably the best tool available to any industry for setting up a system to manage quality and maintain quality assurance.
The following standards (published in 1987) are used as guidelines for quality management systems:

- ISO 9000 - quality management and quality assurance standards—guidelines for selection and use
- ISO 9001-model for quality assurance in design/development, production, installation, and servicing
- ISO 9002-model for quality assurance in production and installation
- ISO 9003-model for quality assurance in final inspection and testing
- ISO 9004-quality management and quality system elements—guidelines

For practical purposes most quality systems that I know about are based on either ISO 9001 or 9002. Figure 1 shows the elemental difference between the models. ISO 9001 is the most comprehensive one, and ISO 9003 is the simplest, as it deals only with final inspection and testing. To add to the confusion, the standards have different reference names in Britain and in the EEC. In the UK, 5750:part 1 is the same as EN 29001 in the EEC; both are identical to what internationally is called ISO 9001 (BSI Quality Insurance publication). Gudmundsson (1992) points out some of the key reasons for using the ISO standards: to provide direction, generate ideas for change, design or redesign systems, implement changes, measure results, and manage change through audits and reviews.

The IFPC Quality Assurance Manual describes a typical ISO 9001 quality system. Figure 2 lists the contents of the manual. Each of the 20 chapters in the manual deals with specific activities.

Many people think of quality in the limited sense of product quality and quality control. However, the standards address all the usual activities taking place in an organization. In the food industry one can easily visualize many
CONTENTS

Statement of Quality Policy
Issue Log

1. Management Responsibility
2. Quality System
3. Contract Review
4. Design Control
5. Document Control
6. Purchasing
7. Customer Supplied Product
8. Product identification and Process Control
9. Inspection and Testing
10. Inspection, Measuring and Test Equipment
11. Inspection and Test Status
12. Control of Nonconforming Product
13. Corrective Action
14. Handling, Storage, Packaging and Delivery
15. Quality Records
16. Internal Quality Audits
17. Training
18. Servicing
19. Statistical Techniques

Appendices:
1. List of Quality Plan and Quality Procedures - Reykjavik
2. List of Quality Plan and Quality Procedures - Hamburg

Figure 2. Contents page of IFPC’s Quality Assurance Manual.
of these activities also being addressed with a HACCP-based system. The main difference between the two systems is that HACCP concentrates on process control and is one of the best tools available for this. ISO 9000 systems, on the other hand, ensure the overall management of quality in all quality-sensitive aspects of the organization.

The company I work for, Icelandic Freezing Plants Corporation, has a long history of using the term quality as a key part of its market approach. The corporation celebrated its 50th anniversary last year, and in March 1992 became certified towards ISO 9001. Commitment to this work was made in the spring of 1991, and I was given the task of compiling the quality assurance manual and quality procedures in cooperation with other IFPC staff and consultants from a British company with extensive experience in this field. It took us at IFPC about eight months to have the system written, implement it, do a number of internal audits, amend procedures, introduce some changes to work routines, and finally pass the assessment of BSI quality assurance (Bogason 1992).

The reason this was possible in such a short time was that there was total commitment and leadership from the top management of the company. Also almost all the personnel participated in some aspect of the work.

There is no mystique involved in this process. Basically what you need is to start organizing and documenting in a formal manner the actual work being carried out within the company. The only new aspect in the process is using the ISO 9000 standard to guide you in setting up the controls required by the individual ISO standard you choose as the model for your quality system. The result is a formally written quality assurance manual and quality procedures that describe your company’s tradition for doing the daily tasks while adding the security of controls in specific areas of work, many of which may be new to the company. The individual chapters in the typical quality assurance manual specify how the company operates and ensures that the requirements of the ISO 9000 standard are met. The quality procedures describe in more detail how they are met.

The IFPC quality management system documentation could be viewed as a pyramid (figure 3). At the top we place the quality policy. In the next layers are the quality assurance manual, quality procedures, and work instructions. The foundation of the documentation is the records that prove we do what we say we will do. The description of the work routines is increasingly detailed toward the base of the pyramid.

Examples of new tasks that most companies would have to deal with are controlling the formal documents, assessing the supplier, and conducting internal quality audits. Figure 4 shows a form that was introduced at IFPC to deal in part with the requirement of the ISO 9001 standard: “Part 4.6.2 Assessment of subcontractors - The supplier (company) shall select subcontractors on the basis of their ability to meet sub-contract requirements, including quality requirements. The supplier (company) shall maintain records of acceptable subcontractors.” Figure 5 shows a sample outline of the quality procedure that corresponds to this part of the standard. Also, we maintain a list of approved suppliers for IFPC, and in many cases we visit the suppliers to perform quality assessments. The reason for taking this as an example from the standard is to point out the obvious. Certified companies will establish criteria for assessing their suppliers, and the main criterion will soon become that the supplier company also be certified. This will reduce the amount of inspection required for goods or services being purchased. Credibility and confidence will be greater for certified suppliers. All competent companies will gradually
## VENDOR ASSESSMENT QUESTIONNAIRE

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<thead>
<tr>
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<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>Fax:</td>
</tr>
<tr>
<td>Products and Services:</td>
<td>(Please list)</td>
</tr>
<tr>
<td>Name and status of person responsible for Quality Assurance:</td>
<td></td>
</tr>
<tr>
<td>Total number of employees:</td>
<td></td>
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<td>Total number of QA personnel:</td>
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<tr>
<td>List of formal quality approvals:</td>
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</tr>
<tr>
<td>What quality approvals do you intend to obtain:*</td>
<td></td>
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<tr>
<td>[* Example would be the ISO 9000 series standards ]</td>
<td></td>
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*Figure 4. Vendor assessment questionnaire.*
ASSESSMENT OF SUPPLIERS

Objective
To ensure that suppliers of goods and services used within the quality system are selected on the basis of their ability and that their performance is monitored.

Procedure

1. Quality Manager
   Suppliers of goods and services are assessed and their performance is monitored in consultation with the Purchasing, Quality Control, Shipping, xxxxx xxxxx xxxxxx xxxxx xxxxxxxxxx xxx xxxxxxxxxxxxxxxxxx.

2. Functional Managers
   Information about suppliers performance and complaints resulting from their services or goods are relayed to the Quality Manager. Complaint xxx xxx xxxxxxxxxxxxxxx xxxxxxxxxxx xxxxxxx xxxxxxx xxxxxxx xxxxxxx xxx xxx xxx xxx xxxxxxxx xxxxx xxxxxxx xxx xxx.xxx A. Manual.

3. Quality Manager
   Wherever possible suppliers registered as firms of assessed capability to ISO 9000 or similar are selected. Other suppliers are selected using one or more of the following criteria:
   - Supplier questionnaire form
   - Evaluation of sample products
   - On site assessment
   - Past history of performance.

   XXXXXXXXXXX XXXXXXXXXXX XXX XXXXXXXXXXXXXX XXXXXX XXX
   XXXXXXXXXXX "Approved".

4. Quality Manager
   XXXXXXX XXXXX XXX XXX XXXXXXXXXXX XXXXXXXXXX X X XXXXXX X X
   XXXXXXXXXXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX
   XXX XXXXX XXXX XXXXXXXXXXX XXX XXX XXX XXX XXX XXX XXX are
   recorded and filed.

Figure 5. Sample outline of a quality procedure.
be pulled on this bandwagon, willing or not. Those who refuse to put their effort into quality issues will lose market shares, just as those who pull their weight with enthusiasm will gain the competitive edge. Remember that at some stage everybody is both a supplier and a customer. The same thing is true within a company as each department needs to be sure who its customers are and what their requirements are.

We found forms to be very useful in efficiently introducing the controls and record-keeping required. In many cases the staff complained about the forms, but that was before they realized that using forms didn't take any longer to relay information than scribbling the information or request on some piece of paper. Also everybody quickly saw that the security gained was immensely important as information was not being lost and actions became more accurate. The number of failures to act upon an internal request was reduced and the staff became more responsible for their actions. Doing it right the first time is extremely important in all organizations because it reduces the cost of redoing the work (Bogason 1992).

At IFPC a new computer system has been set up. In designing its routines, we made an effort to automatically log in as much as possible of the record-keeping information required by the quality system. Consequently, many of the forms introduced when the system was being implemented have now become superfluous. Always remember the kind of motivation needed for the people who have to carry out the routine tasks like working according to procedures and using forms. You have to show the staff why a routine is required and help them see for themselves the benefits coming from this approach. Training is a key element in the effort, and the standard stipulates general requirements for training. Each company has to specify how its training needs will be met.

WHAT ARE THE BENEFITS?

There are four reasons the ISO standards can be useful to a company. First, the standards are internationally recognized. Second, they help organize the internal operations in an organization; in other words they can make all work flow more easily and prevent mistakes from happening. The quality system should reduce the effort needed for internal inspection and double checking within the company. Third, a company receives public benefits from ISO standards. A company that has a certified quality system can tell its customers it has been certified to the ISO standards. As customers are informed about the third-party assessment involved, the company and the quality it stands for gain credibility for the customers. European firms are under increasing pressure to become certified, and more frequently it is becoming a requirement for doing business. The fourth reason ISO standards can be useful is that the standards help establish proof of due diligence on part of the organization in maintaining the safety of processes, products, and services and in meeting legal requirements. Due diligence is the term used when a company has taken all possible steps and preventive measures to ensure the safety of its product.

APPROACH FOR SEAFOOD COMPANIES

How can a quality management system be beneficial specifically to seafood companies? There are no simple answers. Let's put it this way: if a company chooses not to manage quality in any formal manner, will it be competitive or be able to maintain the necessary credibility for customers, consumers, and regulatory bodies? My approach is as follows (Bogason 1992). By setting up a quality management system according to the ISO 9000 standards, any organization has then invested time, effort, and money to develop an immensely powerful tool for managing that organization. A carefully designed quality system is a general management tool for almost all operational activities. The finance department is usually excluded from the ISO 9000-based system. Although the standards do not require the financial department to be a part of the quality management system offered for certification, it can be organized and controlled by the same methods and philosophy.

How long will it take to become registered? If the company has a formal quality system—e.g., a HACCP system—in place, it could take only six months. However, this would be the exception; a company starting without a formal quality system should allow a year or two to become ready for assessment. The ISO 9000 standards do not by themselves specify or demand any specific level of quality or service. Each company has to establish its own standards of excellence or its service level. The standards basically require only