167. Centers for Disease Control, "Botulism Associated With Commercially Distributed Kapchunka—New York City," *Morbidity and Mortality Weekly Report*, 34(35):546, 1985.

168. Badhey, H. et al., "Two Fatal Cases of Type E Adult Food-borne Botulism With Early Symptoms and Terminal Neurologic Signs," *Journal of Clinical Microbiology*, 23(3):616, 1986.

169. Establishment Inspection Reports (EIR's) conducted by FDA.

170. Letter to D. Å. Kautter from Alan L. Hoeting, July 31, 1987.

171. Codex Alimentarius Commission, "Thirteenth Session of the Codex Committee on Fish and Fishery Products, RCP–25, Recommended International Code of Practice for Smoked Fish," 1979.

172. Codex Alimentarius Commission, "Thirteenth Session of the Codex Committee on Fish and Fishery Products, RCP–26, Recommended International Code of Practice for Salted Fish," 1979.

173. Eklund, M. W., "Significance of *Clostridium Botulinum* in Fishery Products Preserved Short of Sterilization," *Food Technology*, 35(12):107, 1982.

174. Schmidt, C. F., R. V. Lechowich, and J. F. Folinazzo, "Growth and Toxin Production by Type E *Clostridium Botulinum* Below 40 °F," *Journal of Food Science*, 26:626, 1961.

175. CPG No. 7108.17; Salt-cured, Air-Dried, Uneviscerated Fish (53 FR 44949, November 7, 1988), Docket No. 88D–0306.

176. Graham, P. P., R. S. Hamilton, and M. D. Pierson, "Influence of Bringing Procedures on Salt Content and Distribution in Smoked Whitefish Chubs," *Journal of Food Processing and Preserving*, 10:295, 1986.

177. Deng, J., R. T. Toledo, and D. A. Lillard, "Effect of Smoking Temperatures on Acceptability and Storage Stability of Smoked Spanish Mackerel," *Journal of Food Science*, 39:596, 1974.

178. Chan, W. S., R. T. Toledo, and J. Deng, "Effect of Smokehouse Temperature, Humidity, and Air Flow on Smoke Penetration into Fish Muscle," *Journal of Food Science*, 40:240, 1975.

179. Pelroy, G. A. et al., "Inhibition of *Clostridium Botulinum* Types A and E Toxin Formation by Sodium Nitrite and Sodium Chloride in Hot-process (Smoked) Salmon," *Journal of Food Protection*, 45(9):833, 1982.

180. Eklund, M. W., testimony presented at New York State Department of Agriculture and Markets' hearing. May 13, 1989.

and Markets' hearing, May 13, 1989. 181. Newberry, R. E., Letter to City Smoked Fish Co., Use of Colors in Smoked Salmon, March 11, 1985.

182. National Fisheries Institute, Inc., "Techniques For Smoking Fish," Washington, DC.

183. Borgstrom, G., "Smoking," in "Fish as Food, Processing: Part I, Vol. 3," p. 88, Academic Press, New York, 1965.

184. Kautter, D. A., memorandum, "Aqueous Phase Salt Concentration for Vacuum Packaged Cold-smoked Fish," April 6. 1990.

185. Eklund, M. W. et al., "Feasibility of a Heat-pasteurization Process for the Inactivation of Nonproteolytic *Clostridium Botulinum* Types B and E in Vacuumpackaged, Hot-process Smoked Fish," *Journal of Food Protection*, 51(9):720, 1988. 186. Eklund, M. W., D. I. Wieler, and F. T. Poysky, "Outgrowth and Toxin Production of Nonproteolytic Type B *Clostridium Botulinum* at 3.3 to 5.6 °C," *Journal of Bacteriology*, 93(4):1461, 1967.

187. Solomon, H. M. et al., "Effect of Low Temperatures on Growth of *Clostridium Botulinum* Spores in Meat of the Blue Crab," *Journal of Food Protection*, 40(1):5, 1977.

188. Ohye, D. F., and W. J. Scott, "Studies in the Physiology of *Clostridium Botulinum* Type E," *Australian Journal of Biological Science*, 10:85, 1956.

189. National Research Council, "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients," p. 249, National Academy Press, Washington, DC.

190. Federal Standard, "Sanitation Standards For Fish Plants," FED-STD-369, Academy of Health Sciences, U.S. Army, Fort Sam Houston, Houston, TX, August 2, 1977.

191. Masso T. W., letters to T. Schwarz With AFDO Resolution No. 8, June 8, 1990. 192. Bryan, F. L., "Application of HACCP to Ready-to-eat Chilled Foods," Food Technology, 44(7):70, 1990.

193. Tartakow, I. J., and J. H. Vorperian, (eds.), "Foodborne and Waterborne Diseases: Their Epidemiologic Characteristics," p. 50–52, AVI Publishing Co., Westport, CN, 1981. 194. Rhodehamel, J. E., N. R. Reddy, and

M. D. Pierson, "Botulism: The Causative Agent and its Control in Foods: A Review," *Food Control*, 3(3):125–143, 1992.

195. FDA, "Human Foods; Current Good Manufacturing Practice (Sanitation) in Manufacturing, Processing, Packing, or Holding Smoked Fish," 34 FR 17176, October 23, 1969.

196. FDA, Part 110—Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (21 CFR part 110)

197. FDA, FDA Inspections Manual, Chapter 5, Establishment Inspection, Subchapter 530, Food.

198. Center for Disease Control, "Fish Botulism—Hawaii, 1990," *Morbidity and Mortality Weekly*, 40(24):412–414, June 21, 1991.

199. FDA, "Studies in Food Sanitation Control—Year Five, Contract No. 223–80– 2295, Task XVI, Effect of Controlled Humidity of Processing Ovens at High Operating Temperatures on Production of Smoked Fish," June 14, 1984.

200. Printout of FDA FY 90/91 Domestic Fish and Fishery Products Assignment Inspection Data as of August 6, 1991.

201. Daniels, Richard W., "Applying HACCP to New Generation Refrigerated Foods at Retail and Beyond," *Food Technology*, June 1991.

202. Consent Decree Regarding Shellfish Sanitation Issues, No. 9213, Subproceeding 89–3, United States of America, et al., *Plaintiffs*, v. *State of Washington*, et al., *Defendants*, May 5, 1994.

203. Taylor, S. L., and S. S. Sumner, "Determination of Histamine, Putrescine, and Cadaverine," *Seafood Quality Determination*, edited by D. E. Kramer and J. Liston, Elsevier Science Publishers B. V., Amsterdam, November, 1986.

204. Wentz, B. A., A. P. Duran, A. Swartzentruber, A. H. Schwab, F. D.

McClure, D. Archer, R. B. Read, "Microbiological Quality of Crabmeat During Processing," *Journal of Food Protection*, 48(1):44–49, January, 1985.

205. Phillips, F. A., and J. T. Peeler, "Bacteriological Survey of the Blue Crab Industry," *Applied Microbiology*, 24:958–966, 1972.

206. Microbiology and Food Safety Committee of the National Food Processors Association, "HACCP Implementation: A Generic Model for Chilled Foods," *Journal of Food Protection*, 56(12):1077–1084, December 1993.

207. FDA Memorandum to Patricia Spitzig from Oliver D. Cook, July 11, 1995, concerning relationships between consumer complaints and process controls.

208. Department of Health and Human Services and Food and Drug Administration, "21 CFR Parts 123 and 1240: Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products; Proposed Rule," 59 FR 4142, No. 19, January 28, 1994.

209. Roberts, T. A., "Contamination of Meat: The Effects of Slaughter Practices on the Bacteriology of the Red Meat Carcass," *Journal of the Royal Society of Health,* (1), 1980.

210. Huss, H. H., "Assurance of seafood quality", *FAO Fisheries Technical Paper 334*, Food and Agriculture Organization of the United Nations, Rome, 1994.

211. Department of Agriculture, Food Safety and Inspection Service, "9 CFR Parts 308, 310, 318, 320, 325, 326, 327, and 381: Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Proposed Rule," 60 FR 6774, No. 23, February 3, 1995.

212. National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, *Fisheries of the United States*, 1993, Current Fisheries Statistics No. 9300, Silver Spring, MD, May, 1994. 213. Bauman, H. E., "Introduction to

Applications, edited by Pierson, M. D., and D. A. Corlett, Van Nostrand Reinhold, New York, 1992.

214. Eklund, M. W., "Significance of *Clostridium Botulinum* in Fishery Products Preserved Short Of Sterilization," *Food Technology*, December 1982.

215. Diane E. Thompson, Associate Commissioner for Legislative Affairs, letter to Representative Edolphus Towns, December 14, 1994, concerning molluscan shellfish safety.

216. FDA, "Import Seafood Products Compliance Program FY*95/96/97*," Compliance Program Guidance Manual, (Program 7303.844), October 1994.

217. July 11, 1995, Memorandum to the Administrative Record for Docket No. 93N–0195 from Don Kraemer, CFSAN, FDA, concerning illegal harvesting of molluscan shellfish.

218. Dowell, S. F., C. Groves, K. B. Kirkland, et. al., "A Multistate Outbreak of Oyster-Associated Gastroenteritis: Implications for Interstate Tracing of Contaminated Shellfish," *Journal of Infectious Diseases, University of Chicago, vol. 171, 1995.*