

Interstate Shellfish Sanitation Conference (ISSC)  
Reduced Oxygen Packaging (ROP) Workshop Report  
November 1-2, 2016 – Atlanta, GA

**I. Purpose**

In 2015, the US Food & Drug Administration(FDA) submitted Proposal 15-208 to the ISSC Biennial Conference addressing reduced oxygen packaging (ROP) of shucked shellfish. The 2015 ISSC Voting Delegates referred the proposal to committee to begin discussions of the appropriateness of incorporating *C. botulinum* controls into the NSSP.

The ISSC held a Reduced Oxygen Packaging Workshop in Atlanta, GA. The purpose of this meeting was to discuss the need for requirements to address the risk of *C. botulinum* associated in reduced oxygen packages in the National Shellfish Sanitation Program (NSSP). *C. botulinum* produces the most potent neurotoxin known. To date, there are no reported cases of botulism associated with consumption of shucked shellfish, however, research indicates that *C. botulinum* can potentially grow in oysters. Many participants in the ISSC question the need to include *C. botulinum* controls in the NSSP. There are many packaging types used in the shellfish industry that have not been evaluated to determine their anaerobic potential and their capacity to allow *C. botulinum* growth.

This meeting brought together expert panelists on *C. botulinum*, shellfish packaging and shellfish shipping. The ISSC Reduced Oxygen Packaging Committee participated in the meeting and developed recommendations for Conference action.

**II. Introduction**

A Reduced Oxygen Environment in Shucked Shellfish Containers

In a 1981, as a result of research published on the risks of vacuum (VAC) and modified atmosphere packaging (MAP) of raw fish products, NMFS issued a moratorium on the use of VAC / MAP for refrigerated fresh fish. In 1985, the National Research Council of the National Academy of Sciences recommended that studies were needed on the potential hazard of non-proteolytic *C. botulinum* toxin production in vacuum and modified atmosphere fresh fish. They were concerned that the non- proteolytic strains of *C. botulinum* commonly associated with seafood products could grow and produce toxin at refrigeration temperatures with no visible signs of growth to alert the consumer. They stated that “This practice is not recommended until safety is validated.”

The National Advisory Committee for Microbiological Criteria for Foods (NACMCF) reviewed the topic in 1991 and determined that refrigeration below 3.3°C (38°F)

was the only control for the growth of non- proteolytic *C. botulinum* in raw fish that is vacuum or modified atmosphere packaged. The NACMCF recommended that unrestricted use of VAC / MAP should not be permitted. They stated that VAC / MAP would be permitted for raw fishery products when: (1) products were packaged under an established HACCP plan, (2) detectable spoilage and rejection by the consumer precedes the possibility of toxin production, (3) high quality raw fish is used, (4) packaged product is stored below 38°F (3.3°C), and (5) product is adequately labeled for storage temperature, shelf life, and cooking requirements.

To address the need to demonstrate that detectable spoilage and rejection by the consumer precedes the possibility of toxin production, several studies were initiated by the FDA. In salmon packaged under modified atmosphere, toxin production coincided with spoilage under moderate temperature abuse at 8°C (46.5°F). Temperatures below 4°C (39.2°F) were needed to prevent toxin formation. Similar studies were done in other seafood including cod, tilapia, and catfish.

A number of conditions can result in the creation of a reduced oxygen environment in packaged fish and fishery products. They include:

- Vacuum, modified, or controlled atmosphere packaging. These packaging methods generally directly reduce the amount of oxygen in the package;
- Packaging in hermetically sealed containers (e.g., double-seamed cans, glass jars with sealed lids, and heat-sealed plastic containers), or packing in deep containers from which the air is expressed (e.g., caviar in large containers), or packing in oil. These and similar processing and packaging techniques 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

### **III. Relevance to Molluscan Shellfish**

The Fish and Fishery Products Hazards and Controls Guidance was issued by the FDA to assist processors in identifying hazards associated with their products. This document addresses both species-specific hazards and process-related hazards. Under process- related hazards, page 73 indicates that raw oysters, clams and mussels have a *C. botulinum* hazard when packed in reduced oxygen packages.

### **IV. Format and Meeting Objectives**

Prior to the ROP Workshop, the ISSC solicited ROP related questions from the membership. 40 questions were received and reviewed for the expert panelists to

address. Each question was assigned to a panelist to answer. Other panelists, members of the Reduced Oxygen Packaging Committee and attendees were given an opportunity to comment and ask questions related to each response of the assigned panelist.

**V. Expert Panelists**

The ISSC invited several panelists with expertise in the use of reduced oxygen packaging and the scientific aspects that pertain to both reduced oxygen packaging and *C. botulinum*. The panelists are listed below.

- A. **Mary Losikoff**  
Senior Regulatory Microbiologist, the FDA Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Seafood Safety, Seafood Processing and Technology Policy Branch
- B. **Pat Barker**  
Rex Refrigerated Express LLC
- C. **Yoon Song**  
FDA Office of Food Safety Process Engineering Branch
- D. **Mike Doyle**  
University of Georgia
- E. **Guy Skinner**  
FDA Center for Food Safety and Applied Nutrition Division of Food Processing Science and Technology
- F. **Melissa Abbott**  
FDA Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Food Safety, Shellfish and Aquaculture Policy Branch
- G. **Rob Bartholomew**  
Berry Plastics/RFC Container Co./ChemStretch/Specialty Industries
- H. **Keith Jackson**  
Performance Food Group
- I. **Paul DiStefano**  
FDA Center for Food Safety and Applied Nutrition, Office of Food Safety, Division of Seafood Safety, Shellfish and Aquaculture Policy Branch
- J. **A.J. Erskine**  
Aquaculture Manager and Field Scientist with Bevans Oyster Company, Cowart Seafood Corp.

- K. **Austin Docter**  
Director of Processing, Retail and Restaurants at Taylor Shellfish Farms
- L. **Joe Goetz**  
C & S Wholesale Grocers Inc.
- M. **Roger Peel**  
Georgia Department of Agriculture

VI. **Questions Answered by Panelists**

A. **Policy Related**

1. Disappointed that the FDA has opted to focus on *C. botulinum* when there are other high priority public health issues that are actually causing illnesses (Vibrio, Norovirus). Could the FDA provide a rationale?

*Paul DiStefano - The the FDA recognizes that epidemiological records of C. botulinum illnesses do not exist related to the consumption of oysters, however, the science shows that C. botulinum is reasonably likely to occur. The FDA wants to see the risk addressed before a death or serious illness occurs. the FDA wants to work with the states through the NSSP to establish effective controls.*

*In determining reasonably likely to occur, the FDA uses illness data, scientific reports or other information that provides the basis to conclude that there is a reasonable possibility that a hazard exist. NACMCF and NWDT, the National Academy of Sciences have indicated that the use of ROP in packaging raw seafood is a hazard due to the potential for growth of non-proteolytic C. botulinum at refrigeration temperatures.*

*It is the process of placing the product in ROP that is primarily responsible for creating the hazard.*

2. While we know *C. botulinum* is a hazard, why is there not a history of illness?

*Mary Losikoff - The FDA believes this could be attributed to difficulties in diagnosing less serious cases as well as mis-diagnosis of more serious cases.*

3. Why are we regulating a question that's not an issue?

*See Question 1*

4. Can the FDA identify the agency priority among the issues of *C. botulinum*, *Vibrio*, and Viruses and communicate how they are demonstrating this prioritization through expended resources?

*Paul DiStefano - The FDA has not prioritized food borne illnesses associated with consumption of shellfish. All illnesses need to be addressed. C. botulinum has always posed a risk. It has just recently become a focus of the FDA.*

5. Provide justification more than “this could happen”.

*Mary Losikoff - The science shows it is possible for C. botulinum to grow in an anaerobic environment and that environment exists in reduced oxygen packaging.*

6. What types of scientific evidence would the FDA be willing to consider in evaluating the actual need for ROP?

*Studies to identify substance inhibitors that do not allow growth of C. botulinum in an anaerobic environment. Studies would have to be done on every type of oysters to make sure the study remains true in all.*

*Mary Losikoff – The FDA follows the advice of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), which recommends that the unrestricted use of vacuum/ modified atmosphere packaging or, collectively, reduced oxygen packaging (ROP) technology for refrigerated raw fishery products not be permitted. The use of ROP technology may be permitted only when it is assured that detectable spoilage and rejection by the consumer precedes the possibility of toxin production. Research should be conducted to define the minimum conditions for control, incorporating reasonable limits for inoculation size, storage temperatures, and stochastic (predictive) modeling techniques.*

*NACMCF provides procedures for inoculated pack studies in the report titled “Vacuum or Modified Atmosphere Packaging for Refrigerated Raw Fishery Products” adopted March 20, 1992 and “Parameters for Determining Inoculated Pack/Challenge Study Protocol” adopted March 20, 2009.*

7. Is there an opportunity for a minor change?

*Mary Losikoff - The proposed controls are the only known controls available to address C. botulinum in ROP. Ice as an alternative to the refrigeration requirement could be used. Comments by the ISSC suggest that packaging types could change and this would lead to a significant cost in research and development. All known alternative controls would not be considered a minor change. The FDA does not plan to change its policy.*

*Several workshop participants indicated that use of ice would be costly and the research and development cost of changing packaging types could be cost prohibitive.*

8. Can the FDA determine an estimated risk level associated with *C. botulinum*, similar to the risk?

*Mary Losikoff - There is no data to estimate the risk level. The available study shows that C. botulinum can grow in shellfish packages, but does not provide an estimates risk. What study?*

9. Does the FDA have data about illnesses related to oyster production that has not been shared?

*Guy Skinner – The FDA has provided all available illness data.*

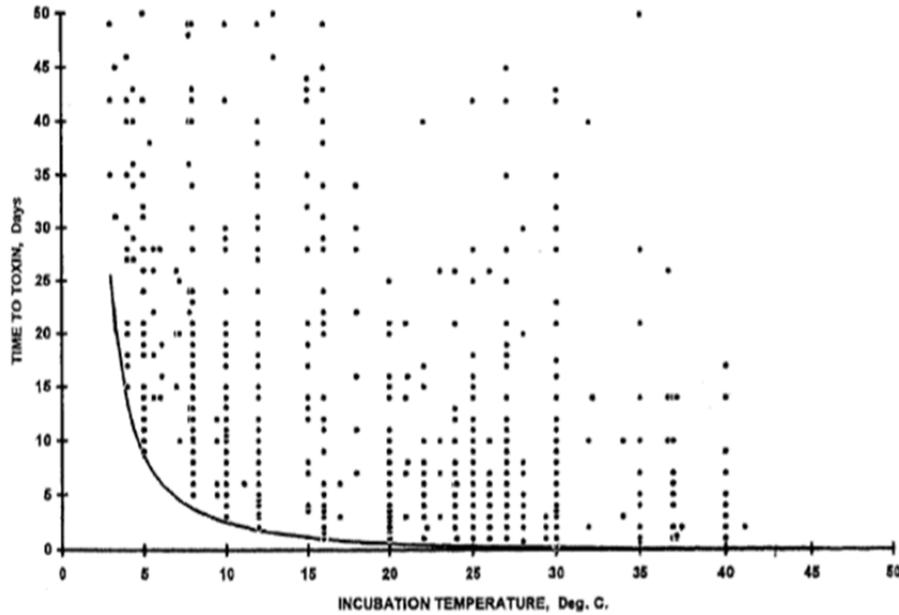
## **B. Science Related**

10. Provide evidence that proves *C. botulinum* can grow in a package of shucked oysters.

*Not aware of studies specific to oysters. Challenge studies were conducted on mussels. Mike Doyle suggested a challenge study should be conducted.*

11. What is the timing of *C. botulinum* formation after the product falls out of temp?

*The higher the temperature, the faster the toxins are produced.*



Skinner-Larkin Curve

12. Will the product actually spoil before *C. botulinum* formation?

*Could expiration date be used as a control?*

*Mary Losikoff - If data could be developed to show this, the FDA would consider. Expiration date has not been used as control in other foods and expiration dates for oysters have not been established. With other food, sometimes yes, sometimes no. Determining timing of spoilage would be difficult.*

*Based on consumer behavior studies relative to consumer reaction to expiration date, the FDA has no reason to believe consumers would react to TTI differently than expiration date.*

*If there is scientific evidence to support that spoilage occurs prior to the growth of *C. botulinum* and an expiration date on the container could indicate a date prior to the growth, this option could be explored. This is not something that has been done before so it would need an in depth study.*

13. Current NSSP storage and shipping conveyance requirements are at or below 45°F. Is 45°F adequate to address the *C. botulinum* hazard?

*Guy Skinner - Studies in published literature suggest that *C. botulinum* can grow at temperatures above 38°F.*

14. Identify other alternatives for *C. botulinum* control.

- a. Can the FDA and or the committee explore validation for theories that suggest pH and packaging play a role in reducing the threat of *C. botulinum*?

*If substances are added the shellfish may no longer be considered a fresh product and would be regulated under the Seafood HACCP Regulation. Studies would need to be conducted.*

- b. Might washing product in ozonized water, which might increase oxygen content (creating an aerobic condition), above where *C. botulinum* could survive provide any reduction of *C. botulinum*?

*Mike Doyle - Studies would need to be conducted to determine if ozonized water would prevent an anaerobic environment*

*Guy Skinner – Ozone is considered a human health hazard.*

- c. Does salinity or salt impact growth? If salt is shown to be an inhibitor, what might the necessary salt level be? In other words, a more thorough investigation of alternate controls rather than just container types.

*Studies would need to be conducted.*

*Jon Bell – Ozonized water in the process could increase rate of spoilage but would have little impact on eliminating an anaerobic environment in the package.*

*Mike Doyle – The rule of thumb is 5% salt serves as an inhibitor for *C. botulinum*. 2.5% salt combination with other substances such as ascorbic acid could be an effective inhibitor for *C. botulinum**

*Guy Skinner – The FDA would need to see an inoculation study*

*Mike Doyle – Responded to the following questions; What temperature is necessary to kill *C. botulinum*? Spores are killed at 100°C. Toxin can be inactivated at 180°F for 5 minutes or boiling.*

**C. Packaging Related**

15. Need to know the packing types that would be affected.

*Yoon Song - The screw cap containers and metal pop lid containers almost definitely pose an ROP concern. It is possible that all of the packaging types could pose an ROP concern. The Oxygen Transmission Rate of each container needs to be determined before a final decision can be made as to which containers may pose a ROP concern.*

16. Existing containers that are not a ROP concern pose significant problems for the industry. Please explain why.

*Austin Docter/AJ Erskine - Many shucking operations have found that the existing packages that are least likely to pose a ROP concern create shipping challenges due to package leakage from lids not staying in place. The leakage problem is compounded in air shipments. Shucking operations are also using seals for tamper proofing in response to customer preference. Using tamper proofing does not solve the leakage problem. Using the existing packages that are least likely to pose a ROP concern would not be a viable option for shucking operations. The industry has attempted to use film seals with containers that have lids which allow oxygen transfer. The films with microscopic holes leak and bulge.*

17. What is the criterion applied to exempt some containers but not others?

*Yoon Song - The oxygen transmission rate of the container determines if the packaging is ROP.*

18. There are presently no vented containers available to address the ROP concern. What containers/packaging alternatives are available to address the concern?

*Yoon Song/Austin Docter - A microporous membrane that has permeability as well as being waterproofed has been developed. Similar materials have been tested but tiny amounts of pressure can cause leakage.*

19. Is it possible to address ROP with containers currently on the market?

*See questions 16, 17 & 18.*

20. Could existing packages be modified to address *C. botulinum* concerns?

*Testing of current packaging must be conducted before this question can be answered.*

**D. Compliance & Logistics Challenges**

21. What would be the compliance options for meeting shipping and receiving requirements associated with reduced oxygen packaging?

*Joe Goetz – Currently, the FDA’s suggested compliance options are to keep the entire supply chain below 38°F with mechanical refrigeration or by completely submerging the product in ice and ensuring that each individual container has a time temperature indicator to ensure that none of the product has been exposed to temperatures above 38°F.*

22. What are the challenges created by requiring storage at 38°F?

*AJ Erskine/Austin Docter/Keith Jackson/Joe Goetz/Roger Peel/Bruce Flippens/Debra Scoville*

*Some processors would have to reconfigure their freezers or install additional ice machines which could be cost prohibitive. This would not be an issue at the retail level as most retailers already have coolers capable of maintaining 38°F.*

*Many companies have differentials in cooler temperatures, often as much as four (4) degrees. A requirement of 38°F could result in lower temperatures that could result in the formation of ice. Dealing with ice in a cooler would be problematic. Wholesalers presently have coolers that are maintained at 38°F and a requirement of 38°F would not affect wholesalers very much. Large retailers would not be affected by a requirement of 38°F. Smaller retailers could be affected.*

*Some retailers place retail packages in cases surrounded in ice. The use of ice requires disposal of water, which can be problematic.*

23. What are the challenges created by requiring shucked shellfish to be shipped at 38°F?

*Pat Barker – Trucks are capable of maintaining 38°F. When rejection is extremely costly, ice is used. The weight of ice increases cost of shipments. Ice can cause boxes to get wet and ruin the integrity of the box. TTR placement in the truck is critical. If individual TTIs were received, receiving customers would want to open every box.*

*Lack of understanding regarding use of TTRs.*

*Every shipment normally has its own TTR monitoring truck temperature.*

*Trucks now have technology available to track temperate from remote locations.*

*At some point there will be a need to address corrective actions.*

24. Confusion associated with different refrigeration requirements:

- i. NSSP - 45° F
- ii. NSSP - Vibrio shellstock internal temp requirement 50° F
- iii. Food Code for potentially hazardous foods - 41° F
- iv. ROP - 38° F

The refrigeration temperatures listed above represent different food safety requirements. Do these different requirements create confusion for wholesalers, retailers, or consumers?

*Wholesalers and retailers already cope with different refrigeration requirements. There is no way to ensure temperature safety for individual consumers.*

*Keith Jackson – There is confusion because most workers usually only have a high school education and do not understand different temperatures for different products. They often have to make split second decisions regarding receipt or rejection.*

*Confusion at retail especially when reduced oxygen package products are involved.*

*Requirements do not exist at retail to ensure that temperature is checked at receipt. Most illnesses occur at home and at restaurants. Inspectors conduct most education. It is not likely these retail inspectors in non-producing states can educate retailers about temperature controls for shellfish.*

25. Would <38°F require separate coolers for shucked shellfish?

*AJ Erskine/Austin Docter/Keith Jackson/Joe Goetz*

*Producer level: Yes for some. No for some.  
Some could adjust existing coolers.*

*Wholesale level: Not a problem.*

*Retail level: Large could. Smaller may need additional cooler or would choose to not handle ROP products.*

26. a) What is the ability for retail establishments to maintain multiple temperatures with their cases, i.e. oysters, at 38°F when other items are held at other temperatures?

*No additional comments. See question 24.*

- b) Will retailers be willing to change infrastructure?

*See question 25.*

27. Cold chain temps are typically > 38°F. What challenges would this create?

*See questions 24 and 25.*

28. Trucking companies won't run mixed load trailers at 38°F just to accommodate shucked shellfish. How do trucking companies address shipping products with different temperature requirements?

*Trucking companies can run mixed load trailers. They ship at the lowest temperature required for the products being shipped.*

*Pat Barker – Trucking companies will inform shipper of temperature the truck is running at. Will run mixed loads.*

*Temperature normally runs about 34°F-36°F.*

*If temperature gets below freezing, live product mortality can occur. See comments associated with ice in question 23.*

29. How will the consumer respond when the temperature device immediately changes color after leaving the deli case?

*How should consumer respond to TTI changes?*

*Mary Losikoff – Consumer should not purchase product if TTI indicates temperature abuse.*

*If TTI indicated change after purchase, consumer should discard.*

*Retail inspectors were not aware TTIs can change while product is in grocery cart before checkout.*

*What products currently require individual TTI? The FDA indicated most other seafood processors have changed packaging to avoid ROP controls.*

*Mary Losikoff – Imports.*

*If TTI requirement was adopted by the ISSC, the FDA would work with Conference of Food Protection to educate consumers.*

*Industry expressed concern that shucked shellfish may be the only domestic product which would be required to use individual TTIs and it appears that consumers do not know how to respond to TTI changes.*

*\*\*\*Ken will get statement from retail how they communicate to consumers.*

30. Would adequate icing be an acceptable alternative to a conveyance maintained at 45°F?

*Mary Losikoff- Yes, as long as the product is completely submerged in ice for the duration of shipment.*

*Pat Barker - questioned what does submerge in ice mean.*

*Submerged in ice and covered in ice might be interpreted differently.*

**E. Cost Related**

31. What is the cost associated with changing packaging?

*Rob Bartholomew - Reduced oxygen packaging could affect volume purchasing prices. To know the cost associated with packaging changes, current packaging must be tested to be classified as ROP or non-ROP.*

*If acceptable film could be identified, there would be a cost associated with applying the film. New packaging could affect shelf life.*

32. What is the cost associated with meeting lower temperature critical limits for shucked meats?

*Cost would vary and could include new coolers, new ice machines, time temperature indicators, etc.*

*Keith Jackson – Rejection cost*

*Joe Goetz – No additional cost at wholesale*

*Pat Barker – Additional cost of transportation at lower temperatures or use of ice*

*Roger Peel – Smaller retailer may need new cooler  
Disposing of ice  
Larger firms no additional cost*

*Debra Scoville – Should not result in additional cost at retail*

*Bruce Flippens – Disposal of water from ice melt  
Smaller retailers will not handle product*

*AJ Erskine – Smaller processors may not be able to pass the added cost to retailer in the present competitive food market*

33. What is the cost of new storage that would be compliant?

*AJ Erskine/Austin Docter/Keith Jackson/Joe Goetz/Roger Peel/Bruce Flippens/Debra Scoville*

*Cost would vary and could include new coolers, new ice machines, time temperature indicators, etc.*

34. If we had to put temperature tracker on every container, what would that cost?

*Joe Goetz- Most firms would pay \$1.00 for each TTI. Smaller firms could pay as much as \$2.50 - \$5.00 each. Bulk purchases could be made to reduce costs. 10,000 -20, 000 units would be around \$0.50 each. Austin Docter- 500,000 units could be as low as \$0.38 each. There is a shelf life for the TTI. This would limit volume purchasing.*

*Austin Docter – Would add \$500, 000 to \$700,000 to Taylor Shellfish's cost.*

*In addition to the cost of the TTI, there is also cost associated with added staff time for attaching the TTI to the package. TTI's must be stored in a specific way and they do have a shelf life. The failure rate is also a concern with TTIs.*

*Austin Docter – TTI's are not common place in the market and one of the smallest food industries in the US should not be the "guinea pig."*

*Mary Losikoff – The FDA asked for TTI cost information.*

*Austin Docter – TTI technology is not as reliable as it is thought to be.*

*Erin Butler – Cost of modifying HACCP plans and HACCP monitoring. TTI must be stored at 27°F. Could require additional equipment for storage.*

*Miranda Ries – May have to be attached in cooler. Could require modification of cooler to accommodate working space.*

*Pat Barker – Difficult to pass cost on to retailers because of imports and competitive pricing.*

35. What is the benefit of that cost especially if not resulting in significant benefit?

*Paul DiStefano - From the perspective of the FDA, spores are in the product so controls are needed. According to science, the benefit is no growth of C. botulinum thus avoiding the risk of illness that could cause death or have lifelong consequences for patients. Preventing an illness would reduce medical costs associated with illness and prevent the loss of human life, which has established monetary value.*

*The shelf life of shucked product is long enough to allow for C. botulinum growth.*

*Pat Barker – Should go with BMPs instead of requirements.*

*Joe Goetz – What is the mortality rate of illness involving shellfish?*

*Guy Skinner – Maybe as low as 15%.*

*Paul DiStefano – Suggested the FDA would consider modification to proposal 15-208.*

*Miranda Ries – Industry is aware of illness associated with Vv and Vp and understands the purpose of additional controls. The industry does not feel ROP controls are necessary without an illness burden.*

**F. Other**

36. Existing data about ROP and seafood lumps shellfish into a general fish category, can this be changed so that shellfish data is separate?

*Mary Losikoff - There has been no recorded cases of C. botulinum in oysters so there is no shellfish data that can be separated out.*

*Mobile Bay study shows C. botulinum was isolated from shellfish  
Mussel data – shows C. botulinum present in shellfish  
There was a C. botulinum case associated with frozen scallops in France in 1998.*

*Mike Doyle – referenced 2 research papers*

*Scallop industry may be using TTIs on paint cans.*

37. Request that the Committee engage with representatives from both the retail and shipping sectors and encourage their participation in these discussions.

*Retail and shipping sectors participated in this meeting.*

**G. Suggested Research**

The following is a list of research needs. The ISSC has some funding, however, it will take much more money to conduct these studies.

38. Need validated studies to determine the impacts of Proposal 15 - 208. Studies should outline shipping options and provide guidance for compliance with regulations.

*Mary Losikoff - Not sure of the intent of this question.*

39. Request proposal from the FDA for funding necessary to complete scientific information and a better understanding of how *C. botulinum* grows within shucked oysters.

*Mike Doyle – C. botulinum research is costly.*

*The FDA was not able to respond but indicated ISSC could make a request for funds to conduct study.*

40. Request scientific experiments – perhaps inoculate oysters and put them in different packages to see how they respond.

*Guy Skinner – Would need to address worst case scenario. May need to address geographical differences.*

*Mike Doyle – Determine if there are inhibitors that could inhibit growth without changing product*

*AJ Erskine – Are there currently inhibitors that explain why illnesses have not occurred?*

41. Is anyone aware of any studies that may offer alternatives?

*Jon Bell – If traditional containers are considered ROP and they have been used for a long time without illness, is there some way to use that as some baseline?*

*Mike Doyle – Shellfish determination is important*

*AJ Erskine – What competitive bacteria exist in the container?*

*Industry Question - What are other countries doing to address ROP concerns?*

## **VII. Reduced Oxygen Packaging Committee Action**

The Reduced Oxygen Packaging Committee developed the following recommendations:

1. The Executive Board identify funding for studies to determine the following:
  - a. Are there inhibitors that may be present or added?
  - b. Are the present shucking and packing practices providing controls that can explain why there are no reported cases of illness associated with *C. botulinum*?
  - c. Determine the effect that normal product deterioration has on PH. Determine if PH reaches a level that prohibits *C. botulinum* growth.
  - d. Determine if a reduced shelf life offers a potential *C. botulinum* control.
  - e. Conduct a study of competitive bacteria and its effect on *C. botulinum* growth.
2. The ISSC Executive Board requested that the FDA conduct a cost analysis of the impact of Proposal 15-208.
3. The ISSC Executive Board requested that the FDA determine how packaging changes would affect exports.
4. The ISSC Executive Board requested that the FDA consult with other countries to determine what they are doing to address *C. botulinum* in shucked shellfish.
5. The ISSC Executive Board requested that the FDA provide the rationale for the Agency's determination that *C. botulinum* is reasonably likely to cause illness associated with consumption of shucked shellfish.