The Food and Drug Administration's Role in the Canned Salmon Recalls of 1982

ARTHUR HULL HAYES, Jr., MD

Dr. Hayes, former Commissioner of Food and Drugs, is now Dean of New York Medical College. Tearsheet requests to Food and Drug Administration, HFE-88, Rm. 1542, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20852.

SYNOPSIS

The Alaska salmon industry conducted 9 recalls of 7¾-oz cans of salmon in 1982 after a 7¾-oz can of Alaskan salmon was implicated in illness and one death in Belgium from Clostridium botulinum *type E toxin. By the code number on the can, the Food and Drug Administration (FDA), Seattle District, traced it to a specific salmon packer. Subsequently, the FDA received a report about a defect in the can. Investigation of the salmon packer's plant by the Agency revealed that the equipment used at the plant to reform the cans—which arrived at the cannery in a nearly flattened state—might have been responsible for the defect.*

The death and illness in Belgium, combined with the results of the FDA inspection of the plant implicated in the Belgian incident, provided strong evidence of the existence of a hazardous situation that might have widespread adverse health effects. The Food and Drug Administration therefore requested the firm to recall its 1980 and 1981 production of salmon packaged in 7¾-oz cans. The Agency then began an investigation of all U.S. salmon packed in cans of this size that had been reformed on the equipment implicated in the can defect. Of 300,000 cans examined, 22 with the defect were found. As additional firms were identified as having used the defective cans, subsequent recalls were initiated.

FOLLOWING A BOTULISM INCIDENT IN BELGIUM early in 1982, the Food and Drug Administration (FDA), cooperating State, county, and city health agencies, health agencies of other countries, the news media, the Alaska salmon industry, and concerned industry associations faced a formidable task in protecting the public health and preventing disease, both in the United States and in other countries. The incident involved a couple in Brussels who, after consuming salmon canned in the United States, were hospitalized with suspected type E botulism, from which the husband died. It resulted in the second largest recall of a product in FDA history.

The Hazard of Botulism

Botulin toxin causes paralysis by blocking the release of acetylcholine at peripheral nerve endings. The paralysis, which usually starts with the eyes and face, progresses downward to the throat, chest, and extremities. When the diaphragm and chest muscles become fully involved, respiration is no longer possible, and death from asphyxia results. Early signs of the poisoning are marked lassitude, weakness, and vertigo, usually followed by diplopia and progressive difficulty in speaking and swallowing. Difficulty in breathing, weakness of muscles, abdominal distension, and constipation are also common symptoms. The interval between onset of symptoms and death may be from 8 to 28 hours. In persons who survive, some symptoms such as thirst, weakness, pharyngeal pain, and abdominal swelling, persist for some time. The diagnosis can be made from clinical symptoms alone, but it is often difficult to differentiate botulism poisoning from a variety of other diseases. Initial misdiagnosis because of confusing the poisoning with other central nervous system disorders is common.

Because of the moisture present, the absence of free oxygen, and a pH above 4.8, most low-acid canned foods are conducive to the growth of *Clostridium botulinum*. The small amount of air that remains in a can after it is sealed usually reacts with the food during heat-processing and storage and thus is not available to microorganisms. The rate of this reaction, however, depends upon the composition of the food, the kind of container, and the temperature to which the canned product is exposed. If the spores of *C. botulinum* are not destroyed by the heat-processing, there is a good chance that they will grow and produce toxin. Even after adequate heat-pro-

cessing, contamination with toxin can occur if spores of the botulinum enter a can through a leak and conditions are favorable for spore growth. An insidious aspect of botulinum contamination, especially type E, is that the toxin sometimes develops without producing evidence of spoilage. The contaminated product may look and smell normal. Plants that process fish such as salmon are believed to be heavily contaminated with spores of *C. botulinum* type E, and the contamination may extend to all areas of the plant.

The dangers that botulism poisoning pose make it imperative that once such poisoning is suspected, quick action is taken to prevent further poisoning incidents. The first step is to determine the cause of the suspected contamination.

Response to the Belgian Incident

The Food and Drug Administration's Bureau of Foods was notified on February 5, 1982, of the Belgian couple's hospitalization with suspected type E botulism. Analysis by Belgian officials had revealed *C. botulinum* type E toxin both in the canned salmon consumed by the couple and in residual food material from within the implicated can.

The lid of the suspect can with an identifying code number was not found until February 8, but in the meantime the can's code number was identified by matching the label with others like it in the Belgian store where the suspect can of salmon had been purchased. The implicated salmon apparently had come from a 7¾-oz can labeled "John West [a firm in Liverpool, England] Pink Columbian River Salmon." By using the reported code number found on the other cans in the store, FDA's Seattle District correctly established on February 6 that the implicated food had been canned on July 24, 1980, and identified a specific Alaskan salmon packer as the manufacturer. The Seattle District reported that 24,384 cans had been packed under the suspected code number.

On February 7, the FDA informed the U.S. Embassy in Brussels that antitoxin for type E botulism was available in Sweden and in the United States should this food poisoning incident extend beyond the Belgian couple. On the same day, warnings not to eat the John West brand of salmon were broadcast throughout Belgium; English-speaking people stationed in the country were warned over the U.S. Armed Forces radio network.

On February 8, the John West firm reported that in addition to the shipment to Belgium, cans of salmon with the suspect code number also had been shipped to the Netherlands and South Africa. The firm initiated a recall of these shipments.

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Also, on February 8, the Food and Drug Administration received its first information about a hole in the suspect can. On that date, a member of the U.S. Embassy in Brussels who had seen the can telephoned the FDA that there was a "small dented-in black spot and tiny hole" near the bottom seam of the can.

On February 10, an FDA canning expert, who had flown to Belgium when the botulism incident was first reported, examined the implicated can and observed a triangular-shaped hole in its side approximately 6 X 3 X 5 mm. A torn piece of tin was folded back flush with the side of the can.

The canning expert subsequently also examined other defective cans discovered by Belgian authorities and confirmed their observations that the defect in the other cans was the same kind as in the can implicated in the botulism incident. He reported that the Belgian couple had used the salmon for a pâté and that an extract of the pâté had killed test mice in a laboratory at the Belgian health institute. In addition, small pieces of salmon that were still in the can were observed to have many spores upon examination by microscope.

On February 15, health officials in England advised consumers not to eat U.S. salmon packed in 7¾-oz cans. They had found a can of U.S.-packed salmon with the same kind of defect as that found in Belgium. This can, however, was the product of a different Alaska cannery.

On February 17, in a can-by-can examination of food warehoused at the Salmon Terminals in Seattle, FDA's Seattle District found two more cans of salmon exhibiting the defect observed in the Belgian incident. These cans had come from the salmon packer whose 1980 product was implicated in the illnesses in Belgium, but were from the firm's 1981 production. Thus, all lots of the firm's production

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became suspect, and that meant that some of these lots might have been distributed in the United States.

Determination of Cause of the Defective Cans

On February 17 and 18, the plant implicated in the Belgian incident was inspected to determine what caused the defective cans. In addition to an FDA investigator, representatives from the salmon canning industry, can manufacturers, and the National Food Processors Association were present and also conducted investigations.

The bodies for the metal cans used by the plant are supplied without ends and in a nearly flattened shape (that is, in collapsed form) by the can manufacturer. At the cannery, the collapsed can bodies are reshaped (rounded) on reforming equipment, and a bottom end is attached. The cans are then filled with salmon, and the coded end (top) is attached.

The usual season for processing fresh salmon is from June to August. Therefore, during the February inspection of the plant, operation of the can-reforming equipment as in normal food-processing had to be simulated. In this test operation, some cans were torn by the reforming machinery, and tiny holes were made in the sides of the cans before the uncoded end (bottom) was attached. These holes closely duplicated the defect in the suspect can in Brussels, as well as defects subsequently found by the FDA Seattle District. Of approximately 3,000 cans that were reformed at the plant during the February inspection under a variety of test conditions, approximately 40 demonstrated this same defect.

The results of the inspection of the plant, coupled with the illnesses and death in Belgium, demonstrated to FDA officials that a life-threatening hazard existed that required immediate action. Therefore, at a meeting with the firm's officials in Washington, D.C., on February 18, FDA officials, after presenting persuasive evidence for their conclusions as to what had happened to the cans to cause the defect, requested a recall. The firm's officers agreed and on the same day initiated a recall of the entire 1980 and 1981 production of salmon that had been packed in 7¾-oz cans at the plant in question.

Market Recalls

The success of a recall depends in part upon the cooperation of the firms whose product or products are involved and their willingness to remove them from the marketplace. However, if a firm refuses to undertake a recall when requested by the FDA to do so, or if the FDA has reason to believe that a recall would not be effective, the Agency may initiate multiple seizures, as was done in the Bon Vivant botulism situation in 1971—that is, in effect, have a court-ordered recall. The FDA can also seek injunctions and initiate criminal prosecution. In addition, it may publicize information about regulated products when there is an imminent danger to consumers' health or when gross deception of the consumer is involved. Thus, prompt protection of the public health and welfare—the purpose of recalls—is not predicated solely on the principle of industry cooperation.

As a general policy, before the Food and Drug Administration formally requests a recall, it will have evidence capable of supporting legal action. In the current case, there was evidence that illness and one death in Belgium had been caused by a can of salmon contaminated with botulinum toxin. This can, which was found to have a defect, was traced to an Alaskan salmon packer. The FDA subsequently found cans with the same defect from several different code lots and 3 different production years of this packer.

The Alaskan firm was requested to conduct a recall because it was reasonable to conclude that other defective cans besides those identified were still on the U.S. and world market. The firm's recall was categorized as class I, which applies to a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. The recall strategy required the firm to conduct 100 percent effectiveness checks to the retail level and provided that the FDA also should audit the recall at the 100 percent level. Every effort was made to assure recovery of the specified salmon from the

market. It was also decided that this recall and subsequent salmon recalls would be publicized to alert consumers not to purchase or consume the possibly contaminated fish.

Followup of First Salmon Recall

After the first salmon recall was initiated, the FDA began an intensive investigation of all salmon in 7¾-oz cans that had been produced on the reforming equipment involved in the index defect. Initially, this investigation involved the examination of about 300,000 cans at the Salmon Terminals in Seattle. Twenty-two cans with the index defect were found; their code numbers indicated that they came from various Alaskan canneries. As additional firms were identified with the same problem, more recalls were initiated. A grand total of 131 defective cans were found in the United States.

To validate the adequacy of the control procedures that had been instituted to identify and segregate defective containers before distribution, the salmon canning industry, the National Food Processors Association, and the Food and Drug Administration reached agreement on the following points on March 3, 1982.

1. If a plant did not routinely run cans through a dud detector [a device that checks for vacuum in cans], it would recall its entire 1980 and 1981 production of 7¾-oz cans of salmon.
2. If a plant routinely used a dud detector, the plant would prove the adequacy of that dudding by passing 50,000 labeled cans over an electronic weighing device and examine all cans rejected. If the index defect was found, recall of all 7¾-oz cans would be necessary.
3. If a firm could not find 50,000 labeled cans, it would examine 50,000 "brite" [unlabeled] cans, either visually or by passing them through both a dud detector and an electronic weigher. If the index defect was found, recall of all 7¾-oz cans would be necessary.

Eight additional class I recalls were conducted; the last one began on May 14, 1982. Nine canneries initiated recalls of all or part of their 1980–81 production—approximately 60 million cans of salmon.

Federal, State, and local officials checked about 314,577 firms in the United States (virtually all U.S. retail food outlets) to ensure that cans of salmon with the suspect codes were removed from the market. When defective cans were found, they were collected for analysis. In all, 700 samples representing 52 canneries were analyzed. By September of 1982, FDA officials were satisfied that all the recalled stocks of salmon had been removed from consumer channels. This result could not have been achieved without the assistance of State and local officials.

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To prevent similar mechanical problems in the future, an agreement was reached in May 1982 among the canned salmon industry, the National Food Processors Association, and the Food and Drug Administration on a control plan for the 1982 canned salmon season. The agreement included a review of the previous season's canning practices and experiences to detect possible processing or sanitation defects and to initiate new practices as indicated by the review. In the 1982 Canned Salmon Control Plan, specific attention was given to quality control practices as they related to the inspection and use of tin stock, the can-handling equipment, and the canned product during production and before distribution.

As a result of the 1982 control plan, the problems that arose in 1982 with Pacific salmon canned in 1980 and 1981 did not reoccur with the 1982 season's production.