Clostridium botulinum and Reduced Oxygen Packaged Refrigerated Seafoods

Mary Losikoff
Senior Regulatory Microbiologist, Seafood
U.S. Food & Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Safety

FDA Concern

- Reduced oxygen packaging (ROP) may extend shelf life - prevent growth of aerobic spoilage organisms

- Potential for growth and toxin production of nonproteolytic *C. botulinum* in seafood at refrigeration temperatures without visible signs of spoilage

FDA Perspective

C. botulinum risk

- Research published on the risks of vacuum (VAC) and modified atmosphere packaging (MAP)
- NMFS (1981) issues a moratorium on VAC / MAP for refrigerated fresh fish

FDA Perspective

Seafood Packaging

- National Research Council – NAS 1985
  - Refrigerated VAC/MAP raw fish
  - Thorough studies needed on potential hazard of nonproteolytic C. botulinum toxin production
  - “This practice is not recommended until safety is validated”

FDA Perspective

Seafood Packaging

- NACMCF Review 1992

  NACMCF determined that refrigeration below 3.3C (38F) was the only control
- NACMCF recommended that the unrestricted use of VAC / MAP should not be permitted
- Described conditions of use

FDA Perspective
NACMCF Recommendations

- VAC / MAP permitted for raw fishery products when:
  - Products packaged under established HACCP plan.
  - Detectable spoilage and rejection by the consumer precedes the possibility of toxin production.
  - High quality raw fish is used.
  - Packaged product is stored below 38°F (3.3°C).
  - Product is adequately labeled for storage temperature, shelf life, and cooking requirements.

FDA Perspective
NACMCF Recommendations

- Detectable spoilage and rejection by the consumer precedes the possibility of toxin production.
  - Several studies were initiated.
- Packaged product stored below 38°F (3.3°C).
  - Verify temperature control with TTI's

FDA Guidance
3rd Edition Seafood Hazard Guide

Reduced Oxygen Packaging

- Vacuum packaging
- Modified atmosphere packaging
- Hermetically sealed containers – double seams/glass jar with lid
- Deep containers from which air is expressed
- Products packed in oil

ROP

- Processing and packaging techniques that prevent the entry of oxygen into the container - Any oxygen present at the time of packaging (including oxygen that may be added during modified atmosphere packaging) may be rapidly depleted by the activity of spoilage bacteria, resulting in the formation of a reduced oxygen environment.

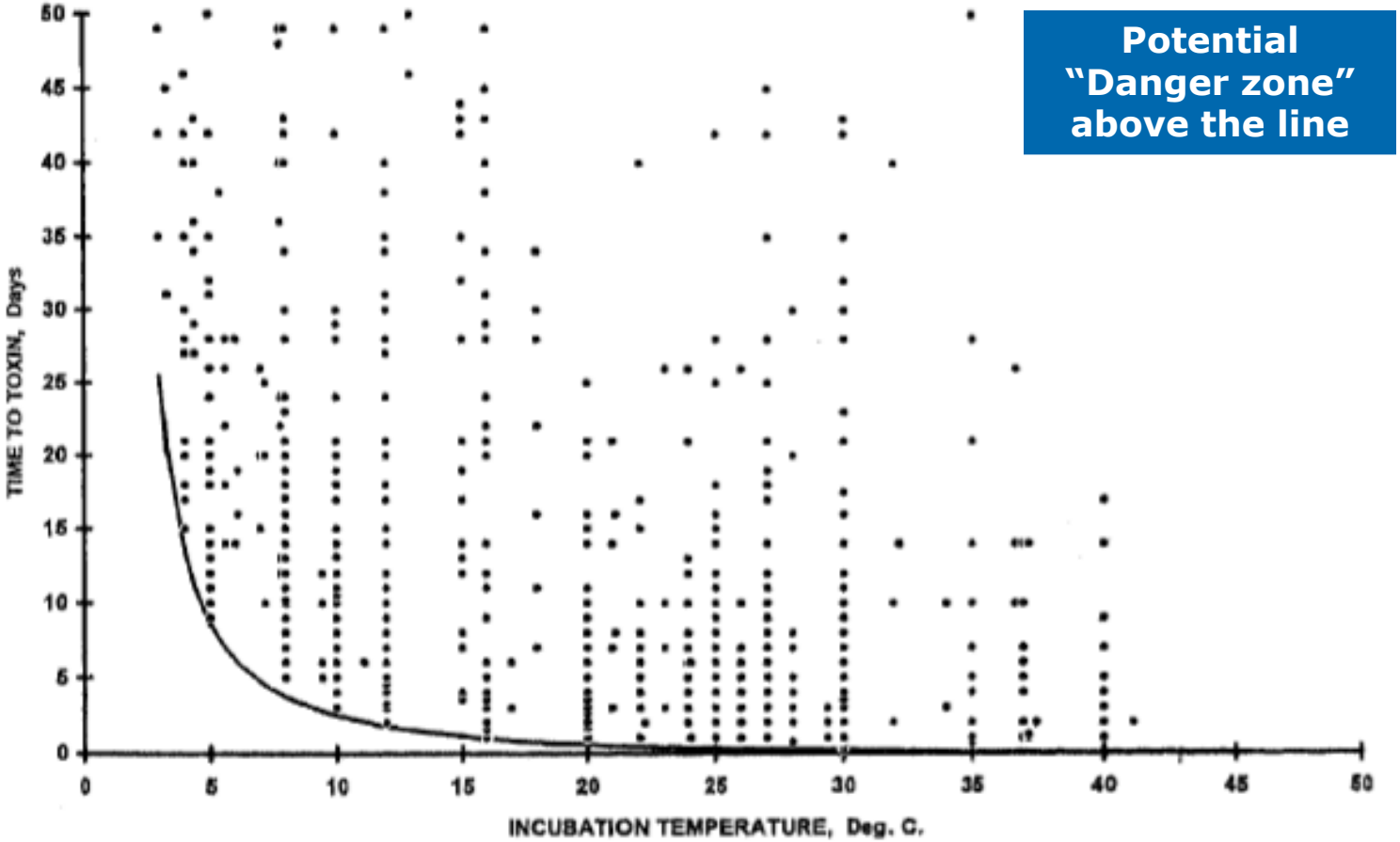
Import Alert

- **IA 16-125** – DWPE Refrigerated ROP Raw Fish and Fishery Products
  - Frozen product (properly labeled) not covered
  - Exempt list
    - Packaging material - 10K OTR
    - 5% wps, pH 5.0, or water activity below 0.97
    - Maintain the product below 38F - validated TTI attached to each individual package, not the master carton

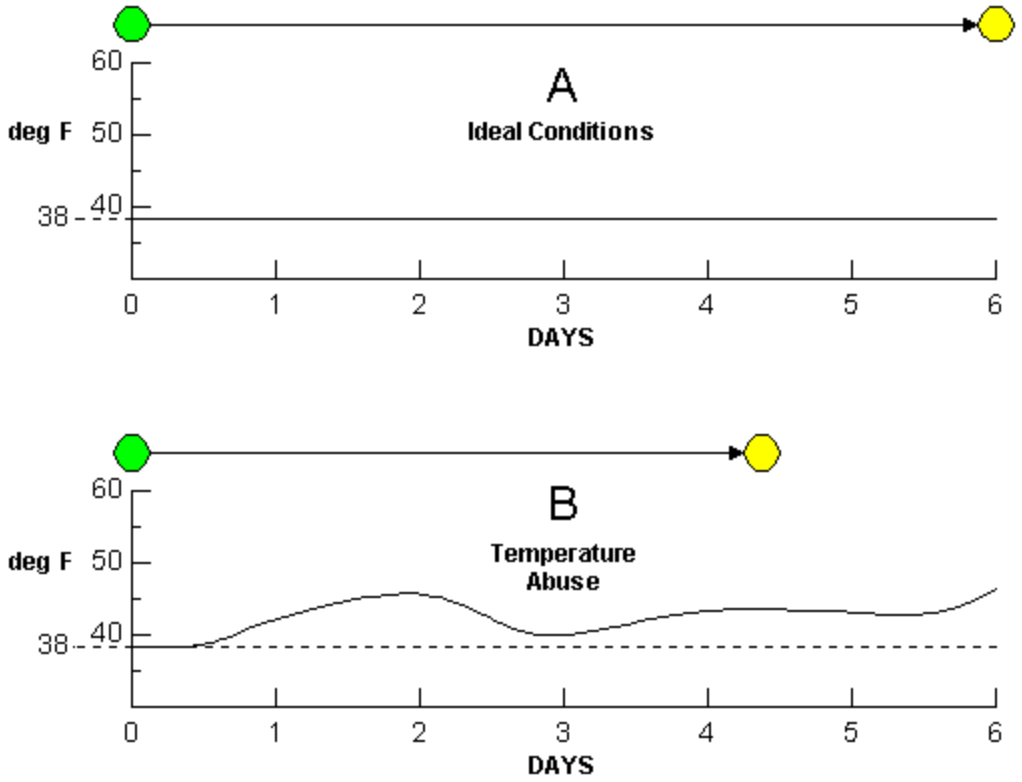
TTI Validation

- TTI is functional and fit for its intended purpose
  - Closely matches the Skinner-Larkin curve
  - Level of confidence, false negative rate
  - Limitations – humidity, heat, storage, etc
  - Descriptive insert - applicability (uses), interpretation criteria, shelf life of the TTIs, environmental factors, etc.

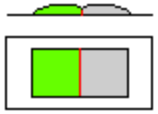
Skinner & Larkin Curve



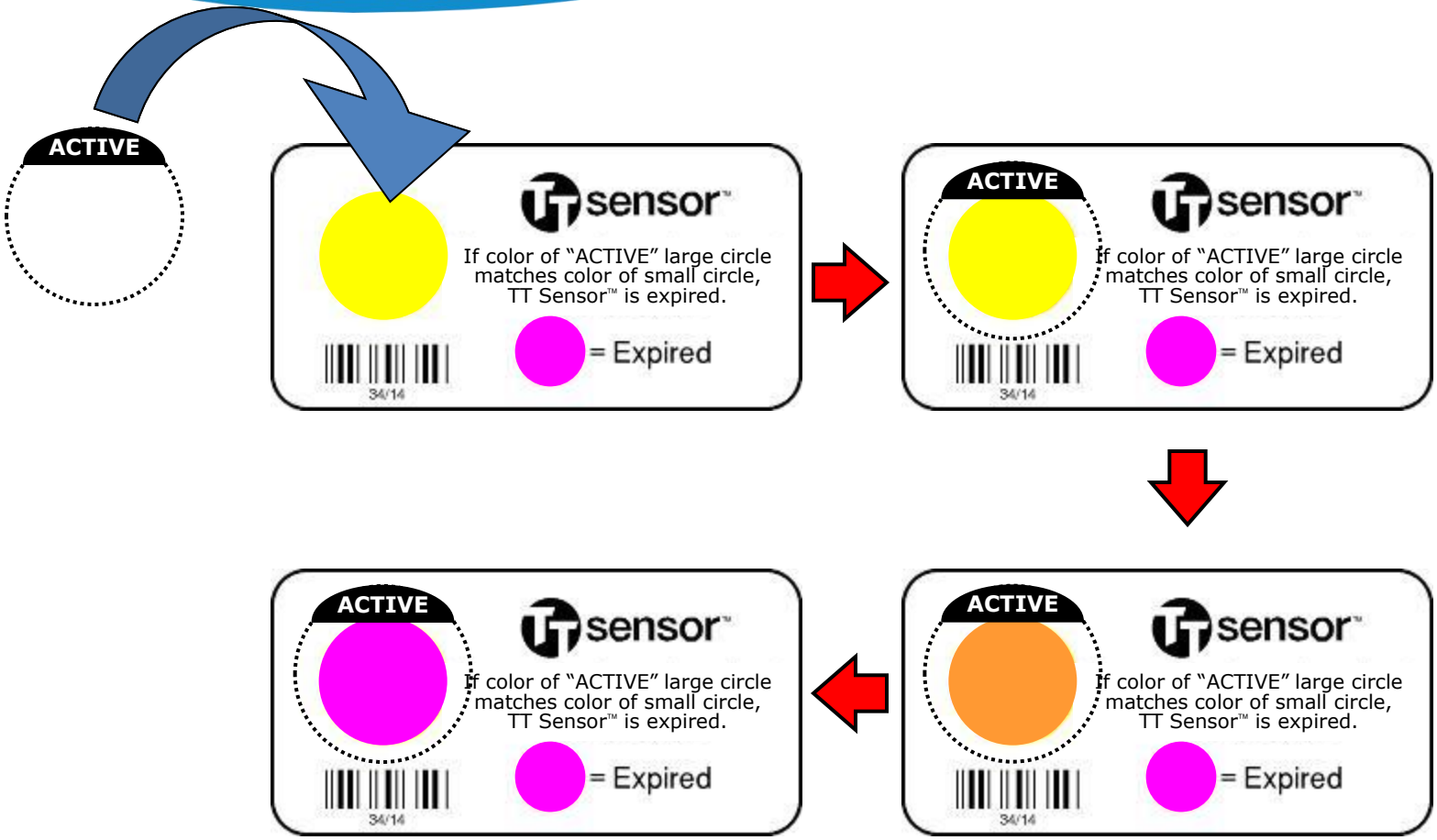
Skinner & Larkin, 1998. *J. Food Protection*, Vol. 61(9):1154-60.



Temperature abuse example



Vitsab Three Dot


ACTIVE
sensor™
If color of "ACTIVE" large circle matches color of small circle, TT Sensor™ is expired.
= Expired
34/14
ACTIVE
sensor™
If color of "ACTIVE" large circle matches color of small circle, TT Sensor™ is expired.
= Expired
34/14
ACTIVE
sensor™
If color of "ACTIVE" large circle matches color of small circle, TT Sensor™ is expired.
= Expired
34/14
ACTIVE
sensor™
If color of "ACTIVE" large circle matches color of small circle, TT Sensor™ is expired.
= Expired
34/14

Problems encountered

- No instructions with the TTI
- Firm changes TTI (manufacturer on list but not using the TTI that got them on the list)
- TTI not activated
- TTI white – should be green or yellow – insufficient fill in chamber
- Partial color change – “slightly yellow”

Refrigeration CCP

- In plant storage, transit, warehouse storage below 38F (same treatment as RTE but lower refrigeration temperature)
    - Keep it cold - TTI lasts longer
    - TTI is a monitor for the consumer

HACCP Plan

- *Shows attachment and activation of each TTI to each package unit*
- *Verifies that each lot of TTIs is functioning properly (e.g., expose a TTI from the lot being used to an abuse temperature to ensure it changes color)*
- *Any additional activity associated with the proper use of the TTI*

Frozen

- Can be safely marketed frozen, with appropriate labeling to ensure that it is held frozen throughout distribution.
- Labeling is a Critical Control Point

OTR of Packaging

- Oxygen Transmission Rate
- 10,000 cc/ m2/24 hours at 24ºC considered oxygen-permeable packaging material for fishery products
- Oxygen impermeable, e.g. 100 cc/m^2/24hrs
- OTR listed in packaging specifications from the packaging manufacturer

Goal of OTR

- An oxygen-permeable package should provide sufficient exchange of oxygen to allow aerobic spoilage organisms to grow and spoil the product before toxin is produced under moderate abuse temperatures.

Determine the safety of a packaging material

Not always appropriate - examples

- Spoilage organisms eliminated or significantly reduced
  - high pressure processing or product heated in the package
- Products packed in oil
- Deep containers from which the air is expressed
- Use of oxygen scavengers in the packaging
- Products with high respiration rate – vegetables
- Cooked products - drive off oxygen

FDA Compliance

- Seafood HACCP regulation (21 CFR Part 123)
- Fish and Fishery Products Hazards and Controls Guide, 4th edition, 2011 page 73
- Raw oysters, clams and mussels in ROP – *C. botulinum* hazard

Botulism

- Onset 12 to 36 hours (2hrs – 14 days)
- Early weakness and vertigo – progressive paralysis
- Causes bilateral, descending weakening and paralysis of skeletal muscles
- Double vision - difficulty in speaking – swallowing – breathing
- Abdominal distention, symptoms may also include vomiting, diarrhea or constipation
- Respiration is inhibited and death from asphyxia
- Early administration of botulinal antitoxin/mechanical ventilation

Clostridium botulinum

- Produces the most potent neurotoxin known, particularly when taken orally (7 – 70 µg for a typical person)
- Classified by toxin type: A, B, C, D, E, F, G – types C and D do not affect man
- Most human illness is caused by types A, B and E and occasionally F

- Spore-forming bacteria (anaerobic)
- Vegetative cells - susceptible to heat
- Spores - heat resistant, survive heat and adverse conditions
- Toxin - not resistant to heat, destroyed by boiling, resistant to acid and freezing
- Low incidence of disease
- High mortality if not treated

Clostridium botulinum

- Widely distributed in nature
  - around the world in soil, marine and freshwater environments
  - sediment of streams, lakes, and coastal waters
- Spores are common in root vegetables, many spices, the intestinal tracts of fish and mammals, and the gills and viscera of crabs and other shellfish

Type E found in oysters/sediment

- Pacific oysters – 5 of 16 tested
- Upper Chesapeake water and sediment
  - 4 of 33 tested
- Mobile Bay oysters – 2 of 74 tested

Clostridium botulinum

- Proteolytic (A,B,F) - degrade protein - visual signs of growth - limit for growth is 10C (50F)

- Non-proteolytic (B,E,F) – do not degrade protein - product may be toxic without signs of growth - limit for growth is 3.3C (38F)
- Type E – non-proteolytic, primarily associated with seafood products

Extension of shelflife

- As the shelf life of refrigerated foods is increased in ROP, more time is available for C. botulinum growth and toxin formation. As storage temperatures increase, the time required for toxin formation is significantly shortened.

Control below 38F

- It is likely that at some point during storage, distribution, display, or consumer handling of refrigerated foods, safe refrigeration temperatures will not be maintained (especially for the non-proteolytic group). Surveys of retail display cases indicate that temperatures of 45 to 50°F (7 to 10°C) are not uncommon. Surveys of home refrigerators indicate that temperatures can exceed 50°F (10°C).

Recent Botulism Outbreaks

- Most cases of botulism are due to home-prepared foods
- Recent botulism outbreaks due to commercial foods are the result of extreme temperature abuse
  - refrigerated foods stored at room temperature (products appear shelf stable)
- Outbreaks due to commercially processed low acid canned foods are rare

1990 to 2000 United States

- 160 foodborne botulism events
- 263 people affected
- an annual incidence of 0.1 per million
- highest incidence Alaska, Idaho, and Washington
- 131 cases (50%) type A,
- 27 (10%) type B
- 97 (37%) type E

Not home made (1990-2000)

Commercial

Salted,uneviscerated fish (mohola) 3

- Palani (surgeon fish) 3
- Burrito 1
- Clam chowder 2
- Bean dip 1

Restaurant-made

- Cheese sauce 8
- Skordalia potato dip 17

Botulism Outbreaks proteolytic

- Refrigerated pasta sauce in a plastic pouch in a cardboard carton
- Refrigerated bean dip
- Refrigerated garlic in oil
- Refrigerated carrot juice in a plastic bottle
- Sautéed onions left in a warm skillet overnight
- Baked potato wrapped in foil

Botulism Outbreaks nonproteolytic

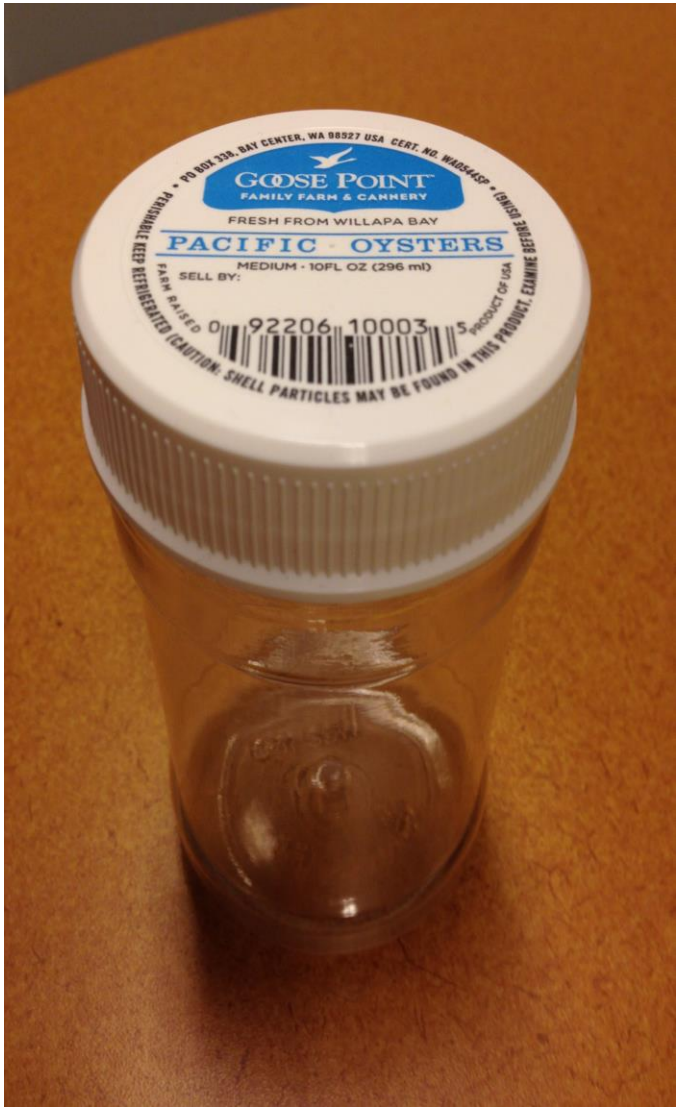
- Kapchunka – uneviscerated fish– New York/Israel, 1987 - 8 cases
- Beached whale – Western AK, 2002 - 8 cases
- Fermented salmon roe – Canada, 2001 – 4 cases
- Frozen vacuum packed scallops – France, 1998 – 1 case
- Frozen vacuum packed prawns – France, 1998 – 1 case

Options - Raw ROP seafood

- Refrigerate below 38F with TTI each package
- Freeze - each package labeled to be kept frozen
- Use oxygen permeable packaging
- Conduct a study demonstrating spoilage precedes toxin production at moderate abuse

References

- Craig, JM, et al. 1968. Incidence of *Clostridium botulium* type E in salmon and other marine fish in the Pacific Northwest. Appl. Micro. 16(4):553-557
- Sayler, GS, et al. 1976. Incidence of *Salmonella spp. Clostridium botulinum* and *Vibrio parahaemolyticus* in an estuary. Appl. Envrion. Micro. 31(5):723-730
- Presnell, JJ, et al. 1967. *Clostridium botulinum i*n marine sediments and in the oyster (*Crassostrea virginica*) from Mobile Bay. Appl. Micro. 15(3):668-669


PO BOX 338, BAY CENTER, WA 98527 USA CERT. NO. WA8544SP
GOOSE POINT
FAMILY FARM & CANNERY
FRESH FROM WILLAPA BAY
PACIFIC OYSTERS
MEDIUM - 10FL OZ (296 ml)
SELL BY:
0 92206 10003 5
PRODUCT OF USA
FARM RAISED
KEEP REFRIGERATED (CAUTION: SHELL PARTICLES MAY BE FOUND IN THIS PRODUCT. EXERCISE REASONABLE CARE WHEN OPENING.


PACIFIC OYSTERS
GOOSE POINT OYSTERS
WILLAPA BAY
WASHINGTON
KEEP REFRIGERATED
PERISHABLE
SIZE: LARGE
SELL BY:
16 FL OZ (473ml)
0 92206 16003 9