Conference for Food Protection
2012 Issue Form

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Issue: 2012 III-001

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

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Title:
Report - Hand Hygiene Committee

Issue you would like the Conference to consider:
At the 2010 Conference for Food Protection Biennial Meeting, the Hand Hygiene Committee was formed and charged "to address:

1. the efficacy/risk reduction strategies of alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses,
2. identify settings where alternatives to handwashing are appropriate,
3. recommend studies that should be completed to get research questions answered for when scientific literature is not available, and
4. report back to the 2012 Conference."

The 2010-2012 Hand Hygiene Committee is submitting four issues to the 2012 Conference for Food Protection:

1. Report - Hand Hygiene Committee
2. Disseminate the 2010-2012 Hand Hygiene Committee Report
3. Re-Create - Hand Hygiene Committee
4. Limit Hand Hygiene Committee Size

Public Health Significance:
The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses.

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.

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Attachments:

- "2010-12 Hand Hygiene Committee Final Report"
- "Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes"
- "2010-12 Hand Hygiene Committee Roster"

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Conference for Food Protection
2012 Issue Form

Internal Number: 075
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Council Recommendation:	Accepted as Submitted	_____	Accepted as Amended	_____	No Action	_____
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Title:
Disseminate the Outcome of 2010-2012 Hand Hygiene Committee

Issue you would like the Conference to consider:
The 2010-2012 Hand Hygiene Committee submits "Scientific, Regulatory and Behavioral Considerations of Hand Hygiene Regimes." This was extracted from the 2010-2012 Hand Hygiene Committee Report, modified and formatted for publication in a peer reviewed journal and for potential posting on the CFP website after publication. Authors include Chairs and Co-chairs of the 2010-2012 Hand Hygiene Sub-committees, and the acknowledgement section recognizes committee members.

Public Health Significance:
The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses.

Effective decision-making on appropriate approaches for removal or reduction of potential pathogens from hands involves consideration of the scientific aspects on what can be achieved, regulatory aspects of approaches that are approved for use, and behavioral aspects of approaches that will be implemented by food handlers. Concise information on each of these elements is not currently available in one document, thus broad dissemination of such information would enable all stake holders to make better informed decisions on hand hygiene approaches, as well as identifying areas where research is needed.

The 2010-2012 Hand Hygiene Committee also believes that listing the Committee as a co-author would make a broader audience aware of the collaborative nature of the work of the Conference for Food Protection, potentially recruiting more food safety professionals to become involved in CFP work to enhance public health.

Recommended Solution: The Conference recommends...:
Approval of the document generated by the Committee titled: *Scientific Regulatory and Behavioral Considerations of Hand Hygiene Regimes,* and*:*

- Submission to a peer reviewed journal, with the 2010-2012 Hand Hygiene Committee listed as a co-author, to make a broader audience aware of the collaborative nature of the work of the Conference for Food Protection.
- Posting the document on the CFP website as an educational tool that illustrates the interaction of scientific, regulatory and behavioral considerations related to alternative hand hygiene regimes compared to handwashing with respect to foodborne pathogens including viruses. When and if the document is accepted in a peer reviewed journal, request to replace the current document with the peer reviewed version.

Attachments:

See *Report* - (document attached to Issue titled: ***Report - Hand Hygiene Committee***, as Attachment #2)

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Conference for Food Protection
2012 Issue Form

Internal Number: 007
Issue: 2012 III-003

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

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

Issue you would like the Conference to consider:
Allow an exception for bare hand contact with ready-to-eat foods immediately before the food is heated as a sole ingredient to a temperature of at least 63°C (145°F). Also, change the current exception for bare hand contact with ready-to-eat food as the ready-to-eat food is being added to another ready-to-eat food to require a kill step temperature of 63°C (145°F).

Public Health Significance:
The 20011 Supplement to the 2009 FDA Food Code added language with the specific intent to allow pizza operators to have bare hand contact with ready-to-eat (RTE) pizza toppings placed on a pizza prior to cooking. Commercially prepared pizzas are heat treated to approximately 165°F -170°F - which is at or slightly above minimum cook temperatures required in paragraphs 3-401.11(A)-(B) or section 3-401.12.

When this additional language was added, there was no intention to create an additional minimum time/temperature cooking parameter or alter the minimum time/temperature parameters for cooking raw animal foods. However, since the Food Code only addressed heat treatment of RTE food in two situations - cooking plant food for hot holding and reheating food for hot holding - the creation of an additional time/temperature cooking parameter to address the added risk of bare hand contact with RTE foods not added to raw animal foods was unavoidable.

If there is scientific importance that makes it necessary to heat RTE ingredients touched by bare hands to 165°F, then all RTE ingredients touched by bare hands should be heated to this same temperature. Otherwise, the RTE ingredients added to food that is not a raw animal product should only be required to be heated to the lowest minimum time/temperature cooking requirement present in paragraph 3-401.11(A)(1) (145°F for 15 seconds).

Additionally, heat treatment of RTE foods that have had bare hand contact are only addressed when the RTE food is added as an ingredient - not when it is simply touched prior to heating on its own (e.g., a washed raw potato placed on a baking sheet). This is an oversight that should be addressed. Allowing bare hand contact with RTE foods heated only immediately prior to heating will ensure the touched food item will not mistakenly be

included in some other menu item that is not subsequently heat treated. Also, restricting the bare hand contact to immediately before heating will reduce the likelihood of the production of Staphylococcus aureau enterotoins due to bare hand contact.
Annex 3 - 3-401.13 and 3-301.11 suggest that RTE foods cooked to the minimum time/temperature required by the Food Code, in combination with proper handwashing and adherence to employee health requirements, provides an adequate means of interrupting disease transmission - whether added as an ingredient or heated alone. There is no indication that bare hand contact with RTE food that will not be added to raw animal food poses a greater risk and therefore requires a higher level of heat treatment than RTE foods added to 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), 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:*
(1) Immediately prior to heating the ready-to-eat food to a temperature of at least 63ºC (145ºF) if heated as a sole ingredient; or
(2) At the time the ready-to-eat food is being added as an ingredient to a food that:
(a) C*ontains 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*
(b) 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 63ºC (145ºF).

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Conference for Food Protection
2012 Issue Form

Internal Number: 101
Issue: 2012 III-004

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

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Title:
Double glove use or glove changing in relation to handwashing

Issue you would like the Conference to consider:
The conditions under which double gloving or glove changing without handwashing would be allowed/acceptable to ensure proper food handling.
Due to current wording and/or interpretations of the 2009 FDA Food Code, the determination has been verbally made that double gloving is allowed even between raw food handling and ready to eat food handling, with handwashing only required when glove in direct contact with hand is removed. (Note: This verbal interpretation was offered by FDA staff members and State of Wisconsin Department of Agriculture, Trade and Consumer Protection (retail establishment regulations) at a HACCP related training opportunity in 2010.)
Confusion regarding proper procedure for double gloving is based on two factors -- the inclusion of single use glove (a type of utensil in the Food Code definitions) and ambiguity in the "When to Wash" procedures in Food Code Section 2-301.14. Currently, 2-301.14 states "before putting on gloves" and "after engaging in other activities that contaminate the hands", but does not specifically state handwashing is required between each new pair of gloves.
There are two established scenarios where a food employee can change gloves without handwashing:

- Working with same type of food product (e.g., ready to eat product, then another ready to eat product) -- For example, making a cold cut sandwich then donning new glove to make a chef salad
- Working with multiple foods, but handling them in an order that will prevent cross contamination based on proper cook temperatures (e.g., moving from ready to eat product to raw product) -- For example, making a lettuce salad with a glove on, then donning new glove to work with raw beef. Handwashing would not be required whether or not an additional glove was used or original glove removed.

However, during inspections at several national franchises in the past several years, the following scenario has been observed:
Step 1: Employee wears glove when making a ready to eat chef salad
Step 2: Employee then uses same glove, or another glove on top of the first glove, to handle raw meat (burger, for example)

Step 3: Employee immediately goes back to handling ready to eat food (assembles burger items-bun, condiments, lettuce, cooked foods, etc) and has done one of the following:

- If only one glove was worn for step 1 and 2, employee removes glove and dons a new glove WITHOUT HANDWASHING
- If glove worn in Step 1, then additional top glove put on for Step 2, employee removes top glove only. Bottom original glove remains on and employee continues ready to eat food handling WITHOUT HANDWASHING

Many believe that at Step 3, all glove(s) are to be removed and hands are to be washed prior to resuming ready to eat food handling. Without specific Food Code clarification, unfortunately, the issue is susceptible to misinterpretation.

It has been explained that the additional glove is a utensil, that if you put on and take off the glove "properly" there's no risk, etc. In these situations, in Wisconsin, establishments are told to seek a variance for this type of procedure.

Is there a risk from improper glove changing and lack of handwashing in the situations noted above? Are we assuming too much if we believe that gloves are impermeable without the potential for "leak contamination"? Are we also allowing a risk during removal and redonning of gloves if handwashing is not done after possible contamination (dirty surfaces, raw food handling, etc.) According to the attached article from Food Safety Magazine, the frequency at which gloves are breached during in-use procedures was 56% of vinyl and 19% of NRL leaked post-procedure (see highlighted areas in attached article).

Public Health Significance:

Improper glove use and improper handwashing contribute to contamination of food. Because of this, cross contamination from hands from primarily fecal-oral pathogens and cross contamination from foodborne pathogens (including those with low infective doses such as Enteropathogenic E. Coli*, Campylobacter jejuni, Staphylococcus aureus, Shigella,* and others based on high risk population susceptibility) remains viable during improper food handling.

Recommended Solution: The Conference recommends...:

That the following charges be assigned to a re-created Hand Hygiene Committee:

- Determine if/when double gloving procedures would be acceptable without handwashing. If so, what would those acceptable procedures be?
- What glove criteria or standards would need to be met for a glove to be considered a utensil and not require handwashing?
- The findings of the committee to be used to recommend FDA Food Code language modifications regarding glove procedures and handwashing and that these findings be presented at the 2014 Biennial Meeting.

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Attachments:

- "CFP Issue Attachment - Clean Operations"

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Conference for Food Protection
2012 Issue Form

Internal Number: 012
Issue: 2012 III-005

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

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Title:
Clarify when handwashing is required before donning/changing gloves

Issue you would like the Conference to consider:
Employees are required to wash their hands whenever there is a risk of cross-contamination of Ready-to-eat (RTE) foods or clean food contact surfaces/equipment. Section 2-301.14 (H) of the 2009 Food Code states that hands need to be washed "before donning gloves for working with FOOD."

The intent in the Food Code is to minimize the risk of cross-contamination of RTE foods; however, gloves may be worn for other reasons than handling RTE food and they may be changed more frequently than is necessary to prevent cross-contamination. In these situations, the need to wash hands before donning/changing gloves is not consistent with the intent of the Food Code nor does it impact public health.

Section 2-301.14 (F) of the 2009 Food Code states that hands should be washed "as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks." [Bold inserted] However, Section 2-301.14 (H) states that hands should be washed "Before donning gloves for working with food." This has been misinterpreted to mean that hands must be washed every time gloves are changed even when performing the same task.

Section 2-301.14 should allow employees to change gloves without having to wash their hands when they are: (1) performing the same task without increased risk of cross-contamination and (2) when handling raw food and not increasing the risk of cross-contamination with RTE foods or clean food contact surfaces.

Public Health Significance:
2009 Food Code Section 2-301.14 (*When to Wash)* states that food employees must wash their hands before food preparation and at other times as listed in subsections A-H, including before donning gloves. As per Annex 3 - *Public Health Reasons / Administrative Guidelines - Chapter 2, Management and Personnel,* "Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to RTE food as well as other pathogens that can be transmitted from environmental sources." Clearly the intent is to minimize the risk of cross-contamination of ready to eat foods and food contact services.

There are many situations when an employee's activity has not changed yet gloves are changed. For example, a store policy may require that an employee change gloves

between the preparation of each customer's sandwich, even though the gloves are not contaminated and there is no increased risk of cross-contamination. However, based on Section 2-301.14, if the employee does not wash their hands between the glove changes, this would result in a critical violation although there is no public health risk. As per Section 2-301.14 (F), gloves should be changed "as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks." In the example above, the employee is not changing tasks and therefore changing gloves is optional as company policy or as consumer preference dictates, but there is not a public health basis for doing so.

The wording in Section 2-301.14 (H) states that hands should be washed "Before donning gloves for working with food." This has sometimes been interpreted to mean that hands must be washed every time gloves are changed, even if the activity has not changed or if there has been no contamination of the gloves or hands.

Furthermore, requiring that hands are washed before every glove change, even when an employee is repeating the same task, may actually serve as a deterrent to wearing or changing gloves. When employees can quickly change gloves without the additional step of handwashing when performing the same task, they are more likely to change gloves more frequently.

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), ¶ 2-301.14 (H), be amended to clarify the situations when hands shall be washed before donning gloves for working with food as follows (new language shown with underline):

(H) Before initially donning gloves for working with food,[P] and when changing tasks; [P]

AND the following language be added at the end of Annex 3, - Public Health Reasons / Administrative Guidelines - Chapter 2, Management and Personnel 2-301.14 *When to Wash:*

"Employees must wash their hands after any activity which may result in contamination of the hands. "When gloves are used to handle food, hands should be washed prior to donning gloves. If there is no change in the task being performed and there are no activities which could potentially result in cross contamination, then hands do not have to be washed between each change of gloves when performing the same task."

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Conference for Food Protection
2012 Issue Form

Internal Number: 076
Issue: 2012 III-006

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

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Title:
Re-create - Hand Hygiene Committee

Issue you would like the Conference to consider:
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, and potentially identify alternative approaches, where appropriate.

Public Health Significance:
The main purpose of washing hands is to cleanse the hands of soil, pathogens and chemicals that can potentially cause disease. Transmission of pathogenic bacteria, viruses and parasites to food from contaminated surfaces, raw food or ill workers by way of improperly washed hands continues to be a major factor in the spread of foodborne illnesses. The 2010-2012 Hand Hygiene Committee believes that the necessary ground work was established during its deliberations to make informed recommendations on specific situations where application of alternatives to handwashing may be appropriate to reduce public health risk.

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).

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.

Attachments:

See *Report - Hand Hygiene Committee*, Attachment #1 titled *2010-2012 Hand Hygiene Committee Final Report*

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Conference for Food Protection
2012 Issue Form

Internal Number: 050
Issue: 2012 III-007

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

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Title:
Rationale for 100 degree F. hot water at hand sink.

Issue you would like the Conference to consider:
There is currently no scientific research that shows hand washing is more effective at removing pathogens when warm water is used as compared to cold water usage. The FDA Food Code currently requires 100º F water at the hand sink. At the 2010 CFP Biennial Meeting, the Conference recommended changing the water temp at hand sinks to 85º F; however, this was not adopted when FDA issued the Supplement to the 2009 Food Code. Is there research or a scientific basis for requiring 100º F water at the hand sink? If not, will the FDA sponsor, support or encourage research to validate the best handwashing water temperature?

Public Health Significance:
Proper handwashing is one of the three pillars for preventing foodborne illness transmitted by food handlers. The objective of water temperature needs to focus on what will encourage and promote more routine and frequent handwashing. Currently, we justify the water temperature requirement based mostly on soft science:

1. Warm water is more conducive to encourage employee hand washing;
2. Warm water is more effective at removing soils in the food environment;
3. ASTM standards require 100-108º F water for testing soap formulation's efficacy.

Is there any research available to justify 100º F water at hand sinks? In fact, the only research we are currently aware of shows just the opposite. Research by Michaels and Paulsen (attached) came to the conclusion that, "*The initial experiment involved testing with bland non-antimicrobial soap at 5 temperatures from 4.4°C (40°F) to 49°C (120°F). Independent of soil or bacterial type (resident or transient) there was no significant difference in efficacy attributed to water temperature.*"

Studies designed to determine the best temperature for handwashing could put to rest the current confusion and debates as to what water temperature should be available at a handsink for hand washing.

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.

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Attachments:

- "Handwashing Water Temperature Effects on the Reduction of Resident and ..."

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Conference for Food Protection
2012 Issue Form

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Issue: 2012 III-008

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

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Title:
Addressing Nontyphoidal Salmonella in the FDA Food Code

Issue you would like the Conference to consider:
Amend the 2009 FDA Food Code to add nontyphoidal *Salmonella* as one of the reportable illnesses for action by the Person in Charge, add Code language to address employee health controls for the exclusion and restriction of nontyphoidal *Salmonella,* and remove exclusion and restriction language in all applicable Code Sections.

Public Health Significance:
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 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.

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:

1. Include illness due to nontyphoidal *Salmonella* (NTS) as an illness that upon diagnosis by a health practitioner:

- Requires food employees to report the diagnosis and any symptoms associated with NTS to the Person in Charge;
- Prompts the Person in Charge to exclude a food employee with symptoms and a diagnosis of NTS until asymptomatic for at least 24 hours; and
- Prompts the Person in Charge to restrict a NTS-diagnosed food employee whose symptoms have resolved for at least 30 days from the date of onset of those symptoms;

2. Develop language in the appropriate sections of Food Code, Chapter 2 that addresses the conditions for exclusion and restriction and reinstatement following exclusion and restriction as stated above.

3. Add language to the public health reasons in Annex 3 contained in Attachment A titled, "Addressing Nontyphoidal Salmonella in the FDA Food Code (new language has been underlined), including associated changes in the Part 2-2 Employee Health Tables (not shown).

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Attachments:

- "Attachment A: Proposed changes to Food Code Annex 3, Public Health Reason"
- "Attachment B: Addressing NT Salmonella.Article1"
- "Attachment C: Addressing NT Salmonella.Article2.Abstract"
- "Attachment D: Addressing NT Salmonella - References"

Conference for Food Protection
2012 Issue Form

Internal Number: 043
Issue: 2012 III-009

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

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Title:
Report - ROP Committee (ROP 1)

Issue you would like the Conference to consider:
At the 2010 Conference for Food Protection, two issues regarding reduced oxygen packaging resulted in the formation of a CFP committee. That committee was charged with:
1.) create a guidance document detailing the scientific evidence of ROP HACCP controls and preventive measures and provide implementation suggestions
2.) recommend clarifications to the Food Code based on charge one
3.) report back to the Conference in 2012
The Reduced Oxygen Packaging (ROP) Committee requests acknowledgement of their final report including attachments, acknowledgement of the committee members for their hard work, and requests disbanding the committee.

Public Health Significance:
ROP offers unique advantages and opportunities for the food industry but also raises several microbiological and potential foodborne illness concerns. Products packaged using ROP may be produced safely if proper scientifically validated controls are in effect. Updates and clarifications of Food Code requirements and public health reasons are essential to ensure proper safeguards and to avoid unproductive confusion for inspectors and operators.

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.

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Attachments:

- "Committee Roster"
- "Report - ROP Committee -new"
- "Supporting information -new"

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Conference for Food Protection
2012 Issue Form

Internal Number: 077
Issue: 2012 III-010

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

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Title:
ROP 2: Definitions for Reduced Oxygen Packaging

Issue you would like the Conference to consider:
The 2010-2012 Reduced Oxygen Packaging (ROP) Committee examined the definitions of ROP provided in the Food Code (Chapter 1 - Purpose and Definitions) and concluded that the definitions of sous vide packaging needed to be harmonized with both the Food Code (Annex 6 - Food Processing Criteria) and with the accepted understanding of the ROP process. It was also felt by the Committee, that a statement of what is excluded from ROP could be useful for inspectors and operators. There is some confusion of what constitutes ROP and the exclusionary language proposed will address that confusion. Finally, the Committee thought that several changes to the definitions in Annex 6 - Food Processing Criteria also warranted some edits to improve the clarity of the definitions and make sure that the language of the annex was aligned with the Food Code itself.

Public Health Significance:
ROP offers unique advantages and opportunities for the food industry but also raises several microbiological and potential foodborne illness concerns. Products packaged using ROP may be produced safely if proper scientifically validated controls are in effect. Updates and clarifications of Food Code requirements and public health reasons are essential to ensure proper safeguards and to avoid unproductive confusion for inspectors and operators. Recommended changes are suggested to the most current Food Code 1-201.10. Iitems 1, 3 and 4 below are simply clarifications to exisiting defintions.
The Committee also recommended the addition of a new paragraph (item 2 below) to the most current Food Code section 1-201.12. This defintion was needed to define what is excluded from ROP. This includes short term storage of food products held in cold storage temperatures of 41°F or below in oxygen barrier bags for less than 48 hours as it does not allow sufficient time for the production of *Clostridium botulinum* toxin nor the rapid and progressive growth of *Listeria monocytogenes*. The current Food Code allows up to 48 hours to cool product from 41° F to 34° F for reduced oxygen packaging. As long as product is stored below 41° F no regulatory action would be taken on this product until the product reached the end of the 48 hour time period. The 48 hour time frame is validated by numerous studies reviewed by the CFP's ROP committee. The Skinner-Larkin model for pathogen growth (see Appendix 4 in the ROP issue report) shows that the 48 hour time

frame is a conservative estimate and *C. botulinum* and *L. monocytogenes* would take far longer to produce toxin or grow to dangerous levels.
Additional rationale for the recommended changes is included in the Table 1 Summary of Food Code and Annex changes proposed by the 2010-2012 ROP Committee. That table is included in the 2010-2012 Reduced Oxygen Packaging Committee Final Report as Appendix 1.

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) Placing product in a bag and sealing it immediately prior to or after, cooking, 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 sealed, 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.

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2012 Issue Form

Internal Number: 104
Issue: 2012 III-011

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

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

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee reviewed the cook chill/sous vide time temperature parameters listed in Section 3-502.12 (D) of the 2009 Food Code relating to conducting ROP for these processes without a variance. The Committee recommends stating that Section 3-502.12 (D) pertains to only 'POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROLLED FOR SAFETY FOOD).' This would help align it with Sections 3-502.12 (A) and (B)

The Committee also recommends requiring that food be cooked to a temperature listed in Section 3-401.11 (A) and (B) of the 2009 Food Code. Right now Subparagraph 3-502.11 (D)(2)(b) references all four paragraphs of Section 3-401.11. Since paragraphs (C) and (D) in Section 3-401.11 refer to raw or undercooked products, these would not be acceptable cook temperatures.

The main changes the Committee recommends for Cook Chill and Sous Vide fall under Subparagraph 3-502.12(e) of the 2009 Food Code. There is no recommended change to Subparagraph (i) or the current (iv). We do recommend changing Subparagraph (ii). This paragraph currently requires that product be cooled to 34° F within 48 hours and then it can be held for up to 72 hours at 41° F. The Committee recommends allowing storage for up to 7 days at 41° F for product which has been properly cooled within the 6 hour timeframe as outlined in Section 3-501.14 of the 2009 Food Code. Research by Skinner and Larkin and listed in the *'Supplemental Information'* attachment to the 2012 CFP issue '*Report - ROP Committee'* shows that there is no significant change in pathogen growth between these two procedures.

Public Health Significance:
The objective of this issue is to clarify what controls are necessary to ensure the safety of food products packaged using Sous Vide or Cook Chill technologies.

Proposed ROP Committee changes to Section 3-502.12 (D) of the 2009 Food Code limits the following subparagraphs of this section to only potentially hazardous foods (PHF) (time / temperature controlled for safety (TCS) foods). Obviously, if a food is non-PHF (non-TCS), it will not support the growth of pathogens and therefore should not be subject to either variance or ROP provisions of the Food Code.

The change to the 2009 Food Code's Subparagraph 3-502.12 (D)(2)(b) limits items which can be packaged using Sous Vide or Cook Chill technologies to only those foods which are fully cooked. Undercooked, partially cooked or raw foods cannot be safely prepared using sous vide or cook chill technologies so these paragraphs are eliminated and only the paragraphs that provide appropriate thermal lethality are included in this reference, i.e., Sections 3-401.11 (A) and (B).

The change to Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code is driven by conservative science which shows that there is no growth of Clostridium botulinum during the first seven days of storage at 41° F or less. This change is based upon research by Skinner and Larkin which can be found in the *'Supplemental Information'* attachment to the 2012 CFP issue entitled *Report - ROP Committee (ROP 1)*. Additionally, Listeria monocytogenes growth is prevented since this pathogen would have been eliminated through the cook step during the sous vide or cook chill process. All other pathogen growth is controlled by storage at temperatures at or below 41° F.

The change to Subparagraph 3-502.12 (D)(2)(e)(iii) of the 2009 Food Code is driven by the original wording now being obsolete and being covered by the change which was made to Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code. The Skinner Larkin model clearly shows that there is no C. botulinum growth during the 7 days after product is cooked and cooled.

Additional changes are recommended in 2012 CFP issue entitled *ROP 6: Updates to Food Code Annexes 2 and 3,* as follows:

1. Changes to the Public Health Reasons, Annex 3 of the 2009 Food Code, which will explain the rationale for these changes; and
2. References included in the 'Supplemental Information' attached to the Committee's report also be included into Annex 2 of the 2009 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 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 (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 <u>(A and B)</u>, 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).

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2012 Issue Form

Internal Number: 105
Issue: 2012 III-012

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

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

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee recommends changing the requirement to obtain a variance when an acidifying agent is used as a method of food preservation so long as the equilibrium pH of the final product is 5.0 or below which is checked using a pH meter and is held at 41° F or below for no more than 30 days.
The ROP Committee asks that the Council and CFP delegates recognize that products with a pH lower than 5.0 and held at 41° F or below controls pathogen growth and allows products to be held safely for up to 30 days.

Public Health Significance:
The change to Subparagraph 3-502.12 (D)(2)(e)(iii) of the 2009 Food Code is driven by 2 factors. First, the original wording is now obsolete and is covered by the recommended change to Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code as requested in 2012 CFP Issue titled: *ROP 3: Sous Vide- Cook Chill Time and Temperature Control.*
The new wording is based upon research which shows that *C. botulinum* and *L. monocytogenes* cannot grow if a food has a pH below 5.0 and a temperature below 41° F. The growth of *L. monocytogenes* and other pathogens are also controlled by the same factors as listed for Subparagraph 3-502.12 (D)(2)(e)(ii) of the 2009 Food Code
Monitoring of pH as a control for pathogens *C. botulinum* and *L. monocytogenes* is important to the safety of the product to ensure that the proper food product pH is consistently maintained.
2012 CFP issue entitled *ROP 6: Updates to Food Code Annexes 2 and 3* is recommending:

1. Changes to the Public Health Reasons, Annex 3 of the 2009 Food Code, which will explain the rationale for these changes; and
2. References included in the '*Supplemental Information'* attached to the Committee's report also be included into Annex 2 of the 2009 Food Code.

Paragraph 3-502.11 (C) of the 2009 Food Code will now allow ROP processes to add an acidifying agent to reduce pH to below 5.0 so that product may be held at below 41° F for up to 30 days. Research has shown that this yields an acceptable method with a built in safety margin to allow ROP processes without the need for going through the variance process. Health Canada uses this pH and temperature combination to ensure safe

production of foods and control of *L. monocytogenes* and *C. botulinum.* Additionally, psychrophilic *C. botulinum* has a pH growth limit at 5.0 at ALL temperatures and *L. monocytogenes* has a pH growth limit of 4.4 at ALL temperatures and a pH growth limit at 5.0 at refrigeration temperatures (41F). The '*Supplemental Information'* attached to the 2012 CFP issue entitled *Report - ROP Committee* includes additional research to support the Committee's recommendation.

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) The following exclusionary language be added to the end of Subparagraph 3-502.11 (C)

3-502.11 Variance Requirement.

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before: Pf

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; Pf

(B) Curing FOOD; Pf

(C) Using FOOD ADDITIVES or adding components such as vinegar, except as specified in 3-502.12 (D)(2)(e)(iii): Pf

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, Pf or

(2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD); Pf

2) That a new paragraph (d) be added Section 3-502.12 (B)(5)

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 ...(no changes to paragraphs 1-4)

(5) Includes operational procedures that:....(no changes to subparagraphs a-c)

(d) If pH is used as a barrier to growth of *Clostridium botulinum* and *Listeria monocytogenes* such as in 3-502.12 (D)(2)(e)(iii), delineate equilibrium pH measurement, instrument calibration, and pH recordkeeping procedures.

3) Replace existing Subpargraph (iii) of Section 3-502.12 (D)(2)(e) with new language

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

~~(iii) *Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from PACKAGING, at which time the food must be consumed or discarded*; P or~~

(iii) Has an equilibrium pH of 5.0 or less, verified by a properly calibrated digital pH meter, and held at 5°C (41°F) or less until consumed or discarded within 30 days after the date of PACKAGING; P or

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

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2012 Issue Form

Internal Number: 089
Issue: 2012 III-013

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

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Title:
ROP 5: Requirement to submit HACCP plan to regulatory authority

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee is recommending that if a food establishment decides to conduct reduced oxygen packaging (ROP) without a variance as specified in Section 3-502.12 of the 2009 Food Code that the food establishment must first submit a copy of their HACCP plan to the regulatory authority. We do not recommend that the food establishment needs to await regulatory authority, but only to notify them through submission of the HACCP plan that they will be conducting ROP operations in conformance to the procedures enunciated in Section 3-502.12 of the 2009 Food Code.

Public Health Significance:
Since the consequences of an ill conceived plan to conduct ROP operations in a food establishment can be serious, and since many food establishments are only inspected by their regulatory authority once or twice a year, requiring notification of the regulatory authority by the food establishment of ROP processes being implemented is a prudent requirement. This will allow the regulatory authority to be made immediately aware of the food establishment's intention to conduct ROP operations and will also give the regulatory authority the option to review the plan to ensure that the requirements of Sections 3-502.12 of the most current Food Code are being followed.
Prior approval is not recommended to facilitate a food establishment initiating operations without a lengthy review process. Furthermore, the Food Code is quite specific in its requirements to conduct this operation safely.

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.

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Conference for Food Protection
2012 Issue Form

Internal Number: 093
Issue: 2012 III-014

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

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

Issue you would like the Conference to consider:
The Reduced Oxygen Packaging (ROP) Committee recommends adopting the ROP Committee's changes to Annex 3, Public Health Reasons as listed in the 'Supplemental Information' attachment to the 2012 CFP issue titled *Report - ROP Committee (ROP 1).* The Committee further recommends inclusion of the references cited in the 'Supplemental Information' attachment to the 2012 CFP issue titled *Report - ROP Committee (ROP 1).*

Public Health Significance:
The changes to Public Health Annex 3 and references for Annex 2 as recommended in the *'Supplemental Information'* attachment to the 2012 CFP issue titled *Report - ROP Committee (ROP 1)* to help further clarify the ROP Committee's rationale in the proposed changes to the 2009 Food Code as they relate to ROP, and also provide guidance to the regulatory authority when evaluating a food establishment's reduced oxygen packaging procedures that are conducted without a variance or prior approval.

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 as follows:

1. include the references cited in the Committee's report into Food Code Annex 2; and
2. include the changes to the Food Code's Public Health Annex 3 as recommended by the ROP Committee and as listed below (using underlining for additions and strike through for language elimination):

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/m^2 ~~cm^2/m^3~~/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), cook-chill 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 5ºC (41ºF). 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 may not be ~~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 5°C (41°F) ~~3°C (38°F)~~ 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. Nickel-sized 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 without a variance[xiii] 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.

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Conference for Food Protection
2012 Issue Form

Internal Number: 042
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Delegate Action:	Accepted	_____	Rejected	_____		

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

Issue you would like the Conference to consider:
The Food and Drug Administration's (FDA) Food Code Consumer Advisory provision was implemented to assure that all consumers are informed about the increased risk to especially vulnerable populations of eating raw or undercooked animal foods. The Consumer Advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as deli's or seafood departments.
Although a variety of statements regarding this issue are currently standard on restaurant menus, the American Association of Meat Processors (AAMP) believes these statements do not provide a sufficient level of protection against foodborne pathogens at food service and restaurants. The meat industry, regardless of facility size (*e.g.,* very small, small, and large), has worked aggressively to do what they can to prevent this harmful *E. coli* O157:H7 pathogen from contaminating meat products. Meat processors rely on numerous interventions intended to specifically address *E. coli* O157:H7 and other harmful meat-related pathogens. Unfortunately, science and historical data indicates that the meat industry cannot guarantee that all ground beef produced is completely free of the *E. coli* O157:H7 pathogen and/or other non-*E. coli* O157 Shiga Toxin-producing *Escherichia coli* (commonly referred to as non-O157 STECs). See the attachment, *Background Information*, for more details.
Therefore, a risk still exists that consumer may get extremely ill by consuming under-cooked ground beef products. The consumer advisory statement may protect the food service or restaurant establishment from financial liability and/or lawsuits, but does very little to actually protect the consumer. The allowance of such dangerous food preparation practices is in complete opposition to U.S. Department of Agriculture (USDA) and FDA cooking recommendations.
AAMP is currently recommending that changes be made to the FDA Food Code for the Consumer Advisory statement on menus and that proper preparation of ground beef be mandated at the food service and restaurants. Specifically, AAMP recommends:

- Amend the FDA Food Code to add a statement that disallows food service/restaurants from serving undercooked ground beef products to consumers. This change would need to include a minimal cooking temperature for ground beef items (*e.g.*, ground beef, hamburgers, etc.) of 160°F to ensure that it has been properly cooked to eliminate the chances for the potential presence of *E. coli* O157:H7.
- Amend the FDA Food Code to allow ground beef or blade tenderized steaks to be cooked at a temperature lower than 160°F, if, and only if that ground beef or blade tenderized steaks has been irradiated.
- Amend the FDA Food Code to add a statement that disallows food service/restaurants from serving undercooked blade tenderized or moisture enhanced steaks. This change would need to include a minimal cooking temperature for blade tenderized or moisture enhanced steaks of 160°F to ensure that it has been properly cooked to eliminate the chances for the potential presence of *E. coli* O157:H7.

The importance of the change is to help alter the mindset of consumers to avoid consuming undercooked ground beef products, since these products carry increased risk of *E. coli* O157:H7 and other non-O157 STECs. When consumers begin to understand the reasons why they are not able to eat/order an undercooked ground beef patty at the food service and restaurant level, then ideally this understanding of food safety will likely transfer to at-home use of the product. The Consumer Advisory statement in its current form also is somewhat of a release of liability for restaurants, who have not in the past taken the responsibility for properly cooking products served to consumers. Instead, the blame is placed back onto the ground beef processor/supplier. With the current structure of the meat industry and the technology available, many of these ground beef processors/suppliers are simply receiving raw materials to produce ground beef and have very little control on potential *E. coli* O157:H7 contamination. Furthermore, the effectiveness of antimicrobial interventions against *E. coli* O157:H7 at the processors level have limitations.

Public Health Significance:

Escherichia coli O157:H7 (commonly referred to as *E. coli* O157:H7) has been a major concern in the meat industry for decades and has increasing concerns with the development of new processing techniques. *E. coli* O157:H7 has been associated with food since 1982, but *E. coli* O157 is naturally found in the intestinal tract of cattle and in cattle feces. A potential cascade effect of *E. coli* O157:H7 contamination can be seen during the slaughter and production process. *E. coli* O157:H7 in the feces of cattle can be transferred to the hide. The feces on the hide are transferred to the carcasses during the de-hiding process and from the carcass the knives and saws become a vector to transfer *E. coli* O157:H7 onto other cuts of meat. The contaminated cuts of meat are then ground and added to other animal's cuts of meat. This is a possible cascade of events that can lead to massive amounts of ground products contaminated with *E. coli* O157:H7.

E. coli is a common kind of bacteria that lives in the intestines of animals and people, and there are many strains of the pathogen. Most are relatively harmless, but *E. coli* O157:H7 is a strain that produces a powerful toxin that makes those affected very ill. *E. coli* can be found in meat, unpasteurized milk, raw fruits and vegetables, and contaminated water sources. Bloody diarrhea and stomach pain are the most common signs of *E. coli* O157:H7 sickness. Some of the population, especially children under 5 and the elderly, can become

very sick from *E. coli* O157:H7. The infection damages the body's red blood cells and kidneys, and can cause hemolytic uremic syndrome. The Centers for Disease Control and Prevention (CDC) estimates that every year at least 2000 Americans are hospitalized, and about 60 die as a direct result of *E. coli* O157:H7 infections and its complications. A study published in the Journal of Food Protection in 2005 by the Emerging Infections Program FoodNet Working Group, estimated the annual cost of *E. coli* O157:H7 illnesses to be $405 million (in 2003 dollars), which included $370 million for premature deaths, $30 million for medical care, and $5 million for lost productivity. Visit http://www.ncbi.nlm.nih.gov/pubmed/16355834# to view the abstract of the study, Economic Cost of Illness Due to *Escherichia* coli O157 Infections in the United States.

According to the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) data, in 2011 there were 11 *E. coli* recalls of beef products. In 2010, there were 9 *E. coli* O157:H7 recalls of beef products. According to CDC FoodNet data, the illness rate associated with *E. coli* O157:H7 was 0.9 in 2010. Although the incidence of STEC O157 infection has declined to reach the 2010 national health objective target of less than one case per 100,000, this still does not justify the undercooking of potentially harmful products.

USDA/FSIS and the meat industry instituted a testing program for the pathogen that focused on components used in the production of ground beef products as well as end-product sampling programs for ground beef. The goal is to keep contaminated product from reaching consumers and to spur industry focus towards pathogen reduction and HACCP-associated verification programs to reduce the risk of this pathogen in beef products. The USDA/FSIS policy is currently reflected in FSIS Directive 10,010.1. Visit http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10010.1Rev3.pdf to download a copy of the document. This testing is random and sporadic and still allows the potential for contaminated product to reach the consumer.

On September 13, 2011, USDA's Under Secretary for Food Safety, Dr. Elisabeth Hagen, announced that six additional serogroups of pathogenic *E. coli* were declared as adulterants in non-intact raw beef. As a result of this action, if the *E. coli* serogroups O26, O103, O45, O111, O121, and O145 (commonly referred to as non-O157 STECs) are found in raw ground beef or its precursors, those products will be prohibited from entering commerce. FSIS will begin testing for these six serogroups of STEC and enforcing the new policy on March 5, 2012.

Over the past two years, FSIS has announced several new measures to safeguard the food supply, prevent foodborne illness, and improve consumers' knowledge about the food they eat. These initiatives support the three core principles developed by the President's Food Safety Working Group (FSWG). When President Obama came into office, he said that "protecting the safety of our food and drugs is one of the most fundamental responsibilities government has." He pledged to strengthen our food safety laws and to enhance the government's food safety performance. As part of its multi-faceted approach to prevent foodborne illness, USDA also launched Food Safe Families, a consumer education campaign with the Ad Council, the FDA, and the CDC. Changing the Food Code to disallow food service/restaurants to serve undercooked ground beef products to consumers is consistent with the goals of the FSWG and would be another tool to protect public health from *E. coli*.

Ground beef makes up the largest market share of beef consumption in the U.S. Billions of hamburgers are consumed annually. Approximately 26.4 billion pounds of beef was

consumed in 2010, and approximately 50% of this amount was in the form of ground beef. Most Americans buy the product at least two times a week, and ground beef accounts for more than half of all beef sales, as well as a quarter of all the meat sold in North America. Consumers eat about 28 pounds of ground beef annually. Because of the amount of ground beef consumed, the concern over *E. coli* O157:H7 and other non-O157 STECs is taken very seriously by the beef industry, USDA/FSIS, and other stakeholders.

The language amendments recommended in this Issue would be more descriptive of products that are currently recognized by USDA/FSIS as foods that are regularly associated with potential *E. coli* O157:H7 contamination. The Food Code was previously amended to disallow the sale of under cooked ground beef (*i.e.*, comminuted meat) when it is selected from a children's menu. The *E. coli* O157:H7 pathogen is non-discriminatory and can potentially affect all people, regardless of age and immune system.

As the meat industry endeavors to prevent the occurrence of *E. coli* O157:H7 and other pathogen contamination, it is our hope that the food preparers and consumers will continue to practice proper food handling and cooking techniques in their kitchens in an effort to prevent food borne illnesses

AAMP doesn't believe that the recommended 160°F internal product temperature will create an unpalatable product for consumers. The National Cattlemen's Beef Association (NCBA), through funding from Beef Check-off dollars, has also developed an approach to teach the public that through proper cooking methods, beef is safe when cooked to 160°F and is also savory to eat when cooked to that temperature. The promotion attempts to educate the public to not ruin the hamburger by cutting into the hamburgers to check the color, but instead they are encouraged to use a meat thermometer to cook the hamburger to 160°F. NCBA has pointed out that the keys to a *Safe and Savory* hamburger are:

- Cook ground beef to an internal temperature of 160°F.
- Don't use visual appearance to determine doneness of the hamburger. An instant-read meat thermometer is the only way to ensure that the ground beef is cooked to the proper temperature of 160°F. Consumers cannot rely on color and juiciness.
- Check the internal temperature of the hamburger by inserting the meat thermometer into the center of the hamburger.

Because proper cooking is the most uniform method that can guarantee ground beef products are safe from *E. coli* O157:H7, AAMP believes that this change is very important to help improve food safety. It is our hope that this change would also improve consumer education on cooking ground beef, as well as the public's understanding of this pathogen. The change in the Food Code would ensure that all restaurants are required to cook their ground beef products to the proper temperature, and remove one more area of risk from the beef industry's concerns.

The American Association of Meat Processors is recommending that the members of the 2012 Conference for Food Protection support the identified changes of the FDA Food Code that will further help protect consumers from potential *E. coli* O157:H7 and/or non-O157 STEC illness.

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 and deleted language shown with strike-through):

1. §3-401.11 (Raw Animal Foods) (D)

A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in ¶ (C) of this section, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:

(1) *As specified under ¶¶ 3-801.11(C)(1) and (2), the food establishment serves a population that is not a highly susceptible population;*

(2) *The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted meat;* [Pf] *and*

(3) *The consumer is informed as specified under § 3-603.11 that to ensure its safety, the food should be cooked as specified under ¶ (A) or (B) of this section; or*

Revise subparagraph (D)(3) to read as follows:

~~*The* consumer is informed as specified under § 3-603.11 that to ensure its safety, the *food* should be cooked as specified under ¶ (A) or (B) of this section~~ The food, if is beef or contains beef which is comminuted beef meat (*e.g.*, ground beef), blade tenderized beef meat, or moisture-enhanced beef meat; it must be cooked to a minimal internal temperature of 160°F unless the food has been irradiated or guaranteed not to contain *E. coli* O157:H7 or other non-O157 STECs; or

2. §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. [Pf]

(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)"; [Pf] or

Revise subparagraph (B)(1) to read as follows:

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

These amendments would be more descriptive of products that are currently recognized by USDA/FSIS as foods that are regularly associated with potential *E. coli* O157:H7 contamination. The Food Code was previously amended to disallow the sale of under cooked ground beef (*i.e.*, comminuted meat) when it is selected from a children's menu. The *E. coli* O157:H7 pathogen is non-discriminatory and can potentially affect all people, regardless of age and immune system.

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Attachments:

- "Background Information"
- "Microbiological Results of Raw Ground Beef Products for E. coli O157:H7"

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Conference for Food Protection
2012 Issue Form

Internal Number: 054
Issue: 2012 III-016

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

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

Issue you would like the Conference to consider:
Clarification on the storing and displaying of 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.
As amended by the 2011 FDA Food Code Supplement, subparagraphs 3-302.11(A)(2) and (3) of the FDA Food Code read:
3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.
(A) Food shall be protected from cross contamination by:
(1) [not relevant to Issue]
(2) *Except when combined as ingredients*, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:
(a) Using separate equipment for each type, [P] or
(b) Arranging each type of food in equipment so that cross contamination of one type with another is prevented, [P] and
(c) Preparing each type of food at different times or in separate areas; [P]
(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
The requirements conflict, because (A)(2) specifies "types of raw animal foods" "such as beef" and "pork" while (A)(3) adds a distinction between comminuted meats and whole-muscle meats of the same type.
Based on the Public Health Reasons for 3-401.11 regarding comminuted meats, the difference in cooking temperatures between ground meats and pork and whole-muscle intact cuts is based on the lack of come-up/come-down time, not different pathogens or different microbial loads. "Come up time" is the time it takes the product to reach the specified temperature, "come down time" is the time it takes for the product to cool down.
The Public Health Reason for 3-401.11 reads, in pertinent part:
"When USDA established the time and temperature parameters for 9 CFR 318.23 Heat-Processing and Stabilization Requirements for Uncurred [sic] Meat Patties (known as the "patty rule"), the Agency based the 5D for *Salmonella* on extrapolations applied to the

research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of Shiga toxin-producing ***Escherichia coli***. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements."
Therefore, there is no reason to impose extra requirements on the storage or display of same types (beef, pork, poultry, fish, etc.) simply because they are ground or otherwise not intact.

Public Health Significance:
This requirement to store non-intact meats separately from whole-muscle cuts of the same type is unnecessary and leads to confusion among regulators and the regulated community.

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.~~

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Conference for Food Protection
2012 Issue Form

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Delegate Action:	Accepted	_____	Rejected	_____		

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Title:
Thawing Vacuum Packaged Frozen Fish

Issue you would like the Conference to consider:
Some small, independent retail grocery stores and food service establishments have stored commercially processed and reduced oxygen packaged frozen fish in their refrigerated seafood service cases/ coolers in a thawed state despite warning labels to use immediately after thawing on boxes of frozen fishery products.
In addition, some retail food establishments may re-package bulk frozen fish in a reduced oxygen package for convenience and hold the fish frozen without use of a warning label for thawing, and not understand the food safety significance of the thawing step for vacuum packaged frozen fish.
Address the food safety concern regarding the thawing of frozen vacuum packaged fish in the Food and Drug Administrations' next edition of the Food Code.

Public Health Significance:
Section 3-502.12 (C) of the U.S. Food and Drug Administrations' 2009 Food Code offers an exception or allowance for the packaging of frozen fish using a reduced oxygen packaging method as long as the *fish was frozen before, during, and after packaging.*
The spores of *Clostridium botulinum* are very common in nature. They have been found in the gills and viscera of fin fish, crabs, and shellfish. *C. botulinum type E* is the most common form found in fresh water and marine environments. Types A and B are generally found on land, but may also be occasionally found in the water. It should be assumed that *C. botulinum* will be present in any raw fishery product, particularly in the viscera.
There are a number of strategies to prevent *C. botulinum* toxin formation during processing, storage and distribution of finished fishery products.
In Chapter 13, Clostridium botulinum Toxin Formation (A Biological Hazard) of the U.S. Food and Drug Administration's Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001, the requirement for the commercial seafood processor who manufactures frozen, reduced oxygen packaged fishery products states:

- Control in frozen, reduced oxygen packaged fishery products

If your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately

before use (e.g. " Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation of ***C. botulinum*** toxin may not be a significant hazard.
.

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 informational items (allowances) to Section 3-501.13, Thawing, and Section 3-502.12, Reduced Oxygen Packaging, Criteria as follows (new language in underline format):
1- Add the following language for thawing of reduced oxygen frozen fish after the exception sentence in Section 3-502.12(c):
To control C. botulinum toxin formation, reduced oxygen packaged fish must be held frozen until used or removed from ROP during the thawing process.
2- Add an informational only statement to section 3-501.13, Thawing:
(E) *Frozen, reduced oxygen packaged fishery products must be kept frozen until used, or removed from ROP during the thawing process.*

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Conference for Food Protection
2012 Issue Form

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Issue: 2012 III-018

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

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

Issue you would like the Conference to consider:
The Food Safety Inspection Service (FSIS) is recommending that changes be made to FDA Food Code § 3-401.11 *Cooking* to:

- Resolve minor discrepancies between the time and temperature combinations specified in the Food Code for cooking of non-intact meat products at retail and what is specified in FSIS Guidance directed at meat and poultry processors;
- Revise the minimum time and temperature requirements for meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham to reflect updated FSIS Guidance for these products;
- Refer to appropriate FSIS Guidance documents for additional appropriate time and temperature combinations not currently specified in the Food Code for cooking of non-intact meat chops, roasts and steaks;
- Clarify what cooking criteria applies to intact meats and which applies to non-intact meats; and
- Establish minimum instantaneous cooking temperatures for products for ones which do not currently exist in the Food Code, including for poultry, baluts and wild game animals.

Public Health Significance:
The differences between specific criteria contained in the Food Code and in FSIS guidance documents are, for the most part, minimal and, therefore, would have negligible impact on food safety. For example, *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* recommends that such products be cooked to 68°C (155°F) for 17 seconds while the Food Code recommends that such products be cooked to a minimum temperature of 68°C (155°F) for 15 seconds. These differences are likely a matter of rounding as all times in the FSIS guidance that were a fraction of a minute or second were rounded up to the next whole number (e.g., 16.2 seconds for 155 °F was rounded up to 17 seconds). Although small, such discrepancies lead to confusion. *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* contains additional time-temperature combinations that are also appropriate for cooking the animal products

covered in 3-401.11(A)(2). FSIS recommends these additional time and temperature combinations be established in the Food Code by reference to the Guidance document.

The time and temperature combinations in § 3-401.11(A)(2) for mechanically tenderized and injected meats should also apply to meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham. The current Food Code time and temperature recommendations for meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham [see § 3-401.11(A)(3)] refer to time and temperature combinations that were derived from USDA/FSIS *Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products (*http://www.fsis.usda.gov/oa/fr/95033f-a.htm).

The time and temperature combinations in *Appendix A* achieve a 6.5 log reduction in *Salmonella*. More recently, FSIS has issued new guidelines specifying that a minimum of 5-log reduction in *Salmonella* is acceptable for lamb, pork, and cured pork roasts such as ham as well as for mechanically tenderized and injected meats. FSIS is considering extending the minimum 5 log reduction to meat roasts including beef and corned beef, prior to issuance of the 2013 Food Code. The time and temperature combinations in the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* will achieve a 5-log reduction in *Salmonella*. Therefore, in order to be consistent, retail and foodservice institutions producing meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham should have the option of meeting criteria that is based on the new guidance.

CFP Issue # 2002-I-33 from the 2002 Conference recommended that USDA and FDA work together to establish instantaneous cooking temperatures for animal products that to date had minimum cooking temperatures that included a minimum dwell time of 15 seconds. FSIS is recommending deleting the 15 second dwell time from the minimum criteria specified in Subparagraph 3-401.11(A)(3) for the products covered under that subparagraph. This recommended change is based on FSIS guidance in the *Time-Temperature Tables for Cooking RTE Poultry Products*. FSIS believes that if poultry products are cooked to the minimum temperatures specified, it is not necessary to specify a minimum 15 second dwell time.

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:

1) Changes be made in strike through to remove language and underline to add language format to § 3-401.11 *Cooking* of the Food Code:

3-401.11 Raw Animal Foods.

(A) Except as specified under ¶ (B) and in ¶¶ (C) and (D) of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for:

(a) Raw eggs that are broken and prepared in response to a CONSUMER's order and for immediate service, and

(b) Except as specified under Subparagraphs (A)(2) and (A)(3) and (B), and in (C) of this section, FISH and <u>INTACT</u> MEAT including GAME ANIMALS commercially raised for

FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2);
(A)(2) 68°C (155°F) for ~~15~~ 17 seconds or for the temperature specified in the following chart that corresponds to the holding time for RATITES, MECHANICALLY TENDERIZED, and INJECTED MEATS, MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under voluntary inspection program as specified under Subparagraph 30201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section:
[See attachment (Table 1) for strike through changes to Table.]
(A)(3) 74°C (165°F) or above ~~for 15~~ for POULTRY, BALUTS, wild GAME ANIMALS as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing containing FISH, MEAT, POULTRY, or RATITES.
~~(A) Whole MEAT roasts including beef, corned beef, lamb, pork and cured pork roasts such as ham shall be cooked:~~
~~(1) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:~~
[See attachment (Table 2) for strike through changes to Table.]
~~and~~
~~(2) As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature:~~
[See attachment (Table 3) for strike through changes to Table.]
2) Food Code Annex 3 Public Health Reasons Section 3-401.11 related to Cooking (pages 396-398 of 2009 Food Code), that describe the background for the time temperature combinations, be updated to reflect these changes.
3) Food Code Annex 3 Public Health Reasons Section 3-401.11 related to Cooking (396-398 of 2009 Food Code), be updated to include further temperatures found in *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks*, available at: http://askfsis.custhelp.com/ci/fattach/get/4648/, and to include an additional recommendation that MEAT roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham may also be cooked using the time-temperature combinations in *Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products*, found at: http://www.fsis.usda.gov/oa/fr/95033f-a.htm.

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Attachments:

- "TIME-TEMPERATURE TABLES FOR COOKING READY-TO-EAT POULTRY PRODUCTS"
- "FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks"
- "Annex 3 Food Code"
- "Table 1"
- "Table 2"
- "Table 3"

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Conference for Food Protection
2012 Issue Form

Internal Number: 010
Issue: 2012 III-019

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

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Title:
Final cooking temperature requirement for non-continuous cooking

Issue you would like the Conference to consider:
Amend 2009 FDA Food Food Code Section 3-401.14, (D) which currently requires a final temperature of 165°F before service to allow an exception for the use of the cooking temperature of 145°F for 15 seconds for intact whole-muscle beef.

Public Health Significance:
The 2009 FDA Food Code requires a final cook for non-continuously cooked raw animal foods of 165 °F based on the USDA/FSIS *Performance Standards for Partially Cooked and Char-Marked Meat Patties and Partially Cooked Poultry Breakfast Strips* found in 9 CFR 318.23[31] and 9 CFR 381.150. Since the initial partial heat treatment may not eliminate the vegetative organisms of concern or spores, the second and final heating process is necessary to eliminate the hazards associated with these products before service. However, the cooking temperatures in FDA Food Code Section 3-401.11 likewise based on USDA/FSIS data are adequate and vary based on scientifically based anticipated load and thermal destruction needed for different types of raw animal products and organisms of concern.

The current requirement for non-continuous cooking limits the time for the initial partial cook and the cooling time/temperatures such that, if done as per the current Code requirements, it will limit the growth of both possible vegetative and spore-forming organisms of concern. Non-continuous cooking is typically done for small mass products such as grill marking of steaks and burgers and poultry, or diced raw animal products for Asian style cooking with brief initial heating and rapid cooling.

Assuming these steps (initial heating and cooling) follow the current Code requirements, the expected load would not have increased significantly relative to a completely raw animal food or a fully cooked animal food that has been properly cooled and can be eaten without reheating as long as it is not going to be held hot. In the case of non-continuous cooked animal foods, these products are going to receive a second heat treatment before service; the final cooking temperatures in Section 3-401.11 will eliminate possible pathogens present, which the initial partial cook did not control.

The cooking requirements used to control both the vegetative and spore forming pathogens such as *C. perfringens*, *B. cereus*, and *C. botulinum* in 3-502.12 (D) (2) (b) for cook-chill or

sous vide products likewise uses the same time/temperature parameters in 3-401.11, not 165°F.

According to the 2009 Food Code Annex 3 Section 3-401.14, the cumulative growth of *C. perfringens*, *B. cereus*, and *C. botulinum* must be taken into account during both the initial heating and cooling steps. The hazard may be compounded with an extended initial "come up" time and /or a prolonged stage. Hence the degree of hazard may be dependent upon the ultimate effect of the initial heating and cooling, as well as the final cooking step.

The hazard of vegetative cell growth and spores of *C. perfringens*, *B. cereus*, and *C. botulinum* can be controlled if the initial cook was within 1 hour and the fast cooling process to less than 70 °F is achieved in less than 2 hours.

Section 3-401.11 (C) also allows for the service of raw or undercooked whole-muscle intact beef steak if the surface temperature reaches 145℉ for 15 seconds based on National Advisory Council on Microbiological Criteria for Foods (NACMCF) and USDA recommendations due to the low probability of pathogenic organisms being present in or migrating from the surface to the interior. This would likewise apply to non-continuously cooked whole-muscle, intact beef steaks. As long as the outside is seared to at least 145°F for 15 seconds during the final heat treatment before service, any pathogens will be controlled as long as Section 3-401.14 (A), (B), and (C) has been met.

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):

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 165°F for 15 seconds: except to allow for the use of the cooking temperature of 145°F for 15 seconds found in 3-401.11 for raw intact whole-muscle beef.*

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Conference for Food Protection
2012 Issue Form

Internal Number: 013
Issue: 2012 III-020

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

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Title:
Reduced Minimum Temperature for Microwave Steam Cooking of Seafood

Issue you would like the Conference to consider:
Section 3-401.12 of the 2009 edition of the FDA Food Code requires that raw animal foods, including seafood, heated via microwave energy must attain an internal temperature of at least 165°F. However, traditional steam heating of seafood products need only attain an internal temperature of 145°F. The recently published paper, "Utilization of Steam Heat Generated via Microwave Energy" (attached) summarized the results of a study that was conducted to evaluate the effectiveness of steam heat processing of seafood within a covered pan containing water with the energy generated via microwaves [1]. The study demonstrated that when water was added in a ratio of 30ml per pound of seafood product and placed within a covered container in a microwave oven, microwave energy effectively converted the water to steam and thoroughly cooked the product within 4 minutes (2 minutes cooking time plus 2 minutes holding time). Internal product temperatures in excess of 145°F were consistently recorded at each of seven sites along the products. The study showed that there was no appreciable difference between the cooking of seafood in a conventional steam oven and that of cooking seafood in a covered pan containing a measured quantity of water with microwaves used as the steam generating energy source.

[1] Specchio, J., Schrade,J., & Unanski, M., 2011, Food Safety Magazine, Utilization of Steam Heat Generated via Microwave Energy

Public Health Significance:
The FDA Food Code permits seafood products to be safely cooked in a conventional steamer to an internal temperature of 145°F. The study referenced above demonstrated that heat transfer within seafood products via microwave generated steam in a covered pan with water added was comparable to the heat transfer within a convention steamer.

There are several advantages to using microwave energy to generate steam to cook seafood in covered pans. First, the microwave units are portable and don't require expensive and complicated steam and waste water plumbing hookups. Second, there are many microwavable-safe containers available in different sizes to economically accommodate the volume of food items being prepared. Third, the stainless steel microwave units as well as the containers are easily cleaned and sanitized. Fourth, cooking time is reduced in comparison to conventional steam units yet safe internal product

temperatures are attained. Fifth, there is a large savings in energy costs using microwaves to generate steam as opposed to using convention gas or electric steaming units.

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;
(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.

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Attachments:

- "Utilization of Steam Heat Generated via Microwave Energy"

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Conference for Food Protection
2012 Issue Form

Internal Number: 074
Issue: 2012 III-021

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

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

Issue you would like the Conference to consider:
Food establishments and regulators often have to make decisions about the safety of refrigerated PHF (TCS food) when product temperature has increased above 5°C (41°F). For example, during emergency power outages, refrigerated food may have a slight increase in temperature until actions can be taken to maintain the food at 5°C (41°F). During these times, it is equally important that food establishments be able to safely sell food to consumers, donate food to the community and prevent the needless destruction of safe food.

Food establishments and regulators need science-based procedures for determining when refrigerated PHF (TCS) food can be safely sold and when it should be destroyed or re-conditioned in the event there is an increase in the food temperature above 5°C (41°F). Such a provision in the FDA Food Code would be most useful in emergency situations such as during a power outage.

This provision would provide disposition recommendations such that refrigerated PHF (TCS) food that exceeds 5°C (41°F) for a specified time and temperature combination can be safely sold, and establish the limits of time and temperature when such food must be destroyed or reconditioned. Based on science, such provisions would offer a sound basis for making disposition decisions of refrigerated PHF (TCS) food, especially during emergency situations.

Food Code Part 3-7, *Contaminated Foods*, should be renamed *Disposition of Food.* This Part of the Food Code should also be revised to include science-based recommendations for the disposition options for refrigerated PHF (TCS) food that is above 5°C (41°F) but which can still be safely sold.

During times of emergencies and follow-up recovery, food establishments and regulators often consult the *CFP Emergency Action Plan for Retail Food Establishments*[1] (See Reference #1 on the list of Attachments) including the section titled *Interruption of Electrical Service, Part III, Recovery*, on page 10. This guide includes a table labeled "Cold Foods Internal Temperature Guidance" which offers guidance for handling refrigerated PHF (TCS) food when the product temperature has increased above 5°C (41°F). The guidance provided is not based on science nor is it reflective of recommendations in the Food Code. The Food Code is of little use in such situations since it does not provide specific

recommendations on the disposition options for such food. Having consistent, science-based recommendations in both the Food Code and the *CFP Emergency Action Plan for Retail Food Establishments* for disposition of refrigerated PHF (TCS) food when the product temperature has increased above 5°C (41°F) would benefit regulators and food establishments, while protecting and serving the public.

Public Health Significance:

The time and temperature parameters for this recommendation were based on the considerable body of science available regarding growth of pathogens at various time/temperature combinations and the current recommendations in the Food Code. It also includes a variety of conservative (fail-safe) assumptions.

The decision was made to review two different data sets regarding pathogen growth, and to use the more conservative numbers when developing disposition recommendations. The first body of science referenced was the 2004 CFP report from the "Time Only as a Public Health Control Committee - Council III[2] (See reference #2 on the list of Attachments) which used the USDA-Pathogen Modeling Program (PMP) to predict the time for a 1-log increase in *Listeria monocytogenes (Lm)* concentration. The second set of scientific data includes model predictions from the ComBase predictor model, found at:

- The results from both the PMP and ComBase models are included in the *Predicted Time for the Increase in Growth of Listeria monocytogenes (Lm) at Various Temperatures* tables.[3] (See reference #3 on the list of Attachments) The 2004 Committee Report using the USDA PMP shows the time needed for a 1-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 53.9 hours and 34.7 hours, respectively. (Table 4, located at Reference #3 on the list of Attachments) The results from the ComBase predictor model shows the time needed for a 1-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 30 hours and 18 hours, respectively. (Table 1, located at Reference #3 on the list of Attachments)

The predicted times using the ComBase model are less than those shown for the PMP, primarily due to the assumption that no lag time occurs. The ComBase predictor model also has the added benefit of being extensively validated with published data for actual pathogen growth in foods. For example, the ComBase database contains 20 growth rates for *Lm* growth in foods, between 8°C and 12°C, pH 6.5 to 7 and water activity between 0.99 and 1.00. In almost every case the ComBase growth rate prediction was equal to or faster than the actual measured growth rate in the food product. In a related analysis, *Lm* is known to be a risk in processed meats. The ComBase database contains 153 potential data sets on *Lm* in processed meats. From those 153 data sets (growth curves), 68 showed growth or were in the range encompassed by the model, further demonstrating good validation of the ComBase model.

Additionally, when making the calculations below, four safety factors were built in:

- The scenario assumes the food is held at 45°F or 50°F for the complete time. It does not take into account the time at which the food is less than 45°F or 50°F as it equilibrates with the ambient or surrounding temperature.
- The model assumes ideal growth conditions in the food.
- The model assumes no lag time, even though most scientific literature does show a lag time for Lm growth in foods.

- The model assumes all food, both raw and RTE, contain Lm at the onset even though RTE foods should not contain pathogens.

The FDA Position Paper in support of using time and temperature for public health control of PHF (TCS) food can be found in the Food Code *Annex 3 - Public Health Reasons/Administrative Guidelines, 3-501.19, Using Time as a Public Health Control (419-422).* The same assumptions used to support *Time as a Public Health Control* in the current Food Code were considered in developing this proposal. Some relevant points from the position paper that provided assumptions for the proposal are cited below:

- Food held without temperature control equilibrates with the environment. Most models are based on the assumption that the food product spent all of the time at the highest temperature. Obviously food equilibrates with the surrounding environment at a gradual rate and would not equilibrate instantly. This assumption adds an extra margin of safety into the predictive models.
- When evaluating the safety of time and temperature control, parameters must be selected to create a conservative (fail-safe) scenario for the potential for pathogen growth.
- When evaluating pathogen growth in refrigerated PHF (TCS) food, it is recommended to use *Listeria monocytogenes (Lm)* is the primary organism of concern due to its psychotropic properties.
- A 1-log growth increase in *Lm* should be used as the critical limit.

To establish the most fail-safe approach to disposition, it was decided to use the data from the ComBase predictor (with no lag time) because it resulted in more conservative estimates and because the model is extensively validated. The conservative time/temperature parameters discussed above should provide a fail-safe system for determining the safe disposition of refrigerated PHF (TCS food) that exceeds 41°F.

However, because this recommendation is intended to provide procedures whereby food can be restored to 41°F and safely sold, the authors opted to use an even more conservative margin of safety. Therefore, the decision was made to use the ComBase predictor for time/temperature combinations that would result in a 0.5-log increase in *Lm*. These results show the time needed for a 0.5-log growth increase in *Lm* at 45°F (7.2°C) and 50°F (10.0°C) is 15 hours and 9 hours, respectively (Table 1, located at Reference #3 on the list of Attachments).

A half-log is generally accepted as the resolution limit of microbial testing, resolution being the capability of making distinguishable two sets of results. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 2010, JFP 73:140-202) has, in general, used <1 log as the criteria for determining the absence of measurable growth of pathogens of concern[4] (See Reference #4 on the list of Attachments) Furthermore, in the same publication, NACMCF has stated that the growth of pathogens at less than a 1-log increase "reflects the inherent variation that exists with enumeration of microorganisms." [4] (See Reference #4 on the list of Attachments)

Using a half-log increase as the critical limit means that the disposition criteria are based on the assumption that food which is allowed to exceed 41°F for a specified time and returned back to 41°F within a specified time will have the same microbiological profile as that which was maintained at 41°F for the same period of time. In other words, there is essentially no microbiological difference, and no increased risk, in the food continually held at 41°F and that which is handled according to the recommended disposition criteria. The ComBase predictor model was again used to verify these time/temperature combinations,

only using a 0.5-log Lm growth increase (Table 1, located at Reference #3 on the list of Attachments.) All other assumptions remained the same.
The new provision would allow refrigerated PHF (TCS food) that has been held up to 45°F and brought back to 41°F in a total of 15 hours or, held up to 50°F and brought back to 41°F in a total of 9 hours, to be sold. At these times and temperatures, there is a significant safety margin, especially when using a half-log *Lm* increase as the critical limit.

Recommended Solution: The Conference recommends...:
1. that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended using strike through to remove language and underline for new language as follows:
Food Code Part 3-7 *Contaminated Food* be renamed *Disposition of Food* as follows:
3-7 ~~Contaminated Food~~ Disposition of Food
AND:
Subpart 3-701 be renamed *Disposition of contaminated food;* the Sections and Paragraphs A-D under 3-701 remain the same; and a new Subpart 3-702 be added named *Disposition of Refrigerated PHF (TCS food)* as follows:
Subparts

- 3-701 Disposition of Contaminated Food
- 3-702 Disposition of Refrigerated PHF (TCS food)

AND:
The new Subpart 3-702 will include a Section and Paragraphs explaining the time/temperature parameters that can be used when determining the disposition of refrigerated PHF (TCS food) held at temperatures above 41°F but still eligible for sale as indicated below:
3-702 Disposition of Refrigerated PHF (TCS food)
3-702.11 Determining when Refrigerated PHF (TCS food) can be Safely Sold Following an Increase in Cold Holding Temperature
(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 Subparagraphs B and C of this section
(B) Refrigerated PHF (TCS food) can be held and sold at a temperature up to 7.2°C (45ºF) provided:
(1) The total time during which the food is above 5°C (41°F) but not over 7.2°C (45ºF) 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 7.2ºC (45ºF) during the 15-hour period, unless an ambient air temperature is maintained that ensures the food does not exceed 7.2ºC (45ºF) during the 15-hour period;
(4) The food shall be destroyed if at the end of 15 hours the food is not at 5°C (41°F) or lower as described in subparagraph 1-3 above, unless using Section 3-501.19 *Time as a Public Health Control* to determine the disposition of the food.
(C) Refrigerated PHF (TCS food) may be held and sold at a temperature up to 10°C (50ºF) 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 at the end of 9 hours the food is not at 5°C (41°F) or lower as described in subparagraph 1-3 above, unless using Section 3-501.19 *Time as a Public Health Control* to determine the disposition of the food.
AND:
2. The Conference further recommends revising the *CFP Emergency Action Plan for Retail Food Establishments, Interruption of Electrical Service, Part III. Recovery*, on page 10, by removing the table labeled "Cold Foods Internal Temperature Guidance" and replacing it with the same language as above in the new Food Code Subpart 3-702 *Disposition of Refrigerated PHF (TCS food)*.

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Attachments:

- "References cited in Attachment: "Disposition of Refrigerated TCS Food""

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Conference for Food Protection
2012 Issue Form

Internal Number: 115
Issue: 2012 III-022

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

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Title:
Revision of the 2006 CFP Listeria Retail Guidelines

Issue you would like the Conference to consider:
With FDA's support, the Food Safety and Inspection Service is recommending the formation of a CFP Committee 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.*" The guidelines should be revised to reflect new information on sanitation of slicers, harborage points for *Lm* at retail, and specific *Listeria* sampling protocols for retail facilities. In addition, the 2009 FDA Food Code Annex 2 (References, Part 3-Supporting Documents) should be amended to include a reference and summary of the revised guidelines.

Public Health Significance:
Listeria contamination at retail continues to be a significant public health issue.
Since the CFP *Listeria* retail guidelines were issued in 2006, new information has been published regarding risk from listeriosis from retail products. In 2010, FSIS published a risk assessment[1] that found that of the listeriosis cases attributed to deli meat, most (approximately 83%) were associated with deli meats sliced at retail. In addition, FDA has issued sanitation guidance for slicers, stating that recent foodborne illness outbreaks have been associated with commercial deli slicers that are difficult to clean and sanitize. Also, new information has been published identifying sources of *Lm* harborage and cross contamination, and demonstrating that *Lm* can survive in the environment of retail delis for more than a year.[2] This information indicates that sampling for *Lm* at retail can be an important tool for retailers to identify and address *Lm* contamination in retail delis and develop focused approaches to prevent deli products from becoming contaminated.
Although the 2006 CFP *Listeria* retail guidelines provided general information about cleaning and sanitizing and sampling in the retail environment, it did not provide steps for cleaning and sanitizing slicers, specific sites of harborage or cross contamination for *Listeria*, or sampling protocols for *Lm* in the retail environment. Therefore, FSIS and FDA jointly recommend that the CFP retail guidelines be revised to better address this new information. By forming a committee to revise the guidelines, CFP can ensure that view-points from a wide variety of backgrounds are considered and that the guidelines provide the best possible information to help retailers protect public health.

[1] FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats, 2010, found at: http://www.fsis.usda.gov/PDF/Comparative_RA_Lm_Report_May2010.pdf.
[2] Sauders, B.D. et al. Prevalence and Molecular Diversity of *Listeria monocytogenes* in Retail Establishments. Journal of Food Protection, Vol. 72, No. 11, 2009, Pages 2337-2349. Found at: http://www.ingentaconnect.com/content/iafp/jfp/2009/00000072/00000011/art00015.

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*" 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 recommendations back to the 2014 Biennial Meeting with Issues to address the 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 guidelines.

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Conference for Food Protection
2012 Issue Form

Internal Number: 107
Issue: 2012 III-023

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

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

Issue you would like the Conference to consider:
The 2009 FDA Food Code Section 3-403.11(C) addresses the reheating for hot holding of product that was received already fully cooked and packaged to prevent contamination during distribution. Product users may remove less than full case quantity out of the package to prepare at a single time. This leaves identical product in the freezer/cooler in a non-intact package. Manufacturers of this type of product and national and regional chain foodservice outlets have expressed concern that the code as stated can and is interpreted that the 135°F reheating temperature is no longer adequate once that package is opened and the provision of Section 3-403.11(C) no longer applies. Since remaining product must then be cooked to 165°F, some chains have taken the position to only have one cook procedure and then cook all products to 165°F for hot holding and therefore dramatically change the quality of the products.

Public Health Significance:
These products were processed under food processing regulations covering the lethality for vegetative pathogens as well as the cooling and/or stabilization of the product after cooking to control C. botulinum and C. perfringens germination and outgrowth. This same product from a previously opened package can also be heated to any temperature for immediate service in response to an individual consumer order per Section 3-403.10.
The following was supplied by FDA Food Specialist John Marcello in response to my enquiry on interpretation of Section 3-403.11(C).
"The cooked meat products and chicken patties have received a thermal process that reduces or eliminates all bacterial pathogens to an acceptable level. The commercially processed, ready-to-eat, packaged cooked meat and chicken patties have received a controlled cooking process that destroys vegetative bacterial cells and a controlled cooling process that prevents the germination of any spores present. Packaging prevents recontamination and refrigeration (freezing in the scenario you submitted) prevents spore germination. Because of the low levels of contaminations in both types of products, a reheating temperature of 135°F is considered safe and adequate prior to hot holding.
Any remaining portions of cooked meat or chicken patties that were not removed from the original package of commercially processed food, may still be reheated to 135°F. for hot

holding provided it has been held under refrigeration at 41°F or below (or as in the scenario you provided - frozen) 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. This seems to me something that can be accomplished with reasonable care.

If any remaining portions of the cooked meat products or chicken patties are held above 41°F, such as a "working supply;" cross contaminated; reheated then cooled; or in some other way had the potential for bacterial levels to increase from recontamination and/or proliferation; the reheating temperature should be 165°F for 15 seconds or the product should be discarded depending on the situation.

While there may be some limited potential for recontamination of the cooked meats or chicken patties during opening and removal of the first portion, reclosing/recovering the package/container and holding the product under refrigeration (frozen) prevents any increase in bacterial numbers (proliferation)."

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) be amended as follows (new language is underlined):

(C) Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact 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] 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.

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Conference for Food Protection
2012 Issue Form

Internal Number: 055
Issue: 2012 III-024

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

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Title:
Cleaning of Food Contact Surfaces between Raw Animal Foods

Issue you would like the Conference to consider:
Deleting the allowance to use food contact surfaces with different types of raw animal foods without intermediate cleaning and sanitizing.
Annex 3, Public Health Reason, for the 2009 FDA Food Code Section 4-602.11 reads, in pertinent part:
"Regarding the possible adulteration from one species of meat to another between cleaning of food-contact surfaces, USDA/FSIS (Food Safety and Inspection Service) does not automatically consider species adulteration as a health hazard. FSIS stated in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between safety and economic adulteration (65 FR 14486, March 17, 2000, Other Consumer Protection Activities). FSIS will review public comments received on the species adulteration issue and further review the scientific literature and risk assessment mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is generally considered by FSIS as an economic issue. However, investigations by FSIS of species adulteration incidents may include a determination regarding the impact of species adulteration as a health hazard on a case-by-case basis."
Annex 3, Public Health Reason, for the 2009 FDA Food Code Section 3-302.11 reads, in pertinent part:
"In addition, raw animal foods having the same cooking temperature, such as pork and fish, shall be separated from one another during storage and preparation by maintaining adequate spacing or by placing the food in separate containers because of the potential for allergen cross-contamination or economic adulteration via inadvertent species substitution."

Public Health Significance:
The provisions described above may result in cross contamination of foods with allergens as well as possible economic adulteration.

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 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*.~~

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Conference for Food Protection
2012 Issue Form

Internal Number: 047
Issue: 2012 III-025

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

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Title:
Dual-step hand cleanse-sanitize protocol without water

Issue you would like the Conference to consider:
Safe and proper changing of single-use gloves at catered events where potable running water is unavailable, is a current danger to public health. Hands must be washed before donning gloves per 2009 FDA *Food Code*, Section 2-301.14(H).
An effective hand cleansing, "equivalent or superior to hand washing with soap and water" (per *Journal of Food Protection*, Vol. 73, No. 12, 2010, Pages 2296-2300, attached) as specified in Section 2-301.12 of the *FDA Food Code*, can be achieved by using alcohol-based hand antiseptic first as a soap substitute to loosen contaminants with a 15 second scrub cycle, followed by their removal onto a single-use paper towel. This cleaning step is followed by a high impact kill step, applying the hand sanitizer to the pre-cleaned hand and allowing it to air dry per label instructions.
The latest testing of this hand cleansing/degerming technique shows it to be effective in the presence of organic food soils and if norovirus is the target pathogen, norovirus-effective sanitizers are available.(See attachment titled *Comparison of the Activity of Alcohol-Based Handrubs Against Human Noroviruses Using the Fingerpad Method and Quantitative Real-Time PCR*)
This adds an additional safety factor to support incorporation of the method into food safety practices. It gives operators a choice and its simplicity and portability adds to compliance. This protocol is not a substitute for handwashing in stationary facilities where cleaning can be accomplished per Section 2-301.12. The economics keep this innovation reserved for special situations.
[Note: After the near unanimous vote for adoption by Council III , a similar issue, III-027, was extracted during the Assembly of Delegates, citing the need for additional testing which has now been concluded along with an additional four years of field testing under the guidance of the Southern Nevada Health District (SNHD). SNHD also cleared this intervention for school foodservice use during water outages, and it has been in use for the past two years.]

Public Health Significance:
Potential contamination of ready-to-eat foods is increased in situations where access to soap and potable running water is limited or simply unavailable. The new proposed option

increases the likelihood of effective hand degerming in those situations, including its use between single-use glove changes.

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 and deleted language shown with strike-through):
5-203.11 Handwashing Sinks (A)(B)
(C) If approved, when food exposure is limited and handwashing sinks are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing or a regimen of sequential application of hand antiseptic wherein the first application is treated as a handwash with full scrubbing action for 15 seconds and then, while wet, wiped off with a single-use paper towel, immediately followed by a second application which is allowed to dry per standard label instructions. (i) Said hand antiseptic shall meet requirements of 2-301.16. Said hand antiseptic shall have supporting test data indicating statistical equivalence to a standard handwash in hand degerming.

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Attachments:

- "Comparison of the Activity...Handrubs Against Human Noroviruses"
- "SaniTwice: A Novel Approach to Hand Hygiene ..."
- "Comparative Efficacy of Alcohol Hand Sanitizers...against Noroviruses..."

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Conference for Food Protection
2012 Issue Form

Internal Number: 045
Issue: 2012 III-026

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

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

Issue you would like the Conference to consider:
The provision in Section 3-501.19 for use of Time as a Public Health Control (TPHC) requires potentially hazardous food time/temperature control for safety (PHFTCS) food be taken from temperature control (have an initial temperature of 5ºC (41ºF) or 57ºC (135ºF). This requires ambient temperature FOODS that become PHFTCS during preparation (such as opening a hermetically sealed container, cutting PHFTCS produce or mixing garlic and oil, etc) to undergo cooling before TPHC is allowed. Expanding the provision, would allow for use of TPHC immediately after preparation (when foods are at ambient temperatures).

Public Health Significance:
The relationship between Time AND temperatures has long been recognized as boundaries of retail food safety because they effectively prevent the growth of foodborne pathogens ((below 41ºF (5ºC) and above 135ºF (57ºC)) or lead to microbial inactivation (above 135ºF). Food Code provides science based guidance for steps in the flow of food (preparation, cooking, cooling, reheating, TPHC where PHFTCS will be exposed to temperatures above 41ºF and below 135ºF.

Proper Cooling requirements (Paragraph 3-501.14(B)) allow for food taken from ambient temperatures (such as hermetically sealed containers, or ambient temperature whole uncut PHFTCS produce) to be cooled to 41ºF within 4 hours. These products are considered Ready-to-Eat and safe for consumption as long as they comply with date marking provisions §3-501.17).

There is currently no provision in Section 3-501.19 to allow for ambient temperature foods that become PHFTCS during preparation to be held under TPHC. There are situations (e.g. opening a hermetically sealed container, cutting PHFTCS produce or mixing garlic and oil) in the flow of food where foods may be taken from ambient temperatures and served to the public within the time frame allowed for proper cooling.

The position paper included in the TPHC Section (3-501.19) of the Public Health Annex (3) supports the allowance of this process (use of TPHC as specified in the Food Code) stating that current time frames (for using TPHC) were "selected to create a worst-case scenario for pathogens growth and possible toxin production." The paper further states that "the 4-hour limit for keeping foods without temperature control allows for a needed margin of

safety if the temperature of the environment is higher than 75ºF" with the assumption that "these foods can reach any temperature as long as they are discarded or consumed within the four hours."

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 include new language to Section 3-501.19 as indicated below in underlined format:

(B) If time temperature control is used as the public health control up to a maximum of 4 hours:

(1) Except as specified in Subparagraph (a), the food shall have an initial temperature of 5ºC (41ºF) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; P

(a) FOOD may be at ambient temperatures if it becomes POTENTIALLY HAZARDOUS during preparation, such as opening a hermetically sealed container or cutting POTENTIALLY HAZARDOUS plan foods.

(3) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control or becomes POTENTIALLY HAZARDOUS; P and

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Conference for Food Protection
2012 Issue Form

Internal Number: 108
Issue: 2012 III-027

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

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Title:
Food Guards

Issue you would like the Conference to consider:
The 2009 FDA Food Code Section 1-103.1 states that THE CODE sets standards for FOOD EQUIPMENT, among other things. Section 3-306.11 provides criteria for the protection of ready to eat (RTE) food from the consumer, and this is shown to be a "Priority item"(^{P}). Sections 4-1 and 4-2 of Chapter 4 are intended to provide minimum reasonable safety criteria for foodservice EQUIPMENT. Therefore, the CODE should establish the minimum safety criteria for FOOD GUARDS and the criteria should be based on the science of preventing disease transmission. Currently, the CODE only refers in section 4-205.10 to an ANSI-accredited program for acceptability, stating that ANSI sanitation certified equipment is "deemed to comply" with the code. Recent changes to ANSI standards are not based on the science of preventing disease transmission and should be subject to criteria established by the conference and documented in the CODE.

Public Health Significance:
Because FOOD guards ^{P} comprise a Priority item in the 2009 FDA FOOD CODE, reasonable minimum safety criteria should be developed by the Conference. These new criteria will provide direction for ANSI's sanitation standards development organizations (SDO's) regarding the FOOD CODE's organisms of concern and guide all revisions to the standard criteria accordingly. Establishing reasonable minimum safety criteria is rightly the scope of the FDA FOOD CODE, whereas ANSI and/or ISO equipment standards are intended to establish best practice criteria for equipment cleanability and durability.
The 2008 ANSI NSF Std 2 section 5.35 "FOOD Shields" standard criteria currently in use is complex and confusing for all stakeholders. The results are very expensive food guard structures that burden the food service operators with unnecessary costs and equipment that often interferes with food service. As a result many operators struggle to purchase equipment that can be adjusted into compliance for inspections and adjusted out of compliance for daily use. There are additional costs to all local jurisdictions as their agents attempt to enforce compliance with the standards and the required measurement calculations. This creates a distraction from risk-based inspection and presents an undue burden to the entire industry. Much if not all of the overly burdensome minutia of the current ANSI NSF Std 2 for food shields lacks validated scientific review or data, and though

current food shield standard criteria may be perceived to theoretically reduce the risk associated with transmission of virus particles from a cough or sneeze, these do not comprise food borne disease organisms of concern and there is no data to suggest the current ANSI NSF Std 2 criteria reduces the risk of disease transmission. It is interesting to note that the food shield is only required on the guest's side of the buffet and not on the server's side, yet the risk of disease transmission from an ill worker is well established by scientific data.

Recommended Solution: The Conference recommends...:

that a Committee be created to:

1. evaluate CDC statistical data relating to risk factors for consumer cross-contamination and disease transmission associated with buffet service,
2. report Committee findings back to the 2014 Biennial Meeting, and
3. recommend revisions to FDA Food Code Chapter 4 by submitting the proposed language in Issues to the Conference.

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Conference for Food Protection
2012 Issue Form

Internal Number: 096
Issue: 2012 III-028

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

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Title:
Acrylamide Management in Retail Preparation of Processed Potato Products

Issue you would like the Conference to consider:
Since acrylamide's discovery in heated food products in 2002, Frozen Potato Products Institute (FPPI) members have invested significant resources in the exploration of acrylamide in processed potato products, as well as methods to reduce or mitigate the accumulation of acrylamide in finished products. This investigation has been and continues to be among the highest priorities for FPPI members.

As the majority of acrylamide is formed during preparation of processed potato products, most of the variability in the recorded levels of acrylamide is a result of differences in cooking method, time and temperature. Variability in cooking apparatuses (e.g., oven and fryer calibration, temperature cycling in ovens, variability in microwave oven wattage) can contribute to variability in the recorded levels of acrylamide in finished products. Similarly, variability in the incoming electrical power to the cooking equipment can contribute to inconsistencies in recorded levels of acrylamide. Slight differences in cooking conditions or product composition (even slight differences in the heat distribution during cooking or raw product from different parts of the process year) can also lead to major differences in acrylamide levels-as much as several multiples between different samples of the same product that have been prepared under the same conditions.

Customer and consumer expectations of color, texture and flavor (hereinafter referred to as "sensory" properties) of processed potato products, particularly French fries, are specific and distinct, and manufacturers implement precise processing techniques to produce products consistent with the taste, color and texture specifications of their customers and consumers. An effective and successful acrylamide mitigation technique must result in meaningful reductions in acrylamide levels; adhere to food safety requirements; contain only ingredients that are permitted for use; be able to implement at the factory level; be cost effective; and deliver a product that consistently meets the specific sensory requirements of customers and consumers.

Since 2002, to the extent that they can be applied safely and without undesired side effects, frozen potato processors presently employ several mitigation techniques, and have, as a result, achieved reductions in acrylamide levels in their products. In 2005 and 2006, members of the U.S. frozen potato product processing industry cooperated in the development of the Confédération des Industries Agro-Alimentaires de l'UE/Confederation

of the Food and Drink Industries of the EU (CIAA) Acrylamide "Toolbox," which continues to serve as a guiding instrument in U.S. efforts to identify effective techniques for the mitigation of acrylamide in foods. CIAA "Toolbox" recommendations for the reduction of acrylamide in processed potato products include measures performed at the agronomical, processing and final preparation stages of processing and as described below.

As mentioned previously the majority of acrylamide is formed during preparation of processed potato products, FPPI would recommend the Conference consider CIAA "Toolbox" recommendations for the retail-foodservice preparation of processed potato products, particularly French fries, to assist with the reduction of acrylamide in processed potato products. In addition, FPPI has created materials in the forms of training videos and a poster that could further aid in helping educate the retail-foodservice industry about measures that can be employed in the storage, preparation, and cooking to assist with acrylamide reduction.

Public Health Significance:

Background

Although some of this research has resulted in successful mitigation methods that have been implemented in the processing of potatoes, the research is incomplete and ongoing. Acrylamide is naturally occurring in many cooked, high-carbohydrate, plant-based foods. It is not a food additive, nor does it come from packaging. Though only recently discovered, it is not a new substance and has been present since humans began cooking foods. Acrylamide forms as food "browns" during high-heat cooking methods, such as frying, grilling, roasting, baking and toasting. Acrylamide has been shown to cause cancer in lab animals when exposed for their lifetimes at very high levels - 1,000 to 10,000 times the acrylamide found in foods; its effect on human health is being investigated, though there is not yet sufficient data to make an official determination. No health authority has recommended any changes in the diet because of acrylamide. Because it can be present in such a wide variety of foods, from coffee, bread, cereal, nuts, potato chips, and French fries to even some cooked fruits and vegetables, it is important to maintain a healthy, balanced diet. There is greater formation of acrylamide in food products that are heavily browned or crisped as a result of cooking. Consumers should fry, grill, bake, roast and toast foods to the lightest acceptable color to reduce the formation of acrylamide at home.

Agronomical Control

Manufacturers have sought to reduce acrylamide levels first by controlling the levels of reducing sugars in raw potatoes. Reducing sugars are among the key reactants in the formation of acrylamide, so controlling sugar content is one of the primary means by which the industry has achieved a reduction in acrylamide levels in processed potato products. All process varieties of potatoes are selected for their low reducing sugar content with a goal of lowering sugars through raw material sourcing, and several additional varieties are under consideration for use. Each is currently being evaluated for its acrylamide formation tendencies. Assessing the quality of a new potato variety for processing and its acrylamide-forming tendencies, however, requires significant time and resources; it can take up to 10 years or longer to develop and evaluate new varieties. Generally, only mature potatoes are considered for processing, as they contain fewer reducing sugars than do young potatoes.

Manufacturers also seek to reduce the formation of acrylamide in frozen potato products by storing and transporting raw potatoes at the "Toolbox" recommended temperature of >6°C or >43°F to suppress build-up of reducing sugars. Continually circulated, tempered air

throughout the storage facility helps ensure the potatoes remain dry and the gas mixtures appropriate. Consistent with Good Agricultural Practices (GAP), sprout suppressant is applied when evidence of sprouting is observed, as sprouting causes potatoes to convert starch to sugar.

Processing

Acrylamide is formed during the Maillard reaction, which is the predominant chemical process determining color, flavor and texture in many cooked foods. Specifically, acrylamide is formed by the reaction of two main components, each occurring naturally in potatoes: free asparagine and reducing sugars. Asparagine is the main free amino acid found in potatoes, and can account for 20 percent to 60 percent of the total free amino acids found in potatoes. Flavor evaluations also show that asparagine has a significant impact on French fry flavor.

Manufacturers have explored many techniques for reducing acrylamide during the processing of potato products, including frying conditions, blanching, acidification and the use of other additives. Par-frying has been shown to have little or no effect on the level of acrylamide found in finished potato products. Blanching, however, can be effective in removing excess reducing sugars and thus lowering acrylamide formation in finished products.

The use of sodium acid pyrophosphate (SAPP) is standard industry practice for reducing after-cooking darkening. The application of SAPP has also demonstrated some ability to reduce acrylamide in finished products. Its efficacy as an acrylamide mitigating agent, however, is limited by the development of bitter "off" flavors that increase as the concentration of SAPP increases. Accordingly, use of SAPP above current industry standards is not a viable mitigation strategy.

Asparaginase, an enzyme that converts asparagine to aspartic acid, thereby reducing asparagine and thus potential for the formation of acrylamide in foods, has been tested with limited success on some products in a laboratory setting. Asparaginase has also been tested at factory scale on a limited basis; however, additional testing is required to determine its efficacy as an effective acrylamide mitigant.

Preparation

As the majority of acrylamide is formed during final preparation of frozen potato products, the industry has taken steps to reduce acrylamide by lowering the recommended preparation temperature on on-pack cooking instructions, and eliminating certain methods of preparation from use. For foodservice, the cooking instructions on par-cooked frozen potato products have been changed to reflect a reduced recommended frying temperature from 360°F to 345°-350°F.

The primary methods of preparing retail frozen potato products are oven baking and stovetop skillet frying. On-pack baking instructions on retail products are being optimized to reduce acrylamide formation and maintain product quality. Still other preparation methods, such as toaster oven cooking, have been eliminated for some retail products, as these methods can produce acrylamide levels in finished products at significantly higher levels than do other cooking methods.

Intensity of browning during cooking is a significant variable determining the level of acrylamide present in a finished product. The frozen potato products industry, therefore, has attempted to encourage over time a change in customer and consumer perceptions and expectations of the color of prepared French fries from "golden brown" to a "golden

yellow" or "light golden" color. FPPI expects this action to help reduce acrylamide exposure over time.

To that end, cooking instructions for retail products prepared in the oven now include cautionary statements such as the following:

- Do not overcook.
- Cook to a golden yellow or light golden color.
- When cooking small amounts, reduce the cooking time.

Conclusion

The food industry, the scientific community and many global government entities are all investigating the prevalence of acrylamide in the human diet, the possible effects of acrylamide on human health and ways to reduce the formation of acrylamide during the cooking process.

Potato growers are growing potato varieties that contain lower levels of sugars, which lead to lower levels of acrylamide during cooking. Growers are also adjusting potato storage temperatures to keep sugar levels low.

Food manufacturers, including potato processors, are incorporating best manufacturing practices to reduce acrylamide formation in food, including reformulating products; increasing moisture levels during processing (blanching); lowering cooking times and temperature levels during processing (par-frying); and providing specific instructions to consumers on packaging, like "cook to a light golden color."

FPPI member companies continue to research strategies and techniques to reduce the formation of acrylamide in its products. The frozen potato products industry is also undertaking efforts to educate consumers and restaurant operators about ways to reduce acrylamide in French fries during the cooking process.

Food producers continue to innovate and find new ways to improve the health and safety of their products. The frozen potato industry is committed to working with the scientific community and government agencies around the world to address the presence and reduction of acrylamide in food.

Recommended Solution: The Conference recommends...:

The frozen potato products industry would support efforts to provide guidance to retail-foodservice operators and consumers on proper preparation (e.g., temperature and time) to aid in the reduction of acrylamide based on easily recognized product characteristics, such as color.

- that the Conference review all relevant documents contained in the CIAA "Toolbox" recommendations for the retail-foodservice preparation of processed potato products, particularly French fries, to determine if the materials can be added to the CFP web site to provide assistance to this sector with the reduction of acrylamide in processed potato products.

In addition, FPPI has created materials in the forms of training videos and a poster that could further assist in education efforts for the retail-foodservice industry about measures that can be employed further in the storage, preparation, and cooking to assist with acrylamide reduction. We recommend the Conference review these materials to determine if there is value in adding these resource tools as links or attachments on the CFP web site."

- that the Conference posts on the CFP web site the links to acrylamide resources that could aide in educating the retail-foodservice industry about measures that can be employed in the storage, preparation, and cooking to assist with acrylamide reduction in processed potato products. These links would include:

European Commission Directorate - General for Health and Consumers
http://ec.europa.eu/food/food/chemicalsafety/contaminants/ciaa_acrylamide_toolbox09.pdf
U.S. Food and Drug Administration
http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Acrylamide/UCM053569
Codex CODE OF PRACTICE FOR THE REDUCTION OF ACRYLAMIDE IN FOODS, (CAC/RCP 67-2009).
www.codexalimentarius.net/download/standards/11258/CXP_067e.pdf
Joint FAO/WHO Expert Committee on Food Additives (JECFA): Seventy-second meeting, Rome, 16-25 February 2010.
http://www.who.int/foodsafety/chem/summary72_rev.pdf.
Frozen Potato Products Institute's "Know Your Fries" poster and educational videos about Fryer Management for Acrylamide Reduction available in both English and Spanish (see https://www.yousendit.com/dl?phi_action=app/orchestrateDownload&rurl=https%253A%252F%252Fwww.yousendit.com%252Ftransfer.php%253Faction%253Dbatch_download%2526batch_id%253DT2djclVBMm1Fd2ZtcXNUQw).

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Attachments:

- "Know Your Fries Poster, English"

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Conference for Food Protection
2012 Issue Form

Internal Number: 118
Issue: 2012 III-029

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

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Title:
Public Release of Food Allergy Resource Document

Issue you would like the Conference to consider:
Public release in 2012 of the eagerly anticipated food allergen management guidelines, being reviewed by the CFP Food Allergen Committee as directed in Issue 2010 III-001, and in accordance with the Food Allergen Labeling Consumer Protection Act (FALCPA) "Section 209. Food Allergens in the Food Code" which states: *the Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.*

Public Health Significance:
A significant number of food allergy reactions occur in restaurants/food service establishments.[i] [ii] [iii] In fact, in two published studies on *fatal* food allergy reactions, *almost half* were triggered by food served in or provided by restaurants / food service. Studies also show significant gaps in restaurants' understanding of food allergies. [iv] Restaurant employees generally receive little or no training on the serious nature of food allergy; reading ingredient labels; the importance of strict allergen avoidance; and avoiding cross-contact during food preparation.[v]
The intent of any guidelines should be allergen management.

i Vierk KA, Koehler KM, Fein SB, Street DA. *Prevalence of self-reported food allergy in American adults and the use of food labels.* J Allergy Clin Immunology 2007;119:1504-10.
ii Furlong TJ, DeSimone J, Sicherer SH. *Peanut and tree nut allergic reactions in restaurants and other food establishments.* J Allergy Clin Immunol 2001;108(5):867-70.
iii Greenhawt MJ, McMorris MS, Furlong TJ. *Self-Reported Allergic Reactions to Peanuts and Tree Nuts Occurring at Restaurants and Food Service Establishments*. Poster presented at the 2008 annual meeting of the American Academy of Allergy, Asthma & Immunology, March 14-18, 2008, Philadelphia, PA.

iv Aline R. Ajalaa, Adriano G. Cruza, Jose A.F. Fariaa, Eduardo H.M. Waltera, Daniel Granatob and Anderson S. Sant? Anab. *Food allergens: Knowledge and practices of food handlers in restaurants.* Food Control, Volume 21, Issue 10, October 2010, Pages 1318-1321.

v Ahuja R, Sicherer SH. *Food-allergy management from the perspective of restaurant and food establishment personnel.* Ann Allergy Asthma Immunol 2007;98:344-48.

Recommended Solution: The Conference recommends...:

public release in 2012 of the food allergen guidelines and recommendations developed by the 2010-12 CFP Food Allergen Committee for use by the CFP membership, and the food preparation and inspection communities.

The Conference further recommends that these documents:

- be posted to the CFP web site, and
- that a letter be sent to the FDA requesting dissemination on the FDA website.

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Conference for Food Protection
2012 Issue Form

Internal Number: 025
Issue: 2012 III-030

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

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

Issue you would like the Conference to consider:
The Allergen Committee has not progressed on any of its charges since the 2010 Biennial Meeting in Providence, Rhode Island. The committee chair did not submit a report for council at the 2012 Biennial Meeting. This Issue is submitted by the Executive Director on behalf of the Conference.

Public Health Significance:
The risk of allergic reactons to foods sold at retail food establishemts is of great concern to consumers and the retail food industry. Many avoidable injuries occur annually in the United States simply because retailers do not have sufficient information and guidance in the proper labeling and handling of potential allergens. Allergic reactions sometimes occur in pesons who consume ordinary foods sold legally throughout the United States. With proper labeling and handling practices retail food facility operators can minimize the potential for injuries and their liability resulting from unitended consumption of food allergens.

Recommended Solution: The Conference recommends...:
1. The disbanding of the CFP Allergen Committee in its current form. This Committee was not active, did not submit a final report for this Biennial Meeting, and the Committee charges assigned at the 2010 Biennial Meeting were not addresed.
2. The issue of prevention of allergic reactions in customers of retail food facilities continues to be a concern of the Conference; therefore, the Conference for Food Protection Executive Board is directed to reach out to interested groups to be better informed about food allergens and preventive measures for allergic reactions to food legally sold in retail food facilities.

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