



Controlling the Hazard of *Clostridium botulinum* Growth and Toxin Formation in Reduced Oxygen Packaged Fish and Fishery Products Including Refrigerated, Vacuum-Packed Crawfish Tail Meat

It has come to FDA's attention that processors of refrigerated, vacuum-packed crawfish tail meat may not be controlling the hazard of *Clostridium botulinum* growth and toxin formation. FDA considers the hazard of *C. botulinum* growth and toxin formation reasonably likely to occur in reduced oxygen packaged (ROP) fish and fishery products including refrigerated, vacuum-packed crawfish tail meat. All seafood processors are required to conduct a hazard analysis and implement a written HACCP plan to control hazards that are reasonably likely to occur within and outside the processing plant according to 21 CFR Part 123.6. FDA's Fish and Fishery Products Hazards and Controls Guidance provides recommendations to assist processors with assessing hazards and developing HACCP plans.

FDA considers ROP fish and fishery products including refrigerated, vacuum-packed crawfish tail meat to be adulterated under section 402 (a)(4) of the Food, Drug and Cosmetic Act when the hazard of *C. botulinum* growth and toxin formation is not controlled. Specific sections addressing primary processors and secondary processors including distributors are provided below in this document.

Background

ROP encompasses a large variety of packaging methods including vacuum packaging, modified atmosphere packaging, hermetically sealed containers, sealed plastic or laminated packaging, packing in oil, and using a material that is not considered oxygen-permeable. Packaging that is not considered oxygen-permeable restricts the exchange of oxygen and can lead to any oxygen present in the packaging being utilized by spoilage organisms resulting in a reduced oxygen environment. By reducing or preventing the exchange of oxygen, a processor introduces the hazard of *C. botulinum* growth and toxin formation.

C. botulinum is an anaerobic bacterium, meaning it can grow in low oxygen conditions, that is widely distributed in nature, in soil, the sediment of streams, lakes, and coastal waters, and in the intestinal tracts of fish and mammals. The toxin produced by *C. botulinum* is considered one of the most poisonous naturally occurring substances known and when ingested can result in paralysis, leading to death from asphyxiation. There are two major groups of *C. botulinum*, the proteolytic and non-proteolytic. Proteolytic strains can grow at 50°F and above. Non-proteolytic strains, commonly found in seafood, can grow at 38°F and above to render a food toxic without any apparent signs of spoilage.

Primary Processors

1. When refrigeration below 38°F is the sole control for the hazard *C. botulinum*, processors should use a Time-Temperature Indicator (TTI) on each reduced oxygen package of product and maintain the product below 38°F. Since product will likely not be maintained below 38°F during distribution, TTIs are needed to monitor time and temperatures exposures throughout distribution until consumption. TTIs should be designed specifically for *C. botulinum* and alert consumers and end users of potentially unsafe time and temperature exposures that could result in toxin formation.



Processors that use a TTI on each ROP package and maintain the product below 38°F should have a HACCP plan that, at a minimum, lists critical control points for finished product storage below 38°F, and TTI use and application. The critical control points and critical limits for the TTIs should be based on the TTI manufacturer's specifications.

2. For seafood, packaging that has an oxygen transmission rate (OTR) of 10,000 cc/m²/24 hours at 24°C, or higher (often referred to as 10K OTR and occasionally printed on the packaging) is considered oxygen permeable and not ROP by FDA. Oxygen permeable packaging should provide a sufficient exchange of oxygen to allow naturally occurring aerobic spoilage organisms on the fishery product to grow and spoil the product before *C. botulinum* toxin is produced under moderate abuse temperatures.
3. Product can be frozen with proper labeling. The product should be immediately frozen after being placed in a reduced oxygen package. The HACCP plan should list a labeling critical control point for each package to be labeled "Important, keep frozen until used, thaw under refrigeration immediately before use."

Secondary Processors Including Distributors

The term secondary processor includes distributors that hold or store product because holding and storing is defined as processing in 21 CFR Part 123.3 (k)(1). Secondary processors should assess the hazard of *C. botulinum* when receiving ROP products and ensure the product is received with proper controls, in addition to implementing proper controls within their own facility, as necessary. For example, distributors of refrigerated ROP products including vacuum-packed crawfish tail meat, should receive product below 38°F with TTIs and have a HACCP plan that lists critical control points for receiving and storage with critical limits that maintain the product below 38°F.

For more information on *C. botulinum* and controls see Chapter 13 of FDA's Fish and Fishery Products Hazards and Controls Guidance (4th ed.) and FDA's Seafood HACCP Video titled "Time-Temperature Indicators" available at www.fda.gov/seafood.