HEALTH REGULATIONS AND QUALITY CONTROL

FEDERAL HEALTH REGULATIONS

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(Eds. note: Copies of federal regulations are available from the above address.)

The purpose of my discussion is threefold: to briefly explain the acts and the regulations enforced by the Food and Drug Administration (FDA) as they apply to smoked fish; to pass out copies of the regulations covering smoked fish; and to invite you to call our office if you have any problems with or questions about the laws we enforce.

All food products, including smoked fish and its variations, shipped in interstate commerce or made from ingredients received in interstate commerce, are subject to the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA); the Fair Packaging and Labeling Act (FLPA), and their regulations. At first, the definition of interstate commerce seems simple: commerce between two states. But what about commerce between a state and a territory, or a state and a foreign country? Under the FDCA, these are also examples of interstate commerce. In fact, commerce between any state and any place outside its borders falls under this act.

In general the FDCA requires that food be prepared, packaged, and held under sanitary conditions. The food must be safe and wholesome. Its labeling must be accurate and informative. The Fair Packaging and Labeling Act requires certain information to be carried on all labels of food intended for retail. This is to distinguish between food which goes on for further processing or institutional trade, and food that is retailed.

Under the Federal Food, Drug, and Cosmetic Act, good manufacturing practice regulations have been established. The first of these regulations, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, is contained in Part 110 of Title 21 of the Code of Federal Regulations. If you are in the food processing business, you should have a copy of Part 110. These regulations cover all foods and are so broad and basic that they are often referred to as the "umbrella GMPs." They cover a wide variety of areas, including personnel cleanliness, disease prevention, employee training, and supervision; sanitation, disposal, and maintenance procedures; use of equipment suitable for the intended function; and control of your process to support the sanitation goals of your organization.

In 1977, the FDA added specific regulations for hot process smoked fish and smoke-flavored fish to the general good manufacturing practices. These regulations were developed after a number of Great Lakes cases where people were poisoned by smoked fish contaminated with Clostridium botulinum. The specific regulations are contained in Part 122 of Title 21 of the Code of Federal Regulations. Among the types of limitations found there are:

- Time, temperature, and salinity parameters for hot process smoked fish and smoke-flavored fish

- Product must be cooled to 50°F or less within three hours after processing

- Product must be cooled to 38°F within 12 hours after processing

- During storage and distribution, the product must be held at 38°F or less.

The East Coast smoked fish industry actively opposed the regulations. They felt these smoked fish regulations were unrealistic. They felt that the regulations would result in an inferior product and soon ruin their product and their trade. Consequently, a number of these fish processors disregarded the GMPs and soon were involved in a legal dispute with the FDA. The case United States vs. Nova Scotia Food Products Corporation occurred about 1977 and involved both district and appellate court proceedings. The appellate court held that the FDA regulations on smoked fish were invalid. The court based its decision on procedural grounds, saying that the FDA had used unpublished data to justify the need for the regulations, and that the FDA had not considered the commercial feasibility of these regulations.

As it now stands, we do not have any good manufacturing practice regulations for the smoked fish industry. However, we offer these regulations as guides. There is a possibility that in the coming years these regulations will again be promulgated and the smoked fish industry will have to follow them.

As I previously indicated, FDA is concerned with microbial contamination of smoked fish. Consequently, we suggest a high processing temperature and a proper salt concentration along with refrigerated storage and distribution. The presence of sodium nitrite and sodium nitrate may also deter toxin formation. Our food additive regulations provide for the use of sodium nitrite and sodium nitrate in smoked fish products.

We do not currently have any literature on the safety of cryo-packing or vacuum-packing smoked fish. However, we are concerned with any kind of packing technique which excludes oxygen. Clostridium botulinum Type E has been shown to grow and produce toxin without oxygen in some media at temperature greater than 38°F. We do not have any data on time necessary to produce these toxins in specific fish products. We also realize that it is very difficult for us, as a regulatory agency, to control the temperature of the smoked fish product during distribution. The processor may have good intentions but who knows at what temperature the retailer is going to keep the fish. However, we have occasionally asked manufacturers to conduct tests on their products at various abuse temperatures before the product becomes organoleptically unacceptable.

Because the main problems occur in distribution, the FDA has insisted that manufacturers place adequate, clearly visible storage information on the labels. Until more definite information is obtained or until we identify a situation where temperature abuse is likely to endanger health, we are not

prepared to prohibit cryo-packing or vacuum packing of refrigerated products. However, everyone should be aware that there is a potential for great danger if these products are not kept at the proper temperature.

So far, we have talked about noncanned items. Let us look at what you have to do if you want to can your smoked fish product. Again, the FDA has promulgated specific regulations for thermally processed, low acid foods canned in hermetically sealed containers because of the dangers of Clostridium botulinum. These regulations are contained in Parts 108 and 113, Title 21 of the Code of Federal Regulations. Among other things, these regulations require that a manufacturer of smoked fish products in hermetically sealed containers must register his plant and must file processing information with the Food and Drug Administration. This processing information has to cover each can size of product processed. If you need any registration or filing forms, you can contact our office.

Now I would like to briefly discuss the labeling requirements for smoked fish products. Federal low requires four statements on the label:

- The name of the product
- A list of the ingredients in a descending order of predominance
- A statement of the net quantity of contents
- The name and the place of business of the manufacturer, packer, or distributor.

Whether your product goes wholesale or retail, you still need this information. If the product goes retail, the label has to show the product name and the net weight statement on the front panel in a particular location, and the net weight statement must be in a specified type size. The statement of ingredients and the name and place of business of the manufacturer, packer, or distributor can either be on the main panel or on a panel to the right of the main panel. These labeling requirements are contained in Part 101, Title 21 of the Code of Federal Regulations.

QUESTION: Must all fish smokers register with the FDA?

MLECKO: If it is a smoking operation only, there are no registration requirements. If the product is canned and if it is a low acid food in a hermetically sealed container, then you must register and you must file your process. Again, if your product is simply smoked and not packed in hermetically sealed containers, you do not register.

QUESTION: If vacuum packaging is used, will Clostridium botulinum grow if the product is frozen?

MLECKO: You will not have the growth of the organism which produces the toxin.

QUESTION: How should the label read if you have two firms, one of which catches the fish and the other firm smokes the fish?

MLECKO: You would have to show the firm that is buying the raw material, processing and packaging it. This firm would be considered the manufacturer as far as we are concerned.

QUESTION: Must salt and spices be listed as ingredients on the label?
MLECKO: You have to include salt. Spices can be declared as spices. Spices and flavoring can be declared as such.

QUESTION: Can the particular type of smoke or the particular wood used to make smoke be included as an ingredient on the label?
MLECKO: The particular type need not be shown. You may want to show it for marketing reasons, such as "alder smoke."

QUESTION: What are the legal requirements for products distributed within a state?
MLECKO: You would follow the state regulations. You don't follow the federal regulations. The Washington and Alaska state regulations are similar to the federal regulations.

QUESTION: Must the species of fish, particularly salmon, be mentioned on the label?
MLECKO: That is a good question. We have a standard of identity for canned salmon. In other words, if you can nonsmoked salmon, the label has to show the species, i.e., coho, chum, whatever. Technically speaking, on your ingredients statement for smoked fish, you may show chum salmon or king salmon or whatever the species, but this is not required. The word salmon will suffice.

QUESTION: Can it be assumed that the federal regulations are more comprehensive than the corresponding state regulations?
MLECKO: What states are we talking about. I am no expert in state laws but I understand that some states have very strict requirements. Alaska, Washington, and Oregon have regulations that are fairly similar to the federal requirements. We work very closely with the state people and, generally speaking, compliance with federal regulations will satisfy state requirements.

QUESION: Must bulk quantity shipments also bear the labels needed for retail packages?
MLECKO: That container still has to bear the four statements that I have given you.

QUESTION: Can adhesive labels be used for this purpose?
MLECKO: Yes, it could be a stick-on label.

QUESTION: Is the FDA checking the salt content of smoked fish?
MLECKO: The regulations are not forceable at this time. We are not checking. But it would be to your advantage because, of course, as a manufacturer, you don't want to harm anybody.

QUESTION: If a poisoning does occur, will the FDA prosecute the responsible parties?

MLECKO: Well, there aren't any enforceable smoked fish GMP regulations. However, the case may involve a violation of the Federal Food, Drug, and Cosmetic Act. But if a person is injured, I would worry more about your product liability. You are probably going to be sued. As far as we are concerned, we would like you to follow the smoked fish GMPs. But if you don't have the proper salt concentration, you are not in violation of the law because there is no law.

QUESTION: Some states base their smoked fish laws on the federal GMPs. Are these laws valid?

MLECKO: What you are referring to is a model food and drug act. Some of the states may have them and they may be enforcing them. But I suspect that if somebody would go to court, the smoked fish GMPs would be held unenforceable, because according to the court, they are based upon unpublished data.

QUESTION: Does the FDA require registration of fish smoking operations?

MLECKO: If we are talking about licensing, we don't license any of these.

QUESTION: Does the FDA inspect smoked fish businesses?

MLECKO: Yes. If you are smoking and shipping fish in interstate commerce, you will be inspected by the Food and Drug Administration. We will inspect you relative to the Federal Food, Drug, and Cosmetic Act. We will inspect your operation relative to the general good manufacturing practice regulations. We will look at your labels. We will not enforce the good manufacturing practice regulations specifically for hot process smoked fish or smoke-flavored fish products.

QUESTION: Does the federal government have GMPs for cold smoked fish products?

MLECKO: No, we do not. The establishment of one of these good manufacturing practice regulations requires a lot of data. It takes a lot of time. The agency does not have the resources to develop these for every specific industry or product. We established a GMP for the hot process because the product had presented a safety problem to the consumer.

QUESTION: Is a processing operation located on a vessel responsible for the same regulations as a land-based business?

MLECKO: Yes, basically the same regulations will apply to a vessel. However, this causes certain logistic problems for us. For example, how do we get to the vessel?

QUESTION: If a smoking operation closely follows the federal GMPs and is sued because of some fault, can the GMPs improve our position?

MLECKO: Well, theoretically if you follow the GMPs, you should be better off than if you didn't follow them.

MICROBIOLOGICAL SAFETY OF SMOKED FISHERY PRODUCTS WITH SPECIAL REFERENCE TO BOTULISM

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(Ed's. note: This is a general review of safety of smoked fish products. Specific papers can be obtained from the author.)

INTRODUCTION

Microorganisms are naturally widespread and are very important in the production, processing, and distribution of foods. In fishery products, yeasts, molds, and bacteria are the most important microorganisms contributing to spoilage. Bacterial species are generally responsible for the deterioration and eventual spoilage of raw fishery products, whereas yeasts, and particularly molds, often play an important role in the spoilage of prepared or semi-preserved fishery products where the competitive bacterial flora has either been selectively eliminated by heat treatment or inhibited by salt and other preservatives. Certain species of bacteria also are very important in causing food poisoning. Of the different types of bacterial food poisoning, botulism is the most serious and of most concern to food processors and consumers throughout the world.

In recent years, the smoked fish industry has experienced an excellent record for producing millions of pounds of products that have been safe. In the early 1960s, however, this same industry suffered serious economic losses following human botulism outbreaks caused by a shipment of smoked chubs that were temperature-abused during distribution. These outbreaks caused 16 botulism cases, nine deaths, and resulted in product recall, adverse publicity, and a loss of consumer confidence in smoked fishery products. Even though the chubs were processed and distributed in the midwestern section of the United States, the outbreaks had a severe national impact on the entire smoked fish industry.

To the average consumer, botulism is a somewhat mysterious disease and panic often accompanies any outbreak. In order to help prevent any future outbreak, it is necessary to develop a sensible attitude toward botulism and to become better acquainted with the facts involved. The purpose of this paper is to discuss:

- botulism food poisoning, the bacteria, and its toxin
- characteristics of the bacteria that are important to the food industry
- conditions required for outbreaks

- general procedures to be considered in the production of safe and acceptable smoked fish products.

BOTULISM FOOD POISONING

Several hundred years ago, before man discovered bacteria, "sausage poisoning" occurred frequently in Germany. Early scientists called the disease "botulism" a name derived from the word "botulus," meaning sausage. The disease remained a mystery until 1895 when a Belgian scientist studied a food poisoning case caused by pickled ham that resulted in a disease identical to sausage poisoning. During his studies, he isolated a bacteria from the ham which produced total paralysis and death in laboratory animals. This bacteria which causes botulism is now known as Clostridium botulinum.

Since 1895, additional C. botulinum (C. or Cl. are used as abbreviations of Clostridium) organisms producing different toxins have been discovered and many different foods have been involved in botulism outbreaks. Based upon the production of different toxins, there are now seven recognized types of C. botulinum designated by the letters A through G. Types A, B, E, and F have caused the majority of the human botulism outbreaks, whereas types C and D are usually involved in animal and bird botulism. Type G has been isolated from the soil in Argentina but has not been involved in any botulism outbreaks.

Food-borne, infant, and wound botulism are the three clinical forms currently recognized. Food-borne botulism is caused by ingesting C. botulinum toxin during its growth in feeds and foods. Infant and wound botulism are associated with the organism's growth and toxin production in the intestines (infants up to 14 months of age) or in damaged tissue. Of these forms, food-borne botulism is of the most concern to processors of preserved fishery products such as smoked fish.

Between 1899 and 1977, there were a total of 766 botulism outbreaks involving 1,962 cases. C. botulinum type A caused 26 percent of the outbreaks; type B, 8 percent; type E, 4 percent; and one outbreak occurred from type F. The causes of over 50 percent of the outbreaks remain unknown because the incriminating food sample was not available or the toxin could not be detected in the victims' serum. The mortality rate from botulism was 60 percent until 1945. Because of oxygen respiratory care and antiserum treatment, the mortality rate has been lowered to 25 percent since 1945.

Most of the botulism outbreaks have occurred from improperly prepared home-canned foods. In contrast, commercially processed canned foods have had a remarkably good record during the past 54 years. Approximately one trillion food cans have been processed by commercial companies in the United States with only a few food poisoning outbreaks.

Table 1 summarizes the food involved in botulism outbreaks. Vegetables, generally home canned, have caused the greatest percentage of the outbreaks. This is followed by fruits and fishery products. Botulism is usually associated with foods that have been inadequately preserved and abused by storage at non-refrigerated temperature. Fresh or raw fishery products have never been implicated in any of the botulism outbreaks.

Table 1. Foods involved in botulism outbreaks in 1899-1977

FOOD	PERCENTAGE OF TOTAL OUTBREAKS
Vegetables	17.8
Fruits	4.1
Fish	3.6
Condiments	2.2
Beef and Pork	1.3
Milk Products	0.6
Poultry	0.1
Other	0.5
Unknown	69.8

GENERAL CHARACTERISTICS OF BACTERIA CAUSING BOTULISM

SPORES

C. botulinum differs from many other bacteria in that it naturally exists either in the spore or vegetative state. The spores are widespread in nature. During optimum growth conditions, they will germinate and develop into the vegetative state in which they grow rapidly and produce their lethal toxin. During later stages of their growth cycle, the vegetative cells again form spores. The spores are resistant to heat, drying, salting, freezing, and other physical and chemical treatments and can remain dormant for many years in the soil and in areas such as food processing plants. When these spores contaminate foods, they are very difficult to destroy.

ANAEROBIC CONDITIONS

Bacteria have various tolerances to air. Some bacteria called "aerobes" can only grow in the presence of oxygen. At the other end of the scale, we have "anaerobes" which cannot grow in and can even be killed by the presence of oxygen. C. botulinum is an anaerobe that grows in the absence of air. This description, however, often leads to a misunderstanding. Some people interpret this to mean that any vacuum-packed or canned foods can become dangerous, whereas unpackaged foods or food packaged in oxygen-permeable films are safe. The truth is that C. botulinum can grow and produce toxin in both unpackaged and vacuum-packaged foods such as smoked fishery products. To understand this, we must remember that the bacterial cell is very small and about 10 million C. botulinum organisms occupy the space equivalent to the head of a common pin (1 to 2 mm). Anaerobic conditions for growth are therefore easily met in most foods only a few millimeters (a fraction of an inch) below the product surface. In addition, if aerobic bacteria are present on the product surface, they will use the oxygen and create favorable conditions for C. botulinum growth. Some species of bacteria, however, can also compete with and even inhibit C. botulinum growth.

ACIDITY OF A PRODUCT

Acidity and alkalinity of a food are measured in terms of a pH scale of 1 to 14 with pH 7 representing neutrality. Values above pH 7 are increasingly alkaline, whereas values below pH 7 become increasingly acidic. None of the C. botulinum types will grow at values lower than pH 4.5. In some cases, yeasts and molds may aid C. botulinum because they grow at a lower pH and oxidize the acids in foods, causing the pH to rise. When the pH values rise above pH 4.5, C. botulinum spores can germinate and grow. The maximum pH supporting growth is 8.5. The only fishery products with pH values below 4.5 are marinated, such as pickled herring. Adjusting the pH of smoked fish to values lower than 4.5 or higher than 8.5 would drastically change the characteristics of the product.

SPECIFIC CHARACTERISTICS OF PROTEOLYTIC TYPES A, B, AND F

The types of C. botulinum involved in human botulism can be divided into two different groups: group 1 consists of the proteolytic types A, B, and F. Group 2 is comprised of the nonproteolytic types B, E, and F. Since these two groups of bacteria differ significantly, some of their characteristics will be discussed separately.

Group 1 bacterial types are the hardiest of the C. botulinum species. The spores of some strains withstand water boiling temperatures for 6 to 8 hours. This is the reason that low-acid foods are canned with the aid of pressure cookers using higher temperatures. This group of organisms also requires 10 percent water-phase salt (sodium chloride) to inhibit their growth and toxin production. The minimum temperature at which they will grow is 50°F (10°C).

The organisms belonging to group 1 are also proteolytic, meaning that they will attack complex proteins, and their growth is often accompanied by off-odors. Food spoilage by this group of bacteria, however, varies with the stage of their growth and the food's composition. Spoilage therefore does not always accompany toxin production and is not a reliable indicator of whether or not a food is safe.

Measurement of water activity is another way to determine whether bacteria can grow in a food product. This is a measure of the available moisture in a food and is often indicated by the symbol "a_w". The different amounts of water, salt, sugar, protein, and so on will all affect water activity and determine whether bacterial growth will occur. The minimum a_w for the growth of the proteolytic C. botulinum types A, B, and F is 0.94 to 0.95.

SPECIFIC CHARACTERISTICS OF NONPROTEOLYTIC TYPES B, E, AND F

These organisms are more sensitive to heat than group 1, and are rapidly killed in buffer solutions at 212°F. The composition of a food (protein, fat, dryness, etc.), however, increases the heat resistance of these spores and they will usually survive processes used to prepare smoked fish products. These three types of C. botulinum have the unique characteristic of growing and producing toxin at temperature as low as 38°F (3.3°C). Because of their nonproteolytic characteristics, they do not attack complex proteins and their growth in foods usually cannot be detected by off-odors and off-flavors. This group of organisms is less tolerant of salt and, under optimum conditions, 5 to 6 percent will inhibit growth and toxin production. The minimum water activity for growth of nonproteolytic types B, E, and F is 0.97.

TOXINS OF C. BOTULINUM

The toxins produced by all C. botulinum types are the most potent poison known to mankind. It is estimated that a tablespoon of purified toxin is sufficient to destroy all human life. This is why this form of food poisoning concerns food processors and consumers.

Under ideal cultural conditions, C. botulinum growth releases potent neurotoxin into the food. When the food is eaten, the toxin enters the circulatory system through the small intestines. The toxin causes paralysis by acting on the nervous system. If sufficient toxin is present in the blood, the diaphragm and chest muscles are paralyzed and death may be caused by asphyxiation. Usually symptoms develop between 8 and 72 hours after eating the toxic food. The toxin is a protein and can be deactivated by boiling foods for 10 minutes. If particulate material such as chunks of meat are present, it is advisable to increase the heat treatment to 20 minutes to permit sufficient heat to penetrate the center of the food. Because of the extreme potency of the toxin, any food in question should not be tasted and should be disposed of so that animals cannot gain access to it.

CONDITIONS NECESSARY FOR BOTULISM OUTBREAKS

In order for food-borne botulism to occur, the following conditions must be met:

- A food must be contaminated with C. botulinum spores or vegetative cells from the environment in which it was grown or during subsequent handling.
- The processing treatment must be inadequate to inactivate the C. botulinum spores or the product must be recontaminated after processing.
- For C. botulinum to grow, the food must support its growth and toxin production when the food is stored above 38°F for sufficient periods of time.
- Ultimately the food containing the preformed botulinal toxin must be consumed without cooking or after cooking insufficient to inactivate the botulinal toxin.

Now that we understand some of the characteristics of C. botulinum, let us look at each of the conditions necessary for botulism to occur with specific reference to smoked fish products.

CONDITION NO. 1

Because C. botulinum is ubiquitous in nature, it is impossible to assure its absence in any raw fishery product. Table 2 summarizes the incidence of C. botulinum in some of the marine and freshwater environments. Type E is very widespread in nature and is the most prevalent type in these environments. Types A, B, and F may also be present in these environments, and in certain areas they may be more prevalent than type E.

CONDITION NO. 2

Even though type E is more heat-sensitive than proteolytic types A, B, and F, previous studies have shown that the surface drying of fish during the smoking operation and the composition of the fish (proteins, fats, and so on) protect type E spores from being destroyed by heat treatment. As a result, some type E spores will survive smoked fish processes where the internal

Table 2. Occurrence of *C. botulinum* in marine and freshwater sediments collected on the Pacific coast of the United States

AREA WHERE COLLECTED	NUMBER POSITIVE/ NUMBER TESTED	NUMBER POSITIVE FOR INDICATED *C. BOTULINUM* TYPE
Washington		
Bay	91/98	1A,9OE
Ocean	51/101	4B,47E
Fresh water	50/55	50E
Oregon	32/92	10A,1B,18E,3F
California		
To 36° N. latitude	19/128	1B,18E
Shore, 41° N. latitutde	2/28	1A,1E
36°to 32° N. latitude	15/160	6A,8B, 1F

temperature of the product exceeds 180°F (82.2°C). If other more resistant C. botulinum types (Group 1) are present on the product, this heat treatment would be even less effective.

CONDITION NO. 4

During smoked fish processing, the predominant fish spoilage bacteria that cause objectionable off-odors and -flavors in raw fishery products are selectively eliminated by heat, smoke, salt, or preservatives. Because of this alteration of the bacterial population on smoked fish, and the nonproteolytic characteristics of type E, off-odors and -flavors often do not accompany C. botulinum toxin growth and production when products containing viable type E spores are stored above 38°F (3.3°C). Spoilage therefore is not a reliable indicator of the safety of this type of food product. In addition, smoked fishery products are usually eaten without any further heat treatment. The chances of inactivating any preformed toxin in a smoked fish product at this point is also eliminated.

CONDITION NO. 3

Based upon our previous discussion, we must assume that smoked fishery products can contain viable C. botulinum spores. Condition 3 is therefore probably the most important to smoked fish processors. In order to prevent botulism food poisoning, the growth of C. botulinum spores must be inhibited during the smoking treatment. Storing the finished product at temperatures below 38°F for short storage periods and freezing for long-term storage are probably the most important conditions for controlling C. botulinum growth. It must be emphasized, however, that these storage temperatures do not destroy C. botulinum spores or their toxin.

Since most botulism outbreaks have been traced to foods that have been poorly processed and temperature-abused, salts and other preservatives are essential in preventing C. botulinum outgrowth and toxin production. Under ideal conditions for C. botulinum growth, 5 percent water-phase salt is inhibitory for type E and 10 percent water-phase salt for proteolytic types A, B, and F. This and other considerations for controlling botulism will be summarized in the last section of this paper.

1963 BOTULISM OUTBREAK AND GOOD MANUFACTURING GUIDELINES

Now that we understand the conditions contributing to botulism, let us examine a specific outbreak. In the early 1960's, three botulism outbreaks occurred from the ingestion of improperly processed stored smoked fish. The largest of these outbreaks occurred in 1963 from the ingestion of smoked chub processed in Michigan. The fish were heat processed, vacuum packaged, and shipped to the southcentral part of the United States. During transit, the smoked chub were subjected to temperatures exceeding 90°F (32.2°C) for several days. The fish were then distributed through supermarkets.

The botulism outbreaks that followed affected 16 people and caused nine deaths. Of the 16 victims involved, only three detected any unusual flavors from the smoked chub and none of them detected any undesirable odors. The finished products also had low concentrations of salt and did not contain sodium nitrite. A brief analysis of this outbreak indicates:

- The C. botulinum organism was in the finished product.
- The smoked fish did not contain enough salt to inhibit the growth of C. botulinum.
- Temperature-abused products do not always show signs of spoilage.
- Toxic foods can be found acceptable and consumed.

Following the 1963 type E botulism outbreak, Good Manufacturing Guidelines (GMPs) for hot-smoked and smoke-flavored fish were published by the Food and Drug Administration. Besides the temperature requirements for brining, storage of the finished product, and plant sanitation, these guidelines required the following processing parameters:

- Smoked fish must be processed to an internal temperature of 180°F for 30 minutes and contain a minimum of 3.5 percent water-phase salt in the deepest part of the loin muscle.
- Smoked fish must be processed to an internal temperature of 150°F for 30 minutes and contain 5.0 percent water-phase salt in the deepest part of the loin muscle.

These processing parameters often resulted in products that were over-processed or too salty and unacceptable to the many consumers. Because of the impracticality of these two processes, the FDA approved a third process for smoked chub only. This GMP required processing smoked chub to an internal temperature of 160°F for 30 minutes, providing the finished product contained a minimum of 3.5 percent salt and between 100 to 200 ppm of sodium nitrite. Since this latter GMP unfortunately was approved only for chub, the remainder of the smoked fish industry had to comply with the first two processes.

The smoked fish processors continued to encounter difficulties in complying with the GMPs which finally resulted in a legal case in 1977. The court ruled that the hot-smoked fish GMP was invalid because it was promulgated in an arbitrary manner. The result was that the GMP processing requirements for salt, processing time, and temperature were no longer enforceable.

Current research at the Northwest and Alaska Fisheries Center in Seattle is developing alternative processing parameters necessary to inhibit the growth and toxin production of C. botulinum in smoked fishery products. These parameters must also permit processors to produce consumer-acceptable products. Until this research is completed, it is strongly recommended that the salt and time and temperature of processing listed in the Good Manufacturing Practice Guidelines for hot-process smoked fish be followed as closely as possible.

GENERAL PROCEDURES TO BE CONSIDERED IN THE PRODUCTION OF SAFE AND CONSUMER-ACCEPTABLE SMOKED FISHERY PRODUCTS

Each processor will have to experiment with the different species of fish or sections of fish that are to be smoked. Some general guidelines for processing smoked fish are discussed in this section. To produce both safe and acceptable smoked products, it is essential that one start with a good quality product. If the raw material is frozen, it must be completely thawed and thoroughly washed before it is placed in the brining solution. It is important to wash the fish with chlorinated water to remove blood, other debris, and as many bacteria as possible. This not only helps to increase the shelf life, but it also reduces bacterial populations that cause food poisoning. Washing the fish after brining is not as effective because once the product has been brined, a water-soluble protein layer covers the fish surface and it is more difficult to remove any entrapped bacteria.

Probably the most difficult, but the most important step in preparing smoked fish is obtaining the desired concentration of salt or other preservative in all parts of the product. Uniform salt concentrations are not only important for the inhibition of spoilage microorganisms and food poisoning bacteria, but also for consumer acceptability.

The factors that contribute to salt variation in smoked fish are: fish size, species, fat content, condition (frozen or fresh, state of rigor), brine concentration, brine temperature, brining time, brine-to-fish ratio, circulation of brine, section of fish, and so on. Before brining, all of the salt added to the water must be in solution and the fish or fish sections should be sorted according to size and thickness. The different sizes should be brined separately so that various brining times or brine concentrations can be used. A longer refrigerated brining time period (18 to 36 hours) with a more dilute brine (20° to 45° salometer) often results in a more uniform salt concentration than a short brining time in a more concentrated brine (over 45° salometer).

As the brine-to-fish ratio increases, the amount of salt per unit weight of fish increases. A ratio of at least 2 to 1 and preferably 3 to 1 should be used. This results in increased salt absorption by fish and more uniformity of salt absorption from fish to fish. During the brining period, the brines should be frequently agitated either by a mechanical device or manually. All pieces of fish should be kept below the brine surface throughout the brining time.

Sodium nitrite enhances the inhibitory effects of salt (sodium chloride) and can be used in smoked chub, sablefish, salmon, and shad up to a final concentration of 200 ppm. It can be added to the brine in premixes or in pure form. It should also be dissolved thoroughly in the brine before the fish are added. As a word of caution: if sodium nitrite is used in pure form, bags or other bulk forms of $NaNO_2$ should be kept in a locked room and only quantities needed in a given brine should be permitted out of the room. Sodium nitrite can be dangerous if it is added to brines at very high concentrations.

In laboratory experiments, a rule of thumb is to add twice as much sodium nitrite to the brine as one desires in the final product. For example, if 200 ppm is desired in the product, add sodium nitrite at a final concentration of 400 ppm in the brine. Again, experimentation by the processor is recommended because of variations in brining conditions. Sodium nitrate is not an effective inhibitor unless it is reduced to sodium nitrite. The nitrite form should therefore be used in combination with salt (sodium chloride). Sodium nitrite will eventually be broken down by bacteria present on smoked fish and the inhibitory effect lost. This bacterial action on sodium nitrite can be reduced by storing the product at 32°F(0°C).

Fish should be processed at a minimum internal temperature of 150°F. This helps eliminate other bacteria such as Salmonella and Staphylococcus which can also cause food poisoning. Heating smoked fish to internal temperatures above 150°F does cause a heat injury to C. botulinum type E spores and it becomes less tolerant of salt. This is the reason for the difference in salt requirements for products heated to internal temperatures of 150°F vs. those heated to 180°F. Smoking, in addition to cooking, not only imparts desirable flavor and color, but also has certain harmful effects on bacteria.

After the heating process has been completed, the product should be removed from the smokehouse and cooled for a short period at room temperature. Then the product should be refrigerated at temperatures less than 38°F. Refrigerate the final product as soon after processing as possible to prevent the growth of microorganisms.

After smoking, it is very important that the finished product be protected from recontamination by bacteria from the raw fish or contaminated areas. The finished product should be stored separately from the raw fish and personnel should also be cautioned about working with the finished product after they have worked in the raw fish area. If the same personnel are used for both operations, they should thoroughly wash their hands and change their contaminated clothing before they work with the finished product.

The smoked products should be handled as little as possible and packaged. Vacuum packaging in general is discouraged because it can delay the spoilage of fish products at abuse storage temperatures--especially those of lower salt content--but have little effect on the growth and toxin production by C. botulinum organisms. The package should be properly labeled to inform the consumer to store smoked fish at less than 38°F. Suitable records should be kept for each lot of fish processed.

Each processor will have to experiment with brining and smoking procedures for the specific fish species that is to be used in the process. Once a desirable procedure has been developed, it should be followed closely.

COLD-SMOKED PRODUCTS

Currently there are no specific GMP regulations for cold-smoked products. With the exception of processing temperatures, the procedures recommended for hot-process products should be followed. Cold-smoked products are usually processed at temperatures below 90°F (32.2°C). These temperatures offer an excellent incubation temperature for spoilage and food poisoning-type

bacteria. Adequate salt content of these products is very important for inhibiting these bacteria during the smoking operation and subsequent refrigerated storage.

Fish to be used in cold-smoked products should be frozen below -20°C (-6.7°F) for 48 hours before they are used. Many marine species can occasionally contain an anasakis nematode which can cause ulcer-like conditions in the digestive tract of people and certain other mammals. These worms withstand high concentrations of salt but are easily destroyed by freezing or by heating the product to internal temperatures above 122°F (50°C).

FISH JERKY

Fish jerky should have a water-phase salt of 10 to 12 percent to inhibit C. botulinum. If it is to be marketed at room temperature, a water activity of less than 0.85 is required to inhibit Staphylococcus, a food poisoning organisms which tolerates high salt.