Conference for Food Protection
2023 Issue Form

Issue: 2023 III-001

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-III-015; new or additional information has been included or attached.

Title:

Report - Eval of Intended Use Hazards During Retail Meat Grinding Committee

Issue you would like the Conference to consider:

The Evaluation of Intended Use Hazards During Retail Meat Grinding Committee (IUMGC) requests acknowledgement of their final report and thanking the committee members for their efforts and hard work.

Public Health Significance:

STECs are hazards that are reasonably likely to occur in raw beef products and in 2011, USDA FSIS declared raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, or O145 adulterated (76 FR 58157; Sep. 20, 2011). A previously published CFP document, "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" (2014), was developed to provide food safety guidelines for grinding raw beef at retail. In addition, in 2015, USDA FSIS published a final rule requiring recordkeeping at retail establishments for raw beef grinding operations, "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" (80 FR 79231; Dec 21, 2015), to facilitate identification of product during foodborne illness investigations.

In continued outreach to the food industry in 2021, USDA FSIS published "Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" emphasizing the importance of considering the intended use of intact and non-intact beef products. USDA FSIS and other issues submitted to CFP in 2020 (August 2021 Conference) requested that the 2014 CFP guidance be updated with additional information on the importance of considering the intended use of beef products prior to grinding to reduce the risk of contamination of STECs in beef ground at retail and the importance of sharing this information.

In order to increase awareness of known hazards as well as to educate retailers with raw beef grinding operations, a committee was formed to evaluate the 2014 CFP document and provide updated guidance based on recordkeeping requirements finalized in 2015 and guidance released in 2021.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the Intended Use Hazards During Retail Meat Grinding Committee Report.
2. Thanking the committee members for their work.
3. Disbanding the Committee, all assigned charges have been completed.

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Content Documents:

- "Intended Use Hazards During Retail Meat Grinding Committee Final Report"
- "Committee Member Roster"
- "Evaluation of Intended Use Hazards During Retail Meat Grinding Guidance"
- "Evaluation of Intended Use Hazards During Retail Meat Grinding Guidance"

Conference for Food Protection
2023 Issue Form

Issue: 2023 III-002

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 III-015; new or additional information has been included or attached.

Title:

IUMGC 2 – Approval of Guidance Document

Issue you would like the Conference to consider:

Approval of the Evaluation of Intended Use Hazards During Retail Meat Grinding Committee's guidance document entitled "Evaluation of Intended Use Hazards During Retail Meat Grinding" and posting of the guidance document on the CFP website in PDF format.

Public Health Significance:

STECs are hazards that are reasonably likely to occur in raw beef products and in 2011, USDA FSIS declared raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, or O145 adulterated (76 FR 58157; Sep. 20, 2011). A previously published CFP document, "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" (2014), was developed to provide food safety guidelines for grinding raw beef at retail. In addition, in 2015, USDA FSIS published a final rule requiring recordkeeping at retail establishments for raw beef grinding operations, "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" (80 FR 79231; Dec 21, 2015), to facilitate identification of product during foodborne illness investigations.

In continued outreach to the food industry in 2021, USDA FSIS published "Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" emphasizing the importance of considering the intended use of intact and non-intact beef products. USDA FSIS and other issues submitted to CFP in 2020 (August 2021 Conference) requested that the 2014 CFP guidance be updated with additional information on the importance of considering the intended use of beef products prior to grinding to reduce the risk of contamination of STECs in beef ground at retail and the importance of sharing this information.

In order to increase awareness of known hazards as well as to educate retailers with raw beef grinding operations, a committee was formed to evaluate the 2014 CFP document and provide updated guidance based on recordkeeping requirements finalized in 2015 and guidance released in 2021.

Recommended Solution: The Conference recommends...:

1. Approval of the committee generated guidance document entitled "Evaluation of Intended Use Hazards during Retail Meat Grinding" (attached as a content document to the Issue titled: Report - Eval of Intended Use Hazards During Retail Meat Grinding Committee); and
2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. Posting the final document on the CFP website in PDF format.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-003

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-III-015; new or additional information has been included or attached.

Title:

IUMGC 3 - Amend Food Code

Issue you would like the Conference to consider:

Inclusion of the committee generated guidance document entitled, "Evaluation of Intended Use Hazards During Retail Meat Grinding" in the most current version of the FDA Model Food Code Annex 2 *(Annex 2 References section K)*.

Public Health Significance:

STECs are hazards that are reasonably likely to occur in raw beef products and in 2011, USDA FSIS declared raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, contaminated with Shiga toxin-producing *Escherichia coli* (STEC) O26, O45, O103, O111, O121, or O145 adulterated (76 FR 58157; Sep. 20, 2011). A previously published CFP document, "Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments" (2014), was developed to provide food safety guidelines for grinding raw beef at retail. In addition, in 2015, USDA FSIS published a final rule requiring recordkeeping at retail establishments for raw beef grinding operations, "Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products" (80 FR 79231; Dec 21, 2015), to facilitate identification of product during foodborne illness investigations.

In continued outreach to the food industry in 2021, USDA FSIS published "Industry Guideline for Minimizing the Risk of Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef (including Veal) Processing Operations" emphasizing the importance of considering the intended use of intact and non-intact beef products. USDA FSIS and other issues submitted to CFP in 2020 (August 2021 Conference) requested that the 2014 CFP guidance be updated with additional information on the importance of considering the intended use of beef products prior to grinding to reduce the risk of contamination of STECs in beef ground at retail and the importance of sharing this information.

In order to increase awareness of known hazards as well as to educate retailers with raw beef grinding operations, a committee was formed to evaluate the 2014 CFP document and provide updated guidance based on recordkeeping requirements finalized in 2015 and guidance released in 2021.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that the most recent edition of the Food Code be amended to include a reference to the guidance document "Evaluation of Intended Use Hazards During Retail Meat Grinding" (attached as a content document to the Issue titled: Report - Eval of Intended Use Hazards During Retail Meat Grinding Committee) in Annex 2. References, 3. Supporting Documents, K. Requirements and Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-004

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-III-017; new or additional information has been included or attached.

Title:

Report – Retail Sushi HACCP Standardization Committee (RSHSC)

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee requests acknowledgement of their final report and thanking the committee members for their efforts and hard work.

Public Health Significance:

Retail sushi establishments prepare sushi products using many different methods of preparation, and for the rice portion of the sushi products, often use acidification methods to render rice, a TCS food, as non-TCS. This preparation method is used throughout the country, and the interpretation of the requirements of a HACCP Plan can vary. There are many retail sushi establishments that operate in different jurisdictions, and standardization of these requirements and interpretations is needed to help ease the burden of variance and HACCP requirements on industry partners. Additionally, guidance and other resources can be created to provide a better understanding of retail sushi preparation, and HACCP/variance requirements for both operators and regulators nationwide.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the attached Retail Sushi HACCP Standardization Committee Report.
2. Thanking the committee members for their work.
3. The Committee be disbanded; all assigned charges have been completed.

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Content Documents:

- "Committee Final Report"
- "Committee Member Roster"
- "Guidance Document for Retail Sushi HACCP Standardization"
- "Review of National Requirements for HACCP/Variance for Acidification of Ric"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-005

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:

RSHSC 2 – Approval of Guidance Document

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee requests acceptance of the guidance document titled "Guidance Document for Retail Sushi HACCP Standardization" and inclusion of the guidance document on the CFP website in pdf form.

Public Health Significance:

To meet the charges given to the Retail Sushi HACCP Standardization Committee, a guidance document was developed to provide uniform guidance on HACCP plan and Variance requirements for retail sushi preparation.

This guidance document was created to provide standardized information for regulators and industry members for sushi variance and HACCP plans. The document provides the background information related to sushi, standardized parameters for critical control points and critical limits, and examples of operating procedures, food flow diagrams, and hazard analysis. The intent of the guide is to provide parameters and examples for sushi HACCP plans so that the variance and HACCP plan approval can be more uniform across jurisdictions. There are retail sushi establishments that operate in many different jurisdictions, and standardization of the HACCP and variance requirements and interpretations is needed to help ease the burden of the requirements on industry partners.

Recommended Solution: The Conference recommends...:

1. Acceptance of the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee (RSHSC) 1); and

2. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP web site to assure consistency of format and non-technical content; edits will not affect the technical content of the document; and
3. Posting the final document on the CFP website in PDF format

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-006

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:

RSHSC 3 – Amend Food Code Annexes to Reference Approved Document

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee requests inclusion of the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization", in the FDA Model Food Code Annex.

Public Health Significance:

To promote uniform review and approval of sushi acidification variance and HACCP plans, the Retail Sushi HACCP Standardization Committee created a guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization." Providing this tool will assist regulatory and industry partners in achieving more uniform review of sushi variance and HACCP plans. Since the FDA Food Code Annex is often the initial resource that is accessed by both regulators and operators for additional information on retail food processes, including a reference to this document will help promote this guidance as a resource.

Recommended Solution: The Conference recommends...:

A letter be sent to FDA requesting that the most recent edition of the Food Code Annex be amended to include a reference to the document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee (RSHSC) 1) in a section determined to be appropriate by the FDA. Suggestions for location of the document reference are Annex 2 - Supporting Documents or Annex 3 - Section 3-502.11.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-007

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:

RSHSC 4 – Review and Streamlining of Retail Sushi HACCP Process

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee would like for FDA to investigate implementing a standardized process for review and approval of HACCP plans from chain food establishments operating in multi-state jurisdictions.

Public Health Significance:

Retail sushi establishments prepare sushi products using many different methods of preparation, and often use acidification methods to render rice, a TCS food, as non-TCS. This preparation method is used throughout the country, and the interpretation of the requirements of a HACCP Plan for acidification or any other specialized processing method found in FDA Food Code Section 3-502.11 can vary. There are many retail establishments that operate in multiple jurisdictions, and standardization of these requirements and interpretations is needed to help ease the burden of variance and HACCP requirements on industry partners. Having each individual jurisdiction with individual procedures and approval guidelines does not make the acidified food or any other food prepared with a specialized processing method any safer, but it does provide obstacles to operators submitting plans for approval.

Although the FDA Food Code states in 3-502.11 that HACCP Plans are required for rendering a food non-TCS, there are no specific parameters outlined for what is needed in the HACCP Plan. Section 8-201.14 provides basic information about the contents of a HACCP Plan but does not provide enough detail to ensure that all jurisdictions are requiring the same information for HACCP Plans and variances to be approved. For example, since it is not explicitly stated that the critical limit for acidification is typically below 4.2, there are multiple values required by jurisdictions across the country as was found during the review and completion of RSRHCS Charge #1. When a chain food establishment prepares a HACCP plan for submission, individual jurisdictions often impose their own requirements. The result is chain establishments submitting and maintaining

multiple, sometimes dozens, of different plans to satisfy the individual jurisdictions. This does not provide a benefit to public health but does create a burden for operators and regulatory jurisdictions, where time and money is spent on these individualized plans.

The Committee is asking that FDA do a review of how HACCP plans are submitted, and what parameters are used for approval. Using this information, FDA can provide improvements to streamline the process. Ideally, this would come in the form of a committee or task force made up of multiple subject matter experts from regulatory, industry and academic partners to provide review of chain HACCP plans. If a group of experts agree that a HACCP plan meets food safety requirements, then individual jurisdictions may more readily accept the plans as submitted to their individual jurisdictions. This will not only be a huge assistance to the operators that are submitting the plans, but also will assist local and state jurisdictions by saving time and resources involved in HACCP plan review.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting that FDA identify a panel of experts that can review HACCP Plans for chain establishments operating in multiple jurisdictions and provide a validation and approval of the HACCP Plan, and that FDA issue a written interpretation encouraging regulatory authorities to accept the HACCP Plans as approved by the panel, in an effort to standardize HACCP Plan review.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-008

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:

RSHSC 5 – Including Rice Acidification Parameters in Food Code

Issue you would like the Conference to consider:

The Retail Sushi HACCP Standardization Committee would like for the FDA to update the FDA Food Code to include the specific parameters for rice acidification.

Public Health Significance:

Retail sushi establishments prepare sushi products using many different methods of preparation, and often use acidification methods to render rice, a TCS food, as non-TCS. Although the FDA Food Code states in 3-502.11 that HACCP Plans are required for rendering a food non-TCS, there are no specific parameters outlined for what is needed in the HACCP Plan. Section 8-201.14 provides basic information about the contents of a HACCP Plan but does not provide enough detail to ensure that all jurisdictions are using the same approach for HACCP Plans and variances and requiring the same information to be approved. For example, since it is not explicitly stated that the critical limit for acidification is typically below 4.2, there are multiple values required by jurisdictions across the country as was found during the review and completion of RSRHCS Charge #1.

Rice acidification is a relatively simple process that only requires a single Critical Control Point. Rice acidifies quickly and is easy to prepare for pH measurement. Rice acidification is likely the most common HACCP plan reviewed in local and state jurisdictions. If the specific parameters such as the critical limit, monitoring procedure, and corrective actions were included in the Food Code, it would ease a burden on regulators and operators, saving time in the submission, review, and approval.

There is already precedent for including parameters for HACCP Plans for individual procedures in the Food Code. Section 3-502.12 provides parameters to follow for reduced oxygen packaging. In addition, there are several states, such as Ohio, that already include this in their individual state code. The Committee is requesting a similar section be added for rice acidification.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most recent version of the Food Code be amended to include specific requirements to follow for rice acidification, including critical control point, critical limit, and corrective action parameters consistent with the parameters in the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization" (attached as a content document to Issue titled: Report - Retail Sushi HACCP Standardization Committee).

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-009

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:

Report – Safe Use of Reusable Containers Committee (SURCC)

Issue you would like the Conference to consider:

The Safe Use of Reusable Containers Committee requests acknowledging their final report and thanking the committee members for their efforts and hard work.

Public Health Significance:

The growing concern of the environmental impact of single use food containers in the retail service industry has led to an increase in wanting to use personal containers or reuse containers offered in the retail food setting. The committee was formed during the 2021 CFP Biennial (rescheduled from 2020) based on issues that were submitted to explore scenarios, review literature and current documentation on the subject, develop guidance on the safe use of reusable containers and finally propose possible food code language. The committee's final report contains developed guidance to assist the operator and regulators on situations where the reuse of containers can be done safely.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the Safe Use of Reusable Containers Committee Report.
2. Thanking the committee members for their work.
3. The Committee be disbanded; all assigned charges have been completed..

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Content Documents:

- "SURCC Final Report"
- "Committee Roster"
- "Guidance Document for Safe Use of Reusable Containers"

Supporting Attachments:

- "Meeting Summations"
- "Scenario Matrix"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-010

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:

SURCC 2 – Approval and Posting of Guidance Document

Issue you would like the Conference to consider:

Approval of the Safe Use of Reusable Containers Committee guidance document entitled "Guidance Document for Safe Use of Reusable Containers" and posting of the guidance document on the CFP website in a downloadable PDF format.

Public Health Significance:

At the 2021 Biennial meeting Issue 2020 I-024 (combined with 2020 I-022 and 2020 I-023) was transferred to Council III. Council III charged the Safe Use of Reusable Containers Committee with clarifying scenarios related to reusable containers within the scope of regulation. It also charged the committee to identify and analyze the scientific and other literature related to consumer-owned containers at retail. And finally, to draft guidance around scenarios identified in the issue.

The guidance document provides food safety best practices for the reuse of containers in the retail setting. It includes the current allowance for the reuse of containers as well as container construction and condition requirements. Five contamination-free filling methods at retail are addressed, with examples of each method. Third-party reuse providers are addressed with an example standard operating procedures provided. Finally, a list of resources is provided in the guidance document which includes current jurisdiction language where this is allowed, current reuse examples, scientific articles related to reusable containers and guidance for reusable containers.

Recommended Solution: The Conference recommends...:

1. Approval of the committee generated draft guidance document entitled "Guidance Document for the Safe Reuse of Containers". (*See document attached to Issue titled:* Report - Safe Use of Reusable Containers Committee (SURCC))

2. Posting the guidance document on the CFP website in a down-loadable PDF format; and
3. Authorizing the Conference to make any necessary edits prior to posting the document to assure consistency of format and non-technical content; edits will not affect the technical content of the document.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-011

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:

SURCC 3 – Amend Food Code to Include Reusable Container Definition

Issue you would like the Conference to consider:

The Food Code be amended to define the term Reusable Container.

Public Health Significance:

At the 2021 Biennial meeting Issue 2020 I-024 (combined with 2020 I-022 and 2020 I-023) was transferred to Council III. Council III charged the Safe Use of Reusable Containers Committee with clarifying scenarios related to reusable containers within the scope of regulation. It also charged the committee to identify and analyze the scientific and other literature related to consumer-owned containers at retail. And finally, to draft guidance around scenarios identified in the Issue.

The committee requests the approval of amended food code language that will define the new term Reusable Container and be supported by the guidance document developed by the committee and presented in SURCC 2 - Approval and Posting of Guidance Document.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting paragraph 1-201.10(B) in the current Food Code be amended as follows:

<u>Reusable Container.</u>

<u>A product or primary packaging to hold food that is used repeatedly, refilled, or returned for multiple uses and conforms to characteristics of sanitary construction as defined in Parts 4-1 and 4-2 of the Food Code.</u>

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-012

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:

SURCC 4 – Amend Food Code Language to include Reuse of Containers

Issue you would like the Conference to consider:

Amend food code language to allow for the reuse of containers in a retail facility.

Public Health Significance:

At the 2021 Biennial meeting Issue 2020 I-024 (combined with 2020 I-022 and 2020 I-023) was transferred to Council III. Council III charged the Safe Use of Reusable Containers Committee with clarifying scenarios related to reusable containers within the scope of regulation. It also charged the committee to identify and analyze the scientific and other literature related to consumer-owned containers at retail. And finally, to draft guidance around scenarios identified in the issue.

The committee requests the approval of amended food code language that will include the new term Reusable Container which will be supported by the guidance document developed by the committee and presented in the Issue titled: SURCC 2 - Approval and Posting of Guidance Document.

The guidance document provides food safety best practices for the reuse of containers in the retail setting. It includes the current allowance for the reuse of containers as well container construction and condition requirements. Five contamination-free filling methods at retail are addressed with examples of each method. Third-party reuse providers are addressed; an example standard operating procedure is provided. Finally, a list of resources is provided in the guidance document which includes current jurisdiction language where this is allowed, current reuse examples, scientific articles related to reusable containers and guidance for reusable containers.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting Section 3-304.17 of the current Food Code be amended as follows:

3-304.17 ~~Refilling Returnables~~ Refilling REUSABLE CONTAINERS.

~~(A) Except as specified in ¶¶ (B) - (E) of this section, empty containers returned to a FOOD ESTABLISHMENT for cleaning and refilling with FOOD shall be cleaned and refilled in a regulated FOOD PROCESSING PLANT.~~[P]

(A) A REUSABLE CONTAINER shall be designed and constructed for reuse in accordance with the

requirements specified under Part 4-1 and 4-2.

(B) ~~*A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with FOOD if the FOOD container is:*~~

(B) Only REUSABLE CONTAINERS returned to a FOOD ESTABLISHMENT may be refilled with READY-TO-EAT

or TIME/TEMPERATURE CONTROL FOR SAFETY FOODS either by a FOOD EMPLOYEE or the CONSUMER, except as specified in ¶¶ (1)-(2) of this section.

(1) ~~*Designed and constructed for reuse and in accordance with the requirements specified under Part 4-1 and 4-2;*~~[P]

(1) A CONSUMER-owned container not specifically designed for reuse may be refilled by the

same CONSUMER with a non-TIME/TEMPERATURE CONTROL FOR SAFETY FOOD or BEVERAGE in a contamination-free transfer process.

(2) ~~*One that was initially provided by the FOOD ESTABLISHMENT to the CONSUMER, either empty or filled with FOOD by the FOOD ESTABLISHMENT, for the purpose of being returned for reuse;*~~

(2) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE

machine or system.

(3) ~~*Returned to the FOOD ESTABLISHMENT by the CONSUMER after use;*~~

(4) ~~*Subject to the following steps before being refilled with FOOD:*~~

~~*(a) Cleaned as specified under Part 4-6 of this Code,*~~

(b) ~~*Sanitized as specified under Part 4-7 of this Code;*~~[P] ~~*and*~~

(c) ~~*Visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified under Part 4-1 and 4-2.*~~[P]

(C) ~~*A take-home FOOD container returned to a FOOD ESTABLISHMENT may be refilled at a FOOD ESTABLISHMENT with BEVERAGE if:*~~

(1) ~~*The BEVERAGE is not a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;*~~

(2) ~~*The design of the container and of the rinsing EQUIPMENT and the nature of the BEVERAGE, when considered together, allow effective cleaning at home or in the FOOD ESTABLISHMENT;*~~

~~(3) *Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;*~~

~~(4) *The CONSUMER-owned container returned to the FOOD ESTABLISHMENT for refilling is refilled for sale or service only to the same CONSUMER; and*~~

~~(5) *The container is refilled by:*~~

~~(a) *An EMPLOYEE of the FOOD ESTABLISHMENT, or*~~

~~(b) *The owner of the container if the BEVERAGE system includes a contamination-free transfer process as specified under ¶¶ 4-204.13(A), (B), and (D) that cannot be bypassed by the container owner.*~~

(C) Establishment or third-party reuse service provider owned, managed, or provided REUSABLE CONTAINERS

returned to a FOOD ESTABLISHMENT for refilling with FOOD shall be cleaned as specified under Part 4-6 and

sanitized as specified under Part 4-7 of this Code prior to refilling.

~~(D) *CONSUMER-owned, personal take-out BEVERAGE containers, such as thermally insulated bottles, nonspill coffee cups, and promotional BEVERAGE glasses, may be refilled by EMPLOYEES or the CONSUMER if refilling is a contamination-free process as specified under ¶¶ 4-204.13(A), (B), and (D).*~~

(D) REUSABLE CONTAINERs returned to a FOOD ESTABLISHMENT for refilling by a FOOD EMPLOYEE

or the CONSUMER must be refilled in a contamination-free transfer process such that:

(1) Any CONSUMER-owned container is isolated from FOOD-CONTACT SURFACES or such surfaces shall be cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code by a FOOD EMPLOYEE after each filling.

~~(E) *CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.*~~

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-013

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:

Report - Disinfectant Committee (DC)

Issue you would like the Conference to consider:

The Disinfectant Committee requests acknowledgement of their final report, thanking the committee members for their hard work, and that the committee be disbanded.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogen outbreak occurs, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but are not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

1) Disinfectants that require a rinse step prior to resuming regular operations; and

2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, do not require a rinse step prior to further use due to their conformity to 40 CFR 180 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments along with a guidance document to provide detailed information on disinfectants and how they should be used would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does not include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

1. Acknowledgement of the Disinfectant Committee Report.

2. Thanking the members of the Committee for their work.

3. The Committee be disbanded; all assigned charges have been completed.

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Content Documents:

- "Final report"
- "Committee roster"
- "Guidance for the Safe and Proper Use of Sanitizers and Disinfectants in Foo"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-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:

DC 2 - Approval and Posting of Guidance Document

Issue you would like the Conference to consider:

The Disinfectant Committee requests approval of the guidance document and that it be posted to the CFP website.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

1) Disinfectants that require a rinse step prior to resuming regular operations; and

2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, does not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments, along with a guidance document to provide detailed information on disinfectants and how they should be used, would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does not include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

1. Approving the "Guidance for the Safe and Proper Use of Sanitizers and Disinfectants in Food Establishments" guidance document (attached as a content document to the Issue titled: Report - Disinfectant Committee (DC)).

2. The guidance document be posted to the CFP website; and

3. Authorizing the Conference to make any necessary edits prior to posting the document on the CFP website to assure consistency of format and non-technical content; edits will not affect the technical content of the document.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-015

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:

DC 3 - Amend Food Code to Address Use of Disinfectants

Issue you would like the Conference to consider:

The Disinfectant Committee feels that several changes to the Food Code are needed to address the use of disinfectants. This issue details those recommended changes.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

1) Disinfectants that require a rinse step prior to resuming regular operations; and

2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, does not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address the use of disinfectants in food establishments, along with a guidance document to provide detailed information on disinfectants and how they should be used, would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does not include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

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

1-201.10 Statement of Application and Listing of Terms.

(B) Terms Defined. As used in this Code, each of the terms listed in ¶ 1-201.10(B) shall have the meaning stated below.

"Disinfection" means the application of a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi, or viruses, but not necessarily bacterial spores on cleaned food-contact or other hard, non-porous surfaces.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in 5 categories:

(1) Cleaners ~~and,~~ SANITIZERS, and disinfectants, which include cleaning ~~and,~~ SANITIZING agents, DISINFECTION agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(2) Pesticides, *except SANITIZERS and disinfectants*, which include substances such as insecticides and rodenticides;

Renumber the current Food Code Sections 4-8 and 4-9 to 4-9 and 4-10, respectively to accommodate the following:

4-8 DISINFECTION OF EQUIPMENT AND UTENSILS

Subparts

4-801 Objective

4-802 Frequency

4-803 Methods

Objective

4-801.10 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

EQUIPMENT, FOOD-CONTACT SURFACES, non-FOOD-CONTACT SURFACES, and UTENSILS shall be disinfected when pathogens of concern are not controlled by available sanitizers.

Frequency

4-802.11 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

EQUIPMENT, FOOD-CONTACT SURFACES, non-FOOD-CONTACT SURFACES, and UTENSILS, shall be disinfected:

(A) If contaminated with vomitus, fecal matter, blood, or any other bodily fluid.

(B) During an outbreak caused by microorganisms not controlled by sanitizers.

(C) When a greater level of microbial control is required.

(D) When instructed by REGULATORY AUTHORITY.

Methods

4-803.11 Chemical.

(A) FOOD-CONTACT SURFACES and non-FOOD-CONTACT SURFACES shall be disinfected in accordance with EPA-registered label use instructions. [Pf]

(B) Disinfectants applied to a FOOD-CONTACT SURFACE shall be rinsed with potable water, unless otherwise specified on the EPA-registered label use instructions.

7-102.11 Common Name.

Working containers used for storing POISONOUS OR TOXIC MATERIALS such as cleaners ~~and,~~ SANITIZERS, and disinfectants taken from bulk supplies shall be clearly and individually identified with the common name of the material. [Pf]

4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices.

A test kit or other device that accurately measures the concentration in MG/L of SANITIZING or disinfecting solutions shall be provided [Pf]

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer or Disinfectant Concentration.

Concentration of the SANITIZING or disinfecting solution shall be accurately determined by using a test kit or other device. [Pf]

Annex 3. Public Health Reasons/Administrative Guidelines

4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices.

Testing devices to measure the concentration of sanitizing and disinfecting solutions are required for 2 reasons:

1. The use of chemical sanitizers and disinfectants requires minimum concentrations of the sanitizer or disinfectant during the sanitization or disinfection ~~final rinse~~ step to ensure sanitization and disinfection; and
2. Too much sanitizer or disinfectant in the final ~~rinse water~~ step could be toxic.

4-501.116 Warewashing Equipment, Determining Chemical Sanitizer or Disinfectant Concentration.

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

Objective

4-801.10. Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

Food establishments must be able to control microorganisms that pose a risk to employees and patrons to protect public health within their establishment. Since sanitizers only reduce, as opposed to eliminate, the number of microorganisms on a surface and do not control all types of microorganisms, i.e., bacteria, fungi, viruses, and spores, a disinfectant with an appropriate EPA-registered efficacy claim may be required.

Several examples of situations when a higher level of antimicrobial efficacy and/or a broader range of microorganisms maybe required are listed below:

- Clean-up of bodily fluid spills
- Microorganism of concern is not listed on the product label, (i.e., viruses, biofilm, fungus)
- A higher level of antimicrobial efficacy is desired
- When required to by a regulatory authority

Frequency

4-802.11 Equipment, Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.

Frequency of disinfection varies depending on circumstances at the time of disinfection. During normal, routine conditions, surfaces should be disinfected at least daily. High-touch surfaces (e.g., door handles, dispensers, restroom surfaces) should be disinfected at least daily when the facility is open. During outbreaks surfaces should be disinfected at the frequency recommended by public health officials. Surfaces should also be disinfected immediately after a bodily fluid event.

Methods

4-803.11 Chemical.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-016

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:

DC 4 - Amend Food Code Annex on Hand Antiseptics

Issue you would like the Conference to consider:

The Disinfectant Committee feels that several changes to the Food Code are needed to address the use of disinfectants. This Issue details those recommended changes.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

1) Disinfectants that require a rinse step prior to resuming regular operations; and

2) Disinfectants that do not require a post-rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, does not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

Updates to the Food Code to address correct some of the language around the use of hand antiseptics that is in the annex will alleviate confusion and potential misuse of disinfectants in food establishments.

This Issue submission does not include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Model Food Code be amended as follows:

Annex 3. Public Health Reasons/Administrative Guidelines

2-301.16 Hand Antiseptics

~~Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement. However, removing~~ Reducing microorganisms from human skin is a totally different process than sanitizing surfaces and sterilization of human skin is nearly impossible to achieve without

damaging the skin. Many antimicrobial hand agents typically achieve a much smaller reduction in microorganisms on hands than the 5-log reduction required for "sanitization." Therefore, the effect achieved from using antimicrobial hand agents (often called "hand sanitizers") is not consistent with the definition of "sanitization" in the Food Code.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-017

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:

DC 5 - Amend Food Code Annex - Use of Disinfectants During Clean-up of V&D

Issue you would like the Conference to consider:

The Disinfectant Committee feels that several changes to the Food Code are needed to address the use of disinfectants. This Issue details those recommended changes, which includes rearranging the bullet points in Annex 3, 2-501.11, paragraph 9 to make sure that the steps listed reflect the order of actions covered by the plan.

Public Health Significance:

The FDA Food Code is relied upon by food facilities and local and state regulatory agencies as the primary guidance for food safety requirements. The lack of clear guidance in the Food Code on use of disinfectants has led to inconsistent interpretations from regulators and industry, potentially leading to misuse. As a result, the residue of the product could negatively impact human health, contaminate food, or be ineffective for control of the microorganisms of concern.

Retail food facility disinfection to stop the spread of norovirus has been a challenge for many years. The global SARS-CoV-2 pandemic has underscored the need to ensure the correct use of chemical antimicrobials to inactivate viruses in addition to bacteria commonly targeted by sanitizers. When a norovirus or other viral pathogens outbreaks occur, local and state regulatory agencies require or recommend disinfection within a food facility to inactivate viral pathogens on food-contact surfaces and throughout the facility. During the SARS-CoV-2 pandemic, regulatory agencies across the country have recommended disinfection in retail food facilities as a preventive measure and/or in the event of any confirmed COVID-19 diagnosis(es) on the premises.

COVID-19 has shown that there is a lack of understanding of the differences between sanitization and disinfection. The differences include, but not limited to efficacy testing requirements, patterns of use, formulations of these products, etc. For example, efficacy tests for most sanitizers are performed against bacteria, not other microorganisms (e.g., viruses, fungi, and parasites). Therefore, most sanitizers should be used only to control

bacteria (unless viruses are listed on EPA registered label or EPA regulations are changed).

The Code of Federal Regulations (40 CFR 158.2203) states, "Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment."

Currently, there are two types of EPA-registered disinfectants which are used on food-contact surfaces in retail food facilities:

1) Disinfectants that require a rinse step prior to resuming regular operations; and

2) Disinfectants that do not require a post rinse step. This group of disinfectants meets food-contact tolerance levels and, similar to food-contact sanitizers, do not require a rinse step prior to further use due to their conformity to 40 CFR 180.940 Tolerances and Exemptions for Pesticide Chemical Residues in Food.

Below are examples of FDA's Food Code sections and current guidance from the CDC which can lead to a misunderstanding of how retail food facilities should use disinfectants on food-contact surfaces.

Example #1

Section 4-702.11 of the 2017 Food Code states, "Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning." There are no similar sections in the Food Code covering disinfection and it is unclear how to use disinfectants in retail and which steps (e.g., washing, rinsing, sanitizing, and air-drying) are required following the use of a disinfectant.

Example #2

In the 2017 Food Code Annex 3, in Hand Antiseptics Section 2-301.16, there is a statement, regarding the efficacy of these products: "Sanitizers used to disinfect food-contact equipment and utensils can easily achieve the 5-log reduction of microorganisms and often far exceed this minimum requirement." This statement indicates that hand sanitizers are used to disinfect food-contact surfaces, causing further confusion about the terms "sanitization", "disinfection", "hand antiseptics" and "hard surface sanitizers".

A specific situation when use of disinfectants in food establishments is appropriate is during clean-up following a vomiting or diarrheal event. Updates to the Food Code to address the use of disinfectants during body fluid clean-up along with a guidance document to provide detailed information on disinfectants and how they should be used would alleviate confusion and potential misuse of disinfectants in such settings.

This Issue submission does not include a request for scientific review, analysis, or approval of disinfectants or no-rinse disinfectants on food-contact surfaces since this evaluation by EPA is part of their registration process.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the current Model Food Code be amended as follows:

Annex 3. Public Health Reasons/Administrative Guidelines

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

paragraph 6

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,~~ non-food contact surfaces may not be effective against some viruses such as Norovirus. It is therefore important that food establishments have procedures for ~~the~~ cleaning and disinfection of vomitus and/or diarrheal contamination events that include ~~address, among other items,~~ the use of ~~proper disinfectants at the proper concentration.~~ EPA-registered disinfectants against the microorganisms of concern.

paragraph 9

When developing a written plan that addresses the need for the cleaning and disinfection of a vomitus and/or diarrheal contamination event, a food establishment should consider:

- ~~The procedures for containment and removal of any discharges, including airborne particulates;~~ The conditions under which the plan will be implemented;
- The availability of effective disinfectants, such as EPA registered disinfection products sufficient to inactivate norovirus, personal protective equipment, and other cleaning and disinfecting ~~appurtenances~~ tools intended for response and their proper use;~~The procedure for cleaning, sanitizing, and, as necessary, the disinfection of any surfaces that may have become contaminated;~~
- The circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;~~The procedures for the evaluation and disposal of any food that may have been exposed to discharges;~~
- Notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;~~The 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;~~
- The procedures for minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage;
- The segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;~~Procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter;~~
- The procedures for containment and removal of any discharges, including airborne particulates;~~The circumstances under which a food employee is to wear personal protective equipment for cleaning and disinfecting of a contaminated area;~~
- The procedure for cleaning, sanitizing, and disinfecting of any surfaces that may have become contaminated;~~Notification to food employees on the proper use of personal protective equipment and procedures to follow in containing, cleaning, and disinfecting a contaminated area;~~

- The procedures for the evaluation and disposal of any food that may have been exposed to discharges;~~The segregation of areas that may have been contaminated so as to minimize the unnecessary exposure of employees, customers and others in the facility to the discharges or to surfaces or food that may have become contaminated;~~
- Procedures for the disposal and/or cleaning and disinfection of tools and equipment used to clean up vomitus or fecal matter; and~~Minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code;~~
- The procedures for minimizing risk of disease transmission through the exclusion and restriction of ill employees as specified in §2-201.12 of the Food Code;~~Minimizing risk of disease transmission through the prompt removal of ill customers and others from areas of food preparation, service and storage; and~~
- ~~The conditions under which the plan will be implemented.~~

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-018

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:

Commercial Space Travel and Food Safety

Issue you would like the Conference to consider:

Creation of a Commercial Space Food Safety Committee

Public Health Significance:

Space missions as defined by space station, lunar mission(s), asteroid mission(s), Mars mission(s) and or other off-Earth missions require food safety for astronauts. Private space missions (commercial flying) are increasing but there are no defined criteria for food safety for these private missions.

This topic is an Issue because we have no evidence that the food is being held to standard. We know that food for Government program astronauts must meet high standards, we don't know if commercial space food must meet those same standards.

Not all food is created equal and not all food can go into space. The commercialization of flights cross that barrier affecting both food that travels into space and is consumed during or after the event.

Various newspaper articles depict commercial space travel food consumption, cold pizza and lamb. See attached PDF documents for reference: Daily Breeze Article, Axiom Article, 2 Million Dollar Bacon Sando article, and Kimchi Article New York Times. It should also be noted that foods like kimchi and a bacon sandwich, were specially developed to fly in space. This took years of research and millions of dollars to achieve. NASA currently has 250 food items that have been approved for space travel; the question still lies within, for commercial space travel, there are no known standards that would protect consumed food - Was it cooled correctly, held at a safe temperature, transported safely, stored correctly, served correctly, disposed of properly/off gassing/crumbs?

In addition, the after travel/space port celebrations: there may be the desire to celebrate with an after-flight toast. Such situations also create circumstances where short duration weightlessness is experienced. If a person experiences nausea, vomiting, and/or diarrhea,

it may not be known if these symptoms are due to weightlessness or a foodborne illness event. There should be standards in place to provide protection for the individuals experiencing the post-flight celebration where alcoholic beverages and food are involved.

Because commercial space companies are already seeking food provisions for their missions, it is important to address commercial space food safety. And to investigate whether or not regulations and policy should be found needed in the protection of people participating in commercial space program missions.

NASA currently has standards which include four areas of food safety: packaging/containerization, facility design, cleaning, and food engineering/testing; however these standards do not apply to commercial space travel. Since NASA guidelines do not address commercial space travel food safety, this gap needs to be addressed.

Recommended Solution: The Conference recommends...:

That a special committee be formed to explore commercial space food safety. This should be done in order to have a more robust conversation about this Issue. The Committee should be charged with:

1. Research and investigate current standards for food safety for commercial space travel;

2. Recommending to the FDA that it considers adding commercial space food providers as part of the definition for FOOD ESABLISHMENT;

3. Drafting standards for food safety and commercial space travel that meet or exceed NASA standards for food safety;

4. Standards should address food handling practices, holding temperatures, cooling parameters, sanitary storage of food, and other associated requirements;

5. Review and update standards as research informs additional needs; and

6. Report back to the Conference in 2025 with recommendations.

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Supporting Attachments:

- "Daily Breeze Article"
- "Axiom Article"
- "2 Million Dollar Bacon Sando Article"
- "Kimchi Article New York Times"

Conference for Food Protection
2023 Issue Form

Issue: 2023 III-019

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:

Create a Committee - Sea Moss and Sea Moss Gel Committee

Issue you would like the Conference to consider:

Create a sea moss and sea moss gel committee to identify the hazards most likely associated with sea moss and the production and storage of sea moss gel, determine if specific predetermined controls can be applied to mitigate the identified hazards when producing and storing sea moss gel in a retail food establishment, and develop a guidance document for the production and storage of sea moss gel (if the Committee's findings support such) for use by retail food establishment operators and regulators.

Public Health Significance:

Sea moss gel poses an inherent *Clostridium botulinum* risk due to the very nature of the product; in addition, the product is often packaged or stored in a state that reduces the oxygen transfer rate.

Sea moss gel is a relatively new product that has become a fast-growing healthy eating trend. The most common sea mosses used to make sea moss gel seem to be Genus Gracilaria and *Chondrus Crispus*, based upon social media searches. The dry sea moss is rehydrated in water and then blended with water to create a gel. Fruit juice and/or herbs are often added in the process to create flavored or infused sea moss gel. The gel is sold as is or added to foods such as smoothies and other beverages, ice cream, custards, broth, etc. In some cases, the sea moss gel and/or products containing sea moss gel are packaged in mason jars or similar containers that could produce a reduced oxygen environment. Sea moss gel gummies are also produced in a similar fashion. Sea moss gel products are being produced in and sold from manufacturing facilities, retail food establishments as well as unregulated, home kitchens. A large variety of sea moss gel products can be found on online ordering sites/platforms.

There is little historical data or guidance available due to the newness of the product. Many state and local regulatory agencies across the country have struggled to identify how best to classify sea moss gel, with some treating sea moss gel as a dietary supplement and

others treating it as a food. Best practices and/or requirements, including a HACCP plan and variance, have been established by some state and local regulatory agencies to address the production of sea moss gel within retail food establishments (see attachment titled "Sea Moss & Sea Moss Gel Guidance" as an example). At least one state has issued a consumer warning for products containing sea moss gel due to the concern of under-processing of a food offered for sale without licensing or inspection (see attachment titled "Consumer Advisory - MDARD Urges Consumers to Dispose of Sea Moss Lemonade").

FDA Retail Food Specialists have provided the following two answers when regulatory agencies have inquired about sea moss gel.

Answer #1

"Sea moss is a type of seaweed that is a sea vegetable also known as carrageenan gum, since carrageenan is one of the components of sea moss. When mixed with water and emulsified, sea moss will become a thick substance due to its carrageenan element. This thick substance is often used in food products as a stabilizer, emulsifier, or thickener.

According to sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is considered a Food Additive that is subject to review, unless the use of the substance is already deemed as a GRAS (generally recognized as safe) substance. 21CFR172.620 lists carrageenan as an approved food additive when used according to the conditions described in this section https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.620 Keep in mind, it is an approved food additive only when derived from the members of the families *Gigartinaceae* and *Solieriaceae* of the class *Rodophyceae* (red seaweed) including, *Chondrus crispus, Chondrus ocellatus, Eucheuma cottonii, Eucheuma spinosum, Gigartina acicularis, Gigartina pistillata, Gigartina radula and Gigartina stellata*.

Additionally, 21CFR182.7255 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=182.7255 lists chondrus extract as a GRAS substance when used as a stabilizer. And Fucoidan concentrate from *Fucus vesiculosus* (a brown seaweed also known as Bladderwrack, Black Tang, or Rockweed) has also been deemed a GRAS substance when used as an ingredient in baked goods (bread, cake, noodles), soups, snack foods, imitation dairy products, and seasonings and flavors at use levels up to 30 milligrams per serving https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=661

Regarding your question whether FDA would classify sea moss gel as a food additive, you must evaluate if the sea moss gel products you are assessing for use in retail establishments fall within the above-mentioned approved food additive or GRAS notices. This would include knowing the species of seaweed the gel was made from and whether any other ingredients were added to the final product. Regarding classification as a dietary supplement, sea moss gel does not fit the definition of a dietary supplement (ingredients such as vitamins, minerals, herbs, amino acids, and enzymes) https://www.fda.gov/food/dietary-supplements/dietary-supplement-products-ingredients and therefore should not be classified as such when added to food products at the retail establishment."

Answer #2:

"...our branch did have a discussion about sea moss. I don't know if the specifics exactly match what you've run into, but we had some discussions on Chondrus crispus (common

name for Irish sea moss). The overall message is that the sea moss doesn't have authorized use as a food or color additive - hence it needs a GRAS conclusion, prior sanction, or other exemption under section 201(s) of the FD&C Act for use of C. crispus in food. FDA is not aware of any of these alternative means of compliance with section 201(s) for this product. The firms might have publicly available safety evidence to support its use to be concluded as GRAS without prior notice to FDA. Ultimately, food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

For the sea moss to be considered a food itself, we have had some internal discussions about sourcing and how it really should be regulated. The Center has not commented and more federal guidance is being worked on... hopefully. You could say this is a plant product, but then it comes from the ocean! Produce? Seafood? Again, more will have to be discussed on that one and we are waiting to hear back ourselves.

Also, if the ingredient imparts color to food, they may meet the statutory definition of "color additive" found in section 201(t)(1) the FD&C Act. Color additives are subject to premarket approval by FDA and require a listing in title 21 CFR providing for such use before they can be lawfully used in products marketed in the U.S. Currently, there is no listing in 21 CFR authorizing use of a C. crispus ingredient as a color additive in beverages. If an ingredient imparts color to the food (and that is the intended use, to color a food) and there is evidence to support the safe use of the ingredients as a color additive in beverages, authorization for use as a color additive can be sought through filing of a color additive petition. More information about color additives and color additive petitions here à https://www.fda.gov/industry/color-additives.

Lastly, regarding these smoothie additions - there's always a chance that some health claims might be made given the type of commercial market smoothies exist within. See this site that has a plethora of FDA FAQs on authorized health claims for food/supplements: https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard. The concern is usually that claims might be made about some of these ingredients treating a medical condition or being some sort of cure for an ailment without scientific evidence."

Sourcing of raw sea moss with which to make sea moss gel is a potential concern due to natural toxins in the harvest area, contaminated waters, heavy metals, etc. (see attachment titled "The Identification of Potential Food Safety Hazards in Seaweed"). The production and storage of sea moss gel may involve increased food safety risks (including *Clostridium botulinum*) that require strict controls to produce a safe product.

Recommended Solution: The Conference recommends...:

A sea moss and sea moss gel committee be created with the following charges:

1. Review current regulations related to sea moss and sea moss gel.

2. Review available scientific literature regarding the production and storage of sea moss gel.

3. Identify the hazards most likely associated with sea moss and the production and storage of sea moss gel.

4. Determine if specific predetermined controls can be applied to mitigate the identified hazards when producing and storing sea moss gel in a retail food establishment and, if so, identify the specific control measures necessary.

5. Identify state and local regulatory agencies that have established best practices, guidance and/or requirements for the production of sea moss gel in retail food establishments and review their materials.

6. Develop a guidance document (if the Committee's findings support such) for posting on the CFP website to be used by retail food establishment operators and regulators for the production and storage of sea moss gel within a retail food establishment.

7. Determine if the production of sea moss gel within a retail food establishment should be considered a specialized processing method and, if so, whether it should be added to section 3-502.11 in the FDA Food Code, a separate section be created in the FDA Food Code, or not be specified in the FDA Food Code.

8. Consider other changes and/or additions to the FDA Food Code that may be relevant to the classification, identification, production, control, labeling, etc. of sea moss gel.

9. Report the Committee's findings and recommendations at the next Biennial Meeting.

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Supporting Attachments:

- "Sea Moss & Sea Moss Gel Guidance"
- "Consumer Advisory - MDARD Urges Consumers to Dispose of Sea Moss Lemonade"
- "The Identification of Potential Food Safety Hazards in Seaweed"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-020

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:

Create a Committee - Retail Cold Brew Coffee Safety & Compliance Committee

Issue you would like the Conference to consider:

Creating a committee to be charged with reviewing available scientific data and recommending uniform standards on food safety, compliance and enforcement of retail cold brew coffee for inclusion in the Food Code.

Public Health Significance:

The Food Code currently does not have any standards specific to retail cold brew coffee. Retailers must determine what food safety and compliance standards to follow, and state and local health inspectors are left uncertain about what standards to adopt and enforce against. This situation has created a patchwork of enforcement interpretation and inconsistent standard adoption across the retail industry. Retail operators need uniformly applied standards to protect the health and safety of cold brew coffee consumers.

Due to very limited published research on cold brew food safety that is available in the public domain, the National Coffee Association (NCA) has initiated a comprehensive cold brew challenge study with a leading third-party, accredited laboratory and intentionally designed the experiment to answer health inspectors' questions. The research findings can help inform the creation of a food code standard and provide supporting evidence that cold brew coffee is not a time/temperature control for safety food (TCS) and whether cold brew stored in airtight packaging for > 48 hours such as a stainless-steel keg should be considered Reduced Oxygen Packaging (ROP). We anticipate study results to be available in a white paper in June 2023. Please see supporting attachments for further details.

Recommended Solution: The Conference recommends...:

a Retail Cold Brew Coffee Safety & Compliance Committee be created and charged with the following:

1. Consider the need for having uniform standards on retail cold brew coffee food safety for consistent enforcement across all U.S. health department and retail food safety jurisdictions.

2. Identify and review available food safety literature and challenge study data on retail cold brew coffee.

3. Propose language on retail cold brew coffee food safety for inclusion in the Food Code.

4. Report the Committee's findings back at the next biennial meeting.

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Supporting Attachments:

- "NCA Support Letter Research_01_23_2023"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-021

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:

Creation of a Committee to Define Heat-Treated

Issue you would like the Conference to consider:

A recommendation is being made to create a Committee to evaluate the science of and construct parameters for heat treatment as it relates to the definition of a TCS food to allow for a more consistent interpretation of foods that are considered TCS.

Public Health Significance:

Heat treatment of food products can have various impacts on microorganism growth, from increasing the likelihood of growth through water absorption for plant foods to the destruction of competitive or pathogenic microflora. Due to the complex nature of the effects of heat treatment on the safety of food products, the use of the term "heat-treated" without further definition leads to confusion regarding when the term is applicable.

The definition of TCS foods in Paragraph 1-201.10(B) includes both plant and animal foods that are heat-treated. When heat is intentionally applied to a food product from a heating element, the categorization of heat treatment seems simple; however, at retail there are many examples of indirect heating through air or liquid that put into question the applicability of the term "heat-treated". For example, drying herbs in a dehydrator is considered heat treatment, but whether the term applies to herbs dried in warm parts of the kitchen or via sun-drying is up for interpretation. When pickling, hot brine is often added to plant foods to maximize acid penetration, but there is currently no guidance on whether this is considered a heat-treated plant food. Additionally, without a standard definition, it is unclear if the temperature of the brine, or any other heat treatment temperature, impacts whether the food is considered heat treated and therefore TCS.

In 2001, the Institute of Food Technologists (IFT) prepared a new framework for what we now refer to as TCS foods, which can be found in Chapter VIII of "Evaluation and Definition of Potentially Hazardous Foods"[1]. As part of this framework, there are two tables which offer pH and water activity values to further aid in determining if a food is non-TCS, with Table A having more lenient values due to being applicable to foods where vegetative cells

have been destroyed[1]. Although the framework prepared by the IFT explains the rationale of having two tables to account for products that are "heat treated to destroy vegetative cells", the document does not provide a definition as to what is considered adequate heat treatment for all types of food products. Instructions for determining which table to use do exist in the Food Code Annex 3 Paragraph 1-201.10(B), where TCS foods are discussed; however, these instructions reference Section 3-401.11, which does not contain final cook temperatures for many foods where table A is applied, such as plant foods. The absence of a definition for "heat treated to destroy vegetative cells" as it relates to Table A causes confusion for determining which table is applicable as well as determining critical limits to set for special processes. Examples of where confusion has been seen at retail are pickled vegetables, products that have been heated and cooled before packaging, and meat and dairy alternative products.

The ambiguity that exists due to the lack of these definitions is causing inconsistent interpretation of foods that are considered TCS, which is potentially leading to temperature abuse of foods that microbiologically pose a threat to public health. This committee formation recommendation is being made to provide clarity of what constitutes "heat-treated" and "heat-treated to destroy vegetative cells" to provide a more robust, microbiologically accurate picture of what foods require time and temperature control that will not be compromised due to differing interpretations.

References

1. Institute of Food Technologists (IFT) Report, Evaluation and Definition of Potentially Hazardous Foods, Food and Drug Administration Contract No. 223-98-2333, Task Order No. 4, December 31, 2001. https://www.fda.gov/files/food/published/Evaluation-and-Definition-of-PotentiallyHazardous-Foods.pdf

Recommended Solution: The Conference recommends...:

That a committee be created to complete the following charges and report the committee's findings at the next biennial meeting.

The resulting Committee will be charged with:

1. Identifying and evaluating risk-based literature that aids in defining a temperature threshold for what is considered heat treatment for all types of foods.
2. Developing a definition for "heat-treated" that will adequately convey the risk and will clarify which processes seen at retail result in a food product being TCS. As part of this definition, it is recommended to also clarify the meaning of "heat-treated to destroy vegetative cells" as it appears in Table A in Paragraph 1-201.10(B) to also include an additional temperature for plant foods that do not have a final cook temperature in Section 3-401.11.
3. Determining appropriate methods of sharing the committee's work, including but not limited to a recommendation that a letter be sent to the FDA recommending the most recent version of the FDA Food Code to include the newly formed definition for "heat-treated" as referenced in Paragraph 1-201.10(B) where Time and Temperature Control for Safety Foods is defined and "heat-treated to destroy vegetative cells" as referenced in Table A of this definition.

4. Report the committee's findings and recommendations at the next biennial meeting.

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Supporting Attachments:

- "Evaluation and Definition of Potentially Hazardous Foods - Chapter V111"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-022

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:

Creation of a Committee: Rehydrated Foods

Issue you would like the Conference to consider:

A recommendation is being made to create a committee to evaluate the food preparation practices related to rehydrated foods and provide food safety guidance and recommendations

Public Health Significance:

There has been an increase in popularity of dehydrated foods in recent years. As food costs are rising, food operators are looking for ways to extend the shelf life on products and use products in different and more cost-effective ways. Several states have seen an increase in freeze drying requests for variances. There have been multiple states with sea moss gel being created, and the process is not adequately addressed in the Food Code, even with an increased risk of *C. botulinum*. The process of dehydrating the food has been considered a specialized process requiring a HACCP Plan and a variance, but there has been little information provided on the process of rehydrating foods.

When looking at the definition of a Time/Temperature Control for Safety (TCS) as stated in the 2022 FDA Food Code Section 1-201.10(B), it is difficult to determine whether rehydrated foods meet this definition. Examples of rehydrated foods include potato flakes, beans, vegetables noodles, etc., As one specific example: when plant foods such as peppers or mushrooms are rehydrated, they are often placed in room temperature water, which means they are not considered a heat-treated plant food during rehydration. The resulting rehydrated food would be similar in pH and water activity to the original vegetable prior to being dehydrated, which is not considered a TCS food. Even if the pH and water activities are similar, the food safety risks of the rehydrated vegetable may be very different than the original raw vegetable product due to changes that occur in the cell structures during processing. However, based on current 2022 FDA Food Code definitions of a TCS food per 1-201.10(B), neither have any time or temperature controls in place.

There may be food safety considerations for the temperature of the dehydration process, rehydration liquid, length of time of rehydration, and storage after rehydration. A review of potential risks associated with these products is needed, as this information is not easily accessible for industry or regulatory partners. Additionally, without Food Code parameters in place, guidance for handling of these products is needed.

Recommended Solution: The Conference recommends...:

that a committee be created to evaluate the preparation of rehydrated foods at retail, the food safety hazards, and the guidance related to controlling these hazards.

Charges for this committee would include:

1. Reviewing of the literature available on rehydration of food practices at retail

2. Analyzing of food safety hazards likely to occur during rehydration process and after during storage

3. Providing guidance on controlling hazards, in a guidance document or another format

4. Identifying the recommended methods to disseminate the committee's findings

5. Reporting the committee's findings at the next CFP Biennial Conference

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-023

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:

Revise definition of Reduced Oxygen Packaging specific to packaging type

Issue you would like the Conference to consider:

The current definition of Reduced Oxygen Packaging (ROP) Cook-Chill Packaging does not include packaging such as film covered trays that are sealed.

Public Health Significance:

The current definition of Reduced Oxygen Packaging (ROP) Cook-Chill Packaging does not include packaging such as film covered trays that are sealed. The FDA identifies that time and temperature control for safety (TCS) food that is heated just prior to packaging in a bag or a film sealed on trays results in a process that aligns with the Food Code definition of ROP (Attachment #1).

There are operations that are packaging hot TCS food in trays with a plastic film. Cooking food drives off oxygen from the food thereby lowering the oxygen level in that food. After the bag or tray with film is sealed, the oxygen level in the headspace and the oxygen level in the hot TCS food will equilibrate. This results in a package with an oxygen level below what is normally found in the atmosphere resulting in a process that aligns with the Food Code definition of ROP.

The definition for cook chill does not recognize the use of a film sealing process on a tray as ROP. Updating the code will allow for it to better align with the FDA guidance.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the definition of the term "Reduced Oxygen-Packaging" under 1-201.10 (B) in the current Food Code be amended as follows:

Reduced Oxygen Packaging.

(2) "Reduced oxygen packaging" includes:

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable ~~bags~~ PACKAGING (such as a bag or film on trays) that ~~are~~ is then sealed or crimped closed. The ~~bagged~~ PACKAGED FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

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Supporting Attachments:

- "Heat sealing without a vacuum v03"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-024

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

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Issue History:

This is a brand new Issue.

Title:

Amend ¶3-501.13(E) thawing of frozen ROP fish

Issue you would like the Conference to consider:

Since the incorporation of paragraph 3-501.13(E) in the 2013 Food Code, there is confusion on how to thaw reduced oxygen packaged fish. There have also been different interpretations of what is meant by removing frozen fish from the reduced oxygen environment. The intent of the Food Code is for reduced oxygen packaged fish to be completely removed from the reduced oxygen packaging, so that the reduced oxygen environment is removed. There was never an intent to just place holes or slits in the reduced oxygen packaging (ROP) to remove it from that environment. Placing holes or slits in the ROP may not ensure that the hazard of *Clostridium botulinum* growth and toxin formation will be eliminated. This is due to uncertainties in the amount of oxygen transmission allowed by holes and slits of unknown size and number that would be needed to revert the reduced oxygen packaging environment to an oxygen content to a level normally found in the atmosphere (approximately 21% at sea level) which would render the packaging no longer ROP. Thus, completely removing the fish from the ROP ensures that the reduced oxygen environment is removed, and the hazard of *C. botulinum* growth and toxin formation is removed.

Public Health Significance:

Fish Retailers should be aware that when a manufacturer processes fish and fishery products, they are required to have and implement a written HACCP plan that controls reasonably likely to occur hazards under 21 CFR Parts 123 and 1240, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (the Seafood HACCP Rule). The hazard of *Clostridium botulinum* growth and toxin formation becomes reasonably likely to occur when fish is placed in reduced oxygen packaging (ROP).

C. botulinum is a pathogen that grows in reduced oxygen environments with little to no oxygen (e.g., ROP) and consists of two groups, proteolytics and nonproteolytics. Proteolytics grow at a minimum temperature of 50°F and can be controlled by refrigeration.

However, nonproteolytics, common in fish, grow at a minimum of 38°F. Nonproteolytics are not adequately controlled by refrigeration alone. Temperature abuse during distribution and subsequent processing including thawing, can occur in addition to improper refrigeration storage between 40-50°F at the consumer level. While nonproteolytics grow slowly at 37.9-41°F and take seven days to exceed maximum cumulative time and temperature exposure limits for growth and toxin formation, when temperatures are at 42-50°F, nonproteolytics can grow and produce toxin within two days. Additionally, if the temperature is increased to 51-70°F, growth and toxin formation can occur in 11 hours and only 6 hours when temperatures are above 70°F. Exceeding cumulative time and temperature exposure limits can render the product unsafe due to the potential formation of botulinum toxin, the most toxic substance known.

FDA's Fish and Fishery Products Hazards and Control Guidance, June 2022, Chapter 13, recommends processing controls for *C. botulinum* in frozen and refrigerated fish. Controls can be either freezing with proper labeling, refrigeration with the use of time temperature indicators (TTIs) or refrigeration in combination with a barrier such as product formulation to achieve a target water phase salt, water activity, or pH. The additional barrier to refrigeration is intended to control for the hazard of nonproteolytic growth and toxin formation during cumulative time and temperature exposures from packaging of the finished product throughout distribution until removal from ROP. Completely removing the fish from ROP removes the reduced oxygen environment and the hazard of *C. botulinum* growth and toxin formation.

Freezing with proper labeling as a control strategy for frozen product is intended to prevent exposure of the product to conditions conducive to the production of toxin by nonproteolytic strains of *C. botulinum* in ROP.

If freezing and proper labeling was chosen by the manufacturer as the control for nonproteolytic strains of *C. botulinum*, then each individual package of the ROP fish should be labeled to be kept frozen until used and thawed under refrigeration immediately before use (e.g., "Important, keep frozen until used, thaw under refrigeration immediately before use."). Alternatively, labeling with instructions to keep the product frozen until used and to remove packaging before thawing instead of instructions to thaw under refrigeration immediately before use, may also be used. If this type of labeling is not present on each individual frozen ROP package unit, it may or may not be acceptable to store under refrigeration, depending in part on whether there is a barrier such as pH or water activity to growth of *C botulinum* in addition to refrigeration.

As an added safeguard to prevent the possibility of *C. botulinum* toxin formation, the Food Code requires that any frozen ROP fish that does not have a barrier to growth of *C. botulinum* in addition to refrigeration be completely removed from the reduced oxygen environment or package prior to thawing. This is to discourage the practice of thawing frozen ROP fish and holding it at 41ºF or less for a prolonged time and/or selling it as a refrigerated product in ROP.

Recommended Solution: The Conference recommends...:

the FDA Food Code be amended to read:

3-501.13 Thawing.

Except as specified in ¶ (D) of this section, TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be thawed:

(E) REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be completely removed from the reduced oxygen environment and packaging:

(1) Prior to its thawing under refrigeration as specified in ¶(A) of this section; or

(2) Prior to, ~~or Immediately upon completion of,~~ its thawing using procedures specified in ¶ (B) of this section.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-025

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code to Clarify Fish Thawing Requirements in 3-501.13(E)

Issue you would like the Conference to consider:

A recommendation is being made to clarify the requirement for frozen fish to be removed from the reduced oxygen environment before thawing as required in FDA Food Code 3-501.13(E).

Public Health Significance:

The FDA Food Code requires fish to be removed from the reduced oxygen environment before thawing in Section 3-501.13(E). This requirement exists due to the risk of *Clostridium botulinum* type E spores present in marine environments. These spores can germinate and produce toxin at refrigeration temperatures in anaerobic environments. FDA Fish and Fisheries Products Hazards and Controls Guidance Appendix 4 states that for *C. botulinum* type E and non-proteolytic types B and F the maximum storage time to ensure there is no germination, growth, and toxin formation is seven days between 37.9°F and 41°F (3.3°C - 5°C).

The "Fish and Fisheries Products Hazards and Controls Guidance" lists freezing as a control for *C. botulinum* in Chapter 13. When freezing is used as the only control, it must remain frozen before, during, and after packaging. Section 3-501.13(E) states "REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment prior to thawing..." "Removed from the reduced oxygen environment" is not specifically defined but is interpreted in the field to mean that once oxygen has been introduced into the package, it has been removed from the environment. Therefore, puncturing, slitting, or opening the packaging has been observed as compliance with this Section of the Code.

There are some specific food safety reasons why the practice of opening the package but not removing the product while thawing has been used by operators. While thawing, there is some liquid that collects around the fish products. Leaving the fish in the bag allows for

better protection from cross contamination. Additionally, the product remains covered if it is in an opened package. This also protects from potential contamination.

There have been multiple interpretations heard throughout the country on the meaning of "removed from the reduced oxygen environment" which has led to confusion among industry and regulators. A consistent interpretation that is based on risk is needed. If introducing oxygen by puncturing or opening the package removes the *C. botulinum* risk, then this interpretation assists industry partners with other food safety risks and should be formally issued for consistency and clarity.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the most recent version of the FDA Food Code Section 3-501.13(E) be amended within the Code Section to clarify the statement "removed from the reduced oxygen environment," with this clarification to allow the package to be opened without the product being removed as long as no additional *C. botulinum* risk exists.

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Supporting Attachments:

- "Fish and Fisheries Products Hazards and Controls Guidance"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-026

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:

Add new defined term “Impermeable” to clarify cook-chill processes

Issue you would like the Conference to consider:

The current definition of Reduced Oxygen Packaging (ROP) includes the term "Impermeable". This is not a defined term in the code. The FDA suggest that packaging hot food with breathable packaging would not be considered ROP as defined in the Food Code. This is supported by the FDA who has stated that for seafood, packaging that has an oxygen transmission rate (OTR) of 10,000 cc/m2/24 hours at 24°C, or higher (often referred to as 10K OTR and occasionally printed on the packaging) is considered oxygen permeable and not ROP and could be grounds for a variance.

The lack of a definition for impermeable in the food code allows for the use of any packaging (bag or film sealed on a tray) that can be demonstrated by the industry to show any oxygen transfer rate to be used and not be considered an ROP process. As long as there is any level of permeability demonstrated by the manufacturer, then the process would not be considered ROP; if the transfer rate is too slow then spoilage may not occur and C. botulinum risks may increase.

Impermeable is also used to define bandages and wound covers in the Food Code. To make "impermeable" a defined term in relation to the ROP process, it is recommended to change the term from "impermeable" in these sections to "waterproof". This change aligns with the terminology used by bandage manufacturers and the food service industry.

Public Health Significance:

There are operators who are packaging time and temperature control for safety (TCS) food using ROP methods in breathable plastic bags or with a breathable plastic film over trays. Breathable packaging may be designed to provide oxygen levels that will allow spoilage organisms to grow and spoil food before it becomes hazardous from C. botulinum or L. monocytogenes. Defining the required level of permeability for the packaging ensures that spoilage will occur before C. botulinum or L. monocytogenes have an impact on the product.

Impermeable is not currently defined and changing 7-202.12(B)(2) to a different terminology would allow impermeable to be defined as it relates to ROP.

Recommended Solution: The Conference recommends...:

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

1-201.10(B)

Impermeable.

(1) "Impermeable" means packaging with an oxygen transmission rate such as 10,000 cc/m2/24 hours at 24°C, or lower for raw FISH which will not provide a sufficient exchange of oxygen to allow naturally occurring aerobic spoilage organisms on the product to grow and spoil the product before C. botulinum toxin is produced under moderate temperature abuse.

(2) "Impermeable" does not include packaging with an oxygen transmission rate of 10,000 cc/m2/24 hours at 24°C or higher that is used for only raw FISH.

Reduced Oxygen Packaging.

(2) "Reduced oxygen packaging" includes:

(c) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring FOOD, and ~~impermeable~~ IMPERMEABLE PACKAGING material;

(d) Cook chill PACKAGING, in which cooked FOOD is hot filled into ~~impermeable~~ IMPERMEABLE bags that are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(e) Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an ~~impermeable~~ IMPERMEABLE bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

2-201.11(A)

Reportable symptoms

(1) Has any of the following symptoms:

(e) A lesion containing pus such as a boil or infected wound that is open or draining and is:

(i) On the hands or wrists, *unless ~~an~~ ~~impermeable~~ waterproof cover such as a finger cot or stall protects the lesion and a SINGLE-USE glove is worn over the ~~impermeable~~ waterproof cover,*[P]

(ii) On exposed portions of the arms, *unless the lesion is protected by ~~an~~ ~~impermeable~~ waterproof cover,*[P] or

2-201.13(I)

Uncovered infected wound or pustular boil - removing restriction

(I) Reinstate a FOOD EMPLOYEE who was RESTRICTED as specified under ¶ 2-201.12(I) if the skin, infected wound, cut, or pustular boil is properly covered with one of the following:

(1) A~~n impermeable~~ waterproof cover such as a finger cot or stall and a ~~single-use~~ SINGLE-USE glove over the ~~impermeable~~ waterproof cover if the infected wound or pustular boil is on the hand, finger, or wrist; P

(2) A~~n impermeable~~ waterproof cover on the arm if the infected wound or pustular boil is on the arm;P or

7-202.12 Conditions of Use.

POISONOUS OR TOXIC MATERIALS shall be:

(B) Applied so that:

(2) Contamination including toxic residues due to drip, drain, fog, splash or spray on FOOD, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES is prevented, and this is achieved by: P

(b) Covering the items with ~~impermeable~~ waterproof covers, P or

Annex 3. Public Health Reasons/Administrative Guidelines

2-201.11 Responsibilities of the Person in Charge, Food Employees, and Conditional Employees.

Reporting Symptoms:

paragraph 4

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing ***Staphylococcus aureus*** into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but a~~n impermeable~~ waterproof bandage is not considered necessary for food safety purposes.

Annex 6: Food Processing Criteria

2. Reduced Oxygen Packaging

(B) Definitions

(1) *Cook-chill* packaging, in which cooked food is hot filled into ~~impermeable~~ IMPERMEABLE bags and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(2) *Controlled Atmosphere Packaging (CAP)* in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and ~~impermeable~~ IMPERMEABLE packaging material.

(4) *Sous Vide*, in which raw or partially cooked food is placed in a hermetically sealed, ~~impermeable~~ IMPERMEABLE bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

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Supporting Attachments:

- "Heat sealing without a vacuum v03"
- "Vacuum packaging and oxygen transfer rate of packaging material"
- "Controlling the Hazard of Clostridium botulinum Growth and Toxin Formation"
- "Technical Assistance Network - Response to your Case 299700_ Food Code"
- "Technical Assistance Network - Response to your Case 301854_ Food Code"

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2023 Issue Form

Issue: 2023 III-027

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code to Include Definition of "Preservation"

Issue you would like the Conference to consider:

The FDA 2022 Model Food Code should provide a definition for the term "preservation" as used in 3-502.11(A) and (C). As a starting point for development of that definition, we would like to propose the language in the recommended solution.

Public Health Significance:

When using "preservation" as the criteria to determine whether a variance and an approved Hazard Analysis - Critical Control Points (HACCP) plan are to be required, the intended meaning of the term needs to be clearly provided. Without clarification, both retail operators and regulators will arrive at their own interpretations. Those conclusions may conflict, deviating from FDA's intended meaning and potentially leading to public health risk resulting from misinterpretation. Searching the 2022 Food Code and previous versions, and the FDA and USDA websites, yields no official definition, and searching numerous Extension Service websites also yields no clearly stated definition. There is need for consistency in application of HACCP and variance requirements across jurisdictions, and clear statements of essential definitions are critical to establishing that needed consistency.

The lack of an official definition leads to increased regulatory burden in addressing processes submitted for approval as preservation, which in fact are often not preservation processes in the way they are used. Common examples include cold pickling of non-Time temperature Control for Safety (non-TCS) foods, and preparation of gravlax, ceviche or similar products. In turn this also creates an unnecessary burden on retail operators when they are requested to apply for a variance that is not necessary. A greater concern exists in that actual preservation processes are often found being conducted at retail without approval. This appears to be due in part to the lack of an official definition for inspector training purposes, as well as the lack of said definition provided as education to the retail food industry.

Recommended Solution: The Conference recommends...:

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

1-201.10 Statement of Application and Listing of Terms.

(B) Terms Defined. As used in this Code, each of the term listed in ¶ 1-201.10(B) shall have the meaning stated below.

"Preservation" means formulating, processing and/or packaging a TIME/TEMPERATURE CONTROL FOR SAFETY FOOD in a manner which extends shelf life of the refrigerated READY-TO-EAT FOOD product beyond seven days as allowed under 3-501.17, or which renders the final product a non-TIME/TEMPERATURE CONTROL FOR SAFETY FOOD.

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-028

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 Council III Issue 031; new or additional information has been included or attached.

Title:

Amend Food Code - Delete 4-101.12 Cast Iron, Use Limitations

Issue you would like the Conference to consider:

Amend Food Code Section 4-101.12 (Cast Iron, Use Limitation) to allow cast iron to be used for utensils or food-contact surfaces of equipment whether or not the surface is heated or used for cooking.

Public Health Significance:

Food Code Annex 3 Section 4-101.12 states that "...the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean." The attached reports conducted by 3rd party laboratories has concluded that microorganisms can be removed from cast iron cookware with similar effectiveness of food grade stainless steel and both plastic and glass tableware.

Recommended Solution: The Conference recommends...:

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

~~4-101.12 Cast Iron, Use Limitation. (A) Except as specified in ¶¶ (B) and (C) of this section, cast iron may not be used for UTENSILS or FOOD-CONTACT SURFACES of EQUIPMENT.~~

~~(B) Cast iron may be used as a surface for cooking.~~

~~(C) Cast iron may be used in UTENSILS for serving FOOD if the UTENSILS are used only as part of an uninterrupted process from cooking through service.~~

~~Annex 3 4-101.12 Cast Iron, Use Limitation. Equipment and utensils constructed of cast iron meet the requirement of durability as intended in section 4-101.11. However, the surface characteristics of cast iron tend to be somewhat porous which renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces the~~

~~residues in the porous surface are not of significant concern as heat destroys potential pathogens that may be present.~~

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Supporting Attachments:

- "Cleaning Effectiveness of Cast Iron Pans and Glass and Plastic Plates..."
- "Microorganism Recovery Equivalence from Cast Iron and Food Grade..."

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-029

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:

Modification of the Definition of TCS Foods

Issue you would like the Conference to consider:

Modification of the definition of Time/Temperature Control for Safety (TCS) foods

Public Health Significance:

The current definition of TCS foods includes only a limited number of cut plant foods. The published literature provides ample evidence that this list could be expanded, and additional publication will likely continue to expand this list. The literature shows that if avocado, cucumbers, zucchini squash, dragon fruit, banana, starfruit, mango, pineapple, guava, or wax apple are cut/diced/peeled/comminuted they will permit significant growth of *Listeria*, pathogenic *E. coli*, and/or *Salmonella* at ambient temperatures. The ability of pathogens to grow on these cut fruits and vegetables (and likely many more) highlight the need to modify the definition of TCS by removing the incomplete list of plant foods and simplifying the code to include all cut fruits and vegetables.

A supporting document is attached (TCS Foods 2022 Food Code Locations) to highlight where the term TCS food occurs throughout the Food Code.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the definition of Time/Temperature Control for Safety (TCS) Food under 1-201.10(B) of the current Food Code be amended as follows:

Time/Temperature Control for Safety Food (formerly "potentially hazardous food (PHF)).

(1) "Time/temperature control for safety food" means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(2) "Time/temperature control for safety food" includes:

(a) An animal FOOD that is raw or heat-treated; a plant FOOD that is raw and cut/diced/sliced/peeled/comminuted or heat-treated ~~or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation;~~ and

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Supporting Attachments:

- "Literature Review- Microbial Growth in Cut Fruits and Vegetables"
- "TCS Foods 2022 Food Code Locations"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-030

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code – Add Laboratory Methods for Reinstating Ill Food Workers

Issue you would like the Conference to consider:

We would like for the U.S. Food and Drug Administration (FDA) to add other validated laboratory methods in addition to culture for reinstating an excluded or restricted food worker.

Currently, the Food Code specifies the use of a culture-based method for removal of an exclusion or restriction of a food handler infected with shigellosis, salmonellosis, and Shiga toxin-*producing E.* coli disease. Culture-based method are still used but are being replaced by culture independent diagnostic tests (CIDTs) such as molecular or enzyme-based methods which do not produce an isolate. We are asking the conference to consider broadening the criteria for readmission of a food handler to include this new generation of diagnostic tests.

Additional support for the adoption of this issue has been received from the National Restaurant Association (see supporting attachment). Patrick Guzzle, Vice President, Food Science with the National Restaurant Association has expressed support for this issue as it will allow for additional tools for excluded or restricted employees to return to work safely and more quickly.

Public Health Significance:

The use of CIDTs in clinical practice continues to increase. FoodNet, a collaboration between CDC, FDA, USDA-FSIS, and 10 state health departments that conducts active population-based surveillance has seen a marked increase in the use of CIDTS since 2012. Access to culture (which is currently the only testing option allowed by the Food Code) is expected to become increasingly limited, making compliance with this Food Code requirement challenging.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the most recent Food Code be amended as follows:

2-201.13 Removal, Adjustment, or retention of Exclusions and Restrictions.

Shigella spp. Diagnosis - Removing Exclusion or Restriction

(E) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella* spp. infection based on ~~test results showing~~ 2 consecutive negative ~~stool specimen cultures~~ test results from a validated laboratory test that is acceptable to the REGULATORY AUTHORITY obtained from stool specimens that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics,[P] and

(b) At least 24 hours apart;[P]

STEC diagnosis - removing exclusions or restriction

(F) Reinstate a FOOD EMPLOYEE who was EXCLUDED or RESTRICTED as specified under Subparagraph 2-201.12(A)(2) or (F)(1) or who was RESTRICTED under Subparagraph 2-201.12(F)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of an infection from SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* based on ~~test results that show~~ 2 consecutive negative ~~stool specimen cultures~~ test results from a validated laboratory test that is acceptable to the REGULATORY AUTHORITY obtained from stool specimens that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics;[P] and

(b) At least 24 hours apart;[P]

Nontyphoidal Salmonella - removing exclusion or restriction

(G) Reinstate a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraph 2-201.12(A)(2) or who was RESTRICTED as specified under ¶ 2-201.12(G) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY[P] and one of the following conditions is met:

(1) The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Salmonella* (nontyphoidal) infection based on ~~test results showing~~ 2 consecutive negative ~~stool specimen cultures~~ test results from a validated laboratory test that is acceptable to the REGULATORY AUTHORITY obtained from stool specimens that are taken;

(a) Not earlier than 48 hours after discontinuance of antibiotics,[P] and

(b) At least 24 hours apart;[P]

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Supporting Attachments:

- "National Restaurant Association Food Safety Compliance Team_support"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-031

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code - Considerations for Bulk Refillable Hand Soap Dispensers

Issue you would like the Conference to consider:

Bulk refillable soap dispensers can become highly contaminated with bacteria and can harbor bacterial biofilms. Remediation of contaminated dispensers to remove the contamination is extremely difficult, and research has shown that contaminated bulk soap dispensers can transfer bacterial contaminants to hands leading to an ineffective handwash. Disease outbreaks have been linked contaminated bulk soap dispensers in healthcare settings. Hand hygiene guidance issued by the Centers for Disease Control and Prevention notes that use of refillable soap dispensers can become contaminated with bacteria if they are "topped off", and several recent studies have identified foodborne pathogens in soap and dispenser samples obtained from food establishment restrooms.

We ask The Conference to support an issue to amend the FDA Food Code by including additional considerations for establishments that choose to use these dispensers, to help prevent these dispensers from becoming contaminated with pathogenic bacteria that may lead to an outbreak.

Public Health Significance:

There are least two recently published peer-reviewed research studies which report the detection of foodborne pathogens in bulk soap.

A 2018 study describes the collection of 296 bulk soap samples from food establishments (e.g., grocery, sit down restaurants, fast food restaurants, and convenience stores) across the United States (1). Samples were screened for total heterotrophic viable bacteria, *Pseudomonas*, coliforms and *Escherichia coli*, and *Salmonella*. The researchers found:

- Bulk soap samples were contaminated with detectable levels of bacteria around 15% of the time, and when contaminated, contained very high levels of bacteria (>7.0 $\log_{10}$ colony forming units [CFU]/mL).

- One sample contained *Shigella sonnei*, the bacteria responsible for most Shigellosis cases in the developed world. Shigellosis is characterized by severe diarrhea and can be caused by less than 100 bacterial cells of *Shigella* species.
- A variety of opportunistic pathogens were identified in the samples, including *Klebsiella pneumoniae*, *Serratia marcescens*, *Enterobacter* species, and *Pseudomonas* species, which may pose a risk to certain individuals (e.g., immunocompromised individuals).

Researchers in Iran published a study in 2020 where they collected of 643 bulk soap and bulk soap dispenser samples from public restrooms in Iran (2). The samples were screened for a variety of bacteria using selective plating and biochemical confirmation methods. There were several key findings from this study:

- Dispensers and liquid soap samples were contaminated with bacteria 97.8% and 16.8% of the time, respectively.
- *Shigella* species were identified in 17 (2.6%) of liquid soap samples.
- Bulk dispensers had a variety of bacteria identified, including *Staphylococcus aureus* (*n*=38 [6.0%]), *Salmonella* species (*n*=10 [1.6%]), *Escherichia coli* (*n*=187 [29.0%]), and *Shigella* species (*n*=12 [1.9%]).

Research has shown that contaminated bulk soap can transfer the bacterial contaminants to the hands of individuals who used the soap in handwashing (3). A 2011 study identified naturally contaminated soap dispensers in an elementary school system, and then had student and staff volunteers wash their hands using the contaminated dispensers. Gram-negative bacteria on the hands of students and staff increased by 1.42 $\log_{10}$ CFU per hand (26-fold) after washing with soap from contaminated bulk-soap-refillable dispensers. The same study found that washing with soap from dispensers with sealed refills significantly (0.30 $\log_{10}$) reduced bacteria on hands.

If not properly maintained, use of bulk soap dispensers for handwashing has demonstrated risks. Foodborne and opportunistic pathogens have been isolated from bulk soap and bulk soap dispenser samples (1, 2). Contaminated bulk soap has been shown to transfer the contaminants to the hands of individuals (3) and contaminated dispensers are extremely difficult to remediate (4). Outbreaks attributed to contaminated bulk soap dispensers have been identified in healthcare settings (5) which has led to hand hygiene guidance by the CDC recommending against topping off of these dispensers (6). We propose this food safety risk should be addressed through amendment of the 2022 FDA Food Code.

References:

1. Schaffner, D. W., Jensen, D., Gerba, C. P., Shumaker, D., & Arbogast, J. W. (2018). Influence of Soap Characteristics and Food Service Facility Type on the Degree of Bacterial Contamination of Open, Refillable Bulk Soaps. J Food Prot. 81(2), 218-225.
2. Matini E, Shayeghi F, Vaghar ME, Nematian J, Hosseini SS, Mojri N, Taherabadi NT, Hakimi R, Ahmadi N, Badkoubeh N, Esmaeili H, Akhlaghi M, Vaseghnia H. A survey of public restrooms microbial contamination in Tehran city, capital of Iran, during 2019. J Family Med Prim Care. 2020 Jun 30;9(6):3131-3135.

3. Zapka, C. A., Campbell, E. J., Maxwell, S. L., Gerba, C. P., Dolan, M. J., Arbogast, J. W., & Macinga, D. R. (2011). Bacterial hand contamination and transfer after use of contaminated bulk-soap-refillable dispensers. Appl Env Micro. *77*(9)
4. Lorenz LA, Ramsay BD, Goeres DM, Fields MW, Zapka CA, Macinga DR. Evaluation and remediation of bulk soap dispensers for biofilm. Biofouling. 2012;28(1):99-109.
5. Buffet-Bataillon S, Rabier V, Bétrémieux P, Beuchée A, Bauer M, Pladys P, Le Gall E, Cormier M, Jolivet-Gougeon A. Outbreak of Serratia marcescens in a neonatal intensive care unit: contaminated unmedicated liquid soap and risk factors. J Hosp Infect. 2009 May;72(1):17-22.
6. Boyce, J. M., and D. Pittet. 2002. Guideline for hand hygiene in health-care settings. Morbid. Mortal. Week. Rep. 51:1-56.

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting the amendment of The FDA Food Code section 6-301.11 (Handwashing Cleanser, Availability) as follows:

6-301.11 Handwashing Cleanser, Availability.

(A) Each HANDWASHING SINK or group of 2 adjacent HANDWASHING SINKS shall be provided with a supply of hand cleaning liquid, powder, or bar soap.[Pf]

(B) If a hand cleaning liquid is used, its associated dispenser must be free from filth, visible debris, or any other sign of gross contamination.

(C) If a handwashing cleanser is dispensed from a receptacle that is designed to be refillable with an open reservoir and an accompanying lid, the receptacle must:

1. Be of durable construction;
2. Contain an interior constructed with a SMOOTH, EASILY CLEANABLE surface;
3. Be cleaned and sanitized as frequently as necessary to protect against contamination with microorganisms of public health concern.
4. Be resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

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Supporting Attachments:

- "Influence of Soap Characteristics and Food Service Facility Type"
- "A survey of public restrooms microbial contamination in Tehran city"
- "Bacterial hand contamination and transfer after use of contaminated bulk"
- "Evaluation and remediation of bulk soap dispensers for biofilm"
- "Outbreak of Serratia marcescens"
- "Guideline for hand hygiene in health-care settings"

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Conference for Food Protection
2023 Issue Form

Issue: 2023 III-032

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

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Issue History:

This is a brand new Issue.

Title:

Amend Food Code - Add Aqueous Ozone as an Approved Sanitizer in 4-501.114

Issue you would like the Conference to consider:

Adding aqueous ozone as an approved sanitizer in section 4-501.114 of the FDA Food Code.

Public Health Significance:

There is long history of use of ozone as a disinfectant in food and beverage processing.

- The application of ozone to disinfect bottled water was approved as Generally Recognized As Safe (GRAS) in 1982;
- The application of ozone for direct contact on foods was approved as GRAS by the U.S. Food and Drug Administration (FDA) in June 2001 under the FDA Final Rule 21 CFR Part 173.336.
  (Source: Ozone Processing of Foods and Beverages - IFT.org)

The FDA Food Code makes an allowance for alternative sanitizers but has specific requirements that places the burden on the permit holder to demonstrate efficacy. (Section 4-501.114)

- (D) If another solution of a chemical specified under ¶¶ (A) (C) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANTIZATION and the use of the solution shall be APPROVED;
- (E) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions; and
- (F) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in (A) - (D) of this section and shall be produced by a device that:

- (1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),
- (2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements,
- (3) Displays the EPA device manufacturing facility registration number on the device, and
- (4) Is operated and maintained in accordance with manufacturer's instructions

The California Retail Food Code expressly allows the use of aqueous ozone as a sanitizer in retail food establishments.

114099.6. Manual sanitization shall be accomplished in the final sanitizing rinse by one of the following:

(4) Contact with a solution of ozone that meets the requirements of Section 180.940 of Title 40 of the Code of Federal Regulations and that is generated by a device located onsite at the food facility that meets all of the following requirements:

(A) Complies with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.).

(B) Complies with federal device requirements as specified in Section 152.500 of Title 40 of the Code of Federal Regulations, and federal labeling requirements as specified in Section 156.10 of Title 40 of the Code of Federal Regulations.

(C) Displays the United States Environmental Protection Agency device manufacturing facility registration number on the device.

(D) Is operated and maintained in accordance with the manufacturer's instructions and manufactured using good manufacturing practices as specified in Part 110 of Title 21 of the Code of Federal Regulations.

Further, the California Department of Public Health has establishment a variance process for an ozone generating equipment that has "demonstrated through challenge studies, the efficacy of the solution produced by its equipment; however, it does not meet the requirements of Title 40 of the Code of Federal Regulations 180.940 as required by Section 114099.6(b)(4) of the" California Retail Food Code.

- Alternate Sanitizer Variance Application for Oxidus* Aqueous Ozone Disinfection System

*Preferred terminology is Aqueous Ozone without use of the word Oxidus

In general, the best practice for determining the appropriate CT value for an aqueous suspension of ozone in a food production environment is to maintain the ozone concentration at as high a value as possible that will ensure the atmospheric ozone concentration will not exceed the OSHA standard for the workplace of 0.1 ppm over an 8 hour work shift. Decades of experience have proven that an aqueous ozone concentration of 1.5 - 2.1 ppm at the faucet is quite appropriate for this purpose. The appropriate contact time will vary depending upon the specific pathogens of concern and the organic products and work surfaces to be disinfected. For many bacteria of concern in food production, if the pathogens are suspended in water, a continuous average aqueous ozone concentration of

approximately 0.04 ppm is sufficient to provide instantaneous 5-log kills, so an ozone concentration of 1.5 - 2.1 ppm would be far more than sufficient.

If the pathogens are attached to a product or work surface, longer contact times will be required depending upon the complexity of the surfaces and the pathogens involved. In this regard, agitation provided by the likes of flume operation or using one's hands to disturb the product surface during rinsing will decrease the amount of time necessary for appropriate disinfection. Also, if there is a large organic load being disinfected in a deep sink, such as several heads of lettuce, freshly ozonated water must be continuously added to the sink, as such an organic load in ozonated water will rapidly reduce the ozone concentration.

Adding ozone as an approved sanitizer in the FDA Food Code will:

- Provide retail food establishments an additional approved method for sanitizing food contact surfaces; and
- Reduce the administrative burden of permit holders to demonstrate the efficacy of this sanitizing method.

Recommended Solution: The Conference recommends...:

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

4-501.114 Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.

(D) An ozone solution shall:

1. Have a concentration at 0.3-2.1 ppm as measured by ORP meter (Oxidation-Reduction Potential) with reading between 695-925 mv or using ozone colorimetric test kit. Exposure time may vary from 30 seconds to up to 5 minutes.
2. Meets the requirements of Section 180.940 of Title 40 of the Code of Federal Regulations;
3. Meet the requirements specified under (G) of this section if the ozone solution is generated by a device located onsite at the food facility that meets all of the following requirements

~~(D)~~(E) If another solution of a chemical specified under ¶¶ (A) - ~~(C)~~(D) of this section is used, the PERMIT HOLDER shall demonstrate to the REGULATORY AUTHORITY that the solution achieves SANITIZATION and the use of the solution shall be APPROVED; P

~~(E)~~(F) If a chemical SANITIZER other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the EPA-registered label use instructions, P and

~~(F)~~(G) If a chemical SANITIZER is generated by a device located on-site at the FOOD ESTABLISHMENT it shall be used as specified in ¶¶ (A) - ~~(D)~~(E) of this section and shall be produced by a device that:

(1) Complies with regulation as specified in §§ 2(q)(1) and 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),P

(2) Complies with 40 CFR 152.500 Requirement for Devices and 40 CFR 156.10 Labeling Requirements, P

(3) Displays the EPA device manufacturing facility registration number on the device, [Pf] and

(4) Is operated and maintained in accordance with manufacturer's instructions [Pf].

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Supporting Attachments:

- "Ozone Data for CFP 2023"
- "Efficacy of Ozonated Water against Various Food-Related Microorganisms"

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