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

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2020-I-004; new or additional information has been included or attached.

Title:

Report – CFP-ISSC JSC Issue #1

Issue you would like the Conference to consider:

The CFP-ISSC Joint Shellfish Committee seeks acknowledgement of the committee's report, with thanks to the members of the committee for their work.

Public Health Significance:

The previous CFP Shellfish Committee identified the lack of shellstock tag and shellstock illness investigation resources available for state and local retail food inspectors and retail food establishments. Delays in investigating a foodborne disease outbreak can occur when shellstock tags are not properly maintained as required by the FDA Food Code. Retail food establishments must understand the importance of shellstock tags and have adequate best practice documents on how to properly maintain shellstock tags to protect public health. Timely investigation of *Vibrio parahaemolyticus* (Vp) cases by State and local health officials are often impeded by unsuccessful efforts to determine product source. Incidences of Vp illnesses associated with molluscan shellfish consumption have increased and continue to be a significant challenge to health authorities. A toolkit for state and local inspectors can assist in gathering the needed data during an investigation, prevent illnesses, and could increase the accuracy of growing area closures.

Recommended Solution: The Conference recommends...:

1. Acknowledgment of the CFP-ISSC Joint Shellfish Committee Final Report.

2. Thank the committee members for their diligent work on the development of a significant number of best practices and guidance documents to further the joint effort between retail food establishments and regulators to protect public health.

3. Disband the committee; all assigned charges have been completed.

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Content Documents:

- "CFP-ISSC Joint Shellfish Committee Final Report"
- "CFP- SSC Shellfish Committee Roster"
- "i. Shellstock Tag Procedures English (see attached PDF)"
- "ii. Shellstock Tag Procedures Spanish (see attached PDF)"
- "iii. Shellstock Tag Procedures Infographic (see attached PDF)"
- "iv. Shellstock Tags English (see attached PDF)"
- "v. Shellstock Tags Spanish (see attached PDF)"
- "vi. Anatomy of Shellstock Tags (see attached PDF)"
- "vii. Molluscan Shellfish The Basics (see attached PDF)"
- "viii. Shellfish Code Language Table (see attached PDF)"
- "ix. Molluscan Shellfish Environmental Investigation Field Worksheet"
- "x. Molluscan Shellfish Investigation Field Checklist (see attached PDF)"

Supporting Attachments:

- "i. Alaska shellfish retail guide 1"
- "i. Alaska shellfish retail guide 2"
- "ii. Assess_AMC Shellfish"
- "iii. Hawaii_retail shellfish requirements"
- "iv. Molluscan Shellfish"
- "v. Molluscan Shellfish Handling"
- "vi. Record Keeping"
- "vii. Retail Shellfish Requirements"
- "viii. Shellfish at Retail 5_08"

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

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2020-I-004; new or additional information has been included or attached.

Title:

CFP-ISSC JSC #2 Approve and Post Guidance and Best Practices Documents

Issue you would like the Conference to consider:

1. Guidance documents to assist regulators during shellstock foodborne illness outbreak investigations

2. Best Practice documents for retail food establishments on the importance and correct process for maintaining shellstock tags.

Public Health Significance:

The previous CFP Shellfish Committee identified the lack of shellstock tag and shellstock illness investigation resources available for state and local retail food inspectors and retail food establishments. Delays in the investigation of a foodborne disease outbreak can occur when shellstock tags are not properly maintained as required by the FDA Food Code. Retail food establishments must understand the importance of shellstock tags and have adequate training on maintaining shellstock tags to protect public health. There is a need for inclusive materials due to the diversity of the population. Having the documents in Spanish and also having a infographic is important so these tools can reach the diverse retail workforce. Timely investigation of *Vibrio parahaemolyticus* (Vp) cases by State and local health officials are impeded by unsuccessful efforts to determine product source. The incidence of Vp illness associated with molluscan shellfish consumption is on the rise and continues to be a significant challenge to health authorities. A toolkit for state and local inspectors can assist in gathering the needed data during an investigation, prevent illnesses, and could increase the accuracy of growing area closures.

Recommended Solution: The Conference recommends...:

1. Approval of the five retail food establishment best practice documents in English and Spanish

- a. Shellstock Tag Procedures English (see attached PDF)
- b. Shellstock Tag Procedures Spanish (see attached PDF)
- c. Shellstock Tag Procedures Infographic (see attached PDF)
- d. Shellstock Tags English (see attached PDF)
- e. Shellstock Tags Spanish (see attached PDF
- 2. Approval of the five guidance documents for state and local food safety inspectors.
- f. Anatomy of Shellstock Tags (see attached PDF)
- g. Molluscan Shellfish the Basics (see attached PDF)
- h. Shellfish Code Language Table (see attached PDF)

i. Molluscan Shellfish Environmental Investigation Field Worksheet (see attached Word document)

- j. Molluscan Shellfish Investigation Field Checklist (see attached PDF)
- 3. Post the approved guidance documents on the CFP website.

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Content Documents:

- "a. Shellstock Tag Procedures English (see attached PDF)"
- "b. Shellstock Tag Procedures Spanish (see attached PDF)"
- "c. Shellstock Tag Procedure Infographic (see attached PDF)"
- "d. Shellstock Tags English (see attached PDF)"
- "e. Shellstock Tags Spanish (see attached PDF)"
- "f. Anatomy of Shellstock Tags (see attached PDF)"
- "g. Molluscan Shellfish the Basics (see attached PDF"
- "h. Shellfish Code Language Table (see attached PDF"
- "i. Molluscan Shellfish Environmental Investigation Field Worksheet (see att")
- "j. Molluscan Shellfish Investigation Field Checklist (see attached PDF)"

Supporting Attachments:

- "a. Alaska shellfish retail guide 1"
- "a. Alaska shellfish retail guide 2"
- "b. Assess_AMC Shellfish"
- "c. Hawaii_retail shellfish requirements"
- "d. Molluscan Shellfish"
- "e. Molluscan Shellfish Handling"
- "f. Record Keeping"
- "g. Retail Shellfish Requirements"
- "h. Shellfish at Retail 5_08"

Issue:	2023	I-003
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above the line is for conference use only.				

Issue History:

This is a brand new Issue.

Title:

Gloves Used as a Single-Use Disposable Utensil

Issue you would like the Conference to consider:

Disposable gloves are defined as a utensil in the 2022 FDA Food Code (3-304.11). Currently, there is no specific provision within the FDA Food Code that covers hand washing and using a disposable glove as a single-use utensil, similar to a tong or spatula. When a glove is used as a single-use disposable utensil, and no contamination of the hand has occurred, there should be no need to wash hands after glove removal or between changes.

Public Health Significance:

Hand washing is a critical activity to ensure against cross-contamination. The FDA Food Code indicates there are specific times when hands must be washed (2-301.14). The various rules within the FDA Food Code are focused on potential contamination events while there is an opportunity to include interpretation for when contamination does not occur, such as when using a disposable glove in a single-use situation, similar to a tong or spatula. Rather than adding an additional hand wash step that would not occur if any other utensil was used, the glove(s) should be allowed to be removed and/or changed without a hand wash procedure in instances where contamination of the hand has not occurred.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting that the most current edition of the *Food Code Annex 7, Guide 3-B, 8. Hands clean and properly washed*, be amended as follows: IN/OUT

This item should be marked IN or OUT of compliance. This item is marked IN compliance only when employees are observed using proper handwashing techniques at appropriate times and places. Hands are not required to be washed between each change of gloves, if it is observed that there was no change in the task being performed and no activities which could potentially result in cross contamination. <u>Also, hands are not required to be washed</u> <u>after or between glove changes if gloves are used as a single-use disposable utensil and</u> <u>no activities resulting in hand contamination were observed.</u>

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

Issue History:

This is a brand new Issue.

Title:

Amend Food Code 2-301.14 – Allow Donning of Loose-Fitting Gloves

Issue you would like the Conference to consider:

Amend 2-301.14 to allow glove use without washing hands under some circumstances.

Public Health Significance:

Gloves are an important tool in food service to prevent bare hand contact with ready-to-eat foods and also to protect hands from sources of contamination, thus reducing the amount of handwashing that needs to occur. Many food establishments use loose-fitting gloves as a utensil to handle food items like raw meat and do not follow 2-301.14(H), which requires a hand wash prior to donning gloves.

While the Food Code does specify that gloves can be a utensil (see the definition of "utensil" in the code) it further does not specify when gloves should no longer be treated as gloves. According to 2-301.14(H), hands must be washed before gloves are donned to initiate food preparation. If gloves/utensils are still considered gloves, then the procedures in place in many restaurants are not allowed since they generally do not include a hand washing step prior to donning the glove. Furthermore, if the process includes the use of double-gloving (traditional gloves under loose-fitting gloves), this process is not allowed at all since gloved hands cannot be washed prior to placing the loose-fitting glove over the primary glove.

Many state and local agencies have allowed this process and see the use of loose-fitting gloves as a utensil through a variance or some other pathway. The FDA has stated that they do not see this practice as disallowed based on the current language of the Food Code. Industry has expressed frustration as multiple regulatory jurisdictions have interpreted the Food Code to say that this is not an allowed process.

This issue seeks to codify what industry wants to do and many regulators (including the FDA) have allowed in some capacity.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most current edition of the Food Code be amended as follows:

2-301.14 When to Wash.

FOOD EMPLOYEES shall clean their hands and exposed portions of their arms as specified under § 2-301.12 immediately before engaging in FOOD preparation including working with exposed FOOD, clean EQUIPMENT and UTENSILS, and unwrapped SINGLE-SERVICE and SINGLE-USE ARTICLES^P and:

(A) After touching bare human body parts other than clean hands and clean, exposed portions of arms; $^{\rm P}$

(B) After using the toilet room; P

(C) After caring for or handling SERVICE ANIMALS or aquatic animals as specified in § 2-403.11(B); P

(D) Except as specified in ¶ 2-401.11(B), after coughing, sneezing, using a handkerchief or disposable tissue, using TOBACCO PRODUCTS, eating, or drinking; ^P

(E) After handling soiled EQUIPMENT or UTENSILS; P

(F) During FOOD preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks; ^P

(G) When switching between working with raw FOOD and working with READY-TO-EAT FOOD; $^{\rm P}$

(H) Except as specified in \P (J) of this section, B before donning gloves to initiate a task that involves working with FOOD; ^P and

(I) After engaging in other activities that contaminate the hands. P

(J) Loose-fitting gloves may be placed over hands/gloved hands as long as the following <u>criteria are met:</u>

(1) The gloves are donned using a hands-free process such as using a glove holder/dispenser that allows hands/gloved hands to be inserted into the loose-fitting gloves without hand/gloved hand contact with the outside of the loose-fitting glove; and

(2) After use, the loose-fitting gloves are removed using a method that does not contaminate the hands/gloved hands such as shaking the loose-fitting gloves off directly into a trash receptacle.

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Issue:	2023	I-005
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected	-	
All information above the line is for conference use only.				

Issue History:

This is a brand new Issue.

Title:

Add cross contact definition & codified/Annex language within the Food Code

Issue you would like the Conference to consider:

Unintended allergen presence due to allergen cross-contact at food establishments presents a risk to consumers with food allergies. Currently, the FDA Food Code does not define allergen cross-contact nor does it address management of allergen cross-contact within food establishments. This issue recommends that "allergen cross-contact" be defined within the Food Code as well as the addition of codified language addressing control of unintended allergen presence.

Public Health Significance:

Labeling of major food allergens (MFAs) within a food establishment is a major step towards protecting consumers with food allergies by helping them make informed choices based on the labeling information about the intentional addition of MFAs in foods. However, MFA labeling alone does not address all the needed protections. Another source of MFAs within food establishments is unintended allergen presence due to cross-contact that may occur because of the very nature of the small spaces and the high throughput of orders with different allergen profiles being prepared using shared cooking utensils and common food contact surfaces. Addressing allergen cross-contact to reduce the incidences of unintended allergen presence can help achieve the overall goal of safe food for consumers with food allergies.

Food allergies and other types of food hypersensitivities affect millions of Americans and their families with estimates of food allergies in US consumers reported to be as high as 8% in children and 10.8% in adults (Gupta et al., 2011; Gupta et al., 2019). National consumer survey data from the Food Allergy Research & Education (FARE), found that 50% or more of consumers report one or more allergic reactions per year and, of unintentional exposures resulting in reactions, 24% were reported to occur due to cross-contact. Cross-contact also appeared as the most common reason for unintentional exposure to food allergens (Fierstein et al., 2021). A survey conducted by FARE in 2021,

found that restaurants are the second most common location, following home, for food allergy reactions. Another study found similar data where after one's home, restaurants are the second most common location for food allergic reactions (Oriel et al., 2021).

Analysis of food product recall data has shown that allergen cross-contact presents an opportunity for allergens to be present in food products if proper controls are not instituted (Gendel et al., 2013; Sharma et al., 2022). While research has shown that certain model Food Code cleaning procedures are effective at removing allergenic compounds (Bedford et al., 2020) it remains important that the risk of cross-contact be addressed to employ effective cleaning procedures for allergen management within the food establishment.

It has been acknowledged that requirements to control allergen cross-contact in food establishments is a gap in the existing Food Code. Unintentional allergens being present in foods can be mitigated through control measures (Boyd et al., 2018). For the retail industry, taking steps to control allergen cross-contact can be challenging, but taking these steps are important in reducing the risk of allergenic proteins being present unintentionally. Allergen cross-contact control measures should be risk-based and implemented using scientific principles. To reduce the risk to the consumer from unintended allergen presence due to cross contact, special consideration should be placed on the following: (1) the storage and preparation areas provide adequate space and flow, (2) appropriate food preparation and service procedures are followed when foods are prepared for a consumer with a food allergy, and (3) employees are properly trained on food allergen management within the food establishment including employee hygiene and the impact of allergen cross-contact on the risk to a consumer that has a food allergy.

A plethora of information exists to educate stakeholders on allergen cross-contact. Refer to Supporting Document entitled, "Attachment 1 - Summary of FDA Allergen Cross Contact References" to obtain list of resources. Although this information exists, the FDA Food Code lacks explicit recognition of allergen cross-contact to minimize the potential risks associated with allergen cross-contact within a food establishment. The FDA Food Code currently requires labeling of MFAs for packaged food and written consumer notification for unpackaged foods. By addressing allergen cross-contact in the FDA Food Code, regulatory authorities, industry partners, and consumers will formally recognize the risks from allergen cross-contact and take steps to actively manage allergen cross-contact within the food establishment. Labeling of MFAs in packaged food, providing written consumer notification of MFAs in unpackaged food coupled with a plan to address allergen cross-contact provide greater assurance to consumers that MFAs are being addressed within the food establishment.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that:

- 1. FDA define the term 'allergen cross-contact' in the Food Code to address the unintentional incorporation of major food allergens into food.
- 2. FDA incorporate codified language in the Food Code addressing a Food Establishment having a plan in place to address unintended allergen presence in food due to allergen cross-contact.

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Supporting Attachments:

- "Attachment 1 Summary of FDA Allergen Cross Contact References"
- "Bedford et al 2020"
- "Boden et al 2005"
- "Boyd_pre-print research paper"
- "Gendel and Zhu 2013"
- "Gupta et al 2011"
- "Gupta et al 2019"
- "Attachment 8-Allergen cross contact reference_Sharma et al2022 IAFP Poster"

Issue:	2023	I-006
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected	-	
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Issue History:

This is a brand new Issue.

Title:

Regulating use of "may contain" type advisory labels

Issue you would like the Conference to consider:

A proposed definition to establish appropriate limits and definitions for use of the terms "may contain" and "made in a facility that processes" allergens.

Public Health Significance:

Food allergies are affecting more people every day. It is vital that people with allergies know what is in the products they consume so that they do not have a life-threatening reaction.

The Food Allergy Safety, Treatment, Education, and Research Act of 2021 or the FASTER Act of 2021 act which mandates the labeling of sesame as a declared allergen has led to unintended consequences. Companies that never had sesame in their products are deliberately adding sesame to comply with the change in the law rather than engaging in good manufacturing practices. This has led to consumers with sesame allergy to have far fewer choices in bakery products and restaurants where they can eat. The FDA has publicly acknowledged that this is happening and that the practice is not upholding the spirit of the law.

A proposal that may help the issue without causing too much disruption to industry would be for the FDA to establish a legal definition for disclosing cross-contact, like "made in a facility" or "main contain." That way, companies that have sesame products and fear cross contamination can clearly disclose the cross-contact and the consumer can then decide whether they feel safe taking the risk of purchasing the product. This would kill two birds with one stone because there has long been confusion in the allergy community about the significance of these cautionary phrases which are currently unregulated.

Recommended Solution: The Conference recommends...:

sending a letter to the FDA requesting the agency to establish a legal definition for disclosing cross-contact for the presence of food allergens. Such definition should clearly explain the limits and ramifications of terms like "may contain" or "made in a facility that also processes" perhaps using threshold amounts that would trigger the use of the warnings.

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Issue:	2023	I-007
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected	-	
All information above the line is for conference use only.				

Issue History:

This is a brand new Issue.

Title:

Bread bakers adding sesame flour to recipe rather than "may contain."

Issue you would like the Conference to consider:

I would like the conference to consider a way to induce bread bakers to stop making breads more dangerous by adding sesame flour to their recipes. Perhaps by changing the requirements of a "may contain" statement to be more protective of the manufacturers yet still alerting consumers of the possible presence of sesame. Many sesame allergic people have safely eaten many breads for years that had possible cross contact with sesame seeds. The seeds are less allergenic than the flour that is now being added. Eating bread anywhere outside the home has become much more dangerous and nearly impossible for sesame allergic people. It was much safer and easier before the FASTER Act went into effect.

Public Health Significance:

The public health consequences of bread makers adding sesame four is massive. Many previously safe places are now dangerous. Caregivers of small children, and many parents themselves, may not know of the additional risks of their previously safe spots. Accidental ingestion risks for sesame allergic people have increased tremendously.

Recommended Solution: The Conference recommends...:

Working with the stakeholders to find a solution or maybe labeling language that protects consumers, but does not compel the bakers to add the allergen to previous recipes that did not contain sesame. There has to be a better solution than adding a dangerous and potent form of the allergen to recipes rather than to have an appropriate label. Maybe also consider an incentive for eliminating sesame since it isn't a critical ingredient in many of these products. It does not offer additional nutritional value and is only ornamental for most breads.

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Issue:	2023	I-008
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected	-	
All information above the line is for conference use only.				

Issue History:

This is a brand new Issue.

Title:

Sesame Update To Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1))

Issue you would like the Conference to consider:

I would like the Conference to consider advocating to update the Food, Drug, and Cosmetic Act (FD&C) to authorize food manufacturers to label products with an advisory warning of cross contamination of sesame, in order to prevent food manufacturers from adding sesame flour to their bread as a substitute for compliance with the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act.

Public Health Significance:

The FASTER Act, which was enacted to "protect" those with sesame allergies by identifying sesame as the 9th "major food allergen" has backfired and resulted in bakeries adding a small amount of sesame flour to bread - not to enhance flavor - but solely to identify sesame as an ingredient, due to their perceived inability to comply with Section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)). The current law requires that food manufacturers label for the 9 major food allergens. If an allergen is not an ingredient in the food, the manufacturer is prohibited from listing it as an ingredient. In addition, good manufacturing practices are required for food allergen preventative controls. Due to the financial burden of "good manufacturing practices," for decades, it has been an accepted practice for companies to label a product with an advisory warning, such as "made in a facility with _____" or "may contain ____" or "made on shared lines with _____", in order to warn of the potential cross contamination of an allergen, without adding that allergen as an ingredient to the food. When the FASTER Act was passed, rather than rely upon this accepted practice, food manufacturers (and in particular bakeries), have become fearful that an advisory warning is insufficient to comply with the FD&C Act. As such, these manufacturers are adding a small amount of sesame flour to their bread for the sole purpose of declaring an allergen. As a consequence of this decision, it has become nearly impossible for a sesame allergic person to find safe bread to eat. Of note, sesame is a unique allergy. Many with sesame allergies are not affected by cross contamination of seeds, due to the fact that the protein that causes a reaction is located inside the seed. The

waxy coating of the seed acts as a barrier. Although some people may be sensitive to cross contamination, there are many people who have safely been able to consume bread made in a facility with sesame seeds without any issue. However, it is unlikely that someone with an active sesame allergy can consume sesame flour baked into the bread. People with sesame allergies are no longer able to safely eat hamburgers, hot dogs, pizza, and rolls due to sesame flour being added to these foods to avoid compliance with good manufacturing standards. Children with sesame allergies who rely upon hot lunch programs are now struggling to find safe foods to eat. Restaurants such as Wendy's, Chikfli-a, Culver's, Olive Garden and Maggiano's are being impacted by their bread suppliers adding sesame to their bread. Of concern, this change is not well known or advertised to the public, and many restaurant managers are not being educated about these changes. As such, those with sesame allergies are at an extremely high risk of an accidental reaction, due to the fact that reliable restaurants where they safely ate weeks ago may no longer be safe for them. It is not a question of if, but a question of when someone will get sick and possibly die from eating a burger at Wendy's because they did not know that sesame flour was added to the bread. Unlike sesame seeds, the small percentage of flour being added is not visible or noticeable; however, also unlike sesame seeds (which are less potent due to how they are digested), a small amount of sesame flour could be deathly.

Recommended Solution: The Conference recommends...:

A preferable law, which would benefit both bakeries and those with sesame allergies, would allow for bakeries to label their packages with an advisory warning to clearly indicate whether 1) Sesame seeds and/or flour is the facility; and 2) Sesame seeds and/or flour is used on a shared line. With this information, a person with sesame allergies can make an informed decision about whether the potential cross contamination is a risk based upon their sensitivity to the allergen. In addition, bakeries will not need to add a small percentage of sesame flour to otherwise sesame-free bread. Of note, people with sesame allergies who can tolerate cross contamination have been safely eating bread from bakeries that use sesame seeds without issue. Adding sesame flour to bread is NOT the answer to protect those with sesame allergies. Rather, truth in labeling and allowing for advisory warnings is the answer to protect those with sesame allergies. It is necessary to update the FD&C Act and codify the permissive use of advisory labels. Although advisory labels have been an accepted practice with respect to other allergens, it is clear that food manufacturers (and in particular bakeries) are not comfortable relying on this practice with respect to sesame seeds. Rather, they need the security and protection of a statute to prevent the fear of litigation. Notice of a risk of cross contamination would prevent litigation. It would be at the consumer's risk to consume food with such a warning. As noted above, those with sesame allergies should be trusted to make their own informed decisions about their health when provided with accurate information about the potential for cross contamination in a facility. However, adding sesame flour directly to bread takes that right away. This is overt discrimination. It is despicable to add a small amount of an allergen to food solely to exclude a class of people. There is a better way. An update to the FD&C Act with respect to advisory warnings is long overdue.

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Content Documents:

- "FARE responds to companies intentionally adding sesame"
- "Bread Suppliers Adding Sesame"

Supporting Attachments:

• "Tough New Labeling Law For Sesame Prompts Companies To Add It"

Issue:	2023	I-009
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	_
All information above the line	is for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Companies adding sesame to products previously safe for sesame-allergic

Issue you would like the Conference to consider:

The Food Allergy Safety, Treatment, Education, and Research (FASTER) Act was a positive change for the allergy community, bringing sesame labeling in line with other top allergens. Unintended consequences of this change have included companies adding small amounts of sesame to their products, rendering them unsafe for those with sesame allergies, which impacts products available for retail sale and those supplied to restaurants.

The purpose of the change in the law was to increase safety for those who are sesameallergic. However, in response to the changes in the law requiring sesame labeling, manufacturers, including members of major baking organizations, have opted, in some cases, to add sesame flour to products. This action impacts restaurants and retail sales downstream, as once-safe products now pose a life-threatening risk for those with sesame allergies. Some people have multiple allergies, so choices are already limited, and this change has caused great upheaval in the sesame allergy community.

Public Health Significance:

More than a million people in the United States are allergic to sesame, or approximately 0.49% of the population. Many of these individuals have co-morbid allergies and other allergic diseases, such as asthma.

A balanced diet requires the ability to safely eat whole grains in the form of bread, tortillas, crackers, and other products. Severely limiting safe options is not only inconvenient, but it can have harmful effects on health.

Recommended Solution: The Conference recommends...:

We recommend that restaurants and retail organizations that sell bread and related products to consumers communicate with manufacturers that the strategy of adding risk to foods to mitigate risks to avoid the requirements for cross-contact mitigation is **not**

acceptable in a country where approximately 6% of the population has food

allergies. Negotiations with major baking companies to introduce sesame-free lines of common products such as bread loaves, hot dog and hamburger buns, crackers, breadcrumbs, etc. should be prioritized. In the short-term, risk communication about product changes should be amplified to avoid potentially fatal outcomes.

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Issue: 2023 I-010

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

Issue History:

This is a brand new Issue.

Title:

Labeling under Food Allergy Safety, Treatment, Education & Research Act

Issue you would like the Conference to consider:

The Food Allergy Safety, Treatment, Education and Research Act ("FASTER Act") added sesame to the list of major food allergens which manufacturers are required to declare on product labels. The intent of the law was to make food safer for consumers with food allergies, as sesame was frequently included in categories such as "spices" or "natural flavors." As a parent of a child who manages a sesame allergy, we celebrated this news, and looked forward to January 2023. Manufacturers had 18+ months to comply with the new labeling laws. Rather than taking the steps needed to segregate sesame, and apply safe manufacturing practices, nearly every company who manufactures ANY product with sesame has instead opted to ADD small amounts of sesame to their products so that they can declare it on the label. It appears they are interpreting the FASTER Act to mean they must guarantee there is no cross contamination with sesame, and they have declared that impossible to comply with. Because the FASTER Act does not include permission or quidance on the issue of when a product is run on the same line, or produced in the same facility with sesame, they felt it was "safer" for food allergy consumers if they added the allergen and declared it as an ingredient on the label. The list of companies who have taken this approach is not short. Previously some companies chose to label for sesame consumers with sesame allergy had several options of bread and hamburger buns to choose from in their local grocery stores, and generally could eat out at a number of places without issue. "Go to" restaurants were places where they did not use sesame seeded buns. As a consumer, I could choose to accept the risk that bread products may have been cross contaminated with a product containing a sesame seed, knowing that whole seeds cannot be digested and are unlikely to cause a reaction. None of these items are now safe, and that choice has been taken away from my family, and others with sesame allergies. By choosing to add sesame flour to all bread products as their way to "comply" with the FASTER Act, the following is a short list of products that we have identified and can no longer use in our home: most fast food restaurants (nearly all buns now contain sesame flour), many chain restaurants (addition of sesame flour to bread and pizza has increased

risk of cross contamination), nearly every sliced bread, hamburger and hot dog bun supplied to restaurants now contains sesame flour, plain and cinnamon raisin bagels now contain sesame flour, many pizza places have now added sesame flour. The list goes on and on. This has created a tremendous danger to consumers with sesame allergies, as products they have used for years are now changing recipes. A collection of articles was recently published by the Food Allergy Research & Education ("FARE") summarizing these challenges and is available at

http://www.foodallergy.org/resources/fare-response-companies-intentionally-adding-sesame-flour-faster-act-goes-effect

Public Health Significance:

330 million people in the US have been diagnosed with a sesame allergy. It's the 9th most common allergen, and has been the most difficult to navigate. Restaurants will now be under increased challenges to try to accommodate their allergic clientele, and the risks of cross contamination have significantly INCREASED because the number of products containing this allergen has increased so significantly. Children who eat in school cafeterias will no longer be able to eat the things they used to eat, and are not likely to know of changes in the laws, or company practices. Food servers have not been properly educated. In the times we have eaten out since January 2023, I have educated 75% of the servers on the new changes - none were aware of the new law, and had no idea so much sesame was in their kitchen. I have read about 3 food allergy deaths since December 2022 in the US. Children should not be put at risk because companies have cut corners and chosen to work around the legal requirements put in place to keep them safe.

If companies and restaurant establishments have the obligation to segregate allergens and train employees, but could simply label that a product is "made on a shared line with products containing [insert allergen]" that would give consumers the option to decide whether to eat that product or not. If a product was labeled "made in a facility with [insert allergen] but made on dedicated [insert allergen] free line" that would provide enough information to food allergy families to be able to make an educated decision. Currently any "may contain" or "made in a facility with" or similar label is voluntary, the absence of such a warning does not mean the product is safe to consume, and consumers are simply left guessing as to whether products are safe or not.

Recommended Solution: The Conference recommends...:

Amend the FASTER Act and the Food Code to standardize labeling options for food allergens in addition to existing good manufacturing practices. Include standard definitions for labeling cross contamination that will inform consumers and allow them to make their own choices about what is safe for their families. This would render the absence of such a label meaningful, allowing food allergic consumers the ability to make meaningful decisions for their health and safety. Include strict penalties for changing recipes to intentionally add any of the top 9 allergens to existing recipes for the purpose of being able to declare it as an ingredient.

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Issue:	2023	I-011
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	_
All information above the line	s for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Manufacturers have begun to add sesame to protect from legal action.

Issue you would like the Conference to consider:

The conference needs to address the current problem around food labeling and the manufacturers ability to change formulations to include allergens as a way to circumvent liability.

Public Health Significance:

As of the change in labeling requirements to include a "contains" statement for sesame ingredients, manufacturers have begun to put trace amounts of sesame into products that had not before contained sesame. This is in an attempt to alleviate any possible legal responsibility in the event a person allergic to sesame consumed their product and sustained damages. It is a legal loophole which allows these companies to change their formulations for the sole purpose of covering themselves from liability. This creates further hardships for anyone who has to deal with a sesame allergy. It may be legal at this point, but it is not the right thing for these companies to be allowed to do. It has far reaching consequences for people who already have a limited ability to purchase and consume products safe for them.

This has caused extreme hardships for those with a food allergy to sesame . For example, it is now incredibly difficult to find a safe bread if you are a person with a food allergy to sesame. Prior to the change in labeling requirements, I was able to find multiple bread products which did not label for sesame, and were therefore "safe". Of those breads, none are now safe- because they have ADDED sesame in trace amounts to their formulation. How is this allowed? They didn't change their recipes for any other reason except to protect themselves.

For those families that have to navigate the world around food allergies this has created an unintended hardship. The purpose of labeling for sesame was to ensure those with a sesame allergy were properly informed so they could make safe choices and protect themselves and those they love from a potential fatal reaction. However, the way in which the law has been allowed to be implemented has caused even greater hardship.

It is imperative that we are able to have proper labeling for the top 9 allergens, while not having companies add allergens into food to prevent lawsuits. It's unfair, it's unsafe and it needs to be addressed.

Recommended Solution: The Conference recommends...:

Lawmakers must create a prescription for changing labeling while not allowing manufacturers to change formulations to evade potential liability.

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Issue:	2023	I-012
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	is for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Establish written procedures for managing food allergy events

Issue you would like the Conference to consider:

Food establishments should have written procedures that clearly state if and how food employees should respond to patrons having allergic reactions and severe allergic reactions resulting in anaphylaxis. Explicit guidance should be specified for, but not limited to: who is qualified to intervene during an allergic reaction event; whether a food establishment does or does not stock epinephrine injectors, antihistamines, and/or corticosteroids; and when food employees should seek medical help. The 2022 Food Code does not require written procedures for managing food allergy events.

Public Health Significance:

Approximately 10% of adults in the United States have food allergies, and retail food establishments are a frequent location of food allergy events (Gupta 2016, Radke 2017). A 2017 publication from the CDC's Environmental Health Specialist's Network (EHS-Net) reported that managers and staff were not confident in their establishment's ability to effectively respond to an emergency event arising from a food allergen exposure. Among 2,822 individuals included in the Food Allergy Research & Education registry were surveyed and over 50% of respondents who experienced a reaction at retail had informed restaurant staff of the allergy, over 25% of respondents also reported that allergens had been declared on the menu, and 14% occurred when allergens were declared on the menu and establishment staff were informed (Oriel 2020).While recent changes to the Food Code have improved requirements for informing consumers of common allergens, as well as food handler training for food allergens, responding to food allergy event is not addressed.

Currently, the person in charge (PIC) is required to demonstrate knowledge by "Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction" in section 2-102.11(C)(9). In section 2-103.11 (O) the PIC is required to ensure that: "EMPLOYEES are properly trained in FOOD safety, including FOOD allergy awareness, as

it relates to their assigned duties. FOOD allergy awareness includes describing FOODS *identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction.*" Additionally, sections 3-602.11 (B)(5) and 3-602.12 (C) require labeling for major food allergens. However, the 2022 Food Code does not require any form of written plan or procedures for responding to an allergy event.

A written plan for responding to food allergy events can help food establishments to manage liability and designate appropriate individuals to respond, if appropriate. All food employees should feel confident about whether they should or should not intervene during a food allergy event, and if intervention is necessary, what intervention entails.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting the following to be added to 2-501 Responding to Contamination Events of the most recent edition of the Food Code

2-502.11 Responding to Food Allergy Events.

<u>A FOOD ESTABLISHMENT shall have written procedures for EMPLOYEES to follow when</u> responding to an allergic reaction, and severe allergic reactions resulting in anaphylaxis, experienced in the FOOD ESTABLISHMENT.

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Supporting Attachments:

- "Food Allergy Knowledge and Attitudes of Restaurant Managers and Staff"
- "Characteristics of Food Allergic Reactions in the United States"

Issue:	2023	I-013
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Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action	
Delegate Action:	Accepted		Rejected		
All information above the line is for conference use only.					

Issue History:

This is a brand new Issue.

Title:

PSC14 Re-create Plan Review Committee

Issue you would like the Conference to consider:

Through their committee process, the Conference for Food Protection developed the Plan Review for Food Establishment 2016 guidance. Since the guidance was based on an earlier edition of the FDA Food Code (2013), it is recommended that the Plan Review Committee be re-created to update the document for conformance with the FDA 2022 Food Code and present findings at the 2025 CFP Biennial Meeting.

Public Health Significance:

Plan Review lays the foundation for an operation to be in long term compliance with the FDA Food Code. Jurisdictions conducting plan review benefit from technical guidance that is based on the most current edition of the FDA Food Code. A Conference for Food Protection document fosters consistency and standardization across jurisdictions for the plan review process.

Recommended Solution: The Conference recommends...:

Re-creation of the Conference for Food Protection Plan Review Committee with the following charges:

- 1. Review and update the 2016 Plan Review for Food Establishment guidance
- 2. Consider the inclusion of food safety management system components into the guidance document
- 3. Present an updated document for approval at the 2025 biennial meeting

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Supporting Attachments:

• "PSC Issue #14 list of supporting attachments"

Issue: 2023 I-014

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

Issue History:

This is a brand new Issue.

Title:

Re-Establish Plan Review Committee

Issue you would like the Conference to consider:

Plan Review Committee be re-established to review and update the Food Establishment Plan Review Manual and present their findings at the 2025 CFP Biennial Meeting. The current manual was last updated to be consistent with the FDA 2013 Food Code.

Public Health Significance:

The plan review process aims to prevent foodborne illness by verifying the installation and design of a sanitary facility. The process further includes menu review, food preparation, and food flow.

Recommended Solution: The Conference recommends...:

that the Plan Review Committee be re-established with the following recommendations:

1. update the Food Establishment Plan Review Manual, including Appendices, in accordance with the FDA 2022 Food Code, and

2. report back the committee's findings at the 2025 Biennial Meeting.

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

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2014 I-003; new or additional information has been included or attached.

Title:

Re-create the Plan Review Committee (PRC)

Issue you would like the Conference to consider:

The PRC was not re-created following the 2016 CFP Biennial meeting. Since this time, many trends have gained popularity in the food service industry, including shared kitchens, multi-concept ghost kitchens, etc. In addition, two new FDA Food Codes have been published since 2016. No updates to the four guidance documents produced by the PRC have been made during this time. The Conference should recreate the PRC to review and revise, if needed, all previously published PRC guidance documents available on the CFP website in light of the 2022 Food Code and popular industry practices.

Public Health Significance:

The PRC's work has historically provided recommendations to promote public health and prevent environmental health related illnesses through proper planning of food establishment construction. Previous guidance documents provided by this committee may be out of compliance with the current FDA Food Code and may fail to address recent trends and practices within the food service industry.

Recommended Solution: The Conference recommends...:

The PRC be recreated following the 2023 CFP Biennial meeting with the following charges:

1) Review and revise the following documents as needed to address changes in the latest version of the FDA Food Code, as well as latest and popular industry trends.

a) Plan Review for Food Establishments 2016

b) Recommended Guidance for Permanent Outdoor Cooking at Permanent Food Establishment 2014

c) Recommended Guidance for Mobile Food Establishments 2014

d) Temporary Food Establishments 2011

2) Determine if there are other guidance documents that should be developed to address newer technologies and begin the process of developing these resources.

3) Report back to the next biennial meeting of the Conference for Food Protection

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Issue:	2023	I-016
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Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		Rejected			
All information above the line is for conference use only.						

Issue History:

This is a brand new Issue.

Title:

Re-creation of the Hand Hygiene committee

Issue you would like the Conference to consider:

Foodservice and food processing operators spend considerable time and money training food handling staff to wash their hands, but there is no definition or standard for a clean hand. The Food Code includes definitions for a handwashing sink and a cleaning procedure for washing hands [2-301.12], but there is no standard for a clean hand. Finally, there is only one written process for cleaning hands. Further, given the potential for unintentional or intentional contamination of potable water (e.g., from flooding, aging infrastructure), alternative handwashing or hand cleansing methods are necessary.

Public Health Significance:

Per the CDC's website, washing hands with soap and water could reduce diarrheal deaths by up to 50%; if everyone washed their hands, approximately 1M lives would be saved (https://www.cdc.gov/hygiene/fast-facts.html). Handwashing is one of 4 preventive measures CDC lists for prevention of foodborne illness. Current recommendations require a 20 second handwash, which is a challenge for food service operators who, it has been suggested, should wash their hands 29 times per hour (Strobehn et al, 2008). A study of street food vendors found employees were not able to take the time to wash their hands when they had a large number of orders to prepare because of time pressure (Green et al. 2005). The Union of Concerned Scientists article Troubled Waters (Persad et.al, 2020), outlines the challenges with California's water system. Drought, flooding, and an aging infrastructure is putting stress on the water supply, leading to potential shortages, and risk for contamination. There is no reason to believe California is the only state experiencing such issues. Handwashing data from 436,125 foodservice inspections conducted between January 1, 2017 and December 31, 2019 indicate 15% of inspections found noncompliance for handwashing sinks (i.e., people could not wash their hands according to the written process) and 13% found non-compliance with handwashing requirements.

Recommended Solution: The Conference recommends...:

The re-creation of a Hand Hygiene Committee with the following charges:

- 1. Define what is a clean hand, e.g. a two-log bacterial load reduction on the hands.
- 2. Identify more than one method for effective hand washing when:
 - o Potable water is available, and
 - When potable water is not available.
- 3. Report the Committee's findings and recommendations at the next Biennial Meeting.

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Supporting Attachments:

- "References"
- "Factors Impacting Food Workers' & Managers' Safe Food Preparation Practices"
- "Hand Washing Frequencies and Procedures Used in Retail Food Service"

Issue:	2023	I-017
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	-
All information above the line	is for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Amend Food Code 3-301.11 - Double Handwashing and Nail Brush Usage

Issue you would like the Conference to consider:

Amend 3-301.11(E)(6) to specify that double handwashing means washing hands twice whenever a hand wash is required and that nail brushes must be used every time hands are washed.

Public Health Significance:

Bare hand contact with ready-to-eat foods is disallowed by the Food Code because of the potential for transmission of fecal-oral route pathogens by asymptomatic food employees. The Food Code allows food establishments to engage in bare hand contact under certain circumstances as long as two or more "control measures" are in place; two of the control measures specifically listed in the Food Code are "double handwashing" and "nail brushes." The Food Code does not provide any specific information about those control measures. Operators have interpreted this section of the Food Code to imply that double handwashing means washing hands inside the restroom and then again when returning to the kitchen (see attachments) and that nail brushes can be used occasionally instead of every time hands are washed.

In regards to the double hand washing issue, we have found several online sources, both from industry and regulatory, that defines "double handwashing" as washing hands in the restroom and then again in the kitchen. Further clarification would address the conflict between this interpretation and the guidance from the FDA.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most current edition of the Food Code be amended as follows:

3-301.11 Preventing Contamination from Hands

(E) FOOD EMPLOYEES not serving a HIGHLY SUSCEPTIBLE POPULATION may contact exposed, READY-TO-EAT FOOD with their bare hand if:

(6) Documentation that FOOD EMPLOYEES contacting READY-TO-EAT FOOD with bare hands use two or more of the following control measures to provide additional safeguards to HAZARDS associated with bare hand contact:

(a) Double handwashing,

(i) For the purposes of this section, double handwashing means washing hands twice whenever required to do so as specified under § 2-301.14.

(b) Nail brushes used every time hands are washed,

(c) A hand antiseptic after handwashing as specified under § 2-301.16,

(d) Incentive programs such as paid sick leave that assist or encourage FOOD EMPLOYEES not to work when they are ill, or

(e) Other control measures approved by the REGULATORY AUTHORITY; and

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Supporting Attachments:

- "California_Double Handwashing"
- "West Virginia_Double Handwashing"
- "ResPro_Double Handwashing"
- "State Food Safety_Double Handwashing"

Issue:	2023	I-018
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above the line	is for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Chemical Sanitizing test strips Expiration Date

Issue you would like the Conference to consider:

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration. Concentration of the SANITIZING solution shall be accurately determined using a test kit or other device according to manufacturer instructions. Language should be added regarding expired test strips.

Public Health Significance:

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

These strips ensure that the right dilutions have been done & proper strengths of sanitizing/disinfection chemicals will work as needed.

According to manufacturer guidelines, expired tests strips may no longer be accurate in assessing the concentration or pH of the sanitizer and therefore, would no longer hold up as an accurate test to take enforcement on.

Some operators and inspectors may not realize that their test strips expire and could be checking their concentrations with expired strips that may not be giving an accurate reading, producing a potential health risk by being under or over the accepted limit. This false reading could cause someone to not be sanitizing at a high enough concentration which would be an issue, or they could be over sanitizing which would also lead to a potential health risk.

Recommended Solution: The Conference recommends...:

That a letter be sent to FDA requesting that Section 4-501.116 be modified as follows (new language is underlined)

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration.

- 1. Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device.
- 2. <u>Sanitizing test kit shall be used according to manufacture instructions and date</u> <u>marking limitations.</u>

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

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2020-I-015; the recommended solution has been revised.

Title:

Report - Foodborne Illness Investigation Committee

Issue you would like the Conference to consider:

The Foodborne Illness Investigation Committee seeks acknowledgement of the committee's final report, with thanks to the members of the committee for their work.

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to a) stop additional people from being exposed and becoming ill; b) understand the system failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment. In addition, quickly identifying the source of outbreaks through purchase records is crucial to identify the specific product so that public health advisories can warn consumers to avoid certain implicated products instead of broad categories (such as Romaine, tomatoes, or papayas). Such advisories have an enormous economic impact on the food sector and retail food establishments. Solving outbreaks quickly using consumer purchase records also reduces the number of people that may become ill and subsequent industry liability. Some regulatory authorities have been denied access to consumer food product purchase information, and clarification that the Food Code provides authority to access these records will reduce illnesses and associated economic impacts.

The Food Code appendix 2's supporting documents reference the Voluntary National Retail Food Program Standards (VNRFPS) along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks and having the ability to trace food back to its source. Jones, T. F., & Angulo, F. J. (2006). Eating in Restaurants: A Risk Factor for Foodborne Disease? *Clinical Infectious Disease*, *43*, 1324-1328. doi:1058-4838/2006/4310-0017

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., ... Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis, 17*(1), 7-15. doi:10.3201/eid1701.091101p1

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the Foodborne Illness Investigation Final Report.
- 2. Thanking the Committee members for their work.
- 3. Disbanding the committee since all charges have been met.
- 4. Posting a PDF of the Committee developed "Food Establishment Consumer Purchase Best Practices" guidance document for CFP branding under Conference-Developed Guides and Documents on the CFP website.

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Content Documents:

- "Final Report Foodborne Illness Investigation Committee"
- "Food Establishment Best Practices for Providing Consumer Purchase Informati"
- "Foodborne Illness Investigation Committee Roster"

Supporting Attachments:

• "SHOPPER HISTORY Best Practices for Use during Foodborne Illness Investigati"

Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	_
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Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2020-I-015; the recommended solution has been revised.

Title:

FBIIC2-Interpret if 2022 FDA Food Code Provides Investigation Authority

Issue you would like the Conference to consider:

The Committee would like for the U.S. Food and Drug Administration (FDA) to provide a Food Code interpretation to inform regulatory authorities that Food Code Section 8-304.11(H) coupled with Section 8-402.11 provides sufficient authority for the regulatory authority to investigate and obtain information, including records, that are needed as part of the foodborne illness investigation from food establishments.

Food Code section 8-402.11 states that:

After the REGULATORY AUTHORITY presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the PERSON IN CHARGE shall allow the REGULATORY AUTHORITY to determine if the FOOD ESTABLISHMENT is in compliance with this Code by allowing access to the establishment, allowing inspection, and providing information and records specified in this Code and to which the REGULATORY AUTHORITY is entitled according to LAW, during the FOOD ESTABLISHMENT'S hours of operation and other reasonable times.

Food Code section 8-304.11(H) states that the permit holder shall:

Comply with directives of the REGULATORY AUTHORITY including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the REGULATORY AUTHORITY in regard to the PERMIT HOLDER'S FOOD ESTABLISHMENT or in response to community emergencies:

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011), and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to a) stop additional people from being exposed and becoming ill; b) understand the system

failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment.

The Food Code explicitly gives regulators authority to conduct inspections. Authority to access the facility, conduct the inspection, and enforce the Food Code is clear throughout Chapter 8 - Compliance and Enforcement. However, there is no direct reference to foodborne illness investigations which are more focused on obtaining information, including traceback records, and customer purchase history needed to investigate and quickly identify the source of the outbreak and to ensure that control measures are in place to prevent additional illnesses. In addition to public health, the economic impact and industry liability can be mitigated when the source of a foodborne illness outbreak is quickly identified.

The Food Code Annex 2's supporting documents reference the Voluntary National Retail Food Program Standards (VNRFPS) along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks.

Despite not including investigations specifically in the Food Code, an FDA interpretation is needed to determine if that authority is implied.

Jones, T. F., & Angulo, F. J. (2006). Eating in Restaurants: A Risk Factor for Foodborne Disease? *Clinical Infectious Disease, 43*, 1324-1328. doi:1058-4838/2006/4310-0017

Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne illness acquired in the United States--major pathogens. *Emerg Infect Dis*, *17*(1), 7-15. doi:10.3201/eid1701.091101p1

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting an interpretation of the Food Code clarifying that

Section 8-304.11(H) coupled with Section 8-402.11 and other relevant sections provide sufficient authority for a regulatory authority to conduct a foodborne illness investigation and obtain access to needed information.

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

Issue History:

This issue was submitted for consideration at a previous biennial meeting, see issue: 2020-I-015; the recommended solution has been revised.

Title:

FBIIC3-Amend 2022 FDA Food Code to Provide Access for FBI Investigation

Issue you would like the Conference to consider:

The Committee would like for the U.S. Food and Drug Administration (FDA) to add language to provide the regulatory and/or health authority access to investigate reports of foodborne illness.

Currently, the Food Code does not provide access for regulatory/health authorities to gather information in a food establishment for a foodborne illness investigation. It contains language to assess information on code compliance (what is currently occurring) and plan review (what will occur in the future) but lacks language to assess and gather historical information such as processing record review, product traceback, purchase history, etc. (which is the primary focus of a foodborne illness investigation).

Furthermore, Standard 5 of the FDA Voluntary National Retail Food Program Standards (VNRFPS) assesses whether a regulatory program has developed policies to investigate foodborne illness. These policies implicitly rely on States' public health authorities for preventing disease transmission. Language permitting access in the Food Code will ensure that all jurisdictions that adopt the Food Code will have the same baseline authority to investigate foodborne illness.

Public Health Significance:

Every year in the United States there are millions of cases of foodborne illness (Scallan et al., 2011), and a majority of these cases are attributable to food establishments (Jones & Angulo, 2006). Investigation of these reports of illness is of paramount importance to a) stop additional people from being exposed and becoming ill; b) understand the system failure within a food establishment that led people to become ill; and c) identify a source of contaminated food that may have entered the food establishment.

The Food Code Annex 2's supporting documents reference the Voluntary National Retail Food Program Standards along with the Council to Improve Foodborne Outbreak Response's Guidelines for Foodborne Outbreak Response. Both documents include the need for investigating foodborne illness outbreaks.

Conducting investigations into how people became sick is an integral part of a food safety program. By understanding the system failures that resulted in a foodborne outbreak, practices can be changed to prevent the failure from happening in the future. Because of the investigation's importance, FDA includes this subject matter in VNRFPS Standard 2 under the epidemiology construct and International Food Protection Training Institute (IFPTI) includes this as a foundational element for the basic competency level. Additionally, the important nature of this work has led to the development of additional advanced courses (e.g., FDA ER324 Epi-Ready for Response Teams, and CDC's Environmental Assessment Training Series).

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that Chapter 8 of the most current published version of the Food Code be amended to include:

The REGULATORY AUTHORITY shall act when it has reasonable cause to believe that a FOOD ESTABLISHMENT may be associated with a foodborne illness investigation; by assessing all relevant facilities, EQUIPMENT, FOOD, personnel, and available records.

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lssue:	2023	I-022
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	_
All information above the line is for conference use only.			

Issue History:

This is a brand new Issue.

Title:

Amend Food Code to allow cooling without time and temperature monitoring.

Issue you would like the Conference to consider:

We propose amending Food Code 3-501.14 to include an option to cool time and temperature control for safety (TCS) foods at a depth of 2 inches or less, uncovered, and refrigerated, without time and temperature monitoring.

Hot foods should be cooled rapidly to minimize pathogen growth and prevent outbreaks. Unfortunately, rapid cooling is often difficult for restaurants to accomplish and for inspectors to verify. The Food Code requirements for achieving proper cooling rely on frequent monitoring of time and temperatures. This monitoring is not always feasible for restaurant operators because of the time required to adequately monitor the cooling process.

The Food Code outlines methods that can promote rapid cooling of TCS foods but does not specify how to apply the methods to various situations or whether some methods are more effective than others. Inspectors and operators are left to evaluate every method, or combination of methods, to determine which meet the time requirement. We recommend that operators and inspectors be allowed to also focus on specified cooling methods that are known to facilitate quick and proper cooling without additional time monitoring.

The recommended solution is intended to reduce the complexities of monitoring cooling time/temperature parameters by offering a safe, simple, and clear alternative: foods can be cooled uncovered, in a refrigerated environment at a depth of 2 inches or less, with no additional time and temperature monitoring required.

Public Health Significance:

Our proposed option of refrigerated cooling at an uncovered depth of 2 inches or less, provides a clear cooling standard for operators. This option is also beneficial to inspectors, as it is easy to verify during an inspection and easy to train new operators on safe cooling methods. Ultimately, this option will potentially reduce operating costs for food establishments and reduce time dedication for operators and inspection staff while providing a more reliable way to reduce foodborne illness.

Improper cooling of hot food by restaurants is a significant cause of foodborne illness outbreaks (Brown et al., 2012). Cooling hot foods too slowly is one of the most common pathogen growth factors contributing to restaurant-related outbreaks (Gould *et al.,* 2013).

The FDA Food Code contains specific time and temperature parameters recommended to achieve proper cooling and suggests methods that can promote rapid cooling. Even with these guidelines restaurants continue to struggle with proper cooling (Hedeen & Smith, 2020; Wittry *et. al,* 2022). An FDA study assessing the occurrence of foodborne illness risk factors in retail settings found that cooling was out of compliance in 72% (196) of the full-service restaurants where cooling was observed (U.S. FDA, "Report on the occurrence", 2018)

Washington State has already adopted this alternative cooling option (in place for 17 years) and it is strongly preferred by operators within the state. Seattle-King County Health Department conducted a risk factor study in 2016, which included 2115 restaurants, and found that 75% of operators reported using the 2-inch cooling option to cool hot foods. Only 12% of operators reported using time and temperature monitoring as outlined by the FDA food code (unpublished data, Seattle-King County Health Department). Since 2-inch cooling without time-temperature monitoring was implemented, no foodborne outbreaks have been associated with this cooling method.

The cooling standard in Washington shows that providing an option to cool at a depth of 2 inches or less, ventilated, and refrigerated provides a solution that is consistently safe and that restaurant operators have adopted enthusiastically.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting 3-501.14 of the current Food Code be amended as specified below:

3-501.14 Cooling.

(A) Except as specified under (B) of this section, Gcooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:

(1) Within 2 hours from 57°C (135°F) to 21°C (70°F); ^P and

(2) Within a total of 6 hours from 57°C (135°F) to 5°C (41°F) or less. P

(B) As an alternative to the cooling provisions of subsection A of this section, FOODS that are being continuously cooled must be cooled in a shallow layer of two inches or less, uncovered, in cooling or cold holding EQUIPMENT maintaining an ambient temperature of 5°C (41°F) or less.

(<u>BC</u>) TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled within 4 hours to 5° C (41°F) or less if prepared from ingredients at ambient temperature, such as reconstituted FOODS and canned tuna. ^P

(<u>GD</u>) Except as specified under \P (<u>BE</u>) of this section, a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD received in compliance with LAWS allowing a temperature above 5°C (41°F) during shipment from the supplier as specified in \P 3-202.11(B), shall be cooled within 4 hours to 5°C (41°F) or less. ^P

(\underline{PE}) Raw EGGS shall be received as specified under ¶ 3-202.11(C) and immediately placed in refrigerated EQUIPMENT that maintains an ambient air temperature of 7°C (45°F) or less. ^P

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Supporting Attachments:

- "Summary of Issue to Amend 3-501-14"
- "Supplemental Materials"
- "Supporting Publications"
- "National Restaurant Association Letter of Support"
- "Taco Time Letter of Support"

Issue: 2023 I-023

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

Issue History:

This is a brand new Issue.

Title:

Amend Food Code to Update Final Cook Temps for Sous Vide under 3-502.12

Issue you would like the Conference to consider:

A recommendation is being made to include alternate cooking time/temperature combinations as found in USDA FSIS Appendix A as acceptable cooking parameters for 3-502.12 (D)(2)(b).

Public Health Significance:

Sous vide is translated to under vacuum from French. This type of cooking uses heat stable pouches to cook foods in a controlled environment. Some of the benefits of sous vide cooking are that the food cooks in its juices, enhancing flavor, and the consistent temperature provides an environment where food does not become overcooked. The food safety aspects of the low temperature, long processing time used in sous vide have been studied, and temperatures below the final cook temperatures provided in the FDA Food Code 3-401.11(A)(3) have been researched. One study titled *Effect of Time and Temperature on Physicochemical and Microbiological Properties of Sous Vide Chicken Breast Fillets* found that the optimum time/temperature combination for cooking chicken using sous vide is 60°C for 60 minutes.

FDA Food Code has made allowances for some reduced oxygen packaging (ROP) to be done without requiring a variance, as stated in 3-502.12. This section of the code allows for food establishments to use a HACCP Plan only for some ROP methods without applying for a variance, since the validation science is well-known. However, 3-502.12 (D)(2)(b) requires that food cooked using sous vide methods must reach final cook temperatures that are provided in 3-401.11(A)-(C). Most retail food establishments that cook using sous vide want to use alternate cooking time/temperatures, so this requirement makes it impractical for establishments to use 3-502.12 to ROP without a variance.

USDA FSIS has written a guidance document that is used to evaluate the production of ready-to-eat foods with respect to salmonella and other pathogens. This document, titled "FSIS Cooking Guideline for Meat and Poultry Products (Appendix A)" has been well

researched in terms of the science behind the pathogen destruction parameters. In this document, there are many additional time/temperature combinations that result in the equivalent destruction of pathogens as the FDA Food Code 3-401.11 parameters. Although relative humidity is included in this document, relative humidity would not be a factor specifically for sous vide cooking, as the food is being cooked in the package. Since the science behind the parameters in this document is widely accepted, cooking sous vide using these parameters does not need additional validation. Therefore, a HACCP Plan for a sous vide product cooked using these parameters should not require a variance.

There is current precedent for inclusion of the FSIS Appendix A in the FDA Food Code. FDA Food Code Section 3-401.11(B) provides some time/temperature combinations acceptable for cooking of whole meat roasts. This does not apply to the current issue however, since poultry products are not included. Providing uniform guidance for cooking across the agencies would increase industry confidence and promote consistency among regulators.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting that the most recent version of the FDA Food Code, Section 3-502.12(D)(2)(b), be amended to include the "FSIS Cooking Guideline for Meat and Poultry Products" as acceptable final cooking parameters for reduced oxygen packaging without a variance.

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Supporting Attachments:

• "Effect of Time and Temperature on Physicochemical Properties of Chicken"

Issue:	2023	I-024
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	-
All information above the line is for conference use only.			

Issue History:

This is a brand new Issue.

Title:

Amend Food Code - Strike "leaking automatic fire sprinkler heads"

Issue you would like the Conference to consider:

The National Fire Sprinkler Association (NFSA) requests that the wording "leaking automatic fire sprinkler heads" be removed from Pages 66, 111 and 127 in the US FDA 2022 Food Code. This language should be stricken as US fire, building, and property maintenance codes address this matter and are enforced by other code officials and authorities having jurisdiction (AHJ) through nationally adopted model codes and standards. These codes and standards are developed through a full, open, consensus-based process. Language to be changed is here:

FDA 2022 Food Code

Page 66 3-305.12 Food Storage, Prohibited Areas (G) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed.

Page 111 4-401.11 Equipment.... (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed.

Page 127 4-903.12 Prohibitions. (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed.

Public Health Significance:

The FDA Food Code language "leaking automatic fire sprinkler heads" should be stricken from the 2022 Food Code as fire sprinklers are now regulated by available, enforceable, and most pertinent fire protection codes and standards that address leaking sprinklers and all other fire sprinkler equipment. The specific code and standard references are here: IFC (International Fire Code), Section 903.5 (from 2000 to the current 2021 edition) requires the inspection, testing and maintenance of fire sprinklers to be per NFPA 25.

Since 2000, commercial buildings in the United States have been designed, built, maintained, and inspected under the International Building Code (IBC) and the International Fire Code (IFC). These codes and referenced standards require leaking fire

sprinkler heads or any leaking fire protection equipment, including piping, to be repaired immediately. These same codes have shifted the inspection, and enforcement of building fire protection maintenance through more direct local and legally required mechanisms - usually fire department/fire marshals.

ICC free code viewer: https://codes.iccsafe.org

NFPA (National Fire Protection Association) 1 Fire Code, Section 13.3.3.4.1.1.1 (from the 1997 to 2021 edition) requires the inspection, testing and maintenance of fire sprinklers to be per NFPA 25.

NFPA (National Fire Protection Association) 25, Section 5.2 (beginning in the 2002 Version), first requires leaking fire sprinkler heads, as well as other leaking equipment, piping, etc. to be replaced.

NFPA (National Fire Protection Association) free code viewer: www.nfpa.org/1 and www.nfpa.org/101

History

The 1986 Conference for Food Protection first developed food safety regulatory rules in 1986 and the processes for all US states to adopt these rules. Conversely, National Building and Fire Protection regulatory rules (by the ICC - International Code Council and NFPA - National Fire Protection Association) were also developed and adopted in the mid-90s and early 2000s. The Conference for Food Protection initially regulated fire protection maintenance concerns around food areas because there was not a nationally accepted building and fire code in prior to the 1990's. Today, several codes and standards require leaking fire sprinklers to be replaced and there is no reason for fire protection to be addressed by the food code.

Today, and since 2000, all editions of the US model construction code, i.e., the IBC, IFC, IPMC (International Property Maintenance Code), NFPA 1 Fire Code, and the NFPA 101 Life Safety Code all reference specific inspection, testing, and maintenance standards (like NFPA 25, the Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems) for all existing buildings and occupancies. This referenced and enforced standard requires leaking sprinklers to be replaced immediately by the building owner through licensed contractors and enforced by local code officials and authorities having jurisdiction (AHJ).

Recommended Solution: The Conference recommends...:

A letter be sent to the FDA requesting the current Food Code be amended as follows:

3-305.12 Food Storage, Prohibited Areas.

FOOD may not be stored:

- (A) In locker rooms;
- (B) In toilet rooms;
- (C) In dressing rooms;
- (D) In garbage rooms;
- (E) In mechanical rooms;

(F) Under sewer lines that are not shielded to intercept potential drips;

(G) Under leaking water lines, including leaking automatic fire sprinkler-

heads, or under lines on which water has condensed;

(H)Under open stairwells; or

(I) Under other sources of contamination

4-401.11 Equipment, Clothes Washers and Dryers, and Storage Cabinets,

Contamination Prevention.

(A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler-

heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

4-903.12 Prohibitions.

(A) Except as specified in ¶ (B) of this section, cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be stored:

(1) In locker rooms;

(2) In toilet rooms;

(3) In garbage rooms;

(4) In mechanical rooms;

(5) Under sewer lines that are not shielded to intercept potential drips;

(6) Under leaking water lines including leaking automatic fire sprinkler-

heads or under lines on which water has condensed;

(7) Under open stairwells; or

(8) Under other sources of contamination.

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Supporting Attachments:

• "All 3 IFC and NFPA Code References for FDA Food Code"

Issue:	2023	I-025
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	_
All information above the line is for conference use only.			

Issue History:

This is a brand new Issue.

Title:

Amend Food Code to include procedures for clean-up of vomit and diarrhea

Issue you would like the Conference to consider:

The clean-up of vomiting and diarrheal events, as stated in the 2022 FDA Food Code, does not specify what exactly is required for a proper response. Due to vague language in the 2022 FDA Food Code, regulatory agencies have deferred to the 2022 FDA Food Code 2-501.11 Annex 3 Public Health Reasons, which lists what a food establishment should "consider" (11 bullet points) when developing a written plan, in order to minimize the spread, exposure, and contamination. The word "consider" leads to confusion, a lack of understanding, and inconsistencies of what is actually required (at a bare minimum) among industry and regulatory agencies.

Public Health Significance:

"According to the CDC, Norovirus is the leading cause of foodborne disease outbreaks in the United States." (2022 FDA Food Code 2-501.11 Annex 3- Public Health Reasons/Administrative Guidelines)

"When an employee, customer, or other individual vomits or has a diarrheal event in a food establishment, there is a real potential for the spread of harmful pathogens in the establishment. Putting the proper response into action in a timely manner can help reduce the likelihood that food may become contaminated and that others may become ill as a result of the accident." (2022 FDA Food Code 2-501.11 Annex 3-Public Health Reasons/Administrative Guidelines)

A timely response cannot occur without having the following in a written plan and onsite:

- EPA registered disinfection products sufficient to inactivate norovirus
- Personal Protective Equipment (PPE)
- Cleaning and disinfecting equipment
- Procedures for cleaning, sanitizing, and disinfecting

• Procedures for containment and removal

"Effective clean-up of vomitus and fecal matter in a food establishment should be handled differently from routine cleaning procedures. It should involve a more stringent cleaning and disinfecting process. Some compounds that are routinely used for sanitizing food-contact surfaces and disinfecting countertops and floors, such as certain quaternary ammonium compounds, may not be effective against Norovirus. It is therefore important that food establishments have procedures for the cleaning and disinfection of vomitus and/or diarrheal contamination events that address, among other items, the use of proper disinfectants at the proper concentration." (2022 FDA Food Code 2-501.11 Annex 3- Public Health Reasons)

"Additionally, exposed food employees are also at risk of contracting Norovirus illness and can subsequently transfer the virus to ready-to-eat food items served to consumers." (2022 FDA Food Code 2-501.11 Annex 3-Public Health Reasons)

"Once such an episode has occurred, timely effective clean-up is imperative. Key to achieving an appropriate, timely response by food employees is the availability and access to a written plan upon which to refer to for reference." (2022 FDA Food Code 2-501.11 Annex 3- Public Health Reasons)

The recommended language was developed to provide guidance to assist the operator and regulators when a vomiting and/or diarrheal event occurs. Adding clarifying language and specific requirements to the FDA Food Code will:

- Create consistency in requirements among industry and regulatory agencies.
- Better support regulatory agencies in the enforcement of requirements.
- Allow for a proper response in a timely manner due to having specific supplies onsite.
- Minimize the spread, exposure, and contamination due to adding the following supplies to the requirements: EPA registered disinfection products sufficient to inactivate norovirus, PPE, and cleaning and disinfecting equipment.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Section 2-501.11 of the most current edition of the Food Code be amended as follows:

2-501.11 Clean-up of Vomiting and Diarrheal Events.

A FOOD ESTABLISHMENT shall have procedures for EMPLOYEES to follow when responding to vomiting or diarrheal events that involve the discharge of vomitus or fecal matter onto surfaces in the FOOD ESTABLISHMENT. The procedures shall address the specific actions EMPLOYEES must take to minimize the spread of contamination and the exposure of EMPLOYEES, consumers, FOOD, and surfaces to vomitus or fecal matter^{Pf} and shall include the following: ^{Pf}

(A) Availability of effective disinfectants, such as EPA registered disinfection products sufficient to inactivate norovirus, personal protective EQUIPMENT, and other cleaning and disinfecting EQUIPMENT and appurtenances intended for response and their proper use. ^{Pf}

(B) Procedures for cleaning, sanitizing, and disinfection of surfaces and cleaning and disinfecting EQUIPMENT that may have become contaminated. ^{Pf}

(C) Procedures for containment and removal of any discharges, cleaning and disinfecting EQUIPMENT, and food that may have been exposed. ^{Pf}

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Issue:	2023	I-026
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	-
All information above the line is for conference use only.			

Issue History:

This is a brand new Issue.

Title:

Add off-site warewashing facilities for multiuse articles to Food Code

Issue you would like the Conference to consider:

The language in the Food Code does not provide adequate guidance surrounding off-site cleaning of multiuse utensils, tableware, take-home food containers and take-out beverage containers (multiuse articles). While some jurisdictions approve variances (see supporting attachments) for the use of off-site warewashing facilities for multiuse articles, the Food Code does not explicitly address or allow this, creating a confusing patchwork of regulations amid increasing public concern over single-use articles.

Public Health Significance:

While the Conference for Food Protection is currently creating a definition for consumerowned reusable containers and the appropriate handling of Time/Temperature Control for Safety Foods when sold in reusable containers (Safe Use of Reusable Container Committee (Issue 2020-I-024)), not all consumers will want to bring their own container. Food handling regulations must accommodate the need for off-site warewashing and associated transportation of multiuse articles to reduce waste and excess packaging. Reducing uncertainty in the language of the regulation encourages nonhazardous time/temperature controlled practices that are safe, convenient and sensitive to the beliefs and desires of many consumers.

Updates to the Food Code will have benefits for state regulatory agencies who rely on federal synthesis of these pertinent issues. Significant time and resources can be saved with the adoption of guidance that is clear and uniformly enforceable, removing the need for individual local variances. Consensus on off-site warewashing standards and associated transportation for multiuse articles is critical for agencies and industry, along with public health and environment.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Part(s) 3-3, 4-4, 4-6, 4-7, 4-9 and/or Annex 3 (whichever portions FDA deems appropriate) of the most current edition of the Food Code be amended (using applicable language developed by FDA) to clarify how to safely use offsite warewashing facilities for multiuse utensils, tableware, take-home food container and take-out beverage container cleaning.

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Supporting Attachments:

- "ME Refilling Returnables Policy 2021, Page 2, Section II "Variance""
- "Plymouth MA Mitigating Use of Plastics 2019, Page 1, Bullet 2"
- "CA Bring Your Own Container Act vendor fact sheet 2019, Page 1 "rent""
- "Philly Zero Waste Guide Food Establishments 2021, Page 4"
- "WA State Retail Food Code, 2022, page 38, Section 03348, (2b)"

Issue:	2023	I-027
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	_
All information above the line is for conference use only.			

Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Packaging Requirements for Vended TCS Foods

Issue you would like the Conference to consider:

Amend 3-305.13 to allow for Time/Temperature Control for Safety foods dispensed from vending machines to be packaged within the vending machine.

Public Health Significance:

Complex vending machines have become more commonplace throughout the United States. Vending machines, which traditionally have been used to dispense pre-packaged, non-TCS foods, now have the capability to cook and package TCS foods entirely within the machine. These machines, which meet other Food Code requirements, like section 4-204.111 requiring automatic temperature-triggered lockouts, are often equipped with self-cleaning systems, which can clean and sanitize food-contact surfaces between products. Furthermore, these machines have the capability to safely store food packaging and package food in a sanitary manner.

Certification bodies already certify machines that vend time/temperature control for safety foods into packaging that is stored within the vending machine. Harmonizing the requirements between the Food Code and certification bodies will help remove undue confusion for equipment developers, certifiers, and regulators. Furthermore, adopting additional language addressing how foods are packaged within a vending machine will help bring parity between regulations and current vending technology.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting Section 3-305.13 and Annex 3 of the current Food Code be amended as follows:

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

(A) Except as specified in $\P(B)$ of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD dispensed through a VENDING MACHINE shall be in the PACKAGE in

which it was placed at the FOOD ESTABLISHMENT or FOOD PROCESSING PLANT at which it was prepared.

(B) FOODS that are to be PACKAGED within the VENDING MACHINE must be held, PACKAGED, and dispensed in a sanitary manner.

Annex 3. Public Health Reasons/Administrative Guideline

3-305.13 Vended Time/Temperature Control for Safety Food, Original Container.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended time/temperature control for safety food allows microbes that may be present an opportunity to contaminate the food. <u>Therefore, it is critical that holding, packaging, and dispensing of food within a vending machine be performed in a safe and hygienic manner.</u> Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, time/temperature control for safety foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

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Issue:	2023	I-028
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above the line	is for conference use only.			

Issue History:

This is a brand new Issue.

Title:

Creation of a Committee - E-Commerce Best Practices

Issue you would like the Conference to consider:

During COVID, grocery stores saw a drastic spike in how consumers obtained their foods. Stores in Wisconsin reported 5 years of growth in 6 months' time as well as E-Commerce sales increasing 4 times greater than normal. Stores were not equipped for shopping the increase in orders and did not have storage areas to hold shopped items while they were in the queue for pick up. Since then, E-Commerce shopping has become a routine way of feeding families. Concerns regarding E-Commerce shopping have arisen including cross contamination of raw proteins bagged with ready to eat foods, TCS foods not properly held refrigerated or frozen, surface characteristics in storage areas and equipment concerns. Questions have also arisen on who is the responsible party for the purchased items that have not been yet picked up by the consumer.

Public Health Significance:

The creation of guidance on how to address food safety requirements for E-Commerce would provide benefits for both regulators and industry. It would detail how to safely handle foods as well as construction requirements for areas used for holding shopped items. It will also benefit industry in providing training when employees are shopping for items as well as what to do with foods that might not be picked up by the consumer and responsible parties during the process.

Recommended Solution: The Conference recommends...:

that an E-Commerce Committee be created and charged with the following:

1. Identify best practices and existing guidance that pertain to E-Commerce shopping at retail.

2. Develop a comprehensive guidance document for retail food establishments with best practices specific to E-Commerce shopping to ensure general Food Code

recommendations are followed. These recommendations would include proper handling during the shopping process to ensure adequate temperature control and cross contamination, construction and equipment requirements for areas where shopped products are held, procedures to address items that were shopped but not picked up by the consumer and any other concerns that may arise during guidance development.

- 3. Determine appropriate mechanisms for distributing the committee's work.
- 4. Report the committee's findings and recommendations at the next Biennial Meeting.

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Issue:	2023	I-029
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted _	Rejected		
All information above the line is for conference use only.				

Issue History:

This is a brand new Issue.

Title:

Amend the Food Code, Section 8-401.10

Issue you would like the Conference to consider:

Under section 8-401.10, Establishing Inspection Interval allows for less frequent inspections. Adapt a new subparagraph in italics under paragraph B to say that the regulatory authority can increase the interval between inspections if the food establishment has a third-party inspection program. This will allow the use of inspections performed by a third party in combination with regulatory inspections to meet the required FDA Food Code regulatory quota for number of inspections. This subsection should be voluntary for industry and regulatory with an option to opt out of the program if either party is not satisfied. The regulatory agency has final approval of the third-party program submitted and can request any changes, updates, or edits as needed. This will allow increased inspection interval for regulatory agencies and support food safety programs under fiscal constraints.

Public Health Significance:

Third-party inspections at retail and manufacturing facilities are already an established part of food safety management systems. This allows an opportunity to further establish a food safety partnership between industry and regulatory. For regulators challenged by funding issues and staffing, this would alleviate the financial constraints and allow them to focus on high risk establishments and other areas of public health work. Industry has proven that they have "self-policing" in place by the provision of internal programs where third-party certified food safety auditors can provide technical expertise and knowledge across a wide range of different food businesses. The impact to industry for such a program would allow participation in the regulatory process and provide an opportunity for a partnership approach to food safety which could benefit and meet future needs.

Recommended Solution: The Conference recommends...:

a letter be sent to FDA requesting the follwing:

1)Under 8-401.10 Establishing Inspection Interval, provide sub-section under paragraph B -

"Regulatory authority can increase the interval between inspections if the food establishment has an approved third-party audit system in place."

2)The conference recommends to establish a process whereby the food establishment receives a third-party food safety inspection at least every 6 months under a program approved by the regulatory authority. The establishment is contacted at least once every 6 months by telephone or other means by the regulatory authority to ensure that the establishment manager and the third-party inspection program have not changed.

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Content Documents:

- "Food Safety News"
- "Food Safety Capacity Assessment"
- "Differences Between Official Inspections and Third Party Audits"
- "The Role of Auditing , Food Safety and Quality"

Supporting Attachments:

• "The Integrity of Private Third Party Food Compliance Monitoring"

Issue: 2023 I-030

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

Issue History:

This is a brand new Issue.

Title:

Creation of a Food Traceability Rule Committee

Issue you would like the Conference to consider:

A Food Traceability Rule Committee be created, composed of members from all constituencies of the CFP. The Committee will be charged with:

- 1. Identifying best practices and existing guidance documents that relate to traceability of foods on the Food Traceability List (FTL).
- 2. Developing a guidance document(s) for food establishments that includes best practices for requirements for records for foods on the FTL.
- 3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code include requirements as specified in the Food Traceability Rule as they relate to retail food establishments (RFE).
- 4. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to FDA requesting that the Food Code, Annex 2 (References, Part 3-Supporting Documents) be amended by adding references to the new Food Traceability Rule as well as any existing guidance documents that the committee recommends, and the posting of information on the CFP website. Include Food Traceability in Annex 3 (Public Health Reasons/Administrative Guidelines).
- 5. Reporting the committee's findings and recommendations to the next Biennial Meeting of the Conference for Food Protection

Public Health Significance:

The final rule is a key component of FDA's New Era of Smarter Food Safety Blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA).

Recommended Solution: The Conference recommends...:

Creation of a Food Traceability Rule Committee to report findings and recommendations to the next Biennial Meeting of the Conference for Food Protection.

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Issue:	2023	I-031
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	-
All information above the line	is for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Clarify 7-204.12 (D) to separate EPA and FDA jurisdictions

Issue you would like the Conference to consider:

We request that a modification of 7-204.12 (D) be made to clarify EPA and FDA regulatory authority

Public Health Significance:

The benefits of a produce wash to control pathogenic microorganisms on the surface of produce and in the wash/crisping water compared to water treatment alone is well established in literature and EPA stamped pesticide labels.

The Environmental Protection Agency (EPA) recognizes the complexity of produce washes by stating, "The most complex area [of regulation] involves the use of antimicrobials in or on food" (EPA Pesticide Registration Manual Chapter 18). Currently, the Food and Drug Administration (FDA) has primary jurisdiction of antimicrobials used in or on processed fruits and vegetables, whereas the EPA has primary jurisdiction on antimicrobials for preand/or post-harvest crops, and use of antimicrobials by consumers on raw agricultural commodities.

Under these conditions, produce washes can be used on processed fruits and vegetables under FDA authority without needing to comply with 40 CFR 156. At the moment, 7-204.12 states the produce wash must meet FDA and EPA criteria, which is not true. This may inadvertently force food establishments to opt for more expensive or higher concentrated products to wash their processed fruits and vegetables.

Recommended Solution: The Conference recommends...:

1. A letter be sent to the FDA requesting that section 7-204.12 (D) of the most current edition of the Food Code be amended as follows (added language underlined and italicized)

1. 7-204.14 (D) - Meet the requirements in 40 CFR 156 Labeling Requirements for Pesticide and Devices *if the product is intended for use on raw agricultural commodities or to control microorganism in the wash/crisping water*

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Issue:	2023	I-032
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Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	-
All information above the line	is for conference use only.		

Issue History:

This is a brand new Issue.

Title:

Reducing Cross Contamination Risk from Use of Reusable Wiping Cloths

Issue you would like the Conference to consider:

The use of reusable cloth wiping towels for quick cleanup of food spills on non-food contact surfaces is a common practice in food establishments. However, it remains one of the most frequently encountered Food Code violations due to failure of one the many steps required to ensure this practice doesn't become a risk to guests and patrons of food establishments. Such steps include:

- Ensuring wiping cloths are held in a sanitizer solution at the appropriate concentration required for efficacy to prevent growth of microorganisms on the cloth itself.
- Ensuring wiping cloths are held in a sanitizer solution free from soil, as soils can negatively impact the concentration of the active ingredient in the sanitizer solution.
- Ensuring individual wiping cloths are not used for practices which could promote cross contamination (e.g., use of the same cloth for wiping raw and ready-to-eat food spills)

As noted below, failure of one or more of these steps may lead to microbial contamination of the sanitizer solution, the wiping cloth, or both, which may lead to cross contamination within a food establishment. We are asking The Conference to consider supporting an amendment to The FDA Food Code which would include code language restricting use of these reusable wiping cloths to non-food-contact surfaces only, mimicking language that already appears within the Annex.

Public Health Significance:

Research has shown reusable wiping cloths to be a potentially risky practice for spread of pathogens within food establishments. A summary of research on the topic appears below.

A study in 2006 reported the findings of a bacterial survey of 37 dishcloths and 10 tabletops from bars and restaurants in New York, California, and Arizona (1). The authors detected

coliforms in 89.2% of cloths (mean bacterial count: 7.6×10^5 CFU/cloth) and *Escherichia coli* in 54.1% of cloths (mean bacterial count: 1.9×10^3 CFU/cloth). The authors also noted that cleaning tables with in-use dishcloths resulted in a significant increase in both bacterial and coliform counts, as compared to be fore cleaning. Finally, the authors found a variety of bacteria, including *Listeria innocua* in 24.3% (*n* =9) of all dishcloth samples. While *Listeria innocua* is not itself a foodborne pathogen, its presence is sometimes used as an indicator organism for *Listeria monocytogenes*.

A 2020 study evaluated the potential for various food allergens (peanut, milk, and egg) to spread to multiple consecutive surfaces using a variety of methods, including the use of reusable terry cloths (2). It was found that allergen transfer was minimized when terry cloths were stored in appropriate solutions of sanitizer in between use, suggesting the potential for an increased chance of allergen cross contamination if sanitizer levels become inadequate.

Several studies have also demonstrated the potential for reusable wiping cloths to spread bacteria and viruses between surfaces. A 2020 study using large tabletops and reusable terry cloths held in sanitizer solutions found that both bacteria (*E. coli, Listeria innocua*) and virus (MS2 bacteriophage) were readily transferred to multiple consecutive surfaces in the absence of sanitizing solution, illustrating the importance of an appropriate concentration of sanitizer for minimizing cross contamination. Similar to these results, a 2012 study demonstrated the potential for damp terry cloths to readily transfer MS2 bacteriophage and Feline Calicivirus to clean surfaces (4).

Given that reusable wiping cloths can become a risk for bacterial and viral cross contamination within a food establishment, especially when sanitizer concentrations fall to levels inadequate for surface sanitization, the addition of language in the FDA Food Code emphasizing that these reusable wiping cloths are not considered an appropriate cleaning step for food contact surfaces may potentially help reduce the risk of foodborne illness outbreaks associated with cross contamination. This also would align code language more closely to that of the Annex, which states that the use of a reusable wet wiping cloth "does not constitute cleaning and sanitizing of food contact surfaces where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code".

References:

- 1. Yepiz-Gomez, M. & Bright, Kelly. (2006). Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Used to Wipe Down Tabletops in Public Restaurants and Bars. Food Protection Trends. 26. 786-792.
- 2. Bedford, B., Liggans, G., Williams, L., & Jackson, L. (2020). Allergen Removal and Transfer with Wiping and Cleaning Methods Used in Retail and Food Service Establishments. Journal of Food Protection, 83(7), 1248-1260.
- Goulter, R. M., Clayton, J. S., Moore, R. G., Bradshaw, J. M., Frye, J. W., Puntch, E. J., & Jaykus, L. A. (2020). Characterizing Microbial Cross-Contamination on Large Surfaces Using a Traditional "Cloth and Bucket" Disinfection Method. Food Protection Trends, 40(6), 392-401.
- Gibson, K. E., Crandall, P. G., & Ricke, S. C. (2012). Removal and transfer of viruses on food contact surfaces by cleaning cloths. Applied and environmental microbiology, 78(9), 3037-3044.

Recommended Solution: The Conference recommends...:

Recommended Solution:

A letter be sent to FDA requesting to amend FDA Food Code 3-304.14 (Wiping Cloths, Use Limitation) as follows:

3-304.14 Wiping Cloths, Use Limitation.

(A) Cloths in-use for wiping FOOD spills from TABLEWARE and carry-out containers that occur as FOOD is being served shall be:

(1) Maintained dry; and

(2) Used for no other purpose.

(B) Cloths in-use for wiping counters and other EQUIPMENT surfaces shall be:

(1) Held between uses in a chemical sanitizer solution at a concentration meeting the <u>criteria specified</u> under § 4-501.114; and

(2) Laundered daily as specified under ¶ 4-802.11(D).

(C) Use of dry and wet wiping cloths do not constitute an appropriate method for cleaning and SANITIZATION of FOOD CONTACT SURFACES where and when such is required to satisfy the methods and frequency requirements in Parts 4-6 and 4-7 of the Food Code

(D) Cloths in-use for wiping surfaces in contact with raw animal FOODS shall be kept separate from cloths used for other purposes.

<u>(E)</u> Dry wiping cloths and the chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be free of FOOD debris and visible soil.

(<u>F</u>) Containers of chemical sanitizing solutions specified in Subparagraph (B)(1) of this section in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of FOOD, EQUIPMENT, UTENSILS, LINENS, SINGLE-SERVICE, or SINGLE-USE ARTICLES.

(G) SINGLE-USE disposable sanitizer wipes shall be used in accordance with EPA approved manufacturer's label use instructions.

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Supporting Attachments:

- "Identity and Numbers of Bacteria Present on Tabletops and in Dishcloths Use"
- "Allergen Removal and Transfer with Wiping and Cleaning Methods"
- "Characterizing Microbial Cross-Contamination on Large Surfaces"
- "Removal and transfer of viruses on food contact surfaces"