

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-004

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014-I-25; new or additional information has been included or attached.

Title:

Report - Oyster Advisory Committee

Issue you would like the Conference to consider:

Issue 2014-I-25 was extracted by the body of State Delegates at the 2014 Biennial Meeting, in Orlando Florida. This action prompted forming an Executive Board Ad Hoc Committee to discuss the extracted no action decision. After discussion, the Executive Board Ad Hoc Committee determined that a Conference Committee should be formed to discuss and provide a recommendation at the 2016 Biennial Meeting.

Public Health Significance:

The Oyster Advisory Committee was tasked with developing recommendations to update the 2013 Food Code Section 3-603.11 Consumer Advisory, as follows, regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp.* to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means.

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients.

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request;

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the 2014 - 2016 Oyster Advisory Committee Final Report and thanking the committee members for their work.
2. No further action based on:
 - o the Interstate Shellfish Sanitation Conference (ISSC) letter dated July 7, 2014 that states the ISSC does not agree that the recommended solution of Issue 2014-I-025 would improve effectiveness or reduce illnesses; and
 - o the CFP Oyster Advisory Committee determination that the existing language in Section 3-602.11 of the 2013 FDA Food Code is adequate to address consumer advisory for raw molluscan shellfish.
3. The Oyster Advisory Committee be disbanded as they have completed their charges.

Submitter Information 1:

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Submitter Information 2:

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Content Documents:

- "Oyster Advisory Committee Final Report"
- "2014-2016 Oyster Advisory Committee Roster"

Supporting Attachments:

- "FDA References for Consumer Advisory"
- "ISSC letter July 2014"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Conference for Food Protection - Committee FINAL Report

Template rev: 06/21/2013

Committee Final Reports are considered DRAFT until deliberated and acknowledged by the assigned Council at the Biennial Meeting

COMMITTEE NAME: *Oyster Advisory Committee*

COUNCIL or EXECUTIVE BOARD ASSIGNMENT: Council I (established by Executive Board Ad Hoc Committee formed from extracted issue 2014-I-25)

DATE OF REPORT: November 6, 2015

SUBMITTED BY: *Lisa Staley, Committee Co-Chair, Thomas McMahan, Committee Co-Chair*

COMMITTEE CHARGE(s):

1. Develop recommendations to update Food Code section 3-603.11 Consumer Advisory regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp.* to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.
2. Report back to the 2016 Conference for Food Protection Biennial meeting on the committee's work and submit an issue amending the FDA Food Code as recommended by the committee.

COMMITTEE ACTIVITIES AND RECOMMENDATIONS:

1. Progress on Overall Committee Activities:

The Oyster Advisory Committee was tasked with developing recommendations to update the 2013 Food Code section 3-603.11 Consumer Advisory, as follows, regarding raw molluscan shellfish that have not been treated by a process sufficient to reduce *Vibrio spp.* to an undetectable level, as detected by the *Vibrio vulnificus* testing method in the most current edition of the U.S. Food and Drug Administration Bacteriological Analytical Manual.

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(B) DISCLOSURE shall include: (1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; or

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(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; or

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(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.

The Oyster Advisory Committee conducted three phone conferences (December 9, 2014, January 13, 2015, and February 26, 2015). A prevailing discussion during the calls was regarding the content contained in the letter from Interstate Shellfish Sanitation Conference (ISSC) dated July 7, 2014 addressed to Kevin Smith, CFSAN and Lori LeMaster, Conference Chair (see attached letter). In the letter, ISSC recommended that CFP take no action on Issue 2014-1-25 as written. This is due to the direct assertion that Council 1 Issue 2014-1-25 would not improve the Food Code consumer advisory effectiveness or reduce illnesses.

At the conclusion of the January 2015 call, the committee members were tasked to compare a side by side comparison of the recommended language from the original Council 1 Issue 2014-1-25 to the current language in section 3-603.11 of 2013 Food Code.

Committee members submitted written feedback that addressed varying positions that either suggested minor revisions to the current language in section 3-603.11 and the importance of having additional employee/consumer education available at establishments that serve raw oysters or took a position that no changes are warranted as the language contained within the committee charge is already covered within 3-603.11. The written feedback was discussed during the February 26, 2015 call. In addition, due to overwhelming discussion that supported a position that no change to the current language in the FDA Food Code is warranted to meet the intent of the charge, committee members asked to vote on whether the issue required further review. As a result of the vote, the committee determined that the current language in 3-603.11 of the 2013 FDA Food Code are sufficient to meet the intent of the charge and no changes to the FDA Food Code Consumer Advisory language are needed at this time.

2. The committee determined that the current language in the section 3-603.11 of the 2013 FDA Food Code is sufficient to meet the intent of the charge and no further discussions were needed.
 - a. FUTURE OF THE COMMITTEE: Recommendation that this committee be disbanded and not recreated.

CFP ISSUES TO BE SUBMITTED BY COMMITTEE:

1. Acknowledgement of the CFP 2014 - 2016 Oyster Advisory Committee Final Report and thanking the committee members for their work.
2. LIST OF SUPPORTING ATTACHMENTS
 - a. ISSC Letter dated July 7, 2014
 - b. Council 1, 2014-1-025
 - c. 3-603.11, 2013 FDA Food Code

COMMITTEE MEMBER ROSTER: See attached CFP Oyster Advisory Committee Roster

Committee Name: Oyster Advisory

Last Name	First Name	Position (Chair / Member)	Constituency	Employer	City	State	Telephone	Email
Staley	Elizabeth	Co-chair	State Regulator	MD Dept of Health and Mental Hygiene	Baltimore	MD	410 767-8407	lisa.staley@maryland.gov
McMahan	Thomas	Co-chair	Retail Food Industry	Meijer	Grandville	MI	616 481-5350	thomas.mcmahan@meijer.com
Marra	Paul	Voting Member	Retail Food Industry	Wegmans Food Markets, Inc.	Rochester	NY	585 328-2550	paul.marra@wegmans.com
Caldwell	Richard	Voting Member	State Regulator	SC DHEC	Columbia	CS	803 896-8995	caldwert@dhec.sc.gov
Henderson	Julie	Voting Member	State Regulator	Virginia Department of Health	Richmond	VA	804 864-7455	julie.henderson@vdh.virginia.gov
Jackson	Keith	Voting Member	Vending and Distribution Food Industry	Performance Food Group	Richmond	VA	804 484-7975	keithjackson@pfgc.com
Nardone	Angela	Voting Member	Food Industry Support	N2N Global	Longwood	FL	407 331-5151	anardone@us.n2nglobal.com
Davis	Douglas	Voting Member	Food Service Industry	Marriott Intenational	Bethesda	MD	301 318-8698	douglas.davis@marriott.com
Nesel	Nancy	Voting Member	Retail Food Industry	Amazon Fresh	San Bernardino	CA	502 641-9314	nesnancy@amazon.com
Ingham	Barbara	Voting Member	Academia	University of Wisconsin	Madison	WI	608 263-7383	bingham@wisc.edu
Ferko	Francis	Voting Member	Vending and	US Foods	Rosemont	IL	847 232-5896	frank.ferko@usfoods.com
Weddig	Lisa	Voting Member	Processing Food Industry	National Fisheries Institute	McLean	VA	703 752-8886	lweddig@nfi.org
Brown	Robert	Voting Member	Retail Food Industry	Whole Foods Market	Austin	TX	512 944-7405	robert.brown@wholefoods.com
Moore	Michael	Voting Member	State Regulator	MA Food Protection Program	Jamaica Plain	MA	617 983-6754	michaelmoore921b@gmail.com
Adams Hutt	Dr. Catherine	Voting Member	Food Service Industry	National Restaurant Association	Aubrey	TX	630 605-3022	cadams@rdrsol.com
Pilonetti	Therese	Voting Member	State Regulator	Colorado Dept of Public Health & Environment	Denver	CO	303 902-4372	therese.pilonetti@state.co.us
Frappier	Robert	Voting Member	Retail Food Industry	Ahold USA, Inc.	Quincy	MA	617 689-4090	rfrappier@aholdusa.com
Flippens	Bruce	Voting Member	District/Territory Regulator	District of Columbia Department of Health	Washington	DC	202-442-9039	bruce.flippens@dc.gov
Dela Cruz	Hector	Voting Member	Local Regulator	LA County Environmental Health	Van Nuys	CA	818 902-4468	hsdelacruz@gmail.com
Graham	Joe	Voting Member	State Regulator	Washington State Department of Health	Olympia	WA	360 236-3305	joe.graham@doh.wa.gov
Roxanne	Sharp	Voting Member	Local Regulator	Springfield/ Greene County Health Department	Springfield	MO	417 864-1424	rsharp@springfieldmo.gov
Stephens	Martin	Voting Member	District/Territory Regulator	National Park Service / US Public Health Service	Flagstaff	AZ	928 638-7355	martin_stephens@nps.gov
Plunkett	Davie	Voting Member	Consumer	Center for Science in the Public Interest	Washington	DC	202 777-8319	dplunkett@cspinet.org
Ewell	Harold	Non-Voting	Food Industry Support	N2N Global	Longwood	FL	412 418-7018	
Hails	Steve	Non-Voting	Food Industry Support	Sealed Air	Castle Rock	CO	303 910-5571	steve.hails@sealedair.com
Puente	Eric	Non-Voting	Retail Food Industry	Whole Foods Market	Austin	TX	512 415-6617	
Newton	Anna	Non-Voting	Federal Regulatory	CDC			404 639-2839	AENewton@cdc.gov
Cartagena	Mary	Non-Voting	Federal Regulatory	FDA	College Park	MD	240-402-2937	mary.Cartagena@fda.hhs.gov

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Page 405 Annex 3 – Public Health Reasons/Administrative Guidelines

3-201.15 Molluscan Shellfish.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses. Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *Listeria monocytogenes* that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite, cooperative action plan involving Federal and State public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical conditions.^{Pf}

July 7, 2014

Kevin Smith
CFSAN
5100 Paint Branch Parkway
College Park, MD 20740

Lori LeMaster
CFP Conference Chair
TN Department of Health
Environmental Health
Andrew Johnson Tower, 4th Floor
Nashville, TN 37234

Dear Kevin Smith and Lori LeMaster

The Interstate Shellfish Sanitation Conference (ISSC) has reviewed the Conference for Food Protection (CFP) action on Issue I-025 and offers the following comments for consideration by the CFP and the USFDA.

The background information included in the Public Health Significance of the Issue is misleading. Recent increases in *Vibrio* illnesses are not at all related to *Vibrio vulnificus* (*V.v.*). The increases are associated with the spread of O4:K12 and O4:Kunttypeable strains of *Vibrio parahaemolyticus* (*V.p.*). Historically these strains have caused illnesses in the Pacific northwest, but recently, illnesses have begun to occur on the northeast coast of the United States. The risk of death associated with *V.p.* is overstated. Death from *V.p.* is extremely rare. The rate of illness associated with *V.v.*, the species associated with severe illness and death, has not increased and remains stable at approximately 35 illnesses annually.

The ISSC supports the use of consumer advisories and welcomes efforts to improve their effectiveness. However, the ISSC does not agree that the recommended solution of Issue I-025 would improve effectiveness or reduce illnesses.

The ISSC is continuing to focus efforts to better understand the virulent strains of *V.p.* associated with recent increases in illnesses. The risk of *V.p.* illnesses associated with these virulent strains appears to be a regional problem. There are harvest regions of the U.S. that have not been the source of shellfish associated with increases in reported illnesses. Additionally, the language does not recognize that the risk level is not constant throughout the year. At lower water temperatures the risk of *V.p.* illness greatly diminishes. The proposed language would not be helpful to consumers in identifying raw shellfish that actually pose a higher risk of illness. Additionally, the proposed burden for providing proof of post-harvest processing (PHP) in Section E. is not necessary. Presently the FDA Interstate Certified Shellfish Shippers List (ICSSL) contains the relevant information and shellfish that have been PHP treated are labeled as such. The reference for the analytical method is also inaccurate.

The recommended solution assumes that the relative risk of consumption of raw shellfish is much higher than other animal foods that are consumed raw, undercooked, or not otherwise processed to eliminate pathogens. The recommended solution in the Issue is not the most appropriate way to address relative risk.

July 7, 2014

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The ISSC recommends that the CFP take no action on Issue I-025 as written. The CFP is encouraged to continue to pursue steps to improve the effectiveness of consumer advisory and compliance with existing temperature control, handling and record keeping requirements at retail and food service establishments. The ISSC offers its assistance in any way that you think appropriate.

Sincerely,



Maryanne Guichard
Executive Board Chair

/nsd/ccm

cc: ISSC Executive Board
David McSwane, CFP Executive Director
Paul DiStefano, USFDA