

Status of Botulism in the United States

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INCREASED incidence of botulism in the United States in 1963, the year of the Michigan outbreak from canned tuna fish, heightened the keen and continuing interest of the Public Health Service, the Food and Drug Administration, other Federal agencies, and industry in control and suppression of this disease.

Epidemiology

Meyer, in his classic review on food poisoning, says of botulism (1): "This is a specific intoxication with toxins of *Clostridium botulinum* or *parabotulinum*. The five serotypes, A, B, C, D, and E, exist in nature as sporulating saprophytes and grow freely in a great variety of inadequately preserved animal or plant foods. During resultant spoilage a powerful toxin is formed and, on ingestion, is absorbed, ultimately inducing some changes in the motor-nerve terminals at the neuromuscular junction; acetylcholine output is diminished, with effects resembling denervation. The name botulism (from *botulus*, sausage) has, at least in the United States, lost its significance, since animal products play a subordinate role here. Most outbreaks are caused by inadequately preserved, understerilized plant products. . . .

"Up to 1925, commercially canned foods manufactured in the United States were at fault in

32 cases, but intensive research, supported by the protective measures originally devised by the State of California, led to the adoption of scientific procedures by the canning industry."

In another paper, Meyer and Eddie present a collection of tabular data on botulism in the United States and Canada for the period 1899-1949 (2). Much of their information on outbreaks of botulism relates to a wide variety of home-processed foods. Unfortunately since the paper was published, additional information of this kind has not been available in so complete a form.

The Public Health Service has records, however, on reported cases of botulism for the years 1950-63 (State reports received by the National Office of Vital Statistics and the Communicable Disease Center). A recent Public Health Service *Morbidity and Mortality Report* presents an overview and analysis of the known epidemiology to January 1964 (3).

From 1899 through 1963, 1,561 cases of botulism were reported in the United States (table 1). The greatest number was in the decade 1930-39; the second greatest, 1920-29; the third greatest, 1940-49. Home-processed foods have been the most commonly implicated sources of infection in the past three or four decades. *C. botulinum* types A and B were most often responsible for outbreaks arising from the noncommercially processed foods.

Records relating to botulism in the United States caused by consumption of commercially prepared foods (records more accurate than those relating to noncommercially prepared foodstuffs) are summarized in table 2. In the period 1906-63, 51 outbreaks involving commercially prepared foods were reported, with 109

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deaths in a total of 219 cases. To the best of our knowledge the implicated foods had been processed by canning, pickling, smoking, and vacuum packaging. Little information is

available on the relationship of the specific temperature and time of food processing to the reported outbreaks.

A review of the commercially prepared foods

Table 1. Botulism cases in the United States, 1899-1963, by decade

States	1899-1909	1910-19	1920-29	1930-39	1940-49	1950-59	1960-63	Total
California.....	11	104	87	105	109	50	12	478
Washington.....	0	23	43	46	30	15	8	165
Colorado.....	0	17	27	31	23	25	2	125
New Mexico.....	0	0	0	37	33	7	3	80
New York.....	0	18	21	19	12	0	2	72
Michigan.....	0	15	34	0	2	0	9	60
Oregon.....	0	3	18	20	12	3	0	56
Tennessee.....	0	0	7	15	6	5	15	48
Kentucky.....	0	0	0	11	11	11	10	43
Montana.....	0	7	5	17	3	2	0	34
North Dakota.....	0	0	0	21	9	0	0	30
Ohio.....	0	14	12	3	0	1	0	30
Wyoming.....	0	0	21	8	0	0	0	29
Nebraska.....	0	2	3	12	10	0	0	27
New Jersey.....	0	3	2	5	4	13	0	27
Idaho.....	0	4	2	8	0	6	3	23
Mississippi.....	0	0	0	0	4	17	0	21
Indiana.....	0	7	11	0	0	2	0	20
Pennsylvania.....	0	0	9	1	3	2	3	18
Illinois.....	0	4	4	0	2	6	0	16
Utah.....	0	1	0	1	12	0	0	14
Minnesota.....	0	0	0	5	0	3	5	13
Alaska ¹	0	0	0	0	0	10	3	13
Texas.....	0	0	6	4	0	1	0	11
Arizona.....	0	0	5	0	4	2	0	11
Virginia.....	0	0	0	2	5	2	0	9
Florida.....	0	7	0	0	0	0	1	8
Massachusetts.....	0	6	0	2	0	0	0	8
Maryland.....	0	0	0	0	4	3	0	7
Alabama.....	0	0	3	0	1	0	3	7
South Dakota.....	0	0	0	5	2	0	0	7
Nevada.....	0	0	0	0	3	3	0	6
Wisconsin.....	0	3	2	1	0	0	0	6
Oklahoma.....	0	0	0	2	1	3	0	6
Connecticut.....	0	0	0	1	4	0	0	5
Iowa.....	0	5	0	0	0	0	0	5
Maine.....	0	0	4	0	0	0	0	4
West Virginia.....	0	0	0	0	3	0	1	4
Louisiana.....	0	0	0	0	0	3	1	4
Washington, D.C.....	0	0	0	0	3	0	0	3
Arkansas.....	0	0	0	2	0	0	1	3
Missouri.....	0	0	2	0	0	0	0	2
North Carolina.....	0	0	0	0	0	2	0	2
Georgia.....	0	0	0	0	1	0	0	1
Hawaii ¹	0	0	0	0	0	0	0	0
New Hampshire.....	0	0	0	0	0	0	0	0
Vermont.....	0	0	0	0	0	0	0	0
Rhode Island.....	0	0	0	0	0	0	0	0
Kansas.....	0	0	0	0	0	0	0	0
Delaware.....	0	0	0	0	0	0	0	0
South Carolina.....	0	0	0	0	0	0	0	0
Total.....	11	243	328	384	316	197	82	1,561

¹ Since 1950 only.

SOURCE: 1899-1949 based on data collected by K. F. Meyer and B. Eddie (2); 1950-63 data from State reports to National Office of Vital Statistics and the Communicable Disease Center.

implicated in outbreaks in the period 1950-63 indicates that only 5 cases of a total of 44 were attributable to canned food products. The remaining 39 cases were associated with the consumption of products receiving no heat treatment, such as cheese or smoked fish not processed at temperatures capable of destroying *C. botulinum*. Table 2 shows *C. botulinum* type E has been the major cause of cases of botulism from commercially prepared foods in the United States in the past two decades. A review of the known outbreaks of type E botulism in the pe-

riod 1932-63 (table 3) shows that the foods most often implicated were unprocessed, processed at relatively low temperatures, or simply air dried.

In 1963, 46 cases of botulism were reported in the United States (table 4). These cases, which included 14 deaths and occurred in 12 outbreaks, represent the highest total for any one year since 1939 and the eighth highest since 1899. Commercially canned food products accounted for 5 cases with 2 deaths; commercially smoked products, for 19 cases with 7 deaths; home-processed foods for 22 cases with

Table 2. Botulism outbreaks in the United States associated with commercial foods

Year	Food	Outbreaks	Cases	Deaths	Type
1906	Pork and beans	1	3	3	
1910	String beans	1	4	4	
1912	Clam juice	1	2	1	
1913	do	1	3	2	
1914	do	1	2	2	
1915	Tomato catsup	1	2	0	
	Sausage	1	2	2	
	Corn	1	1	0	
1918	Minced olives	1	2	2	
	Tuna	1	1	1	
1919	Olives	3	28	17	A
	Summer sausage	1	3	0	
	Ripe olives	1	7	7	A
	do	2	2	0	
	Minced olives	1	5	1	A
	do	1	1	1	
1920	Spinach	1	6	3	A
	do	1	2	2	
	Ham	1	4	4	
	Milk	1	4	0	
	Beets	1	5	5	B
1921	Spinach	3	32	4	A
	Ripe olives	1	5	3	A
1922	Spinach	2	11	6	
1924	Ripe olives	2	13	6	
	do	1	9	2	A
	Sardines	1	2	2	
1925	do	1	2	2	A
	Spinach	1	5	1	B
	Potted meat	1	4	4	B
1929	Shallots	1	2	1	B
	Antipasto	1	3	1	
1931	Milk	1	1	0	A
	Sardines	1	2	1	
1934	Sprats	1	3	1	E
1936	Clams (Japanese canned)	1	4	4	B
1938	Tuna	1	2	2	
1941	Mushroom sauce	1	3	1	E
1951	Cheese	1	1	1	
1960	Smoked ciscoes	1	2	2	E
	Tuna	1	3	2	E
	Smoked whitefish	1	2	2	E
1963	Smoked whitefish chub	1	17	5	E
	Liver paste	1	2	0	A
	Total	51	219	109	

SOURCE: 1899-1949 based on data collected by K. F. Meyer and B. Eddie (?); 1950-63 data from State reports to National Office of Vital Statistics and the Communicable Disease Center.

5 deaths. *C. botulinum* type B toxin was identified as the etiological agent in 4 of the 12 outbreaks (11 cases), type E toxin in 3 outbreaks (22 cases), and type A in 2 outbreaks (4 cases). In the remaining three outbreaks (nine cases), the type was unknown (table 5).

Regulations and Recommendations

Application of the Food, Drug, and Cosmetic Act by the Food and Drug Administration helps protect the consuming public against the hazards of botulism from foods in interstate com-

merce. Also in press releases on outbreaks, such as those in 1963 caused by canned tuna and smoked fish, the agency warns of the particular hazard and describes emergency actions taken to protect the public health.

Commercially canned foods. Measures for prevention of the development of botulism toxin in canned foods depend on application of heat processes adequate to destroy the spores of *C. botulinum* in foods in hermetically sealed containers. The research laboratories of the canning and can-manufacturing industries have defined these requirements (4), and commercial

Table 3. Known outbreaks of type E botulism in the United States

Year	State	Food	Cases	Deaths
1932	New York	Smoked salmon (Canadian origin)	3	1
1934	New York	Sprats (German origin)	3	1
1941	California	Mushroom sauce (mushrooms Yugoslav origin)	3	1
1950	Alaska (Point Hope)	Muktuk (dried beluga flipper)	5	0
1952	Alaska (Selawik)	do	1	1
1956	Alaska (Kotzebue)	do	3	2
1956	Alaska (Anchorage)	do	2	1
1959	Alaska (Hydaburg)	Stink eggs (salmon eggs)	1	1
1959	Alaska (Scammon Bay)	Seal or whale flipper	7	1
1960	Alaska (Ketchikan)	Stink eggs (fermented Ketdukon salmon eggs)	2	2
1960	Minnesota	Ciscoes (vacuum-packed smoked, caught in Lake Superior)	2	2
1961	Washington	Uncooked salmon eggs	4	1
1963	Michigan	Tuna (Japanese origin, California packed)	3	2
1963	Michigan	Smoked whitefish	2	2
1963	Tennessee, Alabama	Smoked whitefish chubs (vacuum packed in Michigan)	17	5
Total			58	23

SOURCE: Reference 3.

Table 4. Known outbreaks of botulism in the United States, 1963

Location	Food	Processor	Type of botulism	Cases	Deaths
California	Chili peppers	Noncommercial	A	2	0
New York City	Liver paste	Commercial	A	2	0
West Virginia	Green beans	Noncommercial	B	1	1
Kentucky	Corn	do	B	5	1
Colorado	Green beans	do	B	2	1
Pennsylvania	do	do	B	3	0
Michigan	Tuna fish	Commercial	E	3	2
Michigan	Smoked whitefish	do	E	2	2
Tennessee, Alabama, and Kentucky	Smoked whitefish chub	do	E	17	5
California	Mushrooms	Noncommercial	Unknown	6	1
Minnesota	Smoked whitefish	do	do	1	0
California	Figs	do	do	2	1
Total				46	14

SOURCE: State reports to the Communicable Disease Center, Public Health Service, Atlanta, Ga.

Antitoxin Treatment

Administration of antitoxin is the only specific treatment against botulism. A limited supply of type E antitoxin is available on a 24-hour service from the Communicable Disease Center, Public Health Service, Atlanta, Ga. It is otherwise commercially unavailable in the United States.

canners have applied them so generally that their products have virtually been eliminated as sources of botulism. An item in a 1964 issue of the National Canners Association's Information Letter is of interest in this connection (5).

Control of commercially canned foods is based upon the requirements of the Food, Drug, and Cosmetic Act, section 402(a). The act defines a food as adulterated "if it bears or contains any poisonous or deleterious substances which may render it injurious to health; . . . or if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; . . ."

Under provisions of the act, canneries are inspected at intervals to determine, among other things, whether the heat processes recommended by the National Canners Association are applied and the adequacy of the controls exercised by the canning firms. It has been the experience of the Food and Drug Administration that the use of adequate heat processes and of effective can closures is a commercial necessity if canners are to avoid severe economic loss from spoilage.

In its investigation of the 1963 canned tuna outbreak, the Food and Drug Administration showed that the tuna had received adequate heat processes at the California canning plant but was contaminated after processing through defective closures in some cans. Nearly 3,300 (0.5 percent) of the 650,000 cans of tuna from the plant examined by FDA inspectors were classed as abnormal; in a large proportion of the 3,300 cans, abnormalities were caused by

defective closure of the lids at the cannery. Twenty-two cans were found to contain *C. botulinum*; many others were contaminated with nontoxic micro-organisms. *C. botulinum* type E was isolated from four locations on the equipment which handled the cans after heat processing. By contrast, abnormal cans were extremely rare in the shipments of other tuna packers, and no evidence of significant contamination was found.

The Food and Drug Administration warned consumers, through press releases and other publicity, to discard without eating or testing any food which appeared or smelled abnormal and to avoid use of foods in bulging or leaking cans.

The Food and Drug Administration is taking steps to prevent a recurrence of the 1963 tuna episode. It is continuing efforts to determine the basic reason for the defective can closures in the California plant. Whether this resulted from malfunction of the can-closing machines, faults in can structures, or other causes is still not clear. Bacteriological studies in other tuna canneries have been conducted to detect possible sources of contamination with *C. botulinum*; findings have been negative. Since the safety of canned goods depends upon the exercise, on a continuing basis, of strict control of can-sealing and processing operations, the agency is undertaking increased inspections to check on the adequacy of controls exercised by canneries.

Minimum processes for canned foods are not prescribed in the Food, Drug, and Cosmetic Act or in the regulations promulgated thereunder. To our knowledge, only the State of California prescribes such minimum processes in the United States. The Food and Drug Ad-

Table 5. 1963 botulism in the United States, by specific type

Type	Outbreaks	Cases	Deaths
A-----	2	4	0
B-----	4	11	3
E-----	3	22	9
Unknown-----	3	9	2
Total-----	12	46	14

SOURCE: State reports to the Communicable Disease Center.

ministration is considering the desirability and feasibility of promulgating such regulations under the act.

The agency is also examining problems which may arise in connection with new can-making techniques and materials, as well as with high-speed can-handling equipment, including problems of sanitation resulting from improper equipment design.

Home-canned foods. Most outbreaks of botulism in the United States during the past 30 or 40 years have been traced to home canning, as already noted; usually improperly or inadequately processed nonacid foods were implicated. The outbreaks generally result from failure to apply safe and effective processes for home canning. Such processes have been described and given wide distribution in numerous publications (6, 7), announcements, demonstrations, and courses of the Department of Agriculture and its State Extension Service. Prevention and control of botulism outbreaks from home canning obviously depend on continued efforts to teach the homemaker proper food-processing methods, including the safeguards necessary to insure a wholesome product.

Smoked fish and other fish products. After the 1963 outbreaks of botulism in the United States from consumption of fish products, an Advisory Committee on Botulism Hazard (8) was appointed to advise the Food and Drug Administration on emergency measures to prevent botulism from the consumption of smoked fish. Recommended and adopted by the Food and Drug Administration and the smoked fish industry, these measures will remain in effect with respect to interstate commerce in smoked fish products processed in establishments in the Great Lakes area or from Great Lakes fish smoked in establishments in other parts of the country. In our opinion the measures should not be modified until the total research efforts of government and industry provide other or better means to insure the marketing of smoked fish products free from the botulism hazard. *C. botulinum* type E does not produce obvious spoilage in fishery products to warn of its presence. Therefore, measures to eliminate traffic in contaminated fish products are essential to consumer protection.

Research

The increased incidence of botulism during 1963 stimulated a renewed interest in reasearch. At least six agencies of the Federal Government currently support studies related to botulism :

Agency	Number of projects	Funding
Public Health Service.....	7	\$391, 135
Food and Drug Administration.....	2	32, 000
Atomic Energy Commission..	4	225, 300
Department of Defense, Army Quartermaster Corps.....	2	(1)
National Science Founda- tion.....	1	90, 000
Department of Interior, Fish and Wildlife Service.....	2	39, 000
Total.....	18	\$777, 435

¹ Not identifiable.

Both the Food and Drug Administration and the Public Health Service maintain liaison with the other governmental programs through a flow of information and cooperative projects.

Public Health Service. The Public Health Service, through its research grant program, supports the following botulism studies (funds given in total amounts, not annual) :

Effect of irradiation of clostridial antigens (EF-00017), Dr. Nancy W. Walls, Georgia Institute of Technology, September 1, 1961, \$65,494.

Conditions for growth of *Clostridium botulinum* in tomatoes (EF-00130), Dr. Charles T. Townsend, National Canners Association, Berkeley, Calif., April 1, 1960, \$65,549.

Associative growth of *Clostridium botulinum* in milk (EF-00161), Dr. O. W. Kaufmann, Michigan State University, May 1, 1959, \$22,121.

Toxin formation by *Clostridium botulinum* type E (EF-00361), Dr. Ganji Sakaguchi, National Institute of Health, Tokyo, December 1, 1962, \$11,739.

Mechanism of resistance of *Clostridium botulinum* spores (EF-00517), Dr. Nicholas Greca, Illinois Institute of Technology, September 1, 1963, \$125,032.

Thermal destruction of type E *Clostridium botulinum* spores (EF-00517), Dr. Nicholas Greca, Illinois Institute of Technology, September 1, 1963, \$125,032.

Thermal destruction of type E *Clostridium botulinum* (EF-00632), Dr. C. Wallace Bohrer, National Canners Association, Washington, D.C., action pending, \$39,000 (not included in \$391,135 total).

Chemistry and biological activity of *botulinum* toxin (A1-04180), Dr. Daniel A. Boroff, Albert Einstein Medical Center, Philadelphia, \$109,500.

Micro-electrode studies of human skeletal muscle (NB-03080), Dr. T. R. Johns, University of Virginia, \$73,500.

Food and Drug Administration. The Food and Drug Administration is conducting market studies to determine the incidence, if any, of *C. botulinum* type E in smoked fish. It is also conducting intramural research on laboratory methods and on factors affecting the growth of the organism. To determine the foci of *C. botulinum* type E in fish-smoking plants, the agency has contracted for a 1-year ecological study at a cost of \$12,000 (subject to renegotiation in both time and amount). An additional contract is planned for the support of similar studies on the west coast, under Dr. K. S. Pilcher of Oregon State University, at a cost of approximately \$20,000.

Atomic Energy Commission. The Atomic Energy Commission (Biology Branch, Division of Biology and Medicine) is conducting the following work by contracts:

A study on effect of ionizing radiation on resistance, germination, and toxin synthesis of *C. botulinum* spores, types A, B, and E, University of Michigan, 3 years, \$107,000.

Evaluation of public health hazards involved in the prolongation of refrigerated storage life of foods by application of low doses of ionizing radiation, Continental Can Company, 2 years, \$20,000. (Factors which govern the hazards of *C. botulinum* type E in refrigerated foods are to be established.)

Survey of sea mud, crab gut, and flotation tanks for incidence of *Clostridium botulinum* type E spores, Bureau of Commercial Fisheries, Seattle, Wash., 1 year, \$32,300.

Inoculated pack study on irradiated haddock filets and soft shell clams, using *C. botulinum* type E, Massachusetts Institute of Technology, 1 year, \$56,000.

Department of Defense. Under its internal research program, the Defense Department is conducting the following studies, consisting of three major aspects:

The first, termed "process work," is seeking to determine the minimal sterilizing radiation dose for foods, using *C. botulinum* types A and B as indicator organisms. The food is irradiated at various dose levels, and relative resistance is calculated by conventional culture methods or recovery. Also some work is being done on the effect of such processing variables, as acidity, temperature, chemicals present, and

moisture content, as well as on microwave processing in conjunction with radiation.

Under the second, or "basic aspects" phase (that is, the mode of radioresistance of spores), Defense scientists are studying the sporulation, germination, and outgrowth of spores and their biophysical and chemical characteristics as affected by radiation processing.

A third aspect under study on the toxin of *C. botulinum* organisms includes the study of the physiology of toxic production, improved methods for quantitative assay of toxin presence, and the effects of radiation on toxin present in foods.

The second and third aspects of the Defense Department study are in preliminary stages, pending completion of adequate facilities for handling the highly toxic research material; adequately trained personnel for the program is available.

Under Defense Department contract are two rather small projects, both conducted by Swift & Co. The first, now in its final phases, relates to a comparison of thermal processing of cured (canned) meats by radiation. The second project, just beginning, will survey raw meat, chicken, beef, ham, and the like to determine the natural incidence of spores in *C. botulinum* types A and B.

National Science Foundation. The National Science Foundation is supporting one study:

Pharmacology, chemistry, and toxicology of botulinum toxin, Dr Daniel A. Boroff, Albert Einstein Medical Center, Philadelphia, 2½ years, \$90,000.

Department of the Interior. The Fish and Wildlife Service of the Department of the Interior supports two studies by contract, one with the University of Wisconsin and the other with Michigan State University. Both studies are attempting to determine the distribution of *C. botulinum* type E in nature, particularly in the biological media of the Great Lakes.

In addition to basic control measures, including epidemiologic and ecological investigations and recommendations and regulations, the Public Health Service, the Food and Drug Administration, and other interested Federal Government agencies coordinate U.S. basic and applied research programs with foreign governments and industries in order to keep abreast with

and encourage further development of the basic scientific and medical skills necessary to control and suppress botulism.

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Increase in Number of Diabetics

Four million or more persons in the United States have diabetes according to latest estimates of known and unknown cases. As recently as 1962 the total number was estimated to be 3 million.

Data from the Sudbury Health Study, the Tecumseh Community Health Study, the Federal Employee Screening Program, and a study of 6,672 persons carried out by the National Center for Health Statistics show a higher rate of diabetes than would have been expected from past concepts or prevalence.

Dr. Glen W. McDonald, chief of the Diabetes and Arthritis Program, Division of Chronic Diseases, Public Health Service, attributed the rising rate to the increasing number of older persons and of overweight persons, broader diagnostic concepts, the possibility that more persons inherit the disease, and more sensitive screening tests.

Early identification of the diabetic who carries the strain but does not know that he has diabetes is an important health goal, Dr. McDonald said. "By prescribing medication and regulating diet and exercise, we believe that physicians will soon be able to delay the onset of the disease. When diabetes does occur, it should be less severe, bring fewer complications, and be controlled more easily."

"An annual blood test is the best protection a person can have, particularly if he is over 40, overweight, or there is diabetes in his family," Dr. McDonald commented.