

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 III-032

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code Annex – Clarifying ROP of fish requirements

Issue you would like the Conference to consider:

A recommendation is being made to clarify the requirements of reduced oxygen packaging (ROP) of fish that does not require a variance as described in 3-502.12 (C).

The 2013 FDA Food Code Section 3-502.12 discusses ROP of fish that does not require a variance. The public health rationale in FDA Food Code Annex 3 needs to clarify what "after packaging" means and why fish packaged using ROP methods in a retail establishment should not be sold that way to the consumer.

Public Health Significance:

The FDA Food Code Annex 3 explains the rationale for FDA Food Code Section 3-502.12 that "using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic¹." For this reason, ROP has become a very popular method of packaging in retail food establishments. Most raw animal foods require a HACCP Plan only, and not a variance, because high levels of competing microorganisms help to control hazards of concern, mainly *Listeria monocytogenes*. However, ROP of raw fish has additional requirements for storage because of the presence of non-proteolytic *Clostridium botulinum* type E in marine environments. This type of *Clostridium botulinum* can grow at temperatures as low as 37-38F². Given the potency of the toxin that would be created, food products where *C. botulinum* type E is reasonably likely to occur must be stored at frozen temperatures.

The Fish and Fisheries Products Hazard Controls Guidance document outlines that storage temperature for fish products should not exceed 38F at any point while the food is in the reduced oxygen environment. This document also acknowledges that "surveys of home refrigerators indicate that temperatures can exceed 50F²." Also, the FDA Food Code Annex 3 describes the need for retail food establishments to remove fish from ROP packaging before thawing when temperature (freezing) of the fish serves as the only barrier to non-

proteolytic *C. botulinum* type E growth¹. This logic can also be applied to ROP fish that is packaged in the retail food establishment.

There is some difference in interpretation among readers about the meaning of FDA Food Code Section 3-502.12 (C) "Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method." The term "after PACKAGING" has been interpreted as only immediately after packaging by some food service operators, leading to misunderstanding about what is allowed per the FDA Food Code. In order to reduce the risk of *C. botulinum* toxin production, ROP fish packaged at a retail level should not be sold directly to the consumer in ROP form. Furthermore, food service employees need to be clear that fish packaged in the food establishment using ROP must be removed from the ROP environment prior to thawing. Stating this clearly in the FDA Food Code Annex 3 for Section 5-502.12 will reduce confusion among industry and regulatory personnel.

References:

1. "Annex 3." FDA 2013 Food Code. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2013. 465. Print.
2. Fish and Fishery Products Hazards and Controls Guidance Fourth Edition. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2011.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA recommending the 2013 Food Code Annex 3, Section 3-502.12 be amended to include clarifying language for "after packaging." Recommended language to read (new language is underlined):

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria

Reduced Oxygen Packaging with Fish

Unfrozen raw fish and other seafood are specifically excluded from ROP at retail because of these products' natural association with non-proteolytic *C. botulinum* (primarily type E) which grows at 3°C (37-38°F). ROP of fish and seafood that are frozen before, during and after the ROP packaging process does not present this hazard. Fish that has been packaged using an ROP method must be removed from the ROP package before thawing process begins in order to fully satisfy the requirement of frozen "after ROP". Due to the fact the food establishment cannot verify that the fish would remain frozen until removed from the package once the product is sold to the consumer, fish that has been packaged using an ROP method must not be sold directly to consumers in the packaging.

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