

## APPENDIX 7: Bacterial and Viral Pathogens of Greatest Concern in Seafood Processing - Public Health Impacts

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*Bacillus cereus* (*B. cereus*) is the bacterium responsible for *B. cereus* food poisoning. An estimated 27,400 foodborne cases of *B. cereus* food poisoning occur annually in the United States. There are two forms of the intoxication: one causes diarrhea, starting from 6 to 15 hours after consumption, and the other causes vomiting and nausea, starting from 30 minutes to 6 hours after consumption. Symptoms in both forms last about 24 hours. Everyone is susceptible to *B. cereus* food poisoning.

*Campylobacter jejuni* (*C. jejuni*) is the bacterium responsible for campylobacteriosis. An estimated 1,960,000 foodborne cases of campylobacteriosis occur annually in the United States. Symptoms include: diarrhea, fever, abdominal pain, nausea, headache, and muscle pain. Symptoms start from 2 to 5 days after consumption and last from 7 to 10 days. Everyone is susceptible to infection by *C. jejuni*.

*Clostridium botulinum* (*C. botulinum*) toxin is the toxin responsible for botulism. An estimated 58 foodborne cases of botulism occur annually in the United States. Symptoms include: weakness; vertigo; double vision; difficulty in speaking, swallowing, and breathing; abdominal swelling; constipation; paralysis; and death. Symptoms start from 18 to 36 hours after consumption. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness. Mortality is high; without the antitoxin and respiratory support, death is likely.

*Clostridium perfringens* (*C. perfringens*) is the bacterium responsible for perfringens food

poisoning. An estimated 249,000 foodborne cases of perfringens food poisoning occur annually in the United States. Symptoms include: abdominal cramps and diarrhea. Symptoms start from 8 hours to 1 day after consumption and last for about a day.

Everyone is susceptible to perfringens food poisoning, but it is more common in the young and elderly.

While most *Escherichia coli* (*E. coli*) are non-pathogenic, certain strains of the bacterium are responsible for four types of illness: gastroenteritis or infantile diarrhea, caused by enteropathogenic *E. coli* (EPEC); travelers' diarrhea, caused by enterotoxigenic *E. coli* (ETEC); bacillary dysentery, caused by enteroinvasive *E. coli* (EIEC); and hemorrhagic colitis, caused by enterohemorrhagic *E. coli* (EHEC). EHEC is the most severe, with potential for serious consequences, such as hemolytic uremic syndrome, particularly in young children. An estimated 173,000 foodborne cases from all four types of *E. coli* occur annually in the United States. Symptoms vary for the different forms of illness, but include: abdominal pain, diarrhea, vomiting, fever, chills, dehydration, electrolyte imbalance, high body fluid acidity, and general discomfort. Symptoms start from 8 hours to 9 days after consumption and last from 6 hours to 19 days, with both periods varying significantly between the illness types. Everyone is susceptible to all forms of infection from *E. coli*, but EPEC is most commonly associated with infants, and all types tend to result in more severe symptoms in the very young and elderly.

Hepatitis A virus is responsible for foodborne hepatitis. An estimated 4,200 foodborne cases of hepatitis A occur annually in the United States. Symptoms include: fever, malaise, nausea, anorexia, abdominal discomfort, and jaundice. Symptoms start from 10 to 50 days after consumption and last 1 to 2 weeks. Unless previously infected or immunized, everyone is susceptible to infection by hepatitis A virus.

*Listeria monocytogenes* (*L. monocytogenes*) is the bacterium responsible for listeriosis. An estimated 2,500 foodborne cases of listeriosis occur annually in the United States. *L. monocytogenes* can produce mild flu-like symptoms in all individuals. However, in susceptible individuals, including pregnant women, newborns, and the immunocompromised, it can result in more severe symptoms, which include: septicemia, meningitis, encephalitis, spontaneous abortion, and stillbirth. Symptoms start from 3 days to 3 weeks after consumption. Mortality is high in those that display the more severe symptoms.

Norovirus (also known as Norwalk-like virus) is a major cause of viral gastroenteritis. An estimated 9,200,000 foodborne cases of norovirus occur annually in the United States. Symptoms include: diarrhea, nausea, vomiting, abdominal cramps, headache, body ache, and low-grade fever. Symptoms start from 2 to 4 days after consumption and generally last 2½ days. Everyone is susceptible to infection by norovirus.

*Salmonella spp.* is the bacterium responsible for salmonellosis. An estimated 1,340,000 cases of foodborne salmonellosis occur annually in the United States. Symptoms include: nausea, vomiting, abdominal cramps, diarrhea, fever, and headache. Symptoms start from 6 hours to 2 days after consumption and generally last from 1 to 2 days. The most severe form, typhoid fever, is caused by *Salmonella typhi*. Everyone is susceptible to infection by *Salmonella spp.*, but symptoms are most severe in the elderly, infants, and the infirmed. Infections by *Salmonella spp.*

and other closely related bacterial pathogens, such as *Shigella spp.*, *E. coli*, and *Yersinia enterocolitica* infections can lead to chronic reactive arthritic symptoms in pre-disposed individuals.

*Shigella spp.* is the bacterium responsible for shigellosis. An estimated 89,600 foodborne cases of shigellosis occur annually in the United States. Symptoms include: abdominal pain; cramps; diarrhea; fever; vomiting; blood, pus, or mucus in stools; continuous or frequent urges for bowel movement; and death. Symptoms start from 12 hours to 2 days after consumption and last from 1 to 2 weeks. Everyone is susceptible to infection by *Shigella spp.*

*Staphylococcus aureus* (*S. aureus*) is the bacterium responsible for staphylococcal food poisoning. An estimated 185,000 foodborne cases of staphylococcal food poisoning occur annually in the United States. Symptoms include: vomiting, diarrhea, abdominal pain, nausea, and weakness. Symptoms usually start within 4 hours of consumption. Everyone is susceptible to intoxication by *S. aureus* toxin, with more severe symptoms, including occasional death, occurring in infants, the elderly, and debilitated persons.

*Vibrio cholerae* (*V. cholerae*) O1 and O139 are the bacteria responsible for Asiatic or epidemic cholera. No major outbreaks of this disease have occurred in the United States since 1911, but an estimated 49 sporadic foodborne cases occur annually (including *V. cholerae* non-O1 and non-O139). Symptoms include: mild-to-severe diarrhea, abdominal cramps, nausea, vomiting, dehydration, shock, and death. Symptoms start from 6 hours to 5 days after consumption. Everyone is susceptible to infection by *V. cholerae* O1 and O139, but those with weakened immunity, reduced stomach acidity, or malnutrition may suffer more severe forms of the illness.

*V. cholerae* non-O1 and non-O139 are bacteria that are also responsible for vibriosis. *V. cholerae* non-O1 and non-O139 may also cause gastroenteritis and, rarely, septicemia. The

symptoms of gastroenteritis include: diarrhea, abdominal cramps, fever, vomiting, and nausea. Symptoms start from 6 hours to 3 days after consumption and last from 6 to 7 days. Everyone is susceptible to gastroenteritis from *V. cholerae* non-O1 and non-O139, but septicemia usually develops only in those with underlying chronic disease.

*Vibrio parahaemolyticus* (*V. parahaemolyticus*) is another bacterium that is responsible for vibriosis. An estimated 3,600 foodborne cases of vibriosis from *V. parahaemolyticus* occur annually in the United States. Vibriosis from *V. parahaemolyticus*, as with *Vibrio vulnificus*, may cause gastroenteritis and primary septicemia, although primary septicemia is uncommon with *V. parahaemolyticus*. The symptoms of gastroenteritis include: diarrhea; abdominal cramps, nausea, vomiting, headache, fever, and chills. Symptoms start from 4 hours to 4 days after consumption and last for about 2½ days. Everyone is susceptible to gastroenteritis from *V. parahaemolyticus*, but septicemia usually develops only in those with underlying chronic disease.

*Vibrio vulnificus* (*V. vulnificus*) is another bacterium that is responsible for vibriosis. An estimated 47 foodborne cases of vibriosis caused by *V. vulnificus* (mostly septicemia) occur annually in the United States, about half of those resulting in death. Vibriosis caused by *V. vulnificus* can take one of two forms, gastroenteritis and primary septicemia. The symptoms of gastroenteritis include: nausea, chills, and fever. The symptoms of primary septicemia include: septic shock and death. Symptoms of gastroenteritis start from 16 hours to 2 days after consumption, and death from septicemia may occur within 36 hours. Everyone is susceptible to gastroenteritis from *V. vulnificus*, but septicemia usually develops only in those with underlying chronic disease, particularly liver disease.

*Yersinia enterocolitica* (*Y. enterocolitica*) is the bacterium responsible for yersiniosis. An estimated 86,700 foodborne cases of yersiniosis occur annually in the United States. Symptoms

include: fever, abdominal pain, diarrhea, vomiting, arthritis, and, rarely, septicemia. Symptoms start from 3 to 7 days after consumption and last from 1 to 3 days. Everyone is susceptible to infection by *Y. enterocolitica*, but symptoms are more severe in the very young, debilitated, elderly, and immunocompromised.

## BIBLIOGRAPHY.

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of March 29, 2011, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after March 29, 2011.

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