Conference for Food Protection Council III 2012 Issue Recommendations Indianapolis, Indiana

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Conference for Food Protection – 2012

Council III

No.	Title	AS	AA	NA	Other
III-001	Report - Hand Hygiene Committee	Х			
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III-003	Clarification of Section 3-301.11(D) Preventing Contamination from Hands.		Х		
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III-005	Clarify When Handwashing is Required before Donning/Changing Gloves				Moved to C I
III-006	Re-create - Hand Hygiene Committee		Х		
III-007	Rationale for 100 Degree F. Hot Water at Hand Sink.	X			
III-008	Addressing Nontyphoidal Salmonella in the FDA Food Code		Х		
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III-010	ROP 2: Definitions for Reduced Oxygen Packaging	X			
III-011	ROP 3: Sous Vide - Cook Chill Time and Temperature Control	Х			
III-012	ROP 4: Sous Vide and Cook Chill, pH and Temperature Control		Х		
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III-015	Improving Ground Beef Food Safety in Restaurants and Food Service			Х	
III-016	Separation of Non-Intact Meats from Whole-Muscle Cuts of the Same Type	Х			
III-017	Thawing Vacuum Packaged Frozen Fish		Х		
III-018	Harmonize Time/Temperature Charts in Food Code with FSIS Guidance		Х		
III-019	Final Cooking Temperature Requirement for Non- Continuous Cooking		Х		
III-020	Reduced Minimum Temperature for Microwave Steam Cooking of Seafood		Х		
III-021	Determining the Disposition of Refrigerated PHF (TCS food) above 5°C (41°F)		Х		
III-022	Revision of the 2006 CFP Listeria Retail Guidelines	Х			
III-023	Amend FDA Food Code Section 3-403-11(C)		X		
III-024	Cleaning of Food Contact Surfaces between Raw Animal Foods		Х		
III-025	Dual-Step Hand Cleanse-Sanitize Protocol without Water		X		
III-026	Expanded Use of Time Only as a Public Health Control		Х		

No.	Title	AS	AA	NA	Other
III-027	Food Guards			Х	
III-028	Acrylamide Management in Retail Preparation of Processed Potato Products			Х	
III-029	Public Release of Food Allergy Resource Document		Х		
III-030	Allergen Committee - Importance of Allergen Guidance to CFP Members		Х		
I-017	Use of Consumer Advisory for Non-Continuous Cooking			Х	

Council Accepted as Accepted as Amended No Action X

Delegate Action: Accepted x Rejected

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Title: Use of Consumer Advisory for Non-Continuous Cooking

Recommended Solution:

The Conference recommends no action.

Reason:

If the recommended action were taken, there is a potential increased public health risk for certain products.

Issue: 2012 III-001

 Council
 Accepted as
 Accepted as

 Recommendation:
 Submitted
 X
 Amended
 No Action

 Delegate Action:
 Accepted
 x
 Rejected

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Title: Report - Hand Hygiene Committee

Recommended Solution:

The Conference recommends

- acknowledgement of the 2010-12 Hand Hygiene Committee report, and
- thanking the 2010-2012 Hand Hygiene Committee for its work addressing scientific, regulatory and behavioral considerations related to efficacy and risk reduction strategies of alternative hand hygiene regimes compared to handwashing.

The future of the Hand Hygiene Committee is submitted as a separate Issue.

Council Accepted as Accepted as Amended No Action X

Delegate Action: Accepted x Rejected

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Title: Disseminate the Outcome of 2010-2012 Hand Hygiene Committee

Recommended Solution:

The Conference recommends no action.

Reason:

Too many questions associated with procedures involving peer review of the document, publication, and questions associated with ownership of document. There are no procedures in place to submit committee documents for peer review.

Council Accepted as Accepted as Amended X No Action

Delegate Action: Accepted x Rejected

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Title: Clarification of Section 3-301.11(D) Preventing Contamination from Hands.

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-301.11(D), be amended as follows (new language shown with underline):

- (D) Paragraph (B) of this section does not apply to a food employee that contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to a food that:
 - (1) Contains a raw animal food and is to be cooked in the food establishment to heat all parts of the food to the minimum temperatures specified in ¶3-401.11(A)-(B) or §3-401.12; or
 - (2) Does not contain a raw animal food but is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 74°C (165°F) 63°C (145°F).

Issue: 2012 III-004

Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	X		
Delegate Action:	Accepted	X	Rejected		_			
All information above the line	is for conference use	only.						
Title: Double Glove Use or Glove Changing in Relation to Handwashing								
Recommended Solution: The Conference recommends no action.								
Reason:								

Recommended solution has been incorporated into Issue 2012 III-006.

Issue: 2012 III-006

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Council Recommendation:	Accepted as Submitted		Accepted as Amended	X	No Action	
Delegate Action:	Accepted	X	Rejected		_	
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Title: Re-create - Hand Hygiene Committee

Recommended Solution:

The Conference recommends

- 1. Re-creation of the Hand Hygiene Committee to:
 - More closely examine the current Food Code requirements for when employees are required to wash their hands using soap and running water.
 - If credible research suggests that one or more of the situations under which food employees are currently required to wash their hands does not result in meaningful risk reduction, work with FDA to explore whether those mandates could be modified, either in the Code itself or by recognizing when it is appropriate to waive the requirement (e.g., other approaches to hand hygiene are available and practiced).
 - Determine if/when double gloving procedures would be acceptable without handwashing. If so, what would those acceptable procedures be?
 - Determine what glove criteria or standards would need to be met for a glove to be considered a utensil and not require handwashing?
- 2. The re-created committee uses the report of the 2010-2012 committee as a reference, illustrating the interactions of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing. The committee should characterize what recent research tells us about:
 - the extent to which the current minimum requirements for how and when employees are to wash their hands are effective in rendering food employees hands free of various soils, as well as, any pathogens of concern;
 - what other regimens for cleansing employees hands, if any, may deliver outcomes that are similar to or better than handwashing so as to suggest that they could be included as acceptable methods for rendering hands free of soil and pathogens.
- 3. The committee report back its findings to the 2014 Biennial Meeting.

Issue: 2012 III-007

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Council Recommendation:	Accepted as Submitted	X	Accepted as Amended	 No Action	
Delegate Action:	Accepted	X	_ Rejected	 _	
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Title: Rationale for 100 Degree F. Hot Water at Hand Sink

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting that they support and/or fund scientific research that would justify the appropriate water temperature for handwashing at a hand sink.

Issue: 2012 III-008

Council Recommendation:	Accepted as Submitted		Accepted as Amended	X	No Action	
Delegate Action:	Accepted	X	Rejected		_	
All information above the line	is for conference use o	nly.				

Title: Addressing Nontyphoidal Salmonella in the FDA Food Code

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended with language to meet the following intent:

- 1. Include illness due to nontyphoidal *Salmonella* (NTS) in Chapter 2 of the Food Code which:
 - Requires food employees to report the diagnosis of NTS.
 - Prompts the Person in Charge to exclude a food employee with diagnosis of NTS.
 - Reinstates a food employee who provides to the Person in Charge written
 medical documentation from a health practitioner that states the food employee
 is free from NTS and, where appropriate, approval from the regulatory authority.
- 2. Add language noted below addressing nontyphoidal *Salmonella* to the public health reasons in Annex 3 in the FDA Food Code (new language has been underlined), and incorporating associated changes in the Part 2-2 Employee Health Tables (not shown).

Add information about nontyphoidal Salmonella to read:

Nontyphoidal Salmonella (NTS) enterica serotypes are among the most common and important foodborne pathogens. NTS are estimated to cause more than one million domestically acquired foodborne illnesses in the United States each year (Scallan et. al. 2011), and are the leading cause of hospitalizations and deaths due to foodborne illness in the United States (Barton-Behravesh et al. 2011, CDC 2011). Whereas reductions in incidence have been achieved for many other foodborne pathogens in recent years, no significant change in incidence of NTS infections has occurred since the start of FoodNet surveillance during 1996–1998 (CDC 2011). Therefore, further interventions are needed to reduce the incidence of NTS infections.

Commercial food establishments are an important setting for the transmission of NTS, both in the form of recognized foodborne disease outbreaks as well as sporadic infections.

During 1998 to 2002, the 585 Salmonella enterica outbreaks reported to the Centers for

Disease Control and Prevention accounted for 49% of all bacterial outbreaks (Lynch et al. 2006). Fifty-three percent of Salmonella outbreaks occurred in commercial food establishments, the most common setting for Salmonella outbreaks (Lynch et al. 2006). Outbreaks of salmonellosis at commercial food establishments frequently involve direct transmission to patrons from fresh produce or undercooked foods of animal origin, or cross contamination from these foods. However, numerous NTS outbreak investigations have implicated food workers as the source of the outbreak or strongly suggested transmission from food workers (Ethelberg et al. 2004; Greig et al. 2007; Hedberg et al. 1991; Hedican et al. 2009; Hundy and Cameron 2002; Khuri-Bulos et al. 1994; Maguire et al. 2000; Medus et al. 2006; Todd et al 2007a, 2007b).

In a study of restaurant-associated salmonellosis outbreaks in Minnesota published by Medus et al. (2006), the importance of infected food workers as a source of contamination in the outbreaks was supported by several observations. First, a specific food vehicle was statistically implicated or suspected in a low proportion of the restaurant outbreaks (39%), which suggests that the specific food items or food handling errors were not the primary causes for these outbreaks. Second, food workers infected with NTS were identified in the majority (83%) of the outbreak investigations. Overall, 12% of the food workers tested positive for NTS. Infected food workers who reported a history of illness shed NTS in the stool for a median of 1 month. The authors concluded that regardless of the original source of a Salmonella outbreak in a restaurant (e.g., raw meat or eggs), the initial source of a salmonellosis outbreak, food workers frequently serve as reservoirs for NTS and contribute to transmission to patrons. Thus, assessment of food worker history, i.e. symptoms and exposures, stool samples and exclusion or restriction of infected food workers from the food establishment are essential for controlling restaurant-associated outbreaks of salmonellosis.

In a study of food workers with salmonellosis who were detected through routine surveillance (Medus et al. 2010), 2.2% of identified culture-confirmed Salmonella cases were food workers, and identification of these cases were critical to the identification of numerous outbreaks. The authors concluded that the rapid identification and follow-up of food workers among reported cases of salmonellosis is important to the early detection and control of outbreaks in restaurant settings. Importantly, even hostesses, servers, bartenders, and others who theoretically have limited food preparation duties can serve as sentinels of transmission within the restaurant. The authors also stated that food workers should be considered an important source of Salmonella transmission, and those identified through surveillance should raise a high index of suspicion of a possible outbreak at their place of work. Food service managers need to be alert to Salmonella -like illnesses among food workers to facilitate prevention and control efforts, including exclusion of infected food workers or restriction of their duties.

The Food and Drug Administration's Food Code does not currently exclude or restrict food workers with a NTS infection (US FDA 2009). Restriction of food workers infected with NTS after resolution of symptoms is not a national standard. However, because of the prolonged duration of shedding of NTS, evidence that food workers have been the source of foodborne outbreaks, evidence that food workers work while ill (Green et al. 2005), and evidence of inadequate hand hygiene practices (Green et al. 2006; US FDA 2004), exclusion or restriction of infected food worker duties is a reasonable public health

measure. At a minimum, potential for transmission and how to prevent it should be discussed with the food worker and their manager.

The role of infected food handlers in nontyphoidal salmonellosis outbreaks in establishments serving highly susceptible populations has not been examined. Such events are much less frequent than those in establishments not serving highly susceptible populations. For example, from 1998-2011 to date, only 29 nontyphoidal salmonellosis outbreaks were reported to CDC that occurred in nursing home facilities, compared with 731 outbreaks in restaurants or delis. There are many highly susceptible persons in the general population who eat in regular, noninstitutionalized settings. A more restrictive exclusion criteria for establishments serving highly susceptible populations is not warranted at this time.

The biology of NTS and the epidemiology of salmonellosis are complex; food workers may be an underappreciated part of that complexity. In order to decrease the incidence of NTS infections in the United States, commercial food establishments should also be targets for more focused prevention measures, and prevention and control efforts should consider food workers as an important source of NTS transmission.

NONTYPHOIDAL SALMONELLA General Description:

Nontyphoidal Salmonella enterica (NTS) are bacteria that cause a diarrheal illness called salmonellosis. NTS are among the most common and important causes of enteric disease. An estimated 1.2 million cases occur annually in the United States; of these, approximately 42,000 are culture-confirmed cases reported to the Centers for Disease Control and Prevention.

<u>Salmonella</u> lives in the intestines of animals or humans. It can be found in water, food, soil, or surfaces that have been contaminated with the feces of infected animals or humans. People can become infected with <u>Salmonella</u> by:

- Eating foods contaminated with the bacteria. Contaminated foods are often of animal origin, such as beef, poultry, unpasteurized milk, or eggs. Fruits and vegetables may also be contaminated. Any food can be contaminated by an infected food handler.
- Contacting farm animals or pets (including reptiles, amphibians, chicks, and ducklings), animal feces, or animal environments.
- Touching contaminated surfaces or objects and then touching ones mouth or putting a contaminated object into ones mouth.
- Drinking contaminated water

The majority of infections are thought to be acquired through consumption of contaminated food.

Incubation Period:

Symptoms often begin 12 to 72 hours after being exposed to the bacteria, although it can take up to a week or more for symptoms to develop in some people.

Symptoms and Complications:

Symptoms of salmonellosis include diarrhea, abdominal cramps, and fever. The illness usually lasts 4 to 7 days. Persons with NTS infections usually recover without treatment. However, in approximately 20% of persons, the illness is so severe that hospitalization is required. In these patients the NTS infection may spread from the intestine to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. An estimated 400 fatal cases of salmonellosis occur each year. A small number of persons experience long-term consequences from NTS infections, such as arthritis that can last for months or years.

Antibiotic treatment for salmonellosis is generally not indicated for typical intestinal illness. Antibiotics typically do not shorten the duration of illness or eliminate the carrier state. However, antibiotic treatment is recommended for persons who develop invasive (extraintestinal) infections, infants under 2 months of age, the elderly, or those who have certain underlying medical conditions that predispose them to invasive infection.

Infectivity:

The minimum infectious dose of NTS for humans is generally described as 100 to 1,000 organisms. However, doses of fewer than 10 organisms have caused illness in multiple outbreaks. Persistence of NTS in the stool after the acute phase of illness is a well described consequence of NTS infections. This persistence is often referred to as a temporary carrier state, and the term "shedding" is used to describe the excretion of Salmonella in the stool.

Studies have consistently shown that the median duration of shedding in the stool to be 4 to 5 weeks after onset of acute gastroenteritis. Persons who have been exposed to NTS but who never develop symptoms can also be temporary carriers of NTS; these persons shed NTS for a shorter period of time than persons who experienced illness. Carriers of NTS are known to shed the bacteria in the stool intermittently. Treatment with antimicrobials does not eradicate NTS from stool and may actually prolong the duration of shedding.

Council Recommendation:	Accepted as Submitted	X	Accepted as Amended	No Action	
Delegate Action:	Accepted	x	Rejected		
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Title: Report - ROP Committee (ROP 1)

Recommended Solution:

The Conference recommends acknowledgment of the 2010-12 Reduced Oxygen Packaging Committee Report with thanks to the members of the Committee for completing their task, and disbanding the committee.

Issue: 2012 III-010

Council Recommendation:	Accepted as Submitted	X	Accepted as Amended		No Action _			
Delegate Action:	Accepted	x	Rejected					
All information above the line	All information above the line is for conference use only.							

Title: ROP 2: Definitions for Reduced Oxygen Packaging

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions and strike through for language elimination):

1) Modify language in Section 1-201.10(B) Reduced Oxygen Packaging (2) (e) to read:

Sous vide PACKAGING, in which raw or partially cooked FOOD is placed in a hermetically sealed impermeable bag vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

2) Add a new subparagraph (3) to Section 1-201.10(B) Reduced Oxygen Packaging with exclusionary language to read:

Section 1-201.10(B) (3) Reduced Oxygen Packaging does **not** include:

- a) <u>Placing product in a bag and sealing it immediately prior to or after, cooking,</u> cooling or reheating the product as long as the product is:
 - i. Labeled with the time and date the product is placed in the bag; Pf
 - ii. Removed from the bag within 48 hours of the time product is placed in the bag; P
- 3) Modify language on page 572 in Annex 6 Food Processing Criteria, Section 2 Reduced Oxygen Packaging, paragraph (B) Definitions, subparagraph (1) to read:

Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is <u>sealed</u>, or closed with a plastic or metal crimp.

4) Modify language on page 573 in Annex 6 Food Processing Criteria, Section 2 Reduced Oxygen Packaging, paragraph (B) Definitions, subparagraph (5) to read:

Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a near perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

Issue: 2012 III-011

Council Recommendation:	Accepted as Submitted	Х	Accepted as Amended	 No Action	
Delegate Action:	Accepted	х	Rejected		
All information above the line i	is for conference use only	<i>/</i> .			

Title: ROP 3: Sous Vide - Cook Chill Time and Temperature Control

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions and strike through for language elimination):

Cook-Chill or Sous Vide

Section 3-502.12 (D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES <u>POTENTIALLY HAZARDOUS FOOD</u> (<u>TIME/TEMPERATURE CONTROL FOR SAFETY FOOD</u>) FOOD using a cook-chill or sous vide process shall:

- (1) Implement a HACCP PLAN that contains the information as specified under ¶ 8-201.14(D); Pf
- (2) Ensure the FOOD is:
 - (a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER, Pf
 - (b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11 (A and B), P
 - (c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4. P
 - (d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F), P
 - (e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and subsequently: P

- (i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;^P
- (ii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours 7 days, at which time the FOOD must be consumed or discarded; P

This issue recommends no additional changes to remainder of Section 3-502.12 (D).

Issue: 2012 III-012

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Council Recommendation:	Accepted as Submitted		Accepted as Amended	X	_ No Action	
Delegate Action:	Accepted	X	Rejected		_	
All information above the line	e is for conference use	only.				

Title: ROP 4: Sous Vide and Cook Chill, pH and Temperature Control

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code Annex (as modified by the Supplement issued in 2011) be amended to reflect that ROP foods with an equilibrated pH 5.0 or less can safely be stored at 41°F or less for up to 30 days after the date of packaging with a variance. In addition, amend FDA Food Code Section 3-502.12(B)(3)(b), changing 14 to 30 days.

Issue: 2012 III-013

Council Recommendation:	Accepted as Submitted	Х	Accepted as Amended	 No Action	
Delegate Action:	Accepted	х	Rejected		
All information above the line i	is for conference use only	<i>/</i> .			

Title: ROP 5: Requirement to Submit HACCP Plan to Regulatory Authority

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (using underlining for additions):

- 1) Add a new Subparagraph (7) to Subparagraph 3-502.12 (B)
- 3-502.12 Reduced Oxygen Packaging without a Variance, Criteria.
 - (B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:

 Pf...(Subparagraphs 1-6 are unchanged)
 - (7) Is provided to the regulatory authority prior to implementation.
- 2) Modify Paragraph 8-201.13 (B)
- 8-201.13 When a HACCP Plan is Required.
 - (B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN which is provided to the regulatory authority prior to implementation as specified under § 3-502.12.

Issue: 2012 III-014

Council Recommendation:	Accepted as Submitted		Accepted as Amended	X	No Action	
Delegate Action:	Accepted	х	_ Rejected		_	
All information above the line	e is for conference use	only				

Title: ROP 6: Updates to 2009 Food Code Annexes 2 and 3

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the Annex to the 2009 Food Code (as modified by the Supplement issued in 2011) be amended using the text below as appropriate and depending upon the recommendation by the Conference in the recommended solutions on Issues 2012 III-010 through III-013 (new language shown with underline).

FDA Food Code 2009: Annex 3 - Public Health Reasons / Administrative Guidelines - Chapter 3, Food

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). 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 aerobic.

This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cc/m² cm²/m³/24 hours or greater[i]. A reduced oxygen atmosphere will often result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.

If packaging material OTR is to be used as a barrier to *C. botulinum* growth and an exemption from ROP HACCP requirements in sections 3-502.11 and 3-502.12 the operator must provide scientific evidence to the regulatory authority that the packaging, under it's

intended use, maintains an oxygen atmosphere for the duration of the refrigerated shelf life. At the time of this writing, only one packaging product possesses an OTR greater than 10,000 cc/m2/24h with scientific evidence acceptable to the FDA that it maintains an aerobic atmosphere when shrink packaging raw seafood with no inclusions (marinades, oils, etc). The packaging allows oxygen to pass permitting resident bacteria to spoil the seafood before the toxin of *C. botulinum* could develop[ii].

Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic *C. botulinum* and *L. monocytogenes* are able to multiply slowly well below 5°C (41°F). For this reason, *C. botulinum* and *L. monocytogenes* become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of *C. botulinum* and *L. monocytogenes* without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control *C. botulinum* and *L. monocytogenes* when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include a_w of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. *C. botulinum* will not produce toxin below an a_w of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of *C. botulinum* spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic factors can also control the growth and/or toxin production of *C. botulinum* and *L. monocytogenes*.

Non-potentially hazardous food (non-time/temperature control for safety food) as defined by interaction tables A and B (section 1-201.10) contain pH and Aw intrinsic factors that prevent the growth of both *C. botulinum* and *L. monocytogenes*. Therefore these foods are exempt from the reduced oxygen packaing HACCP requirements of 3-502.11 or 3-502.12 provided they are as received and not modified in the operation and labeled as non-potentially hazardous foods.[iii]

Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby,

Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of *L. monocytogenes* under modified atmosphere conditions.

When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of *C. botulinum* and *L. monocytogenes*. Non-proteolytic C. botulinum spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by C. botulinum, an anaerobe, ROP foods must be held at 3°C (38°F) or less. Listeria monocytogenes is able to grow, although very slowly, at temperatures down to - 1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cookchill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential. Cooking at low temperatures below that stated in 3-401.11 (A-C) may not destroy vegetative cells and may in fact become an incubation temperature for some pathogens. Any use of these low cooking temperatures combined with ROP packaging must be approved via the variance process[iv].

Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to 5°C (41°F), 1°C (34°F), removing product to a different refrigeration unit and holding at any temperature up to 5°C (41°F) for up to 7 days 72 hours with the total storage time not to exceed 30 days[v]. This situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or less.[vi] The third option relies on a secondary barrier, pH. When the pH is at or below 5.0 *C. botulinum* and *L. monocytogenes* cannot grow at 5°C (41°F). Therefore, 30 days storage is permitted. Note that when using pH as a barrier, a pH measurement, calibration and recordkeeping SOPs are required. is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging.[vii] The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.

Since there <u>may not be</u> are no[viii] other controlling factors for *C. botulinum* and *L. monocytogenes* in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to

continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or <u>5°C (41°F)</u> <u>3°C (38°F)</u> or less[ix]. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickelsized data loggers are available to record temperatures which can be displayed using computer software. Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.

Time is also a factor that must be considered in ROP. Processes that use ROP packaging for storage less than 48h do not pose a hazard for pathogen growth when refrigerated at 5°C (41°F) or less and are exempt from the HACCP requirement of sections 3-502.11 and 3-502.12. Examples are sous vide cooking provided a proper cooking temperature is used according to 3-401.11 (A-C) followed by immediate service and enhanced cooling of foods using ROP bags. The main factors in this exemption are that the food must be date marked and consumed or removed from packaging after 48h[x]. The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process or inhibiting their growth, preventing recontamination, and then refrigerating at 34°F or less with an option of 3°C (38°F) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements. The 7 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 5°C (41°F) or less[xi]. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill and sous vide processes.

The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.

A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. *C. botulinum* and *L. monocytogenes* are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.

When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended

for use is safe. It is highly recommended that the operator and/or the regulatory authority consult a process authority to validate the scientific evidence the ROP methodology intended for use is safe[xii].

Unfrozen raw fish and other seafood are specifically excluded from ROP <u>without a variance[xiii]</u> because of these products' natural association with *C. botulinum* type E which grows at or above 3°C (37-38°F). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.

- [i] Corrects inaccurate description of OTR to that found in the US FDA Fisheries HACCP Guide.
- [ii] Suggested text to clarify 10 K bag exclusion. Would require variance for all uses other than that approved by FDA Seafood HACCP Guidance for raw seafoods.
- [iii] Adds text to clarify non-PHF exclusion from ROP HACCP 3-502.11 or 3-502.12.
- [iv] Added text to clarify low temperature cooking processes, e.g. sous vide to obtain a variance.
- [v] Changes this section to accommodate changes made to 3-502.12 (D)(2)(e).
- [vi] Just deleting this text. It appears extraneous.
- [vii] Corrects text to accommodate changes made to 3-502.12 (D)(2)(e)(iii).
- [viii] Correct text to acknowledge that there may be other controlling factors.
- [ix] The 38oF option has been deleted.
- [x] This may need to be tweaked somewhat after the committee finalizes the definition change that establishes the 48 h storage point.
- [xi] Clarifies this section to permit the 7 day at 41F code change.
- [xii] This change was discussed by the committee and I am suggesting placing it here.
- [xiii] Corrects text that implies ROP of non-frozen fish with a variance is not permitted.

Council Accepted as Accepted as Amended No Action X

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Improving Ground Beef Food Safety in Restaurants and Food Service

Recommended Solution:

The Conference recommends no action.

Reason:

Impractical for implementation.

Issue: 2012 III-016

Council Recommendation:	Accepted as Submitted	X	Accepted as Amended		No Action		
Delegate Action:	Accepted	x	Rejected _				
All information above the line is for conference use only.							

Title: Separation of Non-Intact Meats from Whole-Muscle Cuts of the Same Type

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to delete Section 3-302.11(A)(3) and delete corresponding Public Health Reason language from the Model Food Code as follows (deleted language shown with strike-through):

Section 3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.

(3) Not storing and displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat unless they are packaged in a manner that precludes the potential for cross-contamination;

(Public Health Reason) Section 3-302.11

Packaged and Unpackaged Food - Protection Separation, Packaging, and Segregation.

Storing or displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat can also present a cross-contamination hazard unless they are packaged and displayed in a manner that creates a barrier to prevent leakage of contents from one package to the other. Cooking recommendations assume that lower levels of contamination will be present in whole muscle products than in non-intact meats. If the whole muscle product is subject to cross-contamination, the recommended cooking temperature may not be sufficient to ensure the safety of the product.

					Issue: 201	2 III-017
Council Recommendation:	Accepted as Submitted		Accepted as Amended	X	_ No Action	
Delegate Action:	Accepted	X	Rejected		_	
All information above the line	e is for conference use	e only.				

Title: Thawing Vacuum Packaged Frozen Fish

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended adding a new Paragraph E to Section 3-501.13, Thawing (new language in underline format):

Frozen fish that is vacuum packaged or otherwise reduced-oxygen packaged and labeled to use immediately after thawing shall be removed from its packaging (or otherwise eliminate the reduced oxygen environment) prior to initiating the thawing procedure.

Issue: 2012 III-018

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Council Recommendation:	Accepted as Submitted		Accepted as Amended	X	_ No Action	
Delegate Action:	Accepted	X	_Rejected		_	
All information above the line	e is for conference use	only.				

Title: Harmonize Time/Temperature Charts in Food Code with FSIS Guidance

Recommended Solution:

The Conference recommends a letter be sent to the FDA and USDA encouraging them to work together and bring to the 2014 biennial meeting of CFP a proposal to address the issue of harmonizing cooking time and temperature requirements for meat and poultry in the Food Code.

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

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Final Cooking Temperature Requirement for Non-Continuous Cooking

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-401.14, (D), be amended as follows (new language shown with underline; deleted language shown with strikethrough):

3-401.14 (D) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature of at least 74°C (165°F) for 15 seconds for full lethality based on the specific product requirements in section 3-401.11 (A)-(C) of the Food Code.

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

Delegate Action: Accepted Rejected x

All information above the line is for conference use only.

Title: Reduced Minimum Temperature for Microwave Steam Cooking of Seafood

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline):

3-401.15 Microwave Cooking of Seafood

Raw seafood cooked in a microwave oven shall be:

- (A) Placed within a covered container with the addition of a sufficient amount of water to cover the bottom of the pan and maintain a saturated steam environment;
- (B) Steam heated to a temperature of at least 62.8°C (145°F) in all parts of the food; and
- (C) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

Issue: 2012 III-021

 Council
 Accepted as
 Accepted as

 Recommendation:
 Submitted
 Amended
 X
 No Action

 Delegate Action:
 Accepted
 x
 Rejected

 All information above the line is for conference use only.

Title: Determining the Disposition of Refrigerated PHF (TCS food) above 5°C (41°F)

Recommended Solution: The Conference recommends:

(1) A letter be sent to FDA requesting that the following be added to the FDA Food Code Annex #4, Management of Food Safety Practices-Achieving Active Managerial Control of Food borne Illness Risk Factors (new language in underline format):

To ensure the safety of food, a food establishment may develop written plans to address how they will handle potentially hazardous food (PHF-temperature controlled for safety food) during emergencies (e.g., interruption of electrical service, loss of power, or equipment failure) using the following criteria:

<u>Criteria for determining when refrigerated PHF (TCS food) can be safely sold following an increase in cold holding temperature</u>

- A. Refrigerated PHF (TCS Food) can be safely held and sold at temperatures above 5°C (41°F) provided:
 - 1. Written procedures are in place to specify the methods used to demonstrate compliance with Parts B and C below.
- B. Refrigerated PHF (TCS food) can be held and sold at a temperature up to 7.2°C (45°F) provided:
 - 1. The total time during which the food is above 5°C (41°F) but not over 7.2°C (45°F) is 15 hours or less
 - 2. By the end of 15 hours the food has returned to 5°C (41°F) or lower
 - 3. The food shall be monitored to ensure the warmest portion of the food does not exceed 7.2°C (45°F) during the 15-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 7.2°C (45°F) during the 15-hour period;
 - 4. The food shall be destroyed if it does not meet the criteria in 1-3 above.
- C. Refrigerated PHF (TCS food) can be held and sold at a temperature up to 10°C (50°F) provided:
 - 1. The total time during which the food is above 5°C (41°F) but not over 10.0°C (50°F) is 9 hours or less
 - 2. By the end of 9 hours the food has returned to 5°C (41°F) or lower
 - 3. The food shall be monitored to ensure the warmest portion of the food does not exceed 10.0°C (50°F) during the 9-hour period, unless an ambient air

- temperature is maintained that ensures the food does not exceed 10.0°C (50°F) during the 9-hour period;
- 4. The food shall be destroyed if it does not meet the criteria in 1-3 above. .

AND

- (2) that the Conference create a committee to review and update the *CFP Emergency Action Plan for Retail Food Establishments* and that the committee be charged to:
 - review and update the CFP Emergency Action Plan for Retail Food Establishments where appropriate
 - incorporate the criteria above into the CFP Emergency Action Plan for Retail Food Establishments
 - report back to the CFP at the 2014 Biennial Meeting with a recommendation to accept the revised plan
 - recommend that FDA include reference to the *CFP Emergency Action Plan for Retail Food Establishments* in Annex 2 of the Food Code

Issue: 2012 III-022

 Council
 Accepted as
 Accepted as

 Recommendation:
 Submitted
 X
 Amended
 No Action

 Delegate Action:
 Accepted
 x
 Rejected

 All information above the line is for conference use only.

Title: Revision of the 2006 CFP Listeria Retail Guidelines

Recommended Solution:

The Conference recommends that a CFP Committee be created to revise the 2006 CFP "Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* (*Lm*)" to incorporate the following:

- 1. Sanitation guidance for slicers,
- 2. Information on cross contamination and harborage points for *Lm*,
- 3. More detailed information about how sampling for *Lm* can be conducted as part of a strategy for preventing *Lm* contamination at retail,
- 4. Updating outdated links to other documents, and
- 5. Other relevant information identified by the Committee.

The Conference also recommends that the Committee report its recommendations back to the 2014 Biennial Meeting with Issues to address the above charges and include recommendations that a letter be sent to FDA requesting that Annex 2 (References, Part 3-Supporting Documents) be amended by adding a reference to the revised voluntary quidelines.

Council Accepted as Accepted as Recommendation: Submitted Accepted x Rejected

Accepted as Amended X No Action

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Amend FDA Food Code Section 3-403-11(C)

Recommended Solution:

The Conference recommends that a letter be sent to FDA requesting Section 3-403.11(C) of the 2009 Food Code (as modified by the Supplement issued in 2011) and associated Annex be amended to include language that captures the intent of the following:

(C) Ready-to-eat food taken from a package from a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 57°C (135°F) for hot holding. P

The following may be considered as an example for the Annex: Product, cooked chicken tenders as an example, that remains after the original package is opened may still be heated to 57°C (135°F) for hot holding provided the product continues to be held under refrigeration at 5°C (41°F) or below at all times; had no bare hand contact; clean and sanitized utensils were used to dispense and process the products; and the packaging was covered/closed to prevent re-contamination.

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

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Cleaning of Food Contact Surfaces between Raw Animal Foods

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (deleted language shown with strike-through):

Section 4-602.11(B)

(B) Subparagraph (A)(1) of this section does not apply if the food-contact surface or utensil is in contact with a succession of different raw meats and poultry animal foods each requiring a higher cooking temperature as specified under § 3-401.11 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board.

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

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Dual-Step Hand Cleanse-Sanitize Protocol without Water

Recommended Solution:

The Conference recommends that:

(1) A letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended with the following intent:

In situations such as catastrophic natural or man-made disasters provisions for handwashing will be in accordance with emergency guidance documents.

(2) The CFP committee created as recommended in Issue 2012 III-021 be charged with revising the CFP Emergency Action Plan for Retail Food Establishments also include in their charge a review and recommendations for situations such as catastrophic natural or man-made disasters provisions for handwashing in accordance with emergency guidance documents.

Issue: 2012 III-026

 Council
 Accepted as
 Accepted as

 Recommendation:
 Submitted
 Amended
 X
 No Action

 Delegate Action:
 Accepted
 x
 Rejected

 All information above the line is for conference use only.

Title: Expanded Use of Time Only as a Public Health Control

Recommended Solution:

The conference recommends:

That a committee be formed to identify safe times at which foods can be held without temperature control and without cooling to 41°F, supported by scientific information (*e.g.*, challenge studies, modeling tools).

The committee's charge shall include, but not be limited to, the following foods and food categories:

- Cut tomatoes
- Cut cantaloupe
- Chopped leafy greens
- Chopped garlic and oil
- Opened canned tuna
- Opened canned beans (e.g., green beans, chickpeas, black beans)
- Hummus
- Opened canned product used as sole item
- Opened canned product used as an ingredient in a formulation

The committee may wish to consider a document published by Institute of Food Technologists (IFT) in 2001 and a National Advisory Committee for the Microbiological Criteria for Foods (NACMCF) challenge study document.

The committee is also charged to report recommendations back to the 2014 CFP biennial meeting.

					12 III-027	
Council Recommendation:	Accepted as Submitted		Accepted as Amended		_ No Action	X
Delegate Action:	Accepted	X	Rejected		_	
All information above the line	e is for conference use	e only.				

Title: Food Guards

Recommended Solution:

The Conference recommends no action.

Reason:

This issue is out of the scope of the CFP council and NSF has a committee addressing the issue.

Council Accepted as Accepted as Amended No Action X

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Acrylamide Management in Retail Preparation of Processed Potato Products

Recommended Solution:

The Conference recommends no action.

Reason:

The council does not believe this is an appropriate issue for CFP.

Council Accepted as Accepted as Amended X No Action

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Public Release of Food Allergy Resource Document

Recommended Solution:

The Conference recommends that a letter be sent to the FDA requesting dissemination of food allergen guidance.

Council Accepted as Accepted as Amended X No Action

Delegate Action: Accepted x Rejected

All information above the line is for conference use only.

Title: Allergen Committee - Importance of Allergen Guidance to CFP Members

Recommended Solution:

The Conference recommends the disbanding of the CFP Allergen Committee.