Conference for Food Protection
Executive Board Meeting Committee Report

This report must be submitted to your Council Chair for review so that it can be approved and submitted to the Executive Board via the Executive Director 30 days before each Executive Board Meeting (held in April and August of each year). The report must be accompanied by an updated committee roster on the Excel spreadsheet provided (Committee Members Template) located here: http://www.foodprotect.org/work/.

COMMITTEE NAME: Cold Holding of Fish in Reduce Oxygen Packaging

COUNCIL (I, II, or III): III

DATE OF REPORT: 8/23/2009 (revised 9/24/09)

SUBMITTED BY: Fred Reimers

COMMITTEE CHARGE(S): Review the science behind CFP 2008 III-020 and make recommendations to the board

REQUESTED ACTION BY BOARD: See recommended action below under progress report.

PROGRESS REPORT / COMMITTEE ACTIVITIES WITH ACTIVITY DATES:

This committee held a conference call on August 21, 2009 after submission of 7 key documents dealing with the science and regulatory oversight of *Clostridium botulinum* type E toxin associated with reduced oxygen packaging of fishery products. To facilitate the discussion among the committee, discussion points were developed by the Chair that addressed A, Issue 2008 III-020 and B, Information available from the documents researched as part of the committee charge:

A. Discussion points addressed in the 2008 III-020 issue:

1. Issue correctly states that "some commercially manufactured reduced oxygen packaged fish products" are labeled "Keep refrigerated at 38^{o}F or less"

2. Implies that the precautionary language on the packing by the manufacturer is possible in some cases to be a safety standard as part of their HACCP plan.

3. Implies that this temperature is an identified CCP for the storage within a retail store when in fact it is really a preventative measure. The CCP per FDA is "Storage" and the control is "temperature."

4. Assumes that if the manufacturer labels 38^{o}F or less, then retailers should be required to refrigerate at this temperature so regulators at retail could enforce temperature not knowing any specific manufacturer's HACCP plan and why this is on the label.

5. FDA Food Code requires all ROP packaged fish products be maintained at or below 41°F regardless of what temperature is on the package.

6. Recommended solution states to have ROP fish products received from manufacturers with temperature less than 41°F be held at the labeled temperature.

B. Discussion Points on Information available on ROP fish products:

1. The issue presented to the CFP omits some important considerations relating to ROP fish products. For example, it lump sums all ROP manufactured fish products as having an implied risk of *C.botulinum* type E.

2. It is widely known that under the FDA mandated seafood HACCP requirements, manufacturers cover the possibility of C. bot type E toxin with temperature control. They add "Keep refrigerated at 38°F or less" as part of their HACCP plans, knowing you can only control product while in your control (i.e. you can't make labeling a "CCP" for retail or customer because you can't control what they do with the product. You can control temperature when in your control).

3. The outgrowth of C. *botulinum* type E in ROP refrigerated fish products is controlled in three different ways. Those ROP fish products that are frozen rely on freezing to control C. *botulinum* type E. Those products that are ROP, refrigerated and have a secondary barrier (i.e. brining, heat, etc.,) to control C. *botulinum* type E, then use refrigeration as a secondary barrier to control C. *botulinum* type A. Those products that are ROP and refrigerated without a secondary barrier rely solely on refrigeration to control C. bot type E.

4. Guidance on ROP seafood has stressed that temperature control alone is insufficient to monitor risk of *C.botulinum* type E toxin since it is a combination of both time and temperature and therefore wholesale manufacturers are expected to outline the time/temperature controls from receipt (including time in transit) through refrigerated storage. The use of time/temperature integrators is only required for those primary processors putting fish in ROP and selling it refrigerated. Additionally the TTI's are for consumer use only and at this point are not recommended as a monitoring device for time and temperature.

5. The issue to address is perhaps not having retailers have a separate temperature control for ROP fish products, but specifically for those based on risk, have TTI on their packages to control it through packaging to consumption by the consumer.

In the discussion on the points related to the issue, it was felt that the issue submitted to the 2008 CFP did not truly define the actual hazard nor did the recommended action control the actual risk. In this regard, the committee consensus was that retailers should have controls in place to assure that any "raw, unpreserved fishery products that are subjected to any form of reduced oxygen packaging and that rely solely on temperature alone as the means of controlling *C.botulinum* type E toxin, should be able to demonstrate these controls to regulatory inspectors upon request. This includes maintaining temperatures at or below 38°F regardless if the packaging by the manufacturer states to or not to. It was stated that labeling was by itself, does not provide sufficient control point for *C. botulinum* type E.

The 2008 III-020 issue should be revised and resubmitted to differentiate the requirement to control "raw, unpreserved fishery products" subjected to ROP either by the manufacturer and shipped to the retailer or the retailer subjecting unpreserved fishery products to any ROP at retail. The committee recognized that controls are in place to preclude ROP of refrigerated fishery products at retail without an approved HACCP plan and oversight by State regulators. It was also agreed that there was little knowledge of retailers that were actually handling raw, unpreserved

fishery products that are subjected to any form of reduced oxygen packaging. Some retailers are thawing ROP frozen fish and selling it as a refrigerated product.

It was further concluded that while manufacturers of ROP fishery products typically state keeping that product at or below 38°F, this is a typical requirement across the board to comply with their mandated seafood HACCP plan at the wholesale manufacturing or warehouse facility. It has long been acknowledged that HACCP Plans are site specific where controls can be implemented (verified and validated) and carry over to a facility outside that site, would not constitute a valid CCP or CP. Documents reviewed by this committee had evidence (this was concurred by several regulatory members on the conference call) that 41°F was sufficient for controlling *C.botulinum* type E toxin in fishery products that had other barriers beside temperature. For manufacturers that were producing consumer ROP packaged fishery products, they were being required under their HACCP plan to provide Time/Temperature integrators (TTI) to the final purchaser of the these products since they could not guarantee the maintenance of the cold chain based on time/temperature combined. Current shelf-life of ROP processed fishery products that have more than one barrier of control, are typically set to allow a combination of time/temperature greater than 38°F and not present a hazard.

Based on the charge given to this committee by the Executive Board, the committee recommends that the 2008 III-020 issue should be revised and resubmitted to differentiate the requirement to control "raw, unpreserved fishery products" subjected to ROP either by the manufacturer and shipped to the retailer or the retailer subjecting unpreserved fishery products to any ROP at retail. Since this hazard has been researched by the FDA and NFI, they should be involved with the revision and resubmission to the 2010 CFP.

References: Provided upon request by the Chair.

Revised based on FDA committee member edits received after submission.