			Internal Number: 028 Issue: 2012 I-001
Council Recommendation:	Accepted as Submitted	Accepted asAmended	No Action
Delegate Action:	Accepted _	Rejected	
All information above	the line is for confer	rence use only.	

Title:

Report - Plan Review Committee

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Plan Review Committee seeks Council I's acknowledgement of its final committee report and requests that the committee be recreated to continue its review of the Permanent Outdoor Cooking Operations and the Mobile Food Establishment documents and present their findings at the 2014 CFP Biennial Meeting.

See additional Committee submitted Issues titled:

- Temporary Food Establishments 2011 Final Document
- Re-Creation of Plan Review Committee

Public Health Significance:

The Plan Review Committee has been tasked with the on-going development of the plan review documents for food establishments, temporary food establishments, mobile food establishments and permanent outdoor cooking operations. The objective of each document is to provide assistance to regulatory jurisdictions during the plan review process with an overarching goal of consistency and standardization.

Recommended Solution: The Conference recommends...:

- 1. Acknowledgement of the CFP Plan Review Committee Report including the following attachments (content attachments presented for approval as the Issue titled: Temporary Food Establishments 2011 final document):
 - Temporary Food Establishments 2011 Final Document
 - Attachment I Application To Operate A Temporary Food Establishment
 - Attachment II Event Organizer Application To Operate Temporary Food Establishments
 - Attachment III Temporary Food Establishment Expanded Process Flow
- 2. Thank the Committee members.

Submitter Information:

Name: Liza Frias, Committee Chair

Organization: Plan Review Committee Address: 1421 S. Manhattan Avenue

City/State/Zip: Fullerton, CA 92831

Telephone: 714-300-6813 Fax: 714-300-6931

E-mail: liza.frias@supervalu.com

Attachments:

- "Plan Review Committee Final Report"
- "Plan Review Committee Member Roster"
- "Temporary Food Establishments 2011 Final Document"
- "Attachment I Application To Operate A Temporary Food Establishment"
- "Attachment III Temporary Food Establishment Expanded Process Flow"
- "Attachment II Event Organizer Application to Operate Temporary Food Estab"

Council Accepted as Accepted as Recommendation: Submitted Amended No Action

Delegate Action: Accepted Rejected

All information above the line is for conference use only.

Internal Number: 029

Title:

Temporary Food Establishments 2011 Final Document

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Plan Review Committee seeks acceptance of the document titled "Temporary Food Establishments 2011 Final Document and Attachments I, II and III".

Public Health Significance:

The Plan Review Committee has been tasked with the on-going development of the plan review documents for food establishments, temporary food establishments, mobile food establishments and permanent outdoor cooking operations. The objective of this document is to assist regulatory authorities and the food industry in understanding the review; approval and operation of Temporary Food Establishments.

Recommended Solution: The Conference recommends...:

that the following documents be accepted and posted on the CFP website (NOTE: documents can be found attached to the Issue titled: Report - Plan Review Committee):

- Temporary Food Establishments 2011 Final Document
- Attachment I Application To Operate A Temporary Food Establishment
- Attachment II Event Organizer Application To Operate Temporary Food Establishments
- Attachment III Temporary Food Establishment Expanded Process Flow

The Conference further recommends that a letter be sent to FDA requesting that these documents also be made available on the FDA website.

Submitter Information:

Name: Liza Frias, Committee Chair Organization: Plan Review Committee

Address: Supervalu, 1421 S. Manhattan Avenue

City/State/Zip: Fullerton, CA 92831

Telephone: 714-300-6813 Fax: 714-300-6931

E-mail: liza.frias@supervalu.com

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

Internal Number: 030 Issue: 2012 I-003

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

Re-Create Plan Review Committee

Issue you would like the Conference to consider:

The Conference for Food Protection (CFP) Plan Review Committee requests that the committee be reinstated to continue its review of the existing Permanent Outdoor Cooking Operations and the Mobile Food Establishment documents and present their findings at the 2014 CFP Biennial Meeting.

Public Health Significance:

The Plan Review Committee has been tasked with the on-going development of the plan review documents for food establishments, temporary food establishments, mobile food establishments, and permanent outdoor cooking operations. The objective of each document is to provide assistance to regulatory jurisdictions during the plan review process with an overarching goal of consistency and standardization.

Recommended Solution: The Conference recommends...:

Re-creating the Plan Review committee following the CFP 2012 Biennial Meeting to continue its review and update of the following Conference for Food Protection documents and present their findings at the 2014 CFP Biennial Meeting:

- a. Permanent Outdoor Cooking Operations (2003)
- b. Mobile Food Establishments (2006)

Submitter Information:

Liza Frias, Committee Chair Name: Plan Review Committee Organization:

Address: Supervalu, 1421 S. Manhattan Avenue

City/State/Zip: Fullerton, CA 92831

Telephone: 714-300-6813 714-300-6931 Fax:

F-mail liza.frias@supervalu.com

				I	nternal Num Issue: 20	
Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		Rejected		-	
All information above	the line is for co	nference	use only.			

Title:

Change definition of PHF/TCS to TCS

Issue you would like the Conference to consider:

Following issuance of the final report "Evaluation and Definition of Potentially Hazardous Foods" (Technologists, 2010) by the Institute of Food Technologists (IFT) on December 31, 2001 the recommendation was made to change the name of "potentially hazardous foods" or "PHF" to "temperature control for safety food" or "TCS". The report advised that use of both terms (e.g. PHF/TCS) during a transition phase would facilitate migration from one term to the next. Now over a decade since the IFT report, the transition term has been in common use in the FDA Food Code since 2005.

The definition of "Potentially Hazardous Food (Time/Temperature Control for Safety Food)", abbreviated PHF/TCS in the FDA Food Code, has now been in common use for over six years. While it has served its purpose for introducing the new term, the time has come to complete the migration to the new definition. The definition and abbreviation for "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" or "PHF/TCS" should be modified to drop the reference to "potentially hazardous food" and "PHF". Instead, the definition should read "Time/Temperature Control for Safety Food" abbreviated as "TCS".

Public Health Significance:

By eliminating use of both terms, the final intent of the IFT report will be realized by simply using the term "Time/Temperature Control for Safety Food" or "TCS". Stakeholders that use the FDA Food Code will be able to communicate clearly with others and the public more effectively using this simple term. Emphasis on time and temperature in the name of this definition will focus attention on critical elements of food safety that can be effectively controlled.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the following change to the 2009 Food Code (as modified by the Supplement issued in 2011):

Replace the current definition "Potentially Hazardous Food (Time/Temperature Control for Safety Food)" abbreviated as "PHF/TCS" with the new term "Time/Temperature Control for Safety Food" abbreviated "TCS" throughout the entire FDA Food Code.

Submitter Information:

Name: Chris Gordon

Organization: Virginia Department of Health

Address: 109 Governor Street City/State/Zip: Richmond, VA 23219

Telephone: 804-864-7417 Fax: 804-864-7455

E-mail: christopher.gordon@vdh.virginia.gov

Attachments:

• ""Technologists, 2010""

Internal Number: 004

			Issue: 2012 I-005
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	onference use only.	

Title:

Sore throat with fever

Issue you would like the Conference to consider:

Food and Drug Adminstration 2009 Food Code, section 2-201.13(G) requires a person with sore throat and fever to not return to work until they have medical documentation of being free of <u>Streptococcus pyogenes</u> or have received professional medical treatment for same.

This requirement is too strict considering the risk.

Public Health Significance:

A sore throat is a frequent symptom of the common cold or other acute respiratory tract infections. Strep throat is caused by Group A *streptococcus*.

Antibiotics are needed if a healthcare provider diagnoses you or your child with strep throat, which is caused by bacteria. Strep throat cannot be diagnosed by looking in the throat - a lab test must also be done. Antibiotics are prescribed for strep throat for the purpose of preventing rheumatic fever . If the test result shows strep throat, the infected patient should stay home from work, school, or day care until 24 hours after starting an antibiotic.

The following links are CDC references that do not support the need for such a strict requirement -

CDC 2011 Foodborne Illness Estimates located at

- http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html#annual
 Top 5 pathogens contributing to foodborne illness
 - http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS_updated4-13.pdf

Trends in Foodborne Illness in the US

- http://www.cdc.gov/foodborneburden/trends-in-foodborne-illness.html#foodnet Get Smart: Know when antibiotics work Sore throat
 - http://www.cdc.gov/getsmart/antibiotic-use/URI/sore-throat.html

Changing this requirement will reduce a misplaced effort on rare foodborne illness. Change will promote reporting of symptoms. Requirements will be more in line with risk to public health.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) Section 2-201.13(G) be amended so that persons with sore throat and fever can return to work after being free of symptoms for 24 hours.

Submitter Information:

Name: Sean Dunleavy

Organization: Great Lakes Conference on Food Protection

Address: P.O. Box 16082 City/State/Zip: Lansing, MI 48091

Telephone: (517) 243-8895 Fax: (517) 373-3333

E-mail: dunleavys@michigan.gov

				11	Issue: 20	
Council Recommendation:	Accepted as Submitted		ccepted as mended		No Action	
Delegate Action:	Accepted	R	ejected			
All information above	the line is for co	nference us	se only.			

Title:

Report-Wild Harvested Mushroom Committee

Issue you would like the Conference to consider:

During the 2010 Conference for Food Protection Biennial Meeting in Providence, Rhode Island the Wild Harvested Mushroom committee was created and given the following charges as an outcome of Issue 2010 I-008:

The Conference recommends that the Council consider forming a committee to continue discussion of this issue and that the following language and attachments for consideration to be placed on the CFP website as guidance listing steps that states can use to develop and implement a wild harvested mushroom program for their state. The charges will be:

- (1) Develop guidelines to help regulators address the issue of wild mushrooms in food establishments;
- (2) Report back at the 2012 CFP;
- (3) The name of the committee will be Wild Harvested Mushrooms Committee.

This Issue presents the Wild Harvested Mushrooms Committee's final report along with committee roster and requests acknowledgement of the attached report.

The Wild Harvested Mushrooms Committee worked to complete their charges by developing a model program that regulatory agencies can use when addressing the issue of wild harvested mushrooms in retail and food service establishments.

Public Health Significance:

Due to public health food safety concerns, regulatory agencies in many jurisdictions follow the lead of the US FDA model Food Code (*hereafter model Food* Code) in requiring that wild harvested mushrooms sold to the public be identified by "an approved mushroom identification expert" (2009 model Food Code, *Section 3-201.16*). However, the pathway both for becoming an "approved mushroom identification expert" and having a regulatory agency recognize one are not well established or defined. The model Food Code recommends that all food served to the public must come from safe sources. The model Food Code further stipulates that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert. However the model Food Code does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses, some regulatory jurisdictions

entirely prohibit the sale of wild harvested mushrooms. Other states have a limited program to allow specific species to be sold. The model program proposed here addresses this "gap" in public health interventions by providing clear guidance for regulatory agencies to use when addressing the issue of wild harvested mushrooms in foodservice establishments.

Recommended Solution: The Conference recommends...:

acknowledgement of the Wild Harvested Mushrooms Committee's final report and recognize the effort that committee members put forth in completion of the charges issued by the 2010 biennial meeting.

Submitter Information:

Name: Chris Gordon, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Virginia Department of Health 109 Governor Street5th Floor-Office of

Environmental Health Services

City/State/Zip: Richmond, VA 23219

Telephone: 804-864-7417 Fax: 804-864-7475

E-mail: christopher.gordon@vdh.virginia.gov

Attachments:

- "Wild Harvested Mushroom Committee List"
- "CDC MMWR Wild Mushroom reports 2011"
- "Food Safety News-California Wild Mushroom statement"
- "New Hampshire statement on wild mushrooms"
- "Washington Post article on consumption"
- "Wild Harvested Mushroom Committee Final Report"

			internai Num Issue: 20	
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above	the line is for co	nference use only.		

Title:

Redefine "approved mushroom identification expert" in Food Code § 3-201.16

Issue you would like the Conference to consider:

By its own admission § 3-201.16 in Annex 3 of the 2009 FDA Food Code identifies that "regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom identification expert" and enforcing the Food Code provisions associated with it." An attempt was made in 1998 by a Conference for Food Protection committee to more precisely provide guidance, however they were unable to provide the information in a useful way for stakeholders. Following two reported wild mushroom poisonings linked to exposure at food establishments in 2008 in Maine, the Health Inspection Program brought forward a proposal to the 2010 Conference for Food Protection (2010 Issue I-08) to overhaul § 3-201.16, but instead a committee was again charged to 'develop guidelines to help regulators address the issue of wild mushrooms in food establishments'. Since 1993, this section has required an 'expert' to identify wild mushrooms. However after nineteen years, regulators are still having 'difficulty' identifying what an 'expert' is or how to evaluate one. Instead of documenting 'difficulty' with this section as described in Annex 3, this issue proposes a way forward to remove the challenges associated with this term to provide clarity for all stakeholders.

Public Health Significance:

Following the guidance set forth in the Food and Drug Administration's model Food Code, regulations in many jurisdictions require that wild harvested mushrooms sold to the public be identified by "an approved mushroom identification expert". However, the criteria for becoming an approved identifier are not identified or well established. The Food Code recommends that all food served to the public must come from safe sources. The Food Code stipulates that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert, but does not establish what constitutes the basis for approval of an identification expert. Some jurisdictions require the identification expert to be someone who has successfully completed an identification course provided either by a college, university or mycological society. Due to the lack of established criteria and recognized training courses, eleven states have now entirely prohibited the sale of wild

harvested mushrooms. Other states have a limited program to allow specific species to be sold.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows: (new language in underline format, language to be removed in strike-through)

- 1) remove the term 'approved mushroom identification expert' from Section 3-201.16 (A) and replace it with the term 'approved mushroom identifier' as noted below.
- (A) Except as specified in ¶ (B) of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an APPROVED mushroom <u>identifier identification expert</u>. P
- 2) include the definition noted below regarding an approved mushroom identifier.

Approved Mushroom Identifier: One who has successfully completed a required course on identification of selected species of harvested mushrooms, the appropriate harvest, storage and preparation of those species; and who has demonstrated competence by passing an exam acceptable to the regulatory authority.

Submitter Information:

Name: Lisa Roy, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Maine Health Inspection Program286 Water Street

City/State/Zip: Augusta, ME 04330

Telephone: 207-287-5691 Fax: 207-287-3165

E-mail: lisa.roy@maine.gov

Internal Number: 058 Issue: 2012 I-008

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

A coopted co

Title:

Ca...a.ii

Resources and Criteria to Select Wild Mushroom Species

Accepted on

Issue you would like the Conference to consider:

This issue describes two of the five important elements of a model wild harvested mushroom program, which will permit a variety of wild harvested mushrooms to be sold to and by retail and foodservice establishments. Mushroom species vary from state to state and region to region. The recommended solution provides a method for jurisdictions to create a species list for mushrooms approved for sale or service. This will also provide a basis for regulatory agencies to collaborate with colleges, universities and/or local mycological organizations to approve wild mushroom identifiers.

Public Health Significance:

The trade of wild harvested mushrooms is an established and rapidly growing industry that impacts consumers through wholesale, retail and restaurant services. The inability of Regulatory Authorities to effectively regulate and approve individuals as competent to identify mushrooms fosters the back door trading of wild harvested mushrooms and poses a threat to the consumer population through the potential ingestion of mushrooms that have been misidentified.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that Annex 3 Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include the information noted below regarding recommended resources and criteria to select wild mushroom species. (new language in underline format).

Recommended Committee Resources

A regulatory authority may choose to form a committee to determine which fresh, wild harvested mushroom species are appropriate for commercial harvest in their state.

Representatives from the following groups may be considered for membership:

- Regulatory agencies from departments that oversee restaurants, markets and farmers' market;
- Local Poison Centers;
- Local mycological organizations;
- Restaurant Associations:

- College or university personnel who are competent identifiers of wild mushrooms;
- Commercial wild mushroom foragers;
- Wild Mushroom Brokers:
- Chefs who serve fresh wild harvested mushrooms

Criteria to Select Wild Mushroom Species

Individual regulatory authorities may use the following criteria to establish a list of wild mushroom species for harvest and sale to the public. Wild mushrooms on the approved list for an approved mushroom identifier may be sold to or by a food establishment. Wild Mushroom Species that are:

- currently in commerce according to foragers, chefs and dealers in the jurisdiction;
- easily identified with field characteristics as determined by the jurisdiction;
- common, in a specific jurisdiction as determined by the committee;
- generally considered a low allergic reaction risk as determined by the committee;
- consideration may be given for wild mushrooms approved for sale in other states (to be imported from those states), if accompanied by appropriate records.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

Submitter Information:

Name: Lisa Roy, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Maine Health Inspection Program286 Water Street

City/State/Zip: Augusta, ME 04330

Telephone: 207-287-5691 Fax: 207-287-3165

E-mail: lisa.roy@maine.gov

Internal Nu	ımber	:: 059
Issue:	2012	I-009

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

Title:

Wild Harvested Mushroom Record-Keeping and Traceability

Issue you would like the Conference to consider:

From 1960-2010, the CDC's Morbidity and Mortality Weekly Report documented at least twenty-four reports attributed to environmental health-related mushroom and plant poisoning (Henry Falk, 2011). More recently, the California Department of Public Health (CDPH) reported that 1,748 cases of mushroom ingestion were reported for 2009-2010 where two people died and ten others suffered major health consequences including liver failure or kidney dialysis (Food Safety News, 2011). Following heavy rains from a hurricane and tropical storm that affected the US east coast this past fall, the New Hampshire Department of Health and Human Services (Services, 2011) issued a warning regarding consumption of wild mushrooms and the Washington Post (Stephens, 2011) featured an article where two men went into liver failure after consuming wild mushrooms that were more abundant due to the wet weather. While the majority of these cases document recreational exposure as compared with food establishment exposure, these incidents of wild mushroom ingestion highlight the effects of foodborne intoxication and illness that follow. Along with this cautionary information, it is important to acknowledge that wild mushrooms can also be a healthy, edible source of nutritious food provided they are from a safe source. Unfortunately, the admitted "difficulty" that regulatory agencies have found when relying on the guidance provided by the FDA model Food Code (hereafter model Food Code) to define "approved wild mushroom identification expert" to assure safe sources has left regulators without sufficient avenues to address the issue of wild harvested mushrooms at retail and foodservice establishments (2009 FDA Food Code, Annex 3, Section 3-201.16). In fact, eleven states have gone on to ban the sale or service of wild harvested mushrooms at restaurants and farmers markets due to the lack of clearly identified safe sources from 'approved wild mushroom identification experts'.

This issue seeks to provide regulatory authorities with a mechanism for initiating prompt tracebacks or recalls if wild harvested mushrooms are implicated in a foodborne illness or outbreak following ingestion at a foodservice establishment or retail.

Sources:

Henry Falk, M. (2011). Environmental Health in MMWR-1961-2010. *Morbidity and Mortality Weekly Report*, 86-96.

Newsdesk. (2011, November 26). Wild Mushrooms Can Kill, California Health Officer Warns. *Food Safety News*.

Services, N. H. (2011, August 27). DHSS Issues Warning About Accidentally Eating Poison Mushrooms. Concord, New Hampshire.

Stephens, J. (2011, September 18). 2 Discover Tasty Mushrooms Can Be Dangerous. *Washington Post*. Washington, DC.

Public Health Significance:

In the event of a foodborne illness or outbreak related to wild harvested mushrooms, regulatory authorities that are responsible for assuring food safety must be able to conduct traceback investigations for implicated foods or initiate recalls as required. Additionally, food service operations and retail stores must have the ability to quickly segregate and remove implicated foods from sale or use.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be modified by placing into Annex 3, Section 201.16 guidelines indicated below for wild harvested mushroom recordkeeping and tracebacks (new language in underline format).

In order to assure traceability, the responsibility of the approved mushroom identifier must be delineated. Therefore each batch of mushrooms obtained from a wild mushroom approved identifier must be accompanied by a tag or label and include the following information:

- 1. Approved identifier name:
- 2. Address & phone number;
- 3. Latin binomial name and locally used common name;
- 4. Harvest date:
- 5. Harvest location (town, county, township, etc);
- 6. Harvest weight;
- 7. Name of forager if not harvested by an approved identifier;

All foodservice establishments and retail or wholesale stores that receive wild harvested mushrooms should retain the wild harvested mushroom tag or label and make them available upon request by the regulatory authority. The wild harvested mushroom tags are to remain attached to the container in which the wild harvested mushrooms were received until the container is empty. The tags are to be retained for at least sixty (60) calendar days from the date the container is emptied as illness may take up to two (2) weeks to present, two (2) more weeks for diagnosis, and up to thirty (30) days for epidemiological investigation and traceback. Commingling of wild harvested mushroom lots is not recommended as it serves to confound traceback investigations and hinder efforts to remove implicated product from the food chain.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

Submitter Information:

Name: Chris Gordon, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Virginia Department of Health 109 Governor Street5th Floor-Office of

Environmental Health Services

City/State/Zip: Richmond, VA 23219

Telephone: 804-864-7417 Fax: 804-864-7475

E-mail: christopher.gordon@vdh.virginia.gov

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

Title:

Wild Harvested Mushroom Curriculum

Issue you would like the Conference to consider:

This issue describes one of the five important elements of a model wild harvested mushroom program, which will permit a variety of wild harvested mushrooms to be sold to and by retail and foodservice establishments.

The FDA Food Code specifies that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert, but does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses the best way to protect public health is to provide education and training which includes a curriculum on how to safely and properly identify wild harvested mushrooms.

Public Health Significance:

The trade of wild harvested mushrooms is an established and rapidly growing industry that impacts consumers through wholesale, retail and restaurant services. The inability of regulatory authorities to effectively regulate and approve individuals as competent to identify mushrooms fosters the back door trading of wild harvested mushrooms and poses a threat to the consumer population through the potential ingestion of mushrooms that have been misidentified.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that Annex 3 Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include the information noted below regarding Curriculum for the Approved Mushroom Identifier (new language in underline format).

<u>Curriculum for the Approved Mushroom Identifier this is to be developed and administered by the committee established by the regulatory authority. The curriculum should include general information about the following:</u>

- Mushroom anatomy as it relates to identification;
- Mushroom toxins and case histories of poisonings;

- Specific information regarding habitat, including information on areas that are considered inappropriate for harvest (treated areas, brownfields, etc.);
- Proper collection, including information on proper harvesting and species conservation techniques; and
- Information on areas where harvesting is not permitted, or permitted only with permission.

The curriculum should also include specific information about the approved species including:

- <u>Latin binomial and approved common name;</u>
- Specific characteristics required for proper identification, including differentiating characteristics of similar toxic and non-toxic species;
- Characteristics for determining that (if) the mushroom is in good condition;
- Information about proper storage;
- Information about proper preparation; and
- Information about regulations that the harvester must comply with.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

Submitter Information:

Name: Lisa Roy, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Maine Health Inspection Program286 Water Street

City/State/Zip: Augusta, ME 04330

Telephone: 207-287-5691 Fax: 207-287-3165

E-mail: lisa.rov@maine.gov

			Internal Number: 061 Issue: 2012 I-011
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	nference use only.	

Title:

Wild Harvested Mushroom Exam

Issue you would like the Conference to consider:

This issue describes one of the five important elements of a model wild harvested mushroom program, which will permit a variety of wild harvested mushrooms to be sold to and by retail and foodservice establishments.

The FDA Food Code specifies that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert, but does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses, the best way to protect public health is to provide education and training including an exam to demonstrate knowledge on how to safely and properly identify wild harvested mushrooms.

Public Health Significance:

The trade of wild harvested mushrooms is an established and rapidly growing industry that impacts consumers through wholesale, retail and restaurant services. The inability of Regulatory Authorities to effectively regulate and approve individuals as competent to identify mushrooms fosters the back door trading of wild harvested mushrooms and poses a threat to the consumer population through the potential ingestion of mushrooms that have been misidentified.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that Annex 3 Section 3-201.16 of the 2009 Food Code (as modified by the Supplement issued in 2011) be amended to include the information noted below regarding a Wild Harvested Mushroom Exam.

Exam for the Approved Mushroom Identifier

This is to be developed and administered by individuals who have demonstrated competence as a trainer and are competent in the field identification of wild harvested mushroom species in their jurisdiction, as verified by a mycological association or other educational institution. The regulatory authority may choose to have the exam designed by a psychometrician or standardized by a third party authority. If these are not deemed

<u>reasonable</u>, the regulatory authority may use another technique to ensure that the exam is <u>legally defensible</u>.

The exam should test individuals on the information in the curriculum with special emphasis on species identification. Use of photos is highly recommended. In some cases it may be appropriate to include a lab practicum with fresh samples of the approved species and their similar species to test identification skills. The passing score is to be determined by the regulatory authority.

For the purposes of this recommendation, the *trainer* is defined as an individual who has demonstrated competence as an educator, competence in the field identification of wild mushroom species, and whose competence has been verified by a mycological association or educational institution recognized by the regulatory agency. Examples of organizations are North American Mycological Association (NAMA), Cooperative Extensions, Mycological Society of America, local or regional mycological associations, schools, colleges and universities. An advanced degree in Mycology does not necessarily qualify an individual as an approved trainer in the field identification of mushroom species.

The Conference also recommends that the above language be incorporated into a single Wild Harvested Mushroom Guidance Document and posted on the CFP website so that state and local jurisdictions can use this information to develop and implement their own wild harvested mushroom program.

Submitter Information:

Name: Lisa Roy, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Maine Health Inspection Program286 Water Street

City/State/Zip: Augusta, ME 04330

Telephone: 207-287-5691 Fax: 207-287-3165

E-mail: lisa.roy@maine.gov

Internal	Num	ber:	015
lss	ue: 20	12 I-	012

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

Title:

Re-create Wild Harvested Mushroom Committee

Issue you would like the Conference to consider:

Due to public health food safety concerns, regulatory agencies in many jurisdictions follow the lead of the US FDA model Food Code (hereafter model Food Code) in requiring that wild harvested mushrooms sold to the public be identified by "an approved mushroom identification expert" (2009 model Food Code, Section 3-201.16). However, the pathway both for becoming an "approved mushroom identification expert" and having a regulatory agency recognize one are not well established or defined. The model Food Code recommends that all food served to the public must come from safe sources. The model Food Code further stipulates that mushrooms species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert. However the model Food Code does not establish what constitutes the basis for approval of an identification expert. Due to the lack of established criteria and recognized training courses, some regulatory jurisdictions entirely prohibit the sale of wild harvested mushrooms. Other states have a limited program to allow specific species to be sold.

Public Health Significance:

Continuing the work of the Wild Harvested Mushroom Committee will assure that the committee's charge, issued in 2010 to "develop guidelines to help regulators address the issue of wild mushrooms in food establishments", is fully realized. Only when state and local regulators, who currently do not have clear way forward to address this issue, are able to assure the safety of wild mushrooms in food establishments will the work of the committee be complete.

Recommended Solution: The Conference recommends...:

re-creating the Wild Harvested Mushroom Committee for the next biennium with the following charges:

- 1. develop guidelines to help regulators address the issue of wild mushrooms in food establishments.
- 2. report back its findings and recommendations to the 2014 CFP Biennial Meeting.

Submitter Information:

Name: Chris Gordon, Co-Chair

Organization: Wild Harvested Mushroom Committee

Address: Virginia Department of Health 109 Governor Street5th Floor-Office of

Environmental Health Services

City/State/Zip: Richmond, VA 23219

Telephone: 804-864-7417 Fax: 804-864-7475

E-mail: christopher.gordon@vdh.virginia.gov

Council Accepted as Accepted as Recommendation: Submitted Accepted Rejected

All information above the line is for conference use only.

Title:

HACCP-based Guidance for Meat and Poultry Processing at Retail

Issue you would like the Conference to consider:

The Food Safety and Inspection Service (FSIS), in collaboration with the Association of Food and Drug Officials (AFDO), is seeking input on comprehensive Hazard Analysis Critical Control Points (HACCP) guidance materials under development to assist in providing a uniform standard available for all regulatory jurisdictions to control meat and poultry processing activities at retail when a variance is required. This guidance is intended for developing or reviewing HACCP plans for multifaceted processing activities at retail (i.e., smoked, cured, fermented, jerky). Guidance materials previously developed by the Minnesota Department of Agriculture (DOA) are being further developed by FSIS and AFDO into comprehensive HACCP guidance materials to assist all regulatory jurisdictions in complying with FDA Food Code variance requirements.

[i] FSIS and AFDO jointly recommend that a Committee be formed so that input can be received from a wide variety of backgrounds on the guidance under development. By forming a Committee, this would ensure that this guidance provides acceptable, ready-to-use materials available to all regulatory jurisdictions to strengthen their control of meat and poultry processing at retail by utilizing HACCP-based guidance to meet variance requirements. Also, by forming a Committee, this will assure that input is received from a wide variety of backgrounds so that the guidance under development provides suitable guidance materials to control meat and poultry processing activities at retail when a variance is required.

[i] Minnesota Department of Agriculture. *Model HACCP Plans*, and *A Retail Food Establishment Guide for Developing a HACCP Plan*. Links are found at:

https://docs.google.com/open?

id=0ByXV4y__bb1JMmQ3ZTFhODAtNzk0MC00MDExLTk5NTktYTgyMTA3NWUzNTk3 https://docs.google.com/open?

id=0ByXV4y__bb1JNDM0NmQ4ZTEtNmYxNy00NzZhLTk1NTgtM2RjM2E3OTEzOTQ3

Public Health Significance:

Some retail processing activities under the Food Code (as per § 3-502.11 Variance Requirement), including much of the meat and poultry processing, would require a variance based on a HACCP plan. However, relatively few state and local jurisdictions have

procedures in place requiring that retailers have variances based on HACCP plans. FSIS believes that more guidance is needed on the preparation of HACCP Plans and HACCP-based variance requirements for multifaceted processing activities (i.e., smoked, cured, fermented, jerky), and currently available guidance is inadequate. In developing HACCP plans for meat and poultry processes, retail establishments must consider all possible hazards in accordance with Title 9 CFR 417.2 Hazard Analysis and Critical Control Point (HACCP) Systems.[i] Part 417.2 addresses pathogens of public health concern. Retail establishments are important settings for foodborne-disease outbreaks. If retail establishments do not address pathogen reduction in their HACCP plans, adulterated product may be released into commerce.

In accordance with the preface of the Food Code under "Advantages of Uniform Standards," a retail establishment may be granted a variance from their regulatory jurisdiction to use a specific federal food safety performance standard for a product or a process instead of compliance with applicable provisions in the Food Code. To show compliance with the federal performance standard, however, the retail establishment must demonstrate that processing controls are in place to ensure that the standard is being met similar to a federally inspected establishment. Therefore, a retail establishment's request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to their regulatory jurisdiction.

All regulatory jurisdictions can strengthen their control of meat and poultry processing at retail by utilizing HACCP-based variance requirements if there were available ready-to-use guidance materials on how to accomplish this. While state and local jurisdictions would be the primary audience, such guidance can also be used by retailers to assist in developing their HACCP plans, as they would be able to learn what would be the expectations of their regulators. By forming a Committee, this will assure that input is received from a wide variety of backgrounds so that the guidance under development provides suitable guidance materials to control meat and poultry processing activities at retail when a variance is required.

[ii] Lynch, M., J. Painter, R. Woodruff, and C. Braden. 2006. Centers for Disease Control and Prevention. Surveillance for foodborne-disease outbreaks-United States, 1998-2002. MMWR Surveill. Summ. 55(SS10):1-42. Found at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5510a1.htm

Recommended Solution: The Conference recommends...:

- 1. That a Committee be established to:
- (a) provide input on comprehensive Hazard Analysis Critical Control Point (HACCP) guidance materials under development by the Food Safety and Inspection Service (FSIS), in collaboration with the Association of Food And Drug Officials (AFDO),
- (b) to assist in providing a uniform standard available for all regulatory jurisdictions in the evaluation of variance requests involving the processing of meat and poultry at retail, and (c) to better control meat and poultry processing activities at retail, utilizing the attached guidance materials that are being further developed by FSIS and AFDO, *Model HACCP Plans for Retail Processing*, and *A Retail Food Establishment Guide for Developing a HACCP Plan Meeting the Requirements of the FDA Food Code Variance in the Relation to Specialized Meat and Poultry Processing Methods)*,
- (d) report back to the 2014 Biennial Meeting.

- 2. That the Conference send a letter to FDA asking that they consider if and how these guidance materials, once finalized, can best be incorporated into:
- (a) FDA Food Code Annex 2 (References, Part 3 Supportive Documents);
- (b) FDA Food Code Annex 4 (Management of Food Practices Achieving Active Managerial Control of Foodborne Illness Risk Factors), and
- (c) FDA's two HACCP Manual "Managing Food Safety; A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments," and "Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems")

Submitter Information:

Name: John Hicks Organization: USDA/FSIS

Address: Address: Stop Code 3782, Patriot's Plaza III, 8-163A, 1400

Independence Avenue, S.W.

City/State/Zip: Washington, DC 20250

Telephone: 301-504-0840 Fax: E-mail: john.hicks@fssis.usda.gov

Attachments:

- "HACCP Development for Retail Processing 1"
- "HACCP Development for Retail Processing 2"
- "HACCP Development for Retail Processing 3"
- "HACCP Development for Retail Processing 4"
- "HACCP Development for Retail Processing_5"

			Internal Numbe Issue: 2012	
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above	the line is for co	onference use only.		

Title:

Beef Grinding Log Template for Retail Establishments

Issue you would like the Conference to consider:

The Food Safety and Inspection Service (FSIS) recommends that a CFP Committee be created to review the FSIS grinding log template and provide feedback to FSIS on its use at retail. The draft grinding log template will become the basis of the FSIS compliance guidelines that accompanies the planned proposed rule, "Records to be Kept by Official Establishments and Retail Stores That Grind or Chop Raw Beef Products". The FSIS proposed rule is expected to require establishments and retail stores to keep records that disclose the identity of the supplier of all source materials that they use in the preparation of raw ground or chopped product. FSIS is seeking feedback on the grinding log template and any additional comments on developing the log for use at retail.

In the interim, FSIS also recommends an update to the supporting documents for retail grinding logs in the Food Code Annex 2 (Page 305) so that retail establishments will have more detailed information on how to maintain grinding logs and understand its importance during recalls and outbreak investigations. Recently over the past few years, FSIS has been unable to determine the source suppliers of contaminated ground beef product because of inadequate retail grinding logs. FSIS developed and published a grinding log template and example on the FSIS website entitled "Sanitation Guidance for Beef Grinders" http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf. FSIS will consider the feedback from CFP for incorporation into a future FSIS compliance guideline that will accompany the FSIS rule.

Public Health Significance:

Ground beef contaminated with pathogens such as *Escherichia coli* O157:H7 or *Salmonella* is a known source of illness. During outbreak investigations, traceback of contaminated beef to the producing facility is often unsuccessful because of inadequate recordkeeping at retail establishments that grind beef products. FSIS enforcement strategy relies heavily on being able to identify the source material and the producing facility. FSIS has reviewed foodborne investigations in which FSIS investigators found that retail facility grinding logs were a limiting factor for the Agency's ability to pursue public health investigations. FSIS conducted a retrospective review of 16 investigations (2006 through 2008) in which beef products were ground or reground at retail stores. In only 5 of 16 (30%)

of investigations, were records kept by the retail stores present and adequate to enable traceback to the official establishment supplying the beef. FSIS results are supported by Gould et al [Gould LH, Seys S, Everstine K, Norton D, Ripley D, Reimann D, et al. J Food Prot. 2011;74(6):1022-4] in a review of retail grinding records. Of 125 stores surveyed, 60(49%) kept grinding records. In those stores keeping grinding records, 22% of 176 records were judged complete (JFP 2011; 74:1022-1024). Schneider et al also reported a multistate outbreak with 42 illnesses. Investigators used shopper card information for 12 stores, but were unable to identify the identity of the source (JFP 2011, 74:1315-1319). Additonal References:

- "Marler Clark calls on Hannaford to Release Meat Grinding Logs and Identify All Suppliers Linked to Salmonella Outbreak" 12/23/2011 http://www.foodpoisonjournal.com/foodborne-illness-outbreaks/marler-clark-calls-on-hannaford-to-release-meat-grinding-logs-and-identify-all-suppliers-linked-to-s/
- Beef Grinding Logs Study: Restaurant Policies and Practices and Food Worker Practices/Behavior (CDC)http://www.cdc.gov/nceh/ehs/ehsnet/Restaurant Policies Practices.htm

Recommended Solution: The Conference recommends...:

- 1.) That a CFP Committee be created to:
- a. review the FSIS grinding log template
- b. Create a new committee to review the FSIS grinding log template and provide feedback to FSIS for consideration into the future FSIS compliance guide on retail grinding logs and on its use at retail
- c. report back to the 2014 Biennial Meeting.
- 2.) That a letter be sent to the FDA to request amending the 2009 Food Code (as modified by the supplement issued in 2011) Annex 2 Supporting Documents, References under Part 3, K Supplemental Documents (Page 305), using strike through to remove language and underline format to add language to read as follows:
- K. Guidance for Retail Facilities Regarding Beef Grinding Logs Tracking Supplier Information

This document may be found at the web site for "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7"

http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf On October 7, 2002, USDA/FSIS published a Federal Register Notice (67 FR 62332) entitled, *E. coli* O157:H7 Contamination of Beef Products,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf in which the Agency discussed its views on the application of the Hazard Analysis and Critical Control Point (HACCP) system regulations with respect to *Escherichia coli (E. coli)* O157:H7 contamination.

USDA/FSIS announced in 2002 that there is sufficient new scientific data on the increased prevalence of *E. coli* O157:H7 in live cattle coming to slaughter and on its impact on public health to require that all establishments producing raw beef products reassess their HACCP plans, in light of these data.

Of particular concern to the USDA/FSIS is its ability to quickly and adequately traceback *E. coli* O157:H7 contaminated product that is in commerce to its source and to remove it from

commerce. In <u>Spring March</u> 2004, <u>FSIS began conducting sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground beef products at federally inspected establishments, retail facilities, as well as at import facilities. the agency issued "FSIS Directive 10,010.1; revision 1, Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components" available at</u>

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-25504-filed.pdf. In this Directive, the Agency stated that, effective May 17, 2004, it would-conduct sampling and microbiological verification testing for *E. coli* O157:H7 in raw ground-beef products at federally inspected establishments, retail facilities, as well as at import-facilities. Some of the products most likely to be sampled and tested at retail facilities are:

- Ground beef products produced from retail steaks and roasts.
- Manufacturing trimmings derived at retail.
- Ground beef that is formulated at retail by co-mingling in-store trim and trim from federally inspected establishments.
- Irradiated ground beef co-mingled with non-irradiated meat or poultry.

Additionally, ground beef products have been implicated as a transmission vehicle in foodborne outbreaks of infection with pathogens such as *Escherichia coli* O157:H7 and Salmonella. To facilitate product traceback and to meet regulatory requirements, USDA/FSIS expects retail facilities as well as federally inspected establishments to maintain and provide FSIS with access to all applicable records associated with the source material used for ground beef products. In cases where USDA/FSIS identifies adulterated ground beef, *E. coli* O157:H7 ground beef in a product, and a product recall is necessary, grinding logs will facilitate identifying the source of the product and narrowing the scope of the recall.

FSIS recently published "Sanitation Guidance for Beef Grinders" which contains an example of a fresh ground beef production log. The guidance is located at the following website: http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf

The following information would be used to facilitate traceback of contaminated ground beef products:

- The manufacturer name of source material used for product produced
- The type of product or description of the purchased or received article(s).
- The establishment information from the label of source product used such as the name, address, and establishment number.
- The supplier lot numbers, product code or production or pack date of source materials used.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce such as time of grind, grinder sanitation records, and amount (in pounds) and lot/batch numbers, production codes, name and package size of products produced.

In addition to the references cited above, the following references also provide information:

- 1. Federal Meat Inspection Act (21 USC Sec. 642).
- 2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.
- 3. Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products
- 4. Best Practices for Raw Ground Products

- 5. FSIS Sanitation Performance Standards Compliance Guide:
- U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Program and Other Verification Activities For *Escherichia coli* O157:H7 http://www.fsis.usda.gov/oppde/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf

The following information would be adequate for meeting federal transaction requirements:

- The name or description of the purchased or received article(s).
- The name, address, and establishment number of the seller of the articles purchased or received.
- The supplier lot numbers and production dates of the articles purchased or received.
- Any other information that would be useful in the quick removal of adulterated product from the market or commerce.

In addition to the references cited above, the following references also provide information:

1. Federal Meat Inspection Act (21 USC Sec. 642).

2. Title 9 of the Code of Federal Regulations, section 320.1 Records required to be kept.

1. U.S. Department of Agriculture, Food Safety and Inspection Service, April 13, 2004, Compliance Guidelines For Establishments On The FSIS Microbiological Testing Programand Other Verification Activities For Escherchia coli O157:H7

http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010-1/ecolio157h7dirguid4-13-04.pdf.

Submitter Information:

Name: Jennifer Webb Organization: USDA/FSIS

Address: Address: 1400 Independence Avenue, SW, 8th Floor, Cube, PP3

City/State/Zip: Washington, DC 20024

Telephone: 301-504-0854 Fax: E-mail: jennifer.webb@fsis.usda.gov

Attachments:

- "FSIS Sanitation Guidance for Beef Grinders"
- "Canadian Beef Good Retail Practices Ground Meat Management (Example Log)"
- "Multistate Outbreak of Multidrug-Resistant Salmonella Newport"
- "Recordkeeping Practices of Beef Grinding Activities Retail Establishments"
- "BIFSCO Best Practices For Retailer Operations Producing Raw Ground Beef"

				Internal Number: 069 Issue: 2012 I-015	
Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action	
Delegate Action:	Accepted		Rejected		
All information above	the line is for co	nference	use only.		

Title:

Addition to Original Containers and Records Section in the FDA Food Code,

Issue you would like the Conference to consider:

The 2009 FDA Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some retailers may grind intact beef or beef trim to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers, because intact beef may not be subject to the same rigorous pathogen control as ground beef. In addition, mixing of product from various suppliers and lots can spread contamination among the resulting ground product. Failure to adequately separate lots, clean and sterilize grinding equipment can contribute to the risk.

Public Health Significance:

Grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Mixing of lots from the same or varied suppliers can spread contamination among resulting product. Outbreaks resulting from these products may be more difficult to trace as a result of the mixed nature of the product. Adequate recordkeeping is thus essential to provide traceback data for public health officials investigating an outbreak.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline): 3-203.13 Recordkeeping, Ground Product.

- (A) Every FOOD ESTABLISHMENT that performs grinding or packaging of MEAT on PREMISES shall maintain adequate records sufficient to assist public health officials with traceback or other relevant investigation.
- (1) Adequate records shall include:
- (a) Producing store name, address, city/state/zip
- (b) Date of each lot of store ground product produced, where a lot is defined as all identically labeled product produced from full equipment clean-up to clean-up
- (c) Exact name/type of store ground product

- (d) Amount of each lot of store ground product
- (e) Sell by/use by date and/or production code of each lot of store ground product
- (f) Other information used to identify store ground product
- (g) Full name(s) and product code(s) of all source products used to formulate each lot of store ground product
- (h) All Federal or State Establishment numbers of each source product contained in each lot of store ground product
- (i) Each source product sell by, use by, or production date/code
- (j) The source firm name, establishment number and use by/sell by/production date/code for all Shop trim/rework used in each lot of store ground product
- (k) <u>Bills of Sale (e.g. sales receipts) reflecting Item numbers for each ground beef product sold to consumers</u>
- (I) Invoice(s) and Bill(s) of lading for source product(s)

Submitter Information:

Name: Sarah Klein

Organization: Center for Science in the Public Interest

Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

Internal Number: 067

			Issue: 2012 I-016
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for con	nference use only.	

Title:

Addition to Duties: Person in Charge Section 2-103.11 of FDA Food Code

Issue you would like the Conference to consider:

The FDA Food Code recognizes that consumers are at risk of foodborne illness from undercooked or improperly cooked meat items, particularly ground beef. Some food establishments-retailers as well as restaurants-may grind intact beef to produce ground beef "in house". While this practice is lawful, it may present an increased risk of foodborne illness to consumers, because intact beef may not be subject to the same rigorous pathogen control as ground beef.

Public Health Significance:

Grinding intact beef "in house" may spread pathogenic contamination from the exterior of an intact product throughout the resulting ground beef, or, may serve as a source of cross-contamination of grinding equipment. Further, consumers may mistakenly believe that ground beef produced "in house" in this way is fresher or safer, and thus may order such products undercooked (i.e., rare or medium rare), which is insufficient to kill pathogens. It is thus imperative that those employees tasked with handling and grinding such meats (and those employees responsible for cleaning the grinding equipment, if different) are specially trained about the importance of rigorous cleaning for the prevention of foodborne illness, the logistics of cleaning, and the maintenance of appropriate records to assist in an outbreak investigation resulting from in house ground products.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting the addition of the underlined language to Section 2-103.11 of the FDA Food Code, *Duties: Person in Charge*:

2-103.11 Person in Charge.

(L) EMPLOYEES are properly trained in FOOD safety as it relates to their assigned duties; with enhanced training for those employees who may be responsible for production and handling of "in house" ground beef, such as the grinding of MEAT, PRIMAL CUTS and WHOLE MUSCLE, INTACT BEEF; and

Submitter Information:

Name: Sarah Klein

Organization: Center for Science in the Public Interest

Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

Internal Number: 009
Issue: 2012 I-017
No Action

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

Title:

Use of Consumer Advisory for Non-Continuous Cooking

Issue you would like the Conference to consider:

Add a new section to Section 3-401.14 of the FDA Food Code to allow for the service of raw intact whole muscle beef cooked using a non-continuous cooking process, to be served undercooked with an adequate consumer advisory as described in 3-401.11 (D).

Public Health Significance:

Section 3-401.11 (D) allows for the service of raw or undercooked animal products with the use of an adequate consumer advisory. This important and balanced public health approach, currently not allowed under Section 3-401.14, provides the same level of protection and fair consumer choice for raw or undercooked, or non-continuous and undercooked animal products, such as when large catered events either cook to order or when they partially cook, cool and cook to order. As long as consumers are informed with an adequate consumer advisory as outlined in 3-603.11, the same level of public health protection is assured.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

Add new language to Section 3-401.14 indicated in underlined language below 3-401.14 Non-Continuous Cooking of Raw Animal Foods.

Raw animal FOODS that are cooked using a NON-CONTINUOUS COOKING process shall be:

- (A) Subject to an initial heating process that is no longer than sixty minutes in duration; P
- (B) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME /TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A); P
- (C) After cooling, held frozen or cold, as specified for POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.16(A) (2); P
- (D) Prior to sale or service, cooked using a process that heats all parts of the FOOD to a temperature of at least 74°C (165°F) for 15 seconds; P

- (E) Cooled according to the time and temperature parameters specified for cooked POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) under ¶ 3-501.14(A) if not either hot held as specified under ¶3-501.16(A), served immediately, or held using time as a public health control as specified under §3-501.19 after complete cooking; P and
- (F) Prepared and stored according to written procedures that:
- (1) Have obtained prior APPROVAL from the REGULATORY AUTHORITY; Pf
- (2) Are maintained in the FOOD ESTABLISHMENT and are available to the REGULATORY AUTHORITY upon request; Pf
- (3) Describe how the requirements specified under \P (A)-(E) of this Section are to be monitored and documented by the PERMIT HOLDER and the corrective actions to be taken if the requirements are not met; Pf
- (4) Describe how the FOODS, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as FOODS that must be cooked as specified under \P (D) of this section prior to being offered for sale or service; Pf and
- (5) Describe how the FOODS, after initial heating but prior to cooking as specified under \P (D) of this section, are to be separated from READY-TO-EAT FOODS as specified under \P 3-302.11 (D).
- (G) Allow for the service of raw intact whole-muscle beef cooked using a non-continuous cooking process to be served undercooked with an adequate consumer advisory.

Submitter Information:

Name: David Martin

Organization: Oregon Public Health Division

Address: 800 NE Oregon St City/State/Zip: Portland, OR 97232

Telephone: 971 673-0450 Fax:

E-mail: dave.c.martin@state.or.us

Council Accepted as Accepted as Recommendation: Submitted Accepted Rejected

All information above the line is for conference use only.

Title:

Report - Recall Evaluation Committee

Issue you would like the Conference to consider:

The Food Recall Evaluation Committee (REC) was tasked with the evaluation of current policy and practice of food recalls of the U.S. Food and Drug Administration and the U.S. Department of Agriculture, with the goal of providing feedback and recommendations that these agencies could consider in improving food recalls and recoveries.

The committee met via a series of webinars for the past 18 months. Membership included a diverse cross-structure of industry and regulators as well as academia and public interest representatives.

The committee believes we have reached consensus on the items included herein and detailed in the attached reports.

Public Health Significance:

Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process. Consider:

- FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- Firms affected by the recall throughout the complex food system (distributers, subproducers, brokers) have no official FDA guidance
- There is no time limit for executing a Class I Recall, or any other Class
- There are no minimum requirements for the information required in a recall notice
- There is no consideration of cost to benefit
- Current Classification system is ambiguous and confusing

Recommended Solution: The Conference recommends...:

- acknowledgement of the Food Recall Evaluation Committee (REC) report and attachments,
- thanking the Committee members for their efforts, and
- disbanding the Committee as the charges are completed.

Submitter Information:

Name: Greg Pallaske, Co-Chair Organization: Recall Evaluation Committee

Address: US Foods6133 N River Rd Suite 300

City/State/Zip: Rosemont, IL 60018

Telephone: 847.232.5884 Fax: E-mail: greg.pallaske@usfood.com

Attachments:

"Final Roster 1_6_12"

"Recall Evaluation Committee Final Report"

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

Delegate Action: Accepted Rejected

All information above the line is for conference use only.

Title:

Uniform Food Recall System

Issue you would like the Conference to consider:

The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing a uniform food recall system that is easier to understand and contains guidelines and best practices that will make the process faster and more efficient.

Public Health Significance:

Beyond question, the current system of recalling food products in the United States in case of real or purported health or quality issues is flawed. While part of the problem resides in the sheer complexity of the global food production and distribution system, the process of recalling a product is difficult for industry and incomprehensible to the general public. While new (pending) food safety legislation will address a few of the problems, there remains the need to overhaul and clarify the current recall classification and notification process. Consider:

- FDA is guided by Ch. 7 of their 2009 Regulatory Procedures Manual/ 21CFR
- Recalling Firm is guided by "GUIDANCE FOR INDUSTRY" document by FDA
- Firms affected by the recall throughout the complex food system (distributers, subproducers, brokers) have no official FDA guidance
- There is no time limit for executing a Class I Recall, or any other Class
- There are no minimum requirements for the information required in a recall notice
- There is no consideration of cost to benefit
- Current Classification system is ambiguous and confusing

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA and the USDA requesting that they work together in collaboration with industry stakeholders on developing a uniform food recall system. Examples of what should be considered in this initiative are:

- A mechanism for working with industry and other stakeholders to further identify the specific changes needed to enhance the current recall system
- A uniform recall process be used by all federal food regulatory agencies

- A revised classification system that is prompt, transparent and meaningful to industry, regulatory, and the general public using consistent definitions for recall classifications
- Consistent information provided with every recall, especially a decision on the classification
- Clarifying instructions and procedures for industry and the public
- A mechanism for engaging relevant private-sector expertise in recall investigations and recall decisions
- Reasonable "best practice" time frames for execution of recall communications and actions including verification of notification
- Clear and consistent information in recall notifications to each segment of the supply chain including information that clearly identifies the product being recalled in sufficient detail
- Consistent protocol for audits and/or effectiveness checks
- Consistent and more specific consumer messages (for example, explaining the
 difference between recalls for pathogens that present a risk to the general public
 versus a recall for an allergen that impacts a select portion of the population)
- A single website and database for all food recalls with a consumer- friendly format

Submitter Information:

Name: Greg Pallaske, Co-Chair Organization: Recall Evaluation Committee

Address: US Foods6133 N River Rd Suite 300

City/State/Zip: Rosemont, IL 60018

Telephone: 847.232.5884 Fax: E-mail: Greg.pallaske@usfood.com

			Issue: 2012 I-020
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	nference use only.	

Title:

Recall Definitions and Decision Tree

Issue you would like the Conference to consider:

The Recall Evaluation Committee requests that a letter be sent to the FDA and USDA requesting they work together in collaboration with stakeholders on developing new terminology for Class I, II, and III recalls that is easier for industry, regulators, and the public to understand. Additionally, that a decision tree be developed that creates more transparency into how a recall should be classified.

Public Health Significance:

Food recalls are the last line of defense when a dangerous or violative food product has entered the marketplace. When a firm is unable to determine proper classification, the process slows down, causing potentially dangerous delays in public notification and distribution chain removal of the product from the marketplace.

Additionally, many suppliers and the general public do not understand the difference in the significance and danger associated with the various classes of recalls. The result is either apathy, where the public pays little attention because of the sheer volume of "noise", or they over-react and needlessly throw out and stop buying perfectly good products. The net result is an unnecessary loss of public confidence in our food supply, as well as a tremendous waste of food.

A great deal of discussion within the Committee centered on the difficulty on the part of industry and the public in distinguishing the differences between a Class I, II, and III Recall. For example, what is the difference between a "reasonable probability" (Class I) and a "remote probability" (Class II)? Many industry members believe the public does not distinguish between them; therefore, to the public, all recalls are "bad."

To address this issue, the Committee felt that different terminology may be helpful. One set of terms under discussion was to use the word "recall" only for what is currently a Class I situation. Thus we defined "Food Recall" as a health risk to the general public, and generally agreed that a "food recall" should coincide with what the FDA generally defines as a "reportable food" or the USDA equivalent thereof.

The equivalent of what is currently a Class II recall was a bit more problematic - many Committee members noted that historically, Class II's have been situations where a major allergen was not listed on the product label, and thought the term "Allergen Alert" would be

appropriate. Other committee members felt the term was too narrow as not all Class II equivalents are caused by one of the big eight allergens. Their term of choice is "Food Alert". Either of these is defined as a health risk to allergic, selected, sensitive populations. Finally, the term agreed upon for the equivalent of a Class III is "Food Notification", defined as little or no health risk.

Regardless of the terminology used, the Committee overwhelmingly agrees that recalls must be classified upon release. To better accomplish this goal, the committee recommends creation of a decision tree for classification of recalls, with the following stipulations:

- Decision tree should be transparent and readily available as a tool to industry and regulators.
- Decision tree should be developed jointly with industry, regulators, and consumer representatives.
- Decision tree is a guideline, not an absolute rule regulators maintain final classification decision.
- The same/ similar tree/ system should be followed by both FDA and USDA.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA and USDA recommending the following:

- a. Change in definitions:
 - Replace Class I Recall with "Food Recall" defined as a health risk to the general public, and should coincide with what the FDA generally defines as a "reportable food" or the USDA equivalent thereof
 - Replace Class II Recall with "Allergen Alert" or "Food Alert" defined as a health risk to allergic/selected/sensitive populations.
 - Replace Class III Recall with "Food Notification" defined as little or no health risk.
- b. Creation of a decision tree for classification of recalls, with the following stipulations:
 - Decision tree should be transparent and readily available as a tool to industry and regulators.
 - Decision tree should be developed jointly with industry, regulators, and consumer representatives.
 - Decision tree is a guideline, not an absolute rule regulators maintain final classification decision.
 - The same/ similar decision tree/ system should be followed by both FDA and USDA.

Submitter Information:

Name: Greg Pallaske, Co-Chair Organization: Recall Evaluation Committee

Address: US Foods6133 N River Rd Suite 300

City/State/Zip: Rosemont, IL 60018

Telephone: 847.232.5884 Fax: E-mail: greg.pallaske@usfood.com

			Internal Number: 065 Issue: 2012 I-021
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for con	nference use only.	

Title:

New Recall Notification Section of the FDA Food Code (Section 3-603.12)

Issue you would like the Conference to consider:

The 2009 FDA Food Code recognizes that consumers may not receive adequate, timely information in the event of a food safety recall, and that retailers play an important role in disseminating critical public health information. Records kept by retailers in the ordinary course of business for marketing or promotional purposes can be extremely useful for notifying consumers and curtailing the spread of an outbreak. Grocery stores and vendors should, when otherwise maintaining customer purchasing data, make every reasonable effort to notify consumers in the event of a Class I Recall.

Public Health Significance:

Removal of contaminated foods is vital to minimizing the adverse impact on consumers and public health, including reducing the size of associated foodborne illness outbreaks. While retailers' actions are essential for rapid removal of recalled foods from shelves, this does not address products that have already been sold. A proposed Food Code amendment offers a solution to better inform consumers about outbreak-associated and recalled products.

Where retailers routinely collect consumer purchasing data, that information can be useful in identifying consumers who may have recalled product still in their homes. Retailers should access purchasing data and the associated consumer contact information to alert consumers to their previous purchases of products that are later associated with a Class I Recall. Such personalized notice will help consumers identify recalled product at home, and will establish the retailer as a source of important public health information.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline): 3-603.12 Recall Notification.

(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers, and that collects data on the purchasing of that food (through customer loyalty cards or other data collection methods), shall, in the event of a Class I Recall of any FDA or USDA product sold by the FOOD ESTABLISHMENT, contact those consumers for which

data is available to indicate the purchase of a product, within the previous 60 days, that is now subject to a recall. Consumers may be contacted via email, text message, telephone, or regular mail, and contact must be initiated within a reasonable time from when the FOOD ESTABLISHMENT receives notice that the FOOD ESTABLISHMENT sold recalled product, not to exceed 2 days from that notice.

Submitter Information:

Name: Sarah Klein

Organization: Center for Science in the Public Interest

Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

			Issue: 2012 I-02	
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above	the line is for cor	nference use only.		

Title:

New Recordkeeping Section of the FDA Food Code (Section 3-603.13)

Issue you would like the Conference to consider:

The 2009 FDA Food Code recognizes that records kept by retailers in the ordinary course of business for marketing or promotional purposes can be extremely useful for public health officials investigating a foodborne illness outbreak and attempting traceback and attribution. Retailers should make every reasonable effort to give public health officials timely access to such records to assist in an outbreak investigation or for other such lawful and reasonable public health purposes.

Public Health Significance:

Where retailers routinely collect consumer purchasing data, that information is critical to identifying consumers who may have purchased products that are later implicated in an outbreak. That data has also proven to be of great importance to public health officials in performing traceback investigations and food attribution during and after an outbreak. Rapid identification of at-risk consumers (those who have purchased recalled product) is essential to curtailing the size and impact of an ongoing outbreak from contaminated products. Retailers should provide public health officials with customer purchasing data that may be helpful in the course of an outbreak investigation, in an effort to assist with attribution and containment of foodborne illness.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline): 3-603.13 Recordkeeping, Public Health Significance.

(A) Every FOOD ESTABLISHMENT that offers PACKAGED FOOD for purchase by consumers, and collects data on the purchasing of that food (through customer loyalty cards or other data collection methods), shall, provide public health officials upon request with timely access to customer purchasing data to assist in a public health investigation or for other such lawful purposes.

Submitter Information:

Name: Sarah Klein

Organization: Center for Science in the Public Interest

Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

Indown at Neurals and OOF

			lssue: 2012 I-023
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	nference use only.	

Title:

Shellstock Record Keeping

Issue you would like the Conference to consider:

Modification of the 2009 FDA Food Code to add language that addresses the use of shellstock being simultaneously used from different sources or growing areas. The facility's record-keeping system must be able to distinguish the shellstock that was served to each customer.

Public Health Significance:

The Interstate Shellfish Sanitation Conference (ISSC) continues to address illnesses associated with consumption of raw molluscan shellfish. Our primary focus is to improve our response time associated with illness outbreaks and to evaluate the effectiveness of control programs associated with pathogens which may result in illnesses.

These activities utilize illness investigation information from retail establishments. In recent years there has been improvement and the suggested change is intended to further improve the ability of illness investigators to accurately identify shellstock sources and growing areas. The ISSC and the Conference for Food Protection (CFP) have jointly worked to enhance record keeping at the retail level. In an effort to provide more accurate information which could be used for illness response and program evaluation, the need for this improvement was demonstrated in recent illness data reported by the Centers for Disease Control (CDC).

Recommended Solution: The Conference recommends...:

1. that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language underlined and deleted language shown with strikethrough):

Section 3-203.12, Shellstock, Maintaining Identification

- (C) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under ¶ B of this section, by: Pf
- (1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under \P B of this section; Pf and

- (2) If shellstock are being used from different sources or growing areas simultaneously that the system can distinguish the source and growing area of the shellstock that was served to each customer; Pf and
- (23) If shellstock are removed from its tagged or labeled container and
- 2. that the Conference for Food Protection (CFP) and the Interstate Shellfish Sanitation Conference (ISSC) jointly write a letter to State retail food programs requesting that retailers be advised of shellstock identification record requirements for the purpose of improving compliance.

Submitter Information:

Name: Ken B. Moore

Organization: Interstate Shellfish Sanitation Conference

Address: 209-2 Dawson Road City/State/Zip: Columbia, SC 29223

Telephone: 803-788-7559 Fax: 803-788-7576

E-mail: issc@issc.org

			internai Num Issue: 20	
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above	the line is for co	nference use only.		

Title:

Food Code Date Marking Provision(s) For Raw, Live In-shell SHELLSTOCK

Issue you would like the Conference to consider:

The 2009 FDA Food Code contains no clear guidance (or exception) regarding date marking of raw, live, in-shell MOLLUSCAN SHELLFISH (i.e., SHELLSTOCK) in a FOOD ESTABLISHMENT when the FOOD is served to the CONSUMER in a raw (i.e., not heated treated) form.

This issue submission seeks clarification from the Conference as to date marking of raw, live, in-shell SHELLSTOCK, received and cold held longer than 24 hours in a FOOD ESTABLISHMENT and served to the CONSUMER in a raw (non-heat treated) form.

Public Health Significance:

Per the 2009 FDA Food Code Section 1-201.10 Statement of Application and Listing of Terms, raw, live in-shell SHELLSTOCK served to the CONSUMER without cooking meets the definition of a commercially processed Ready-To-Eat (RTE) Potentially Hazardous [Time/Temperature Control for Safety Food] FOOD (PHF/TCS FOOD) which was previously harvested and subsequently PACKAGED by a FOOD PROCESSING PLANT before being received by a FOOD ESTABLISHMENT.

During the 2004 Conference for Food Protection (CFP) Biennial Meeting, the subject of Food Code date marking for RTE PHF/TCS FOOD was re-evaluated to focus the provision on "Very High" and "High Risk" foods while simultaneously exempting certain categories of FOOD from the date marking provision. The September 2003 document referenced by CFP, Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-To-Eat Foods, concluded raw seafood to be categorized as "Risk Designation Low" along with other FOOD such as preserved fish products. This designation suggests date marking of raw seafood (including raw, live in-shell SHELLSTOCK) would not be necessary, however neither the 2005 nor the 2009 Food Codes specifically exempt raw, live in-shell SHELLSTOCK from date marking [Section 3-501.17(F)(1-7) Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking] and no elaborative explanation is offered in Annex 3, 3-501.17 (pages 414-419) regarding raw, live in-shell SHELLSTOCK.

The only guidance in the Food Code is located in Annex 3, 3-201.15 Molluscan Shellfish (pages 374-375) which specifically identifies *Listeria monocytogenes* (and others) as a

pathogen of concern at harvest, a position that is elaborated on in recently published research (Moustafa A. et. al *Listeria spp.* in the coastal environment of the Aqaba Gulf; Suez Gulf and the Red Sea. <u>Epidemiol. Infect.</u> 2006; 134; 752-757) (Colburn KG et. al. *Listeria monocytogenes* in California coast estuarine environment. <u>Applied Environ Microbiol</u> 1990; 56; 2007-2011).

Regarding FOOD excluded from date marking, the 2009 FDA Food Code currently lists only the following commercially produced RTE PHF/TCS FOOD categories: deli salads prepared and packaged in a FOOD PROCESSING PLANT; hard and semi-soft cheeses; cultured dairy products; preserved fish products (with exceptions); shelf stable dry fermented sausages not labeled "Keep Refrigerated"; and shelf stable salt-cured products not labeled "Keep Refrigerated".

Once received by a FOOD ESTABLISHMENT, raw live in-shell SHELLSTOCK are typically cold held longer than 24 hours due to the quantity received. And while the Food Code does not specify the number of days raw, live in-shell SHELLSTOCK can be cold held, Annex 3 estimates a shelf-life up to fourteen (14) days [Section 3-203.12 Shellstock, Maintaining Identification; page 382]. This presents a serious potential challenge to REGULATORY AUTHORITIES that adopt and enforce date marking as recommended in the Food Code since date marking for commercially processed RTE PHF/TCS FOOD limits shelf-life to seven (7) days [Section 3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking: and Section 3-501.18 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Disposition]. SHELLSTOCK served in a raw, live in-shell form to the CONSUMER are currently subject to a CONSUMER ADVISORY [Section 3-603.11 Consumption of Animal Foods that are Raw, Undercooked or Not Otherwise processed to Eliminate Pathogens; pages 97-98] and have been identified by FDA as a potential source of pathogen contamination, including Listeria monocytogenes [Annex 3; Section 3.201.15 Molluscan Shellfish; page 375]. Further, raw, live in-shell SHELLSTOCK can be harvested, transported and delivered to the FOOD ESTABLISHMENT at temperatures above 41° F [Section 3-202.11 Temperature; page 54] which can encourage the growth of pathogens such as Listeria monocytogenes. Further, SHELLSTOCK are PACKAGED and shipped in netted bags or other non-reusable shipping containers, none of which are air-tight. Some of the non-reusable containers are opened at receiving to allow the FOOD ESTABLISHMENT to verify the condition and temperature of the raw, live in-shell SHELLSTOCK and the porous nature of the shipped non-reusable bags/containers does not discourage or prevent possible further contamination of the SHELLSTOCK under refrigerated storage in the FOOD ESTABLISHMENT.

In the FOOD ESTABLISHMENT, raw, live in-shell SHELLSTOCK are frequently removed from their original shipping container(s) to be: (1) displayed on ice; or (2) held in refrigerated drawers, cold-rails, walk-in-coolers or reach-in-coolers. These refrigerated environments are subject to splash, dust, condensation drips and other filth that may be contaminated with pathogens, including *Listeria monocytogenes*. These refrigeration units can also simultaneously hold other raw animal FOODS and/or other RTE PHF/TCS FOODS. And these refrigeration units can be subject to temperature variation above 41° F as documented in <u>FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant and Retail Food Store Facility Types (2009) (see attached).</u>

Recommended Solution: The Conference recommends...:

...the language of the 2009 FDA Food Code (as modified by the Supplement issued in 2011) be changed to clearly reflect that date marking provisions apply to raw, live in-shell SHELLSTOCK served to CONSUMERS upon request without cooking or other treatment. (new language is in underline format; language to be deleted in strike-thru format) 3-501.17(B) Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.

- (B) Except as specified in ¶¶ (D)-(F) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and:PF
- (1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1; Pf and
- (a) Except for containers of raw, live in-shell SHELLSTOCK, Day 1 shall be the date or day the SHELLSTOCK are receiving in the FOOD ESTABLISHMENT if the SHELLSTOCK will be served upon CONSUMER request in a raw, RTE PHF/TCS form; Pf and
- (2) The day or date marking by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety. Pf

Submitter Information:

Name: Mark S. Ohlmann, CP-FS

Organization: N/A

Address: 4318 Juniper Forest Place

City/State/Zip: Louisville, KY 40245

Telephone: (502) 552-2204 Fax: (502) 384-2071

E-mail: msohlmann@insightbb.com

Attachments:

- "Listeria monocytogenes Risk Assessment"
- "FDA Report on the Occurrence of Foodborne Illness Risk Factors"
- "Listeria spp. in the coastal environment of the Agaba Gulf, Suez Gulf and.."
- "Listeria Species in a California Coast Estuarine Environment"

Internal Number:	063
Issue: 2012 I-	025

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

Title:

Addition to Consumer Advisory, Section 3-603.11 of the Model Food Code

Issue you would like the Conference to consider:

The 2009 FDA Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the Consumer Advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico. An adequate advisory is modeled in title 17 of the California Code of Regulations § 13675 which provides a basis for the proposed addition to Section 3-603.11.

(http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/fdb%20Raw%20Oyst%20Sale %20Retail.pdf)

Public Health Significance:

Vibrio vulnificus in raw oysters harvested from the Gulf of Mexico poses a well-defined risk of severe illness and death to consumers with compromised immune systems, liver damage, diabetes, the genetic disorder hemochromatosis, and certain gastric disorders. Vibrio is associated with mild gastroenteritis in persons with healthy immune systems, and life-threatening infections in persons with pre-existing medical conditions. Each year 30 or more people are diagnosed with V. vulnificus-induced septicemia from raw oysters sourced to Gulf Coast waters and approximately half die from the infection. Even with aggressive treatment the case fatality rate is 30 to 40 percent and mortality is 100 percent if a patient is not treated within 72 hours of symptom onset. Because V. vulnificus presents as primary septicemia, a common disease with many causes, misdiagnosis almost certainly results in underreporting of the disease. It is critical that persons have adequate notice of the risk so that they will seek early medical care and inform their doctor they have eaten raw oysters. While the strongest prevention is to require all Gulf oysters shipped interstate to be treated post-harvest to eliminate the pathogen, the industry has resisted such requirements. The proposed warning is, therefore, consistent with industry preferences for consumer education in lieu of other controls. It is a critical requirement because other than selfidentification, food establishments have no way of recognizing at-risk patrons. To the extent that patrons have adequate information about their own health status, the warnings may reduce the number of illnesses and deaths (with the attendant bad publicity associated with

news reports and lawsuits). Additionally, since consumer perceptions can alter choices, thus reducing demand, industry interests and public health walk hand-in-hand with providing adequate notice that allows at-risk populations to understand and assess the danger of consuming raw oysters.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-603.11, be amended as follows (new language shown with underline):

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

(D) Every FOOD ESTABLISHMENT that offers raw oysters harvested from the Gulf of Mexico (any oyster harvested from the Gulf waters bordering the states of Alabama, Florida, Louisiana, Mississippi, or Texas) shall provide a written warning to any person who orders raw oysters, stating:

WARNING

THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING
THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS
WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES
THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.

(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce *Vibrio vulnificus* to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

Submitter Information:

Name: Sarah Klein

Organization: Center for Science in the Public Interest

Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

			Internal Number: 034 Issue: 2012 I-026
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	nference use only.	

Title:

Hand Antiseptics

Issue you would like the Conference to consider:

An update to the language in the 2009 FDA Food Code, Section 2-301.16 Hand Antiseptics is needed to account for the regulatory procedures that can also be used to make a hand sanitizer compliant with the Food Code. Due to the absence of any specific regulation in FDA's 21 Code of Federal Regulations (CFR) for hand antiseptics and indirect food contact, the Food Code serves as the sole guidance for the use of hand antiseptics in retail food facilities. These procedures are already referenced in Annex 3 of the Food Code (Chapter 2- 301.16 Hand Antiseptics) and therefore updating the language in Chapter 2 would help avoid any confusion and misunderstandings by Inspectors in the field.

Public Health Significance:

Chemicals may be poisonous or toxic if not used properly and in accordance with FDA regulations. The lack of clear and explicit guidance surrounding the use of hand antiseptics in food facilities poses a risk and could contribute to the improper use of chemicals that may subsequently cause public health issues such as the adulteration of food, or potentially acute and chronic effects to both the consumer and the employee of the food facility.

Recommended Solution: The Conference recommends...:

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

- 2-301.16 Hand Antiseptics.
- (A) A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:
- (1) Comply with one of the following:
- (a) Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; ^{Pf} or
- (b) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, Pf and

- (2) Comply with one of the following:
- (a) Have components that are exempted from the requirement of being listed in federal food additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles;^{Pf} or
- (b) Comply with and bBe listed in the following sections and used up to the maximum allowable concentration permitted by that regulation:
- (i) 21 CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use, Pf or,
- (ii) 21 CFR 182 Substances Generally Recognized as Safe, 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food, ^{Pf} and or
- (c) <u>Have components that have been appropriately cleared for use as hand sanitizers with incidental food contact through GRAS notifications/ affirmations or a Food Contact Notification (FCN) with FDA, and,</u>
- (3) Be applied only to hands that are cleaned as specified under § 2-301.12. Pf
- (B) If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified under Subparagraph (A)(2) of this section, use shall be:
 - 1. (1) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; Pf or
- 2. (2) Limited to situations that involve no direct contact with food by the bare hands. ^{Pf} (C) A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L chlorine. ^{Pf}

Submitter Information:

Name: Dan Dahlman

Organization: Ecolab

Address: 370 Wabasha St N City/State/Zip: St. Paul, MN 55102

Telephone: 651-225-3297 Fax: 651-225-3122

E-mail: dan.dahlman@ecolab.com

Internal Number: 097 Issue: 2012 I-027

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

Title:

Use of Galvanized Metal with Acidic Foods

Issue you would like the Conference to consider:

Restricting the use of galvanized metals from contact with food except by local variance for the specific process it is intended to be used for.

Per the 2009 FDA Food Code Public Health Reasons for 4-101.15, zinc may leach into acidic foods if they contact galvanized metal. However, the solubility of zinc is subject not only to pH but also temperature and the corrosive environment of inorganic salts. The inorganic salts can come into contact with the metal from the food or disinfectants used as part of the process.

Public Health Significance:

Setting this guideline would place the requirement of providing data to the regulatory authority in order to acquire a variance.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline): 4-101.15 Galvanized Metal, Use Limitation.

Galvanized metal may not be used for UTENSILS or FOODCONTACT SURFACES of EQUIPMENT unless, it is shown that zinc does not transfer to FOOD under its specified use.

Submitter Information:

Name: Ronald Tobler

Organization: Utah County Health Department Address: 151 South University Ave Ste 2600

City/State/Zip: Provo, UT 84601

Telephone: 801-851-7525 Fax: 801-851-7521

E-mail: ront@utah.gov

Internal Number: 100

			Issue: 2012 I-028
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for con	nference use only.	

Title:

Chemicals for Washing Fruits and Vegetables

Issue you would like the Conference to consider:

Clarify the language in 2009 FDA Food Code Section 3-302.15 Washing fruits and vegetables, to ensure chemicals used for washing fruits and vegetables follow manufacturer's directions or EPA registered label use instructions.

Public Health Significance:

Food Code Section 7-204.12 specifies that chemicals used to wash fruits and vegetables should meet the requirements specified in 21 CFR 173.315, Chemicals used in washing or to assist in the peeling of fruits and vegetables. In addition to identifying chemicals that may be used, 21 CFR 173.315 also states:

"(d) To assure safe use of the additive... The label or labeling of the additive container shall bear adequate use directions to assure use in compliance with all provisions of this section."

Adding language to the Food Code indicating that use directions should be followed would clarify requirements for safe use, and uphold the public health and consumer food standards set by the Code.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows (new language shown with underline): 3-302.15 Washing Fruits and Vegetables

(B) Fruits and vegetables may be washed by using chemicals as specified under 7-204.12 and shall be used in accordance with the manufacturer's directions or EPA registered label use instructions.

Submitter Information:

Name: Erin Mertz Organization: Ecolab

Address: 655 Lone Oak Rd City/State/Zip: Eagan, MN 55121

Telephone: 651-795-5785 Fax: 651-204-7525

E-mail: Erin.Mertz@ecolab.com

	ber: 099 12 I-029
CouncilAccepted asAccepted asRecommendation:SubmittedAmendedNo Action	
Delegate Action: Accepted Rejected	
All information above the line is for conference use only.	

Title:

Testing for Hot Water Sanitizing

Issue you would like the Conference to consider:

The 2009 FDA Food Code addresses the failure of having test kits for chemical sanitizing (automatic dish machine) as a priority. However, nowhere in the food code does it require the same of hot water sanitization test kits. In fact the Code is silent on this issue (no specificity relating to hot water test kits). Unless a method of ascertaining the level of hot water sanitization occurring in the machine is identified (e.g., the surface of the utensil has met 160°F requirement), validating the machine's operational criteria cannot be objectively measured.

Validating whether the surface temperature has met the required 160°F requirement provides assurance that the utensil has been properly cleaned which includes sanitization. Failure to validate can have negative consequences as failure to validate a temperature of a potentially hazardous food item.

Public Health Significance:

Validation that efficacious sanitization is occurring is an important part of the overall cleaning procedure, whether through manual cleaning (3-compartment sink) or automatic (ware washing machines) cleaning. In automatic operations, heat treatment occurs when the final rinse spray is higher than the upper limit specified by the manufacturer's instructions.

It is commonly understood that if utensils are not cleaned properly, microorganisms are potentially transmitted via foods to other foods by utensils. Therefore, validating that cleaning and sanitization has occurred is an important component in the reduction of disease transmission via food.

Recommended Solution: The Conference recommends...:

that a letter be sent to FDA requesting that the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-703.11(B), be amended as follows (new language shown with underline and deleted language shown with strike-through):

Hot water mechanical operations by being cycled through EQUIPMENT that is set up as specified under §§ 4-501.15, 4-501.112, and 4-501.113 and achieving a UTENSIL surface

temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator; P or shall be validated by the use of a test kit or similar equipment; or

Submitter Information:

Name: James Mack, REHS

Organization: Wisconsin Department of Health Services

Address: 1 West Wilson Street, Room 150

City/State/Zip: Madison, WI 53702

Telephone: 608-266-8351 Fax: 608-267-3241

E-mail: james.mack@wisconsin.gov

			lssue: 2012 I-030
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	nference use only.	

Title:

Food Equipment Certification

Issue you would like the Conference to consider:

The 2009 FDA Food Code contains language in Chapter 4 - *Equipment, Utensils, and Linens* recognizing a single organization for the accreditation of certification programs for food service equipment. Specifically, Section 4-205.10 of the Food Code limits the acceptability of food equipment certification programs to those accredited by the American National Standards Institute (ANSI). ANSI, a private, non-governmental organization, is one of three nationally recognized, U.S. based accreditation bodies that are qualified to accredit product certification programs. The identification of ANSI as the sole (proprietary) source for qualified accreditation providers is unnecessarily restrictive.

Public Health Significance:

The reliance on properly accredited third- party certification programs to evaluate food service equipment to nationally recognized standards that address sanitation and safety is a reliable mechanism to establish compliance with Sections 4-1 and 4-2 of the Food Code. The establishment of clear requirements for determining the acceptability of accreditation bodies is consistent with current practice while supporting an open marketplace based on demonstrated compliance.

Both the American National Standards Institute (ANSI) and the International Accreditation Service (IAS) are U.S. domiciled accreditation bodies that are signatory members of the International Accreditation Forum (IAF), meaning both organizations are recognized nationally and internationally as having equivalent levels of confidence for providing accreditation services. Accreditation is increasingly being used by regulators and the market as an impartial, independent and transparent means of assessing the competence of conformity assessment bodies.

Regulators in the United States increasingly rely on an integrated system of accreditation and certification to demonstrate that products and services comply with regulatory requirements. In the United States, examples of the reliance on systems of accreditation and certification include programs administered by the Environmental Protection Agency (EPA), the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC). The EPA Water Sense® and Energy Star® programs require that manufacturers submit products to an accredited certification agency for testing and evaluation in order to

establish compliance with established standards and criteria. Both programs establish qualification criteria for recognition of accreditation bodies based on a framework for accreditation developed by IAF. IAF provides the technical basis for the recognition of the competence of accreditation bodies. IAF conducts an initial onsite evaluation, routine surveillance and periodic re-evaluations of accreditation bodies to determine compliance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17011 Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies. Accreditation bodies found to be operating accreditation programs that comply with these requirements become signatories to the IAF Multilateral Recognition Arrangement. The criteria for the accreditation of product certifying bodies is detailed in ISO/IEC Guide 65, General requirements for bodies operating product certification systems and the International Accreditation Forum (IAF) Guidance on the Application of ISO/IEC Guide 65.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-205.1, be amended as shown below (new language shown with underline and deleted language shown with strike-through):

Acceptability

4-205.10 Food Equipment, Certification and Classification.

Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI) accredited a certification program accredited by a U.S. domiciled accreditation body that is a signatory to the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) is deemed to comply with Parts 4-1 and 4-2 of this chapter.

Submitter Information:

Name: Ron Coiner

Organization: International Accreditation Service

Address: 5360 Workman Mill Rd. City/State/Zip: Whittier, CA 90601

City/State/Zip: Whittier, CA 90601
Telephone: (562) 364-8201 ext Fax:

3309

E-mail: rcoiner@iasonline.org

Attachments:

"Food Equip Cert Issue Supporting Attachments"

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

(562) 699-8031

				Internal Number: 008 Issue: 2012 I-031	
Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action	
Delegate Action:	Accepted		Rejected		
All information above	the line is for co	nference	use only.		

Title:

Modify FDA Food Code §3-304.11 to include linens and napkins

Issue you would like the Conference to consider:

The current wording of FDA Food Code §3-304.11 states that "food shall only contact surfaces of: (A) equipment and utensils that are cleaned as specified under Part 4-6 of this Code and sanitized as specified under Part 4-7 of this Code; or (B) single-service and single-use articles." By limiting the surfaces that food may contact to <u>only</u> equipment, utensils, single-service and single-use articles, this section negates the allowance for linens and napkins where they are approved for use. Linens and napkins are not included in the definitions of equipment, utensils, and single-service or single-use articles in the Food Code. However Food Code §3-304.13 allows for their use when they are lining containers for the service of food provided they're replaced each time the container is refilled for a new customer.

Public Health Significance:

By emphasizing what is permissible for food contact and what is not, the Food Code can avoid providing conflicting guidance to stakeholders. By including linens and napkins in §3-304.11, the Food Code will clearly identify that linens and napkins can be used for food contact, as specified in §3-304.13, without confusion.

Recommended Solution: The Conference recommends...:

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

3-304.11 Food Contact with Equipment and Utensils

FOOD shall only contact surfaces of:

- (A) EQUIPMENT and UTENSILS that are cleaned as specified under Part 4-6 of this Code and SANITIZED as specified under Part 4-7 of this Code; or
- (B) SINGLE-SERVICE and SINGLE-USE ARTICLES; or
- (C) Linens and napkins as specified in §3-304.13.

Submitter Information:

Name: Chris Gordon

Organization: Virginia Department of Health-Office of Environmental Health

Address: 109 Governor Street5th Floor-OEHS

City/State/Zip: Richmond, VA 23219

Telephone: 804-864-7417 Fax: 804-864-7475

E-mail: christopher.gordon@vdh.virginia.gov

				Internal Number: 056 Issue: 2012 I-032
Council Recommendation:	Accepted as Submitted		Accepted as Amended	No Action
Delegate Action:	Accepted		Rejected	
All information above	the line is for con	nference	use only.	

Title:

Allowance for a Direct Drain Connection in Warewashing Equipment

Issue you would like the Conference to consider:

Deleting the prohibition of a direct drain connection for warewashing sinks or warewashing machines from Section 5-402.11 of the 2009 FDA Food Code (as modified by the Supplement issued in 2011). This prohibition is in direct conflict with the major model plumbing codes such as the Universal Plumbing Code and the International Plumbing Code. Many localities adopt these codes, and this creates a tiered system whereby food establishments in localities without a plumbing code must submit to a requirement that establishments in areas with plumbing codes are often required not to comply with. In warewashing, the final step in the process is a sanitizing step with a solution with residual sanitizer or high temperature water. This step acts as a "fail-safe" to overcome the risk of an unnoticed sewage backup in the sink.

Public Health Significance:

There is minimal risk to public health from allowing a direct drain connection in a warewashing sink.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting an amendment to Section 5-402.11 of the 2009 Food Code (as modified by the Supplement issued in 2011) as specified below (deleted language is in strikethru format).

5-402.11 Backflow Prevention.

- (A) Except as specified in $\P\P$ (B), and (C), and (D) of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are is placed.
- (B) Paragraph (A) of this section does not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.
- (C) If allowed by law, a warewashing machine may have a direct connection between itswaste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of atrapped floor drain and the machine outlet is connected to the inlet side of a properlyvented floor drain trap.
- $(\underline{\ThetaC})$ If allowed by law, a warewashing or culinary sink may have a direct connection.

Submitter Information:

Name: Adam Inman

Organization: Kansas Department of Agriculture

Address: 109 SW 9th

City/State/Zip: Topeka, KS 66612

Telephone: 785-296-5600 Fax: 785-296-6522

E-mail: adam.inman@kda.ks.gov

Internal Number: 006

			Issue: 2012 I-033
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for con	ference use only.	

Title:

Temp Measuring Device for Warewashing Machines w/Hot Water SANITIZING rinse

Issue you would like the Conference to consider:

The next revision of the FDA Food Code should require the Person-in-Charge of a food establishment that has a warewashing machine using a hot water sanitizing final rinse to have a temperature measuring device that measures the utensil surface temperature. The Food Code currently requires under 4-302.14 Sanitizing Solutions, Testing Devices that "A test kit or other device that accurately measures the concentration in MG/L of SANITIZING solutions shall be provided" and furthermore under 4-501.116 Warewashing Equipment, Determining Chemical Sanitizer Concentration that the "Concentration of the SANITIZING solution shall be accurately determined by using a test kit or other device." As far as hot water mechanical operations, the Food Code currently requires, in part, under 4-703.11(B) that "...Hot water mechanical operations...and achieving a UTENSIL surface temperature of 71 degrees C (160 degrees F) as measured by an irreversible registering temperature indicator."

In the case of hot water mechanical operations, the Food Code does not explicitly require both the availability and the use of an irreversible registering temperature indicator or similar device.

It should also be noted that the January 2000 FDA Plan Review Guide, *Part 8 - Warewashing Facilities*, under mechanical warewashing utilizing hot water for sanitization on page 81, states: "An approved maximum registering thermometer or high temperature test papers shall be available and used."

Reliance on the machine's fixed TEMPERATURE MEASURING DEVICE to determine if SANITIZATION has been achieved can be problematic as these devices are not routinely calibrated and may be in disrepair even if the machine itself is working properly. The use of a field temperature indicator (or similar) in conjunction with the fixed pressure gauge and fixed TEMPERATURE MEASURING DEVICE is appropriate to determine if SANITIZATION has been achieved.

Public Health Significance:

Effective SANITIZATION destroys organisms of public health significance that may be present on food equipment and utensils after cleaning or which may have been introduced into the rinse solution.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-302.13, be amended as follows (new language shown with underline):

Temperature Measuring Devices, Manual and Mechanical Warewashing

(A) In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

(B) In mechanical WAREWASHING operations, an approved irreversible registering indicator or waterproof maximum registering thermometer shall be provided and used regularly for measuring the final rinse temperature at the utensil surface.

Submitter Information:

Name: Jessica A. Fletcher

Organization: Mohegan Tribal Health Department

Address: 13 Crow Hill Road City/State/Zip: Uncasville, CT 06382

Telephone: 860-862-6156 Fax: 860-862-6189

E-mail: jfletcher@moheganmail.com

Council Accepted as Accepted as Recommendation: Submitted Amended No Action

Delegate Action: Accepted Rejected

All information above the line is for conference use only.

Title:

The 2009 FDA Food Code Introduced New Confusing Terms

Issue you would like the Conference to consider:

The new terms introduced into the 2009 FDA Food Code are not food safety-related terms that are relevant to educating the public, the regulated industry and regulatory officials. Removing the public health naming convention of identifying violations as risk factors, public health interventions, or good retail practices requires a re-education process that does not emphasize food safety or foodborne illness prevention. Significant progress has been made in linking the terms (risk factors, public health interventions, good retail practices) to a culture of food safety. We are concerned that use of the terms listed below will create confusion and set back progress in improving compliance in all facilities, particularly in "mom and pop" food service operations.

Core item

- 1. "Core item" means a provision in this Code that is not designated as a priority item or a priority foundation item.
- 2. "Core item" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

Priority Item.

- "Priority item" means a provision in this Code whose application contributes directly
 to the elimination, prevention or reduction to an acceptable level, hazards
 associated with foodborne illness or injury and there is no other provision that more
 directly controls the hazard.
- 2. "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and
- 3. "Priority item" is an item that is denoted in this Code with a superscript P? P. Priority Foundation Item.
 - 1. "Priority foundation item" means a provision in this Code whose application supports, facilitates or enables one or more priority items.
 - "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel

- training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
- 3. "Priority foundation item" is an item that is denoted in this Code with a superscript Pf _ Pf.

Public Health Significance:

The main purpose of the FDA Food Code is to assist regulators and the regulated industry in prioritizing actions that proactively improve food employee behaviors and food preparation practices mitigating and eliminating the risk of foodborne illness.

The new terms and levels of priority introduced in the 2009 FDA Food Code are difficult for regulators to articulate and difficult for regulated industry to understand. Without clear understanding there is a high probability of reducing the effectiveness of the Code itself. Time and effort spent re-educating regulators, operators and employees would be better spent on reinforcing the food safety-related and well-understood terms already in use.

Recommended Solution: The Conference recommends...:

the re-creation of the Critical Item Committee. The re-established Committee will be charged with:

- 1. Using the food safety terminology below in lieu of the terms listed above, or
- 2. Recommending easily understood (common usage) replacement terms that must be tested using surveys of both regulators and regulated industry,
- 3. Report back to the 2014 Biennial Meeting on Committee Activities and submit Issues that recommend revsion to the body of the code to align with the the revised language, and strike the existing terminology from the code (Core, Priority, etc.).

Submitter offers the Proposed Revised language for the Committee's Consideration: Good Retail Practices

- 1. "Good Retail Practices" means a provision in this Code that is not designated as a Risk Factor or intervention ITEM.
- 2. "Good Retail Practices" includes an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance.

Risk Factors and Intervention Items

- 1. "Risk Factor Item" means a provision in this Code whose application supports, facilitates or enables one or more RISK FACTOR items.
- "Intervention Item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and
- 3. "Risk Factor Item" is an item that is denoted in this Code with a superscript Rf Rf.
- 4. "Intervention Item" is an item that is denoted in this Code with a superscript I \frac{1}{2}.

Submitter Information:

Name: Chuck Catlin

Organization: P. F. Chang's China Bistro Inc. Address: 7676 E PINNACLE PEAK RD

City/State/Zip: Telephone: Scottsdale, AZ 85255

4808883262 Fax:

E-mail: chuck.catlin@pfcb.com

			Internal Number: 100 Issue: 2012 I-03
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for con	ference use only.	

Title:

Updating of the Food Establishment Inspection Report

Issue you would like the Conference to consider:

We are requesting that the Conference consider the following proposal:

The current Inspection Form 3-A in the 2009 Food Code Annex 7 and Instructions for Marking form 3-B are based on old section designations of critical and non-critical. When the 2009 code was modified to reflect the three tier designations of Priority (P), Priority Foundation (Pf) and Core (C) these forms were not updated.

We would like FDA to format the Inspection Form 3-A and the Instructions for Marking Form 3-B in Annex 7 to reflect the (P), (Pf), and (C) designations.

We have submitted a draft (attached) of an Inspection Form 3-A that has been divided and grouped according to the (P), (Pf) designated violations in the upper part of the form and the (C) designated violations in the lower part of the form. A draft Instructions for Marking document 3-B has been developed to show the (P), (Pf) and (C) designations to ensure that inspection observations are accurately recorded on the Food Establishment Inspection Report.

The documents attached are presented as drafts. The documents submitted were developed for the State of Oklahoma and would need to be made "generic" for use in future Code publications.

Public Health Significance:

The Food Establishment Inspection Report is the official regulatory document that measures compliance of the establishment with regulatory requirements. The goal of the report is to clearly, concisely, and fairly present the compliance status of the establishment and to convey this information to the permit holder or person in charge (PIC) at the conclusion of the inspection.

Reformatting the Food Establishment Inspection Report (3-A) and Guidance Marking Document (3-B) by providing a uniform and consistent inspection process will help bring uniformity and assist permit holders in understanding the three-tier designations in jurisdictions that have adopted the 2009 Food Code.

The formatting of the document to reflect the Priority, Priority foundation and Core designations will communicate to the operator the severity of the violations and will provide

appropriate timeframes for corrective action, thereby reducing foodborne illness risk to the public.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that the 2013 Food Code contain updated versions of the Food Establishment Inspection Report 3-A and Instructions for Marking Form 3-B that are currently provided in Annex 7 of the 2009 Food Code in order to reflect the Priority, Priority Foundation and Core designations.

Submitter Information:

Name: DeBrena D. Hilton, MPH

Organization: Tulsa City-County Health Department

Address: 5051 S. 129th E. Ave. City/State/Zip: Tulsa, OK 74134

Telephone: 918-595-4302 Fax: 918-595-4339

E-mail: dhilton@tulsa-health.org

Attachments:

• "DRAFT Food Establishment Inspection Report- Page 1"

"DRAFT Food Establishment Inspection Report - Page 2"

"DRAFT Instructions for Marking Guide"

I	nternal Number: 053 Issue: 2012 I-036
	No Action

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

Title:

Designation of Water Temperature at Handwashing Sinks as a Core Item

Issue you would like the Conference to consider:

To designate Section 5-202.12 (A) of the 2009 FDA Food Code as a Core Item, thereby changing the designation of delivery of water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet from a Priority Foundation to a Core Item.

Public Health Significance:

FDA Food Code Chapter 5 [Plumbing, Water and Waste] Section 5-202.12, Handwashing Sink, Installation, paragraph (A), recommends that, "A handwashing sink shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet..." This provision is currently designated as a Priority Foundation Item even though the temperature is specific to plumbing equipment and is not included in the handwashing procedures in section 2-301.12.

Hand-washing is an important food safety practice and specific procedures for hand washing are included in the Food Code in Section 2-301.12. The mechanical action of washing one's hands, use of soap, length of time hands are washed, rinsing, hand drying and proper hand-wash training have all been noted as important factors in accomplishing proper hand washing. More specifically, paragraph 2-301.12 (B) recommends that "warm water" be used for hand washing and rinsing, without a specific water temperature. Therefore the water temperature alone will not contribute directly to the elimination, prevention or reduction to an acceptable level, hazard associated with foodborne illness as specified in priority item definition.

Sighting a specific threshold water temperature does not predicate successful handwashing, which can be accomplished at various water temperatures. This is supported by the work of Michaels et al (2002, see attached) which concluded that there was no statistical difference in log reductions for both resident and transient bacteria during handwashing based on water temperature (see attachment). The results reported by Michaels confirm the observations made by Price (Price 1938) and Larson (Larson et al. 1980) indicating water temperature has little or no effect on the removal of bacteria from hands.

In summary, specific procedures such as handwashing frequency, length and technique have been shown to have a direct impact on the risk factors that contribute to foodborne illness, and therefore are aligned with the definition of a priority foundation item. However, the temperature of water delivered at a handwashing sink does not directly contribute to the elimination, prevention or reduction (to acceptable levels) of the hazards associated with foodborne illness. The temperature of the water is more consistent with the definition of a Core Item, which relates to general sanitation, operational controls, sanitation standard operating procedures (SSOP), facilities or structures, equipment design, or general maintenance. The plumbing recommendations listed in section 5-202.12 are consistent with the definition of a core item.

Recommended Solution: The Conference recommends...:

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

Section 5-202.12 Handwashing Sink, Installation.

(A) A HANDWASHING SINK shall be equipped to provide water at a temperature of at least 38°C (100°F) through a mixing valve or combination faucet. Pf C

Submitter Information:

Name: Thomas Ford

Organization: Ecolab

Address: 7900 McCloud DR City/State/Zip: Greensboro, NC 27409

Telephone: 336-931-2209 Fax:

E-mail: tom.ford@ecolab.com

Attachments:

"Michaels, Barry, et al. (2002) "Water temperature as a factor in handwa"

Council Recommendation:			Internal Number: 0 Issue: 2012 I-0		
	Accepted as Submitted	Accepted as Amended	No Action		
Delegate Action:	Accepted	Rejected			
All information above	the line is for co	nference use only.			

Title:

Designation of Manual Warewashing Wash Solution Temperature as a Core Item

Issue you would like the Conference to consider:

To designate Section 4-501.19 of the 2009 FDA Food Code as a Core Item, thereby changing the designation for the provision that, "The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions" from a Priority Foundation to a Core Item.

Public Health Significance:

Effective manual warewashing in retail food establishments is dependent on a number of variables including the cleaning agent used, the type of manual washing processes, the equipment used, the volume and type of wares being washed, as well as where they originate (i.e., hot or cold environments). The temperature of the water used for washing is also a variable and no specific temperature is required to assure an effective process. The washing step is intended to ensure that the wares/equipment being cleaned are visually free of soil prior to sanitization. The washing step is not intended to be a sanitizing step and therefore is not the step that reduces risk or impacts public health. A Priority Foundation item is, by definition, "an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury."

In practice, maintaining a specific wash solution temperature for manual warewashing can be challenging under certain situations such as washing in refrigerated environments in meat markets. To overcome this challenge, food retailers have worked with their chemical suppliers to provide cleaning agents (detergents) that work effectively in a variety of different environments and in various water temperatures with consistent results. Other methods such as applying force to the surface of wares via brush and/or spray devices have proven very effective in removing soil that can easily be rinsed prior to being sanitized, regardless of the water temperature. Employees are more likely to wash wares effectively and for a longer time if doing so in water that is comfortable and which achieves the intended purpose.

A Core Item is defined as "an item that usually relates to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures,

equipment design, or general maintenance." Other provisions in the Food Code that recommend water temperatures for washing are not designated as Priority Foundation and changing Section 4-501.19 to a Core Item would be more appropriate and consistent. Furthermore, the CFP Criticality Committee (CFP, Crit Item, recommendation for changing a Food Code Section, Chapter 2 (part) 3 and 4 and terminology, summary 8-16-07) overwhelmingly (>77%) recommended that Section 4-501.19 be classified as a Core item and not a Priority Foundation.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 4-501.19, be revised to reclassify the designation from a Priority Foundation (Pf) item to a Core (C) item as indicated below (new language shown with underline and deleted language shown with strike-through):

4-501.19 Manual Warewashing Equipment, Wash Solution Temperature.

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions. Pf C

Submitter Information:

Name: Terry Levee

Organization: Food Marketing Institute
Address: 2345 Crystal Drive Suite 800

City/State/Zip: Arlington, VA 22202

Telephone: 202-220-0659

E-mail: tlevee@fmi.org

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

Fax:

			Internal Numbe Issue: 2012	
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above	the line is for co	nference use onlv.		

Title:

Amendments to Public Information and Public Posting

Issue you would like the Conference to consider:

Rigorous health inspections are a critical component of an effective food safety system. The FDA Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:

Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home, compared with only 20 percent linked to home-prepared food. Although food establishments should be routinely inspected, the results of those inspections are not readily available to consumers, who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the Model Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be modified by adding new language in underlined format to Part 8-4 Inspection and Correction of Violations as noted below: 8-403.50 Public Information.

Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law. 8-403.51 Public Posting.

The REGULATORY AUTHORITY shall make available the results of the inspection report by requiring the timely posting of the most recent inspection results in a clear and legible form at the entrance, front window, or similarly prominent consumer-accessible area of the FOOD ESTABLISHMENT. Results may be posted in the form of a letter grade, numerical score, or other form as determined by the REGULATORY AUTHORITY.

Submitter Information:

Name: Sarah Klein

Organization: Center for Science in the Public Interest

Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

Rejected

	Issue: 2012 I-039
Accepted as Amended _	No Action
Rejected	

Title:

Council

Recommendation:

Delegate Action:

Addition to Section 8-4 Inspection and Correction of Violations

Accepted as

Submitted

Accepted

All information above the line is for conference use only.

Issue you would like the Conference to consider:

The FDA Food Code recognizes that the results of restaurant inspections are public documents and should be available for public review. However, complex rules regarding public access create difficulty for consumers who wish to consider inspection results.

Public Health Significance:

Consumer access to the results of these inspections plays an important role in maintaining the efficacy and credibility of the inspection system, and allows consumers to consider critical food safety information when making restaurant choices. Recent data show that nearly half of all foodborne illnesses are contracted from food prepared outside the home. Although food establishments are routinely inspected, the results of those inspections are not readily available to consumers-who thus have no way of minimizing their risk by knowing how an establishment performed on its most recent food safety assessment. In some jurisdictions, consumers must submit a formal Freedom of Information Act request to the regulatory authority to access an inspection report. The addition of the following language to the 2009 FDA Food Code will ensure public access to inspection results at the food establishment, improving consumer access and decision-making, without placing any additional or undue burden on food establishments. For more information, see http://www.cspinet.org/dirtydining/index.html.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended by adding language as follows: 8-403.50 Public Information.

Except as specified in § 8-202.10, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it at the FOOD ESTABLISHMENT and otherwise as provided in law.

Submitter Information:

Sarah Klein Name:

Organization: Center for Science in the Public Interest Address: 1220 L St NWSuite 300 City/State/Zip: Washington, DC 20005

Telephone: 2027778339 Fax:

E-mail: sklein@cspinet.org

Council Accepted as Accepted as Recommendation: Submitted Accepted Rejected

Accepted Rejected

All information above the line is for conference use only.

Title:

Packaged Food Labeling Clarification

Issue you would like the Conference to consider:

Foods can be wrapped in non-durable containers for sale in food service establishments, including carry-out restaurants and delis. It is the interpretation of some regulatory authorities, that foods wrapped in non-durable packaging for self-service are required to be labeled per the current labeling law. There are violations that are currently being reported for this practice. Foods served in non-durable packaging in a food service establishment should not fall under the requirements of the labeling law which was meant for foods in durable packages from a food processing plant.

Public Health Significance:

It is important that all foods requiring labeling under the law are in fact labeled for the protection of the consuming public with special dietary or health needs. It is equally effective to have information available (foodservice employee, signage, written hard copy or online website) for foods in a foodservice environment that do not meet the "packaged" definition.

The 2009 Food Code defines "Packaged" as follows: Packaged.

- (1) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether PACKAGED in a FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT.
- (2) **"Packaged"** does not include a wrapper, carry-out box, or other nondurable container used to containerize FOOD with the purpose of facilitating FOOD protection during service and receipt of the FOOD by the CONSUMER.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2009 Food Code (as modified by the Supplement issued in 2011) be amended as follows:

- 1) The FDA reinforces the legal definition of "packaged" in Section 1-201.10 (2), regarding the difference between durable and non-durable packaging.
- 2) The FDA adds language similar to the following to the next 2013 Food Code, Annex section 3 Public Health Reasons/ Administrative Guidelines; Chapter 1 Purpose and

Definitions, that describes the circumstances that labeling of foods in non-durable packaging is exempt:

- a) Foods in non-durable packaging held in a cold display unit in the service line are available to the customer in a self-service format. Foodservice employees and/ or information are available to address ingredient questions.
- b) "Grab-n-go" type items in kiosks in the front of a restaurant are available as a convenience to the customer in a self-service format. Foodservice employees and/ or information are available to address ingredient questions.

Submitter Information:

Name: Catherine Adams Hutt

Organization: National Restaurant Association Address: 1200 Seventeenth Street, NW

City/State/Zip: Washington, DC 20036

Telephone: 630-605-3022 Fax:

E-mail: cadams@rdrsol.com

				I	Internal Num Issue: 20	
Council Recommendation:	Accepted as Submitted		Accepted as Amended		No Action	
Delegate Action:	Accepted		Rejected		_	
All information above	the line is for co	nference	use only.			

Title:

Reuse-Refill of Multi-use Tableware (To go containers)

Issue you would like the Conference to consider:

Amend 2009 FDA Food Code Sections 3-304.17 and 4-603.17 to allow for institutional type facilities (such as schools or assisted living communities) to provide reusable tableware/containers to consumers, who can then return the tableware for cleaning, sanitizing, and reuse by the food establishment. The consumer at the time of return, would receive cleaned and sanitized reusable tableware/containers that can be refilled with food. Background:

Because of the trend toward recycling and attempting to limit the use of single service dishware in the waste stream, the PA Department of Agriculture has received several variance requests over the last few years to allow for colleges to use refillable containers that are provided to students by the food establishment. The variance requests have been reviewed and approved based on the limited scope of the consumers using the food establishment, as well as the following parameters:

- The reusable containers meet the criteria established in Chapter 4 for Equipment, Utensils and Linens, and are intended for multiple use.
- The facility establishes procedures for return of the containers that include, return
 area outside of any food preparation areas, inspection by a food establishment
 employee for general cleanliness and condition, and a direct pathway to the
 warewashing area which minimizes any potential cross contamination
- Food establishment accomplishes warewashing as required in the Food Code, and complies with storage and other handling requirements.
- A mechanism is in place to identify/verify the consumer population that is purchasing and returning reusable containers.

The trend toward recycling and environmental friendliness will continue - companies are manufacturing reusable containers and marketing them, especially in institutional settings, and more institutions will be looking at reducing waste and cutting costs. Since 2008, FDA has received several interpretation questions regarding re-use of to-go boxes and similar containers, and the Commonwealth of PA has received 2 requests to the Department of Agriculture, and at least one request through a County Health Department.

The 2009 Food Code prohibits a food establishment from refilling containers with PHF/TCS food in Section 3-304.17, and Section 4-603.17 prohibits cleaning and refilling containers,

other than beverages, unless by a food processing plant. Thus any jurisdiction that has facilities utilizing reusable food containers must make independent determinations through the variance process as to what is acceptable and required if approving the reuse or refilling of these multi-use food containers.

Public Health Significance:

Because of the trend toward recycling and attempting to limit the use of single service dishware in the waste stream, the Pennsylvania Department of Agriculture has received several variance requests over the last few years to allow for colleges to use refillable containers that are provided to students by the food establishment. The variance requests have been reviewed and approved based on the limited scope of the consumers using the food establishment, as well as the following parameters:

- The reusable containers meet the criteria established in FDA Food Code Chapter 4, Equipment, Utensils and Linens, and are intended for multiple use.
- The facility establishes procedures for return of the containers that include, return
 area outside of any food preparation areas, inspection by a food establishment
 employee for general cleanliness and condition, and a direct pathway to the
 warewashing area which minimizes any potential cross contamination
- Food establishment accomplishes warewashing as required in the Food Code, and complies with storage and other handling requirements.
- A mechanism is in place to identify/verify the consumer population that is purchasing and returning reusable containers.

The trend toward recycling and environmental friendliness will continue - companies are manufacturing reusable containers and marketing them, especially in institutional settings, and more institutions will be looking at reducing waste and cutting costs. Since 2008, FDA has received several interpretation questions regarding re-use of to-go boxes and similar containers, and the Commonwealth of Pennsylvania has received 2 requests to the Department of Agriculture, and at least one request through a County Health Department. The current Food Code prohibits a food establishment from refilling containers with PHF/TCS food in Section 3-304.17, and Section 4-603.17 prohibits cleaning and refilling containers, other than beverages containers, unless performed by a food processing plant. Thus any jurisdiction that has facilities utilizing reusable food containers must make independent determinations through the variance process as to what is acceptable and required if approving the reuse or refilling of these multi-use food containers. Non-uniformity in determining what criteria must be in place for approving variances related to reuse-refilling of these multi-use containers will result in jurisdictions establishing differing standards for the tableware/container, the types of food establishments that can use the reuseable tableware, the recordkeeping, and the food establishment handling,

Adding a standard set of provisions regarding when this practice is permitted will enhance uniformity among jurisdictions, provide a set of standards for industry to comply with, and protect the public.

Recommended Solution: The Conference recommends...:

cleaning, and sanitizing, and storage of the reusable tableware.

that a letter be sent to the FDA requesting amendments to the 2009 Food Code (as modified by the Supplement issued in 2011), Sections 3-304.17 and 4-603.17 specifically,

and other affected Food Code sections FDA identifies, to allow food establishments operating in institutional type settings with known consumers to provide reusable tableware/containers which can be returned and reused/refilled by that food establishment. In amending those sections, language should:

- identify specific criteria and procedures for food establishment approval of the process
- 2. verify the consumer population (eg, IDs, Swipe Cards)
- confirm tableware/containers comply with 2009 Food Code Chapter 4 standards for Multi-use Equipment & Utensils
- 4. establish procedures for return/reuse of tableware/containers that include inspection by a food employee
- 5. establish procedures for limiting cross-contamination potential when tableware/containers are returned, inspected, cleaned and sanitized, and stored.

Submitter Information:

Name: Melissa Vaccaro

Organization: Pa Department of Agriculture, Bureau of Food Safety

Address: 2301 N. Cameron Street City/State/Zip: Harrisburg, PA 17070

Telephone: 717-787-4315 x104 Fax:

E-mail: mvaccaro@pa.gov

			Internal Numl Issue: 20	
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action	
Delegate Action:	Accepted	Rejected		
All information above	the line is for co	nference use only.		

Title:

Creation of Distribution and Storage, Transportation and Delivery Committee

Issue you would like the Conference to consider:

Food Safety and the prevention of food borne illnesses requires product protection, temperature control and other control steps throughout the food chain (from farm to fork). The process of distribution of food, food packaging, and sanitation chemicals to retail is one area that has been identified by studies (Interstate Food Transportation Project by Michigan Department of Agriculture and others), in publications (see attachments: 1) Food Safety Magazine - Maintaining the Cold Chain. 2) Food Logistics - Cold Chain Champions), and by the media (ABC News and Indiana videos available upon request) as one with food safety risks and opportunities. While Regulations are expected to be forthcoming via the Food Safety Modernization Act (FSMA)/Safe Food Transportation Act (SFTA), there exists a need to define and promulgate best practices and guidance documents in areas like temperature control, allergens, product protection, and other areas.

Public Health Significance:

Products must be protected from contamination, temperature abuse, and microbial growth to prevent food borne illnesses. Industry, Regulatory, Academia, Consumer Organizations, and others collaborating together to identify best practices assure these protections will add additional levels of food safety and consumer protection to the food chain.

Recommended Solution: The Conference recommends...:

the creation of a Distribution and Storage, Transportation and Delivery Committee. The Committee will be composed of Conference members from all constituencies especially subject matter experts in distribution, logistics and transportation. The Committee will be charged with:

- 1) Defining the scope of the distribution industry that will be addressed by the Committee, and identifying risks and opportunities for the Conference,
- 2) Soliciting best practices and existing documents that relate to distribution and storage of foods including Global Food Safety Initiative (GFSI) and other Standards to recommend best practices to the Conference,
- 3) Engaging with Federal and State agencies, especially those involved in Food Safety Moderization Act (FSMA)/Safe Food Transportation Act (SFTA) or existing transportation

inspection programs, to align proposed committee recommendations with regulatory requirements as they may be promulgated,

- 4) Reporting back to the 2014 Biennial Meeting summarizing its activities and recommending best practices in the areas of distribution and storage, transportation and delivery, and
- 5) Submitting Issues to the 2014 Biennial Meeting to recommend new FDA Food Code language and/or identify new charges for the Committee, if any.

Submitter Information:

Name: Francis "Frank" Ferko

Organization: US Foods

Address: 6133 North River RoadSuite 300

City/State/Zip: Rosemont, IL 60018

Telephone: 3123390900 Fax: 8472325045

E-mail: frank.ferko@usfoods.com

Attachments:

"Food SAfety Magazine - Maintaining the Cold Chain"

• "Food Logistics - Cold Chain Champions"

			lssue: 2012 I-043
Council Recommendation:	Accepted as Submitted	Accepted as Amended	No Action
Delegate Action:	Accepted	Rejected	
All information above	the line is for co	nference use only.	

Title:

Cottage Industry/Direct Producer to Consumer Sales

Issue you would like the Conference to consider:

Many states are adopting exceptions and special rules for cottage industries and direct producer to consumer sales. These types of sales include both packaged and unpackaged non PHF/TCS foods processed in residences and sold from the residence over the internet, at roadside stands, and at Farmer's Markets. The inconsistencies and in sometimes complete exemption from regulatory oversight are concerning from a safety persepective. We respectfully request that the Conference for Food Protection establish a Cottage Industry Committee to develop a proposal for the 2014 Conference that more completely addresses cottage industries and direct producer to consumer sales.

Public Health Significance:

States and local jurisdictions have adopted a variety of exemptions and policies with relationship to cottage industry/direct to consumer sales. The most significant public health issue is that jurisdictions without scientific input have developed a variety of standards, exception, and exemptions. This creates a system where a cottage industry/direct to consumer sales may or may not be regulated and inspected. From a state perspective, we see surrounding states that have exempted places from regulation, but the individuals are seeking to come to events and make sales in our State. For example, acidified foods, cheeses, eggs, and other processed foods are subject in some jurisidictions to these exceptions and exemptions. Furthermore, complete and thorough labeling is a concern to individuals with allergies or sensitivities.

Recommended Solution: The Conference recommends...:

creating a Committee to develop a proposal for the 2014 Biennial Meeting that more completely addresses cottage industries and direct producer to consumer sales. We respectfully suggest the Committee undertake the following charges:

- define Cottage Industries and Direct Producer to Consumer Sales
- identify exemptions from the Food Code
- establish labeling requirements
- write advisory statements as appropriate
- recommend Cottage Industry registration requirements

 require the Committee to submit a report at the 2014 Biennial Meeting along with Issues they identify.

Submitter Information:

Name: Mark Speltz

Organization: Iowa Department of Inspections and Appeals

Address: Lucas State Office Building, 3rd Flor321 E. 12th St.

City/State/Zip: Des Moines, IA 50319

Telephone: 515-669-3266 Fax: 515-281-3291

E-mail: mark.speltz@dia.iowa.gov