COUNCIL III – SCIENCE & TECHNOLOGY

Issues and Actions

In this section are the Issues deliberated by Council III. Issues 02-03-04 and 02-03-05, originally assigned to Council III, have been reported out as part of the Council I report.

Issue Number: **02-03-01**

a. **Issue Title: Reduced Microbial Risk Through Alternative Intervention Processes for the Retail Sprout Industry**

Recommended Solution: That a letter be sent to the FDA requesting that they develop recommendations for growing sprouts or treatment of raw sprouts at food establishments for the safe microbial intervention processes for sprouts.

Council Recommendation: **Accept as amended**

Assembly Action: **Affirm**

Issue Number: **02-03-02**

Issue Title: **Retail HACCP Committee of Council III**

Recommended Solution: Continue the momentum that has been established in the development of these guidelines by having the HACCP Committee continue as an ad hoc committee under Council III of the Conference.

The HACCP Committee should be charged with responding in a timely manner to the Executive Council (Board) of the CFP with additional comments to the next iteration of the FDA's document that provides guidance for the voluntary use of HACCP principles. This input from the CFP will ensure a continuation of broad considerations that the food service and retail food industries require when considering the use of HACCP principles.

In addition, the HACCP Committee should be charged with responding to the FDA's HACCP guidelines for regulators that are being developed in parallel with the guidelines for the voluntary use of HACCP principles by industry.

Council Recommendation: **Accept as submitted**

Assembly Action:	**Affirm**
Issue Number:	**02-03-03**
Issue Title:	**Collaboration of FDA and CFP on Retail Food Program Database of Foodborne Illness Risk Factors**
Recommended Solution:	The HACCP Committee provide comments on the existing FDA Retail Food Program Database Reports to the FDA in order to eliminate confusion on any terminology. The FDA and the HACCP Committee work closely together to develop future FDA Retail Food Program Database Reports on foodborne illness risk factors. In addition, the Conference recommends that the Executive Board of the CFP forward the letter submitted with this issue to the Center For Food Safety and Applied Nutrition (CFSAN) to initiate this collaboration.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Affirm**

Issue Number:	**02-03-04**
Issue Title:	**PHF Date Coding System Allowed**
Recommended Solution:	No action. This Issue is referred to Council I because it an issue not of science, but rather of implementation.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-05**
Issue Title:	**Add Flexibility to Current Date Marking Requirements In the Food Code**
Recommended Solution:	No action. This Issue is referred to Council I since it is an issue not of science, but rather of implementation.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-06**
Issue Title:	**RTE, PHF, Date Marking, Section 3-501.17(B)**
Recommended Solution:	Issue withdrawn by submitter

Issue Number:	**02-03-07**
Issue Title:	**RTE, PHF, Date Marking, Section 3-501.17 (A)**
Recommended Solution:	No action
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-08**
Issue Title:	**Remove and Reserve Date Marking RTE PHFs, Sections 3-501-16 and 3-401.17**
Recommended Solution:	No action
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-09**
Issue Title:	**Datemarking, Section 3-501-16, 3-501.17 and 3-501.18**
Recommended Solution:	The Datemarking Committee continue to complete its charge once on-going studies and reports related to the *L.m* risk assessment report are filed and released, and final working of the proposed addendum and PHR under Annex 3d is release3d as relates to Datemarking requirements under 3-501.16. None of these studies and reports were available in order to complete the CFP 2002 Issue submission deadlines. Upon completion of its charge, the Committee will submit recommendations to the CFP Executive Board for forwarding to FDA for consideration.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Affirm**

Issue Number:	**02-03-10**
Issue Title:	**Allow Searing of Fish Steaks and Filets that have been Frozen To Kill Parasites (or which are Exempt from the Freezing Requirements), Rather than Cooking them Until all Parts of the Food Reach 63C (145F)**
Recommended Solution:	No action
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-11**
Issue Title:	**Elimination of Cardboard from Food Preparation Areas**
Recommended Solution:	No action
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-12**
Issue Title:	**FDA Food Code Reference to Allergens**
Recommended Solution:	That CFP establish a committee with representatives from the various stakeholders to work with FDA on food allergens. The Committee will report back to the CFP Executive Board the results of their work not later than the 2004 Conference. The Executive Board will immediately report to the FDA the results of the Committees' work.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Affirm**

Issue Number:	**02-03-13**
Issue Title:	**Preventing Allergic Reactions to Food**
Recommended Solution:	No action. Combined with Issue III-12
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-14**
Issue Title:	**Potentially Hazardous Food Hot-Holding**
Recommended Solution:	Change from the 140F requirement to 135F or above in all parts of the food for hot food holding. It is recognized that science supports the temperature of 130F as a safe holding temperature for hot foods. It is further recognized that there is variability of temperature in foods held at hot temperatures and the variability of temperature measuring devices.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Affirm**

Issue Number:	**02-03-15**
Issue Title:	**Change Hot Holding Temperatures from 140F to 130F**
Recommended Solution:	No action.
Council Recommendation:	**No action. Combine with Issues 03-14.**
Assembly Action:	**Affirm**

Issue Number:	**02-03-16**
Issue Title	**Changing Safe Hot Holding Temperatures from 140F to 130F**
Recommended Solution:	No action
Council Recommendation:	**No action. Combine with Issues 03-14.**
Assembly Action:	**Affirm**

Issue Number:	**02-03-17**
Issue Title:	**Potentially Hazardous Food (PHF) Definition –Committee Report**
Recommended Solution:	That the PHF Definition Committee be continued beyond the April 2002 meeting for the purposes of reviewing and commenting on the IFT Report. The charge to the Committee includes addressing the following six issues identified in the "Public Health Significance" section of this Issue, and making recommendations for actions by the CFP Executive Board and/or the 2004 CFP.

1. Using "Hazard" in a manner that is different than it is used in HACCP.
2. Addressing growth vs. zero tolerance.
3. Defining "rapid and progressive".
4. Clarifying adulterated or contaminated vs. supporting growth.
5. Stating that "non-PHF" can be infectious/ "hazardous"
6. Using a performance standard or listing of commodities.

Council Recommendation: **Accept as amended**

Assembly Action: **Affirm**

Issue Number: **02-03-18**

Issue Title: **Non-Critical Violation Criteria for Hot Holding – Section 3-501.16 (A)**

Recommended Solution: The Chair send a letter to the FDA requesting that if the Code hot holding temperature remain 140F that the Code language in Section 3-501.16(A) include the following provision:

"Where the regulatory standard for hot holding is 140F, violation within the prescribed temperature ranges, between 135F and 140F should be marked as non-critical violations."

Council Recommendation: **Accept as amended**

Assembly Action: **Extract and reject**

Issue Number: **02-03-19**

Issue Title: **Non-Critical Violation Criteria for Hot/Cold Holding**

Recommended Solution: No action.

Council Recommendation: **No action. Combine with Issue 03-18.**

Assembly Action: **Affirm**

Issue Number:	**02-03-20**
Issue Title:	**Discarding Potentially Hazardous Food as Unsafe Because of Temperature Abuse**
Recommended Solution:	No action. There is a lack of scientific evidence that this Issue will protect public health.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-21**
Issue Title:	**Acceptability of Alcohol-based Hand Sanitizers for Minimal Risk (Non Food Preparation) Situations**
Recommended Solution:	No action. There are questions of both efficacy for foodborne viruses of greatest concern and the lack of pairing with proper handwashing
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-22**
Issue Title:	**Time as a Public Health Control**
Recommended Solution:	That a committee be established to develop a report reviewing and summarizing available information regarding the rate of growth of pathogens in food between 7C (45F) and 21C (70F), and 52C (125F) and 60C (140F), and present that report at the next CFP Conference along with their recommendations for changes, if any, in the time allowances for the use of Time as a Public Health Control.
Council Recommendation:	**Accept as submitted**
Assembly Action:	**Affirm**

Issue Number:	**02-03-23**
Issue Title:	**Exemption from Freezing Requirement for Fish Species With no Parasite Hazard**
Recommended Solution:	No action. There is a lack of scientific information to support this Issue.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-24**
Issue Title:	**When Gloves are Required to be Worn by Food Handlers**
Recommended Solution:	That the Conference Chair write a letter to the FDA requesting that they develop language to be added to the Food Code in the appropriate section prohibiting bare hand contact by food employees that prepare or serve ready-to-eat food to highly susceptible populations.
Council Recommendation:	**Refer to Council I for consultation; receive back from Council I; accept as amended.**
Assembly Action:	**Affirm**

Issue Number:	**02-03-25**
Issue Title:	**Preventing Contamination from Hands, Section 3-301.11**
Recommended Solution:	That a letter be sent to the FDA Commissioner to urge the following changes to Section 3-301.11, page 48 of the 2001 Food Code: Section 3-301.11 of the 2001 FDA Model Food Code should be modified to accommodate a more practical approach to limiting bare hand contact. The model Food Code should read as follows: (C) Except when washing fruits and vegetables as specified under Section 3-302.15 or as specified in paragraph (D) and (E) of this section, food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.

(D) Food employees may contract exposed, ready-to-eat food with their bare hands if:

(1) the permit holder complies with Section 2-201.11;

(2) the person in charge complies with sub paragraphs 2-102.11(C)(1)-(3) and (8), paragraph 2-103.11(D), and paragraph 2-201.12 and 2o-201.13.

(3) the person in charge maintains a documented plan in the food establishment that is readily available at all times for use by employees and for regulatory authority review upon request, and that specifies:

(a) why it is necessary for food employees to contact ready-to-eat food in specified situations,
(b) the foods that will be contacted by bare hands,
(c) the hazard presented by bare-hand contact is the possible transfer of bacterial, viral or parasitic pathogens from food employees' hands to the food,
(d) the procedures and practices that require employees to wash their hands before returning to their work stations,
(e) a training program for the food employees that specifies:

(i) who is responsible for the training,
(ii) the program content, including instructions to food employees about the hazard as specified in subparagraph (D(3)(c) of this section, not to work when they are ill with any of the symptoms or diagnoses specified under section j2-201.11, good hygiene practices, proper handwashing, the principles of safe food preparation, procedures, and precluding cross contamination, and
(iii) the frequency of the training including periodic refresher sessions,

(f) how food employees compliance with the plan will be monitored, documented, and verified, and
(g) Corrective actions to be taken when the plan is not followed, such as when an ill food employee is found preparing food;

(4) the person in charge ensures compliance with the plan specified in subparagraph (D)(3) of this section and amends it as required by the regulatory authority; and

(5) food employees comply with the plan specified in subparagraph (
D)(3) of this section, section 2-301.14 and Part 2-4.

(A) A permit holder or person in charge electing to comply with paragraph (D) of this section may also implement one or more of the following:

(1) Vaccination against hepatitis A for food employees, including initial and booster shots or medical evidence that a food employee has had a pervious illness from hepatitis A virus;

(2) Double handwashing;

(3) Use of nailbrushes; or

(4) Use, after proper handwashing, of a hand sanitizer as specified under section 2-301.16.

Council Recommendation: **Accept as amended**

Assembly Action: **Extract and reject**

Issue Number: **02-03-26**

Issue Title: **A More Practical Approach to Limiting Bare Hand Contact**

Recommended Solution: No action. This Issue is combined with Issue 03-25.

Council Recommendation: **No action**

Assembly Action: **Affirm**

Issue Number:	**02-03-27**
Issue Title:	**Preventing Contamination from Hands, Section 3-301.11 Report of Council III Committee formed by the 2000 CFP Per Issue 00-01-07.**
Recommended Solution:	No action. No action is necessary based on acceptance of Issue 03-25 as amended.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-28**
Issue Title:	**No Bare Hand Contact with Ready-to-Eat Food**
Recommended Solution:	No action. No action is necessary based on acceptance of Issue 03-25 as amended.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-29**
Issue Title:	**Prohibit Natural Rubber Latex Gloves in Food Service**
Recommended Solution:	No action. The Conference recognizes the concern regarding the current allergies to natural rubber latex gloves but recommends no action because of the current uncertainty of the scientific evidence relating to foodborne latex allergens.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-30**
Issue Title:	**FDA's Report on Progress of FDA's Investigation of Allergic Reactions Related to Heavea Natural Rubber Latex Products (NRL)**
Recommended Solution:	That the Report be accepted
Council Recommendation:	**Accept as submitted**
Assembly Action:	**Affirm**

Issue Number:	**02-03-31**
Issue Title:	**Latex Gloves, Food Adulteration Through Allergenic Proteins**
Recommended Solution:	No action. This Issue is combined with Issue 03-29.
Council Recommendation:	**No action**
Assembly Action:	**Affirm**

Issue Number:	**02-03-32**
Issue Title:	**Natural Rubber Latex (NRL) Allergens and Good Handling Gloves**
Recommended Solution:	That the Conference Chair send a letter to the FDA urging the Commissioner to continue the food additive review concerning natural rubber latex as it pertains to the use of latex gloves in food operations, based on food safety considerations.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Affirm**

Issue Number:	**02-03-33**
Issue Title:	**Retail-Level Guidance for Minimizing Microbial Contamination of Produce**
Recommended Solution:	That a committee be formed to develop guidance for minimizing the potential of contamination and growth of pathogens in ready-to-eat fruits and vegetables in retail food operations. It is further recommended that the committee seek out ongoing guidance that may be available through government, industry, or academic sources to avoid duplication of effort. Recommend present

committee be allowed to continue to accomplish the required tasking.

Council Recommendation: **Accept as submitted.**

Assembly Action: **Affirm**

Issue Number: **02-03-34**

Issue Title: **The Use of Water Activity as Opposed to Moisture/Protein Ratio for Meat Snacks to Determine Food Safety**

Recommended Solution: No action. Methods and guidance already exist in the Food Code (Annex 4) for determining water activity.

Council Recommendation: **No action**

Assembly Action: **Affirm**

Issue Number: **02-03-35**

Issue Title: **Cross-Contamination via Thermal Protective Apparel ("PPE") and Mitigation of this Risk**

Recommended Solution: No action. Guidance is already provided in the Food Code.

Council Recommendation: **No action**

Assembly Action: **Affirm**

Issue Number: **02-03-36**

Issue Title: **Temperature Measurement Methodology**

Recommended Solution: No action. This information already exists in the Food Code

Council Recommendation: **No action**

Assembly Action: **Affirm**

Issue Number: **02-03-37**

Issue Title: **Addition of Cheese Date Marking Exemption to Section 3-501.17(D)**

Recommended Solution: That the Conference Chair send a letter to the FDA Commissioner to urge the revision of section 3-501.17, pages 69-70 of the 2001

	FDA Food Code by adding an additional paragraph after 3-507.17(C) stating: Paragraphs (A) and (B) of this section do not apply to specific cheeses containing certain moisture content meeting the aging standards of 21 CFR Part 133 and maintained under refrigeration as specified in paragraph 3-501.16.
Council Recommendation:	**Accept as submitted**
Assembly Action:	**Affirm**

Issue Number:	**02-03-38**
Issue Title:	**Guidance on Formation of Clostridium Botulinum Toxin in Frozen Reduced Oxygen Packaged Food**
Recommended Solution:	The following statement be added to Public Health Reasons 3-502.12: Formation of Clostridium botulinum toxin may not be a significant hazard in reduced oxygen packaged products which are properly cooled and frozen immediately after processing, maintained frozen, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use").
Council Recommendation:	**Accept as submitted**
Assembly Action:	**Affirm**

Issue Number:	**02-03-39**
Issue Title:	**Reduced Oxygen Packaging (ROP) – Definition**
Recommended Solution:	Revising the ROP definition to: "Reduced oxygen packaging" means the reduction of the amount of oxygen in a package by removing oxygen, displacing oxygen and replacing it with another gasor combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding, 21% atmosphere. Reduced oxygen packaging does not apply to a cook (above 165 F.) and chill procedure that does not evacuate or replace oxygen, utilizes packaging that has an Oxygen Transfer Rate of 10,000 cc/sq.

	m/24 hours or greater, incorporates immediate cooling according to Section 3-501.14, and limits the storage time to less than 7 days.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Affirm**

Issue Number:	**02-03-40**
Issue Title:	**Cooling Potentially Hazardous Foods – Section 5-501.14(A)(2)**
Recommended Solution:	The Conference Chair write a letter to the FDA requesting that the language be revised in Section 3-501.14(A) and be replaced with the following: Cooked potentially hazardous food shall be cooled from 60 C. (140 F.) to 5 C. (41 F.) or less, or to 7 C. (45 F.) or less as specified under Section 3-501.16 (A) (2) (b), in 6 hrs. provided that the food is cooled from 60 C (140 F.) to 21 C. (70 F.) within the first 2 hours.
Council Recommendation:	**Accept as amended**
Assembly Action:	**Extract and accept**

ATTACHMENTS TO COUNCIL III REPORT

2002 Conference for Food Protection
Council III
Retail HACCP Committee Final Report

In 2000, the Conference for Food Protection recommended the Retail HACCP Committee of Council III be continued from the 1998 -1999 committee. The amended charge indicated a three -part responsibility regarding this committee.

1. The chair(s) of the Retail HACCP Committee report their recent findings to the Executive Board prior to its September, 2000 meeting for consideration and forwarding to FDA. The report should include recommendations and suggestions for changes to the document "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service Retail Stores, and other Food Establishments at the Retail Level";
2. The HACCP Committee analyze FDA's report on foodborne illness risk factors (following its issuance) prior to the next CFP meeting;
3. The HACCP Committee consider other documents relative to retail HACCP as appropriate [with] the primary goal to recommend how this information can be used by specific segments of the retail food industry.

1. The chair(s) of the Retail HACCP Committee report their recent findings to the Executive Board prior to its September, 2000 meeting for consideration and forwarding to FDA. The report should include recommendations and suggestions for changes to the document "Managing Food Safety: A HACCP Principles Guide for Operators of Food Service Retail Stores, and other Food Establishments at the Retail Level".

- The Retail HACCP Committee did not organize until after the September 2000 Executive Board meeting. As a result, the committee was not able to submit recent findings on the FDA HACCP document prior to that meeting to meet the deadline. The Retail HACCP Committee did push forward in 2001 to review the FDA HACCP document and provide a list of specific recommendations to the FDA to complete Charge 1.

  Two tables of recommendations were provided regarding the document. Table 1 reflects the comments from the current Retail HACCP Committee 2000 - 2001. Table 2 reflects comments from the 1998 - 1999 Retail HACCP Committee with revisions/amendments by the current committee. The recommendations also included general comments regarding the direction of HACCP and the application in retail and food service establishments. These recommendations were submitted to the Council III

Chair August 17, 2001 for review and approval by the CFP Executive Board meeting held August 24, 2001.

The CFP Executive Board approved the recommendations from the committee and the subsequent forwarding of the documents to the FDA. The CFP Chair received the committee recommendations and forwarded the documents to the FDA in September 2001. The FDA has completed the revisions to the Retail HACCP document based on comments from the 2000 - 2001 Retail HACCP Committee, which is included as an attachment to this report.

The Retail HACCP committee has submitted an issue to CFP 2002 to continue the Retail HACCP Committee for 2002 - 2003 to provide comments to the revised FDA Retail HACCP document for industry operators and to the forthcoming HACCP Guidelines for Regulators document. The Retail HACCP Committee would like to propose that the committee's review of the revised FDA HACCP document be reported at a future Executive Board meeting prior to CFP 2004.

Rationale for issue submission:

The HACCP committee should be charged with responding in a timely manner to the Executive Board of the CFP with additional comments to the next iteration of the FDA's document that provides guidance for the voluntary use of HACCP principles. This input from the CFP will ensure a continuation of broad considerations that the food service and retail food industries require when considering the use of HACCP principles.

In addition, the HACCP committee should be charged with responding to the FDA's HACCP guidelines for regulators that are being developed in parallel with the guidelines for the voluntary use of HACCP principles by industry.

2. The HACCP Committee analyze FDA's report on foodborne illness risk factors (following its issuance) prior to the next CFP meeting.

- The Retail HACCP Committee reviewed the FDA's "Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors" which was issued August 2000. The committee expressed concerns regarding "% out of compliance" observations on several important foodborne disease risk factors observed during the data collection period of retail food establishments. The committee's concern was that these "out of compliance" risk factors may not accurately reflect a failure on the part of the retail food establishments to manage foodborne disease risk factors. This may in part be due to local regulatory codes vs. the 1997 FDA Food Code, which was used to interpret "% out of compliance" by the FDA.

The Retail HACCP committee has submitted an issue to CFP 2002 for the CFP Chair to request of the FDA for the Council III Retail HACCP Committee to work closely with the FDA together to develop future Retail Food Program Database Reports on foodborne illness risk factors.

Rationale for issue submission:

Industry, state and local regulatory agencies and the FDA all have stakes in foodborne illness risk factor data. The collection and reporting processes describe the current state of the food safety system, and suggest actions necessary to improve it. The impact this data has on the food safety system will increase to the extent that there is joint ownership of the collected data between the FDA, industry, and state and local regulatory agencies. The HACCP Committee of the Conference for Food Protection has membership from each of the stakeholder groups.

Therefore, the Conference recommends that the FDA and the HACCP Committee work closely together to develop future FDA Retail Food Program Database Reports on foodborne illness risk factors. The committee would like to provide comments or recommendations on existing public documents for inclusion or development of the next report. In addition, the Conference recommends that the Executive Council of the CFP forward the letter submitted with this issue to the Center for Food Safety and Applied Nutrition (CFSAN) to initiate this collaboration.

3. The HACCP Committee consider other documents relative to retail HACCP as appropriate [with] the primary goal to recommend how this information can be used by specific segments of the retail food industry.

- The Retail HACCP Committee has considered many other documents relative to retail HACCP. The committee has generated a compilation of industry and regulatory HACCP plans/guidelines to create an annex to the FDA HACCP document, which were submitted to the FDA along with the recommendations to the FDA HACCP document. The Annex includes four (4) food service examples, one (1) retail store example and (2) regulatory examples of HACCP plan/guidelines.

Rationale for recommendation:

The Retail HACCP Committee expressed a desire for greater flexibility in the development and use of Standard Operating Procedures (SOPs) and Critical Control Points (CCPs) in the voluntary use of HACCP guidelines. The Annex examples represent different ways in which HACCP principles can be applied and used within the retail and food service establishments to develop HACCP principles which best suit the needs of that retail or food service segment.

Respectfully Submitted By:

Council III HACCP Committee
Debi Williams – Co-Chair
Pam Williams – Co-Chair

May 1, 2002

Mr. Joseph Levitt, Director
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Mr. Levitt:

The Conference for Food Protection applauds the Food and Drug Administration for their pioneering work to develop a database of foodborne illness risk factors in retail food establishments. The ability to prioritize food safety actions and track food safety trends based on national, industry-wide data clearly will enhance both regulatory and industry food safety efforts.

The Conference brings food industry, academia, and regulatory agencies with local to national interests together to advance food safety. This collaborative effort has produced notable results. A spirit of cooperation has emerged as industry and regulatory communities together develop food safety standards that protect the public's health. Examples include developing a standard for the certification of food managers, developing guidelines for food recovery programs, and crafting many meaningful enhancements to the FDA Food Code in the areas of hand washing and hygiene, temperature control, and cross contamination prevention.

In this spirit of cooperation, the Conference requests the opportunity to collaborate with the FDA in reporting the data collected on foodborne illness risk factors in retail food establishments. The HACCP Committee of Council III is familiar with the August, 2000 Report issued by the FDA, and is well-suited to work with the FDA on future communications of this important project. Local regulators and industry can provide input into methods of communication that are more likely to produce food safety enhancements based on the data. Such collaboration will facilitate the acceptance of this work by industry, and will help address questions that may arise from state and local regulators about the interpretation and use of the information.

The HACCP Committee of Council III has been charged with working with the FDA on future communications of foodborne illness risk factor data collection. This step was taken at the 2002 Conference meeting to create a channel for collaboration between the FDA and the Conference. Please communicate to me at your earliest convenience that you concur with this proposed collaboration. I will facilitate the initial contact between your designee and the Committee Chair.

Thank you for your careful consideration of this matter.

Sincerely,

/s/Conference Chair
Conference for Food Protection

Summary Report of the Datemarking Committee

In April of 2000, The CFP 2000 Council I and Council III shared responsibility for 4 specific issues related to the Datemarking requirements of section 3-501.17 and 3-501.18 of the 1999 FDA Food Code. These issues are attached as Attachment A to this report. While the issues were all assigned initially to Council I, they were referred for deliberation under Council III as a scientific issue due to basis of the datemarking requirement being the risk assessment of Listeria monocytogens in RTE food. Issues 00-01-13 and 00-01-14 were combined with Issue 00-01-16 which was extracted by the CFP delegates and accepted as recommended. Issue 00-01-15 which Council had recommended "No Action" was accepted by the CFP delegates on it's own merits as an FDA action based on their ongoing risk assessment initiatives with respect to L.m. at the time of the Conference. The above Council and Delegate actions then resulted in providing the following final recommendations:

The Conference recommends that a committee under Council III be formed to resolve the issues raised of datemarking and report back to the CFP meeting in 2002.

The Conference further recommends to the FDA to provide guidance to the states to adopt and to hold enforcement of Section 3-501.17 in abeyance until this issue has been resolved.

I. Interpretation of the Charge

Since the committee has not meant as a whole, the interpretation of the charge is not absolute. The committee will review the recommendations of the CFP and carry out the interpretations of the agreed upon charge to "to resolve the issues of datemarking."

Although the four issues were submitted to the 2000 CFP and all dealt with datemarking in general, they each presented different input and had expected outcomes based on that input. The following is a collective list of these concerns which the committee will review:

1. Look at revising Section 3-501.17, pages 64-66 of the of the 1999 FDA Food Code to:

    a. Clarify the language of 3-501.17(A) to include date marking terminology currently used by the supermarket industry, e.g. "Sell By" date and/or "Best If Use By" date.

    b. Allow Date marking to be accomplished through use of identification stickers or tags, color codes or other effective means.

c. Expand 3-501.17(F) listing to include additional exempt products from the date marking requirements that incorporate alternative measures to ensure food safety. These products include:

a. Specific cheeses containing certain moisture content meeting the aging standards of 21 CFR Part 133 (See attached chart below)
b. Commercially processed RTE meat items with a "moisture to one part protein ratio" of 1.9:1 or less, regardless if the casing is on the remaining of the product. These products would not support the Rapid AND Progressive growth of infectious or toxigenic microorganisms.
c. RTE PHFs (ready to eat potentially hazardous foods) containing barriers to ensure food safety, e.g., anion effects from the acidulent use, phosphates, sorbates, and bactrocins, and humectants other than sodium chloride and/or processes known to control the growth of pathogenic bacteria.
d. Should commercially prepared RTE PHF that remain cased per USDA MPI Guideline No.6, "A Glossary of Meat and Poultry Industry Terms be allowed to be sold or used within 10 days if held @ 45oF or less if the remaining portions are maintained with the casing on.
e. Question the validity and application of the USDA Pathogen Modeling Program by specific food commodity groups (based on foods, processes and/or ingredients) prior to providing time criteria within Section 3-501.17. Generally it appears that the temperature requirements throughout the 1999 FDA Food Code are reasonable and applicable to ensure food safety at the retail level, but the time parameters specified in Section 3-501.17 are not supported by science, nor should they be generically applied to all RTE PHFs.

Examples of Hard Cheeses Containing not more than 39% moisture (21 CFR 133.150)	Examples of Semisoft Cheeses Containing more than 39%, but not more than 50% moisture (21 CFR 133.187)
Asiago medium Asiago old Cheddar Gruyere Parmesan and Reggiano Romano Sap sago	Asiago fresh and soft Blue Brick Caciocavallo Siciliano Colby (not more than 40% moisture) Edam Gorgonzola Gouda Limburger Monterey, Monterey Jack Muenster Pasteurized process cheese Provolone Roquefort, sheep's milk blue-mold Swiss and Emmentaller

Cheeses that are NOT exempt from the Food Code provisions for date marking include soft cheese such as Brie, Camembert, Cottage, Ricotta and Teleme
**Source: FDA PIC Dec 15, 1999, Date Marking Cheese*

II. Deliberations and Discussion

Jeanette Lyon as the FDA liaison representative to the Datemarking committee provided a draft of Section 3-501.17 in mid August, 2001 to start our process of review of the issues. However, the late release of the FDA 2001 in conjunction with the holiday period precluded sufficient time for this committee to convene and discuss the issues surrounding development of the committee charge. The revised preliminary list of committee members is provided as Attachment B and have been submitted for approval to the CFP Executive Board in October, 2001. This committee remains open to soliciting other interested members in keeping with achieving balanced equity of shareholders on this committee issue.

There are some other pending actions that the Committee is aware of. This includes a recently released scientific report on Definition of PHF prepared under a contract between IFT and the FDA that warrants discussion by this committee on the validity of certain foods and their restriction to datemarking requirements. Another unreleased report which has been requested to be made available to the committee is a joint working group report with Novigen Sciences, Inc. that has been reviewing the L..m. risk assessment. Further the National Food Processor's Association in conjunction with FDA, FMI and others has been testing for L.m. in selected "risk" foods at retail and this data should be made available to the committee to evaluation for validity of the science behind datemarking requirements.

This committee will, in addition to the reports described above, need to review filed public comments on the L.m. risk assessment not available at this time to assure all stakeholder's concerns are presented on the issues.

III. Datemarking Committee Recommendations

That the committee continue to complete its charge. This includes reviewing and commenting on all known, available and relevant documents discussed in this report as it impacts datemarking issues in 3-501.16 through 3-501.18 and becomes available to the committee. This may result in the need for CFP to approve extension of current committee or approval of a new committee beyond the April 2002.

The committee should complete its charge and recommendations submitted to the CFP Executive Board for forwarding to FDA for consideration and incorporation of recommendations into the Food Code or by other administrative means at their option.

The committee further recommends that the 2000 CFP Issue 00-01-16 recommendation requesting that FDA provide guidance to regulatory agencies to adopt but to hold enforcement of Section 3-501.17 remain as stated.

That this report be included as an attachment to the issue submitted.

Respectfully submittted by the Datemarking Committee

Co-Chairs: Fred Reimers and Mario Seminara

DATE: January 16, 2002

Attachment A

YEAR 2000
CONFERENCE FOR FOOD PROTECTION
ISSUE SUBMISSION FORM

Issue No. 2000- I-13
Internal # 11

Title: Date Marking RTE PHFs, Section 3-501.17

Council Action:	**No Action**	_____	**Accepted**	_____	**Amended**	_____
Delegate Action:	**No Action**	_____	**Accepted**	_____		

Issue you would like the Conference to consider: [Explain in detail the Issue that concerns you. List relevant references.]

Section 3-501.17 provides guidance for date marketing of ready-to-eat (RTE) potentially hazardous food (PHF), requiring that RTE PHF "prepared and held refrigerated for more than 24 hours in a food establishment shall be clearly marked at the time of preparation to indicate the by which FOOD shall be consumed."

The terminology referenced in Section 3-501.17 omits industry practices and date marking terms used by the supermarket/grocery industry.

The time/temperature guidance provided in the same section is based on predictive growth curves utilizing the USDA Pathogen Modeling Program (Ref. 1). The use of this Pathogen Model on all RTE PHF "should be considered as initial estimators of microbial behavior and guides for evaluating potential problems." However, the Pathogen Modeling Program has built in limitations and does not consider control variables where alternative preservation mechanisms are in place to assure food safety and public health. Additionally, insufficient science exists at this time to specify that all RTE PHFs fall under the two shelf life control requirements for food safety, e.g., 4 days @ 45°F and 7 days @ 4

Public Health Significance: [Completely describe what impact this Issue will have on food service, retail food or vending.]

The "date by which the FOOD shall be consumed" referenced in Section 3-5017.17 is a term rarely used by the supermarket/grocery industry. This term is subjective in its interpretation and application within these environments. The National Conference of Weight and Measures Handbook #130 (used as the standard for product labeling within retail operations) provides clear definitions and detailed guidance for uniform open dating requirements as related to date marking perishable foods, e.g., "Sell By" date and "Best If Used By" date. (Ref. 2) The CODEX Allimentarius provides similar date marking terminology and use as cited in their General Standard 1-1985, e.g., "Sell By" dates or "Use By" dates.

b.

Microbiological surveys confirm the presence of *L. monocytogenes* in RTE meats (Ref. 3). Retail surveys have noted the presence of *L. monocytogenes* within retail environments (Ref. 4). The use of the USDA Pathogen Modeling Program to estimate safe shelf life for RTE PHFs incorporates an upper safe limit for *L. monocytogenes* whereas an infectious dose for this pathogen cannot be determine and current U.S. public health policies recognize a **zero tolerance**. Because *L. monocytogenes* is capable of growth at –0.4°C (31°F), quantifying the maximum

time/temperature requirements (shelf life) may not reflect the number of organisms found on the food at the time of handling within the food establishment or at the time of consumption by the consumer.

The use of the USDA Pathogen Modeling Program has inherent limitations that do not solely support food safety time/temperature relationships (shelf life) in Section 3-501.17. The current USDA Pathogen Modeling Program, Version 5.1, clearly notes:

> "*Conclusion The progress in microbial modeling has been impressive and models are becoming a standard research tool and a valuable aid in evaluating and designing food processes. However, it is not possible to rely solely upon models to determine the safety of foods and process systems. Laboratory testing is still necessary to unequivocally determine the propensity for pathogen growth or survival in the food product*."

This same Pathogen Modeling Program warns that results from the model must be validated against studies for particular food products prior to use. At this time the results from the Model are unproven, insufficiently studied and non-supportive due to a lack of scientific data validating the Model prior to implementation by industry and regulatory agencies. The use of the USDA Pathogen Modeling Program is a valuable tool, but its use should be recognized as a small portion of a complete quantitative risk assessment approach to food safety.

Lastly, the general reference of predictive growth curves for 4 days @ 45°F and 7 days @ 41°F for all RTE PHFs needs to take into account the presence of extrinsic variables. The food industry utilizes a variety of approved ingredients and preservatives within RTE PHFs as secondary control mechanisms or in combination with other ingredients to achieve a desired synergistic effect to ensure food safety. According to the current Pathogen Modeling Program:

> "*growth models do not usually include factors such as anion effects from the acidulent used, phosphates, sorbates, and bactrocins, and humectants other than sodium chloride. No broth models include competition from other microorganisms*."

REFERENCES:

1. USDA ARS Eastern Regional Research Center, Pathogen Modeling Program, Version 4.0, 1994. Microbial Food Safety Research Unit, Philadelphia, PA.

2. National Institute of Standards and Technology, Handbook 130 (http://www.nist.gov)

3. Humphrey, T.J., Worthington, D.M. *Listeria* Contamination of Retail Meat Slicers. PHLS Microbiol Digest. 1990;3:57.

4. Schuchat, A., Deaver, K., Wenger, J.D., Plikatytis, B.D., Mascola, L., Pinner, R.W., Reingold, A.L., Broome, C.V. and the Listeria Study Group. Role of Foods in Sporadic Listeriosis. JAMA. 1992:267:2041-2045.

5. USDA ARS Eastern Regional Research Center, Pathogen Modeling Program, Version 5.1. Microbial Food Safety Research Unit, Philadelphia, PA.

6. FDA (Food and Drug Administration), Program Information Manual, Retail Food Safety. Subject Date Marking Cheese, Dec 15, 1999. Center for Food Safety and Applied Nutrition, Washington, DC.

Recommended Solution: [State as precisely as possible what action you would like the Conference to take to address this Issue. Cite the **specific** type of change, location (page and line), and exact wording to be changed in a document, such as the Food Code or Conference document.]

The Conference should direct the Chair to send a letter to the FDA Commissioner to urge the revision of Section 3-501.17, pages 64-66 of the of the 1999 FDA Food Code to:

1. Clarify the language of ¶ 3-501.17(A) to include date marking terminology currently used by the supermarket industry, e.g. "Sell By" date and/or "Best If Use By" date. Reword to read:

   "Except as specified in (¶ (E) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and held refrigerated for more than 24 hours in a FOOD ESTABLISHMENT shall be clearly marked at the time of preparation to indicate the "**Sell By" date, "Best If Used By" date, or** a date by which the food shall be consumed, which is , including the day of preparation. ***Date marking may be accomplished through use of identification stickers or tags, color codes or other effective means.***"

2. Expand 3-501.17(F) listing to include additional exempt products from the date marking requirements that incorporate alternative measures to ensure food safety. These products include:

(i)

   a. Specific cheeses containing certain moisture content meeting the aging standards of 21 CFR Part 133 (See attached chart)
   b. Commercially processed RTE meat items with a "moisture to one part protein ratio**"** of 1.9:1 or less, regardless if the casing is on the remaining of the product. These products would not support the **Rapid <u>AND</u> Progressive** growth of infectious or toxigenic microorganisms.
   c. RTE PHFs containing barriers to ensure food safety, e.g., anion effects from the acidulent use, phosphates, sorbates, and bactrocins, and humectants other than sodium chloride.

(ii)

3. Charge FDA to evaluate the validity and application of the USDA Pathogen Modeling Program by specific food commodity groups (based on foods, processes and/or ingredients) prior to providing time criteria within Section 3-501.17. The temperature requirements throughout the 1999 FDA Food Code are reasonable and applicable to ensure food safety at the retail level, but the time parameters specified in Section 3-501.17 are not supported by science, nor should they be generically applied to all RTE PHFs.

(iii)

4. Re-categorize Section 3-501-17 as non-critical by removal the asterisk (*) at the end of the tagline due to insufficient and non-supportive food safety shelf life data at this time.

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Examples of Hard Cheeses Containing not more than 39% moisture (21 CFR 133.150)	Examples of Semisoft Cheeses Containing more than 39%, but not more than 50% moisture (21 CFR 133.187)
Asiago medium Asiago old Cheddar Gruyere Parmesan and Reggiano Romano Sap sago	Asiago fresh and soft Blue Brick Caciocavallo Siciliano Colby (not more than 40% moisture) Edam Gorgonzola Gouda Limburger Monterey, Monterey Jack Muenster Pasteurized process cheese Provolone Roquefort, sheep's milk blue-mold Swiss and Emmentaller

Cheeses that are NOT exempt from the Food Code provisions for date marking include soft cheese such as Brie, Camembert, Cottage, Ricotta and Teleme
**Source: FDA PIC Dec 15, 1999, Date Marking Cheese*

Attachment A

YEAR 2000
CONFERENCE FOR FOOD PROTECTION
ISSUE SUBMISSION FORM

Issue No. 2000-I-14
Internal # 51

Title: Section 3-501.17 Date Marking RTE PHFs

Council Action:	**No Action**	_____	**Accepted**	_____	**Amended**	_____
Delegate Action:	**No Action**	_____	**Accepted**	_____		

Issue you would like the Conference to consider: [Explain in detail the Issue that concerns you. List relevant references.]

Section 3-501.17 provides guidance for date marketing of ready-to-eat (RTE) potentially hazardous food (PHF), requiring that RTE PHF "prepared and held refrigerated for more than 24 hours in a food establishment shall be clearly marked at the time of preparation to indicate the date by which the FOOD shall be consumed."

The "consumed by" date required is not used in the retail industry. The common terminology found throughout the retail industry is "sell by" or "use by." Additionally, commercially available labels may offer "pull by" or "prep date" Since the intent of "consume by " date is not for the customer to consume, but rather to sell or use the RTE PHF, using common industry terminology will avoid confusion by both regulatory agencies enforcing this requirement and the industry in attempting to comply with it.

Further this section requires all RTE PHF refrigerated food prepared on premises as well as commercially processed food once opened to be used within 4 days if held @ 45^{o}F and 7 days if held @ 41^{o}F. The same requirement is applied to RTE PHF from commercial establishments that are opened at retail and subsequently frozen to assure that cumulative time from opening and after thawing do not exceed the 4 days if held @ 45^{o}F and 7 days if held @ 41^{o}F rule. This unmanageable dating and tracking system is unwarranted and difficult if not impossible to achieve in a high volume retail grocery store. Food Marketing Institute (FMI) has studies that show retail deli's carry an average 238 service items with a turn around time of 3.03 days. Since the majority of RTE PHF's are sold well before the 4/7 day time requirements of this section, imposing the datemarking requirement adds a substantial labor cost to the industry and to the regulatory agencies that have to monitor this requirement. There are some commercially sized packages that make it very difficult to move within the 7-day limit. The industry used the old 10-day limit to move these larger pieces of meat or bulk salads without much difficulty. I know of no reported foodborne outbreaks attributable to having 10 days versus 7 days even when the temperature was at 45^{o}F under the previous food codes. The USDA (and FDA) have also stated a "zero tolerance" for Listeria but it appears this "rule" is based on a 5 log growth of L.m. The retail industry has requirements beyond the 4/7 rule that reduce the risk of pathogen growth (i.e. cleaning and sanitizing requirements which are there to reduce the harborage for pathogens to grow). This section should concentrate only on those specific products known to be at risk as a RTE PHF. Exemptions should be expanded to include the many service items found in our deli that contain preservatives or are subjected to processes that reduce the likelihood of contamination while in cold holding display/storage.

Public Health Significance: [Completely describe what impact this Issue will have on food service, retail food or vending.]

Requiring a "consume by" date on RTE PHF that doesn't exist in the industry does little to promote compliance. The National Conference of Weight and Measures Handbook #130 (used as the standard for product labeling within retail operations) provides clear definitions and detailed guidance for uniform open dating requirements as related to date marking perishable foods, e.g., "Sell By" date and "Best If Used By" date. (Ref. 1) The CODEX Allimentarius provides similar date marking terminology and use as cited in their General Standard 1-1985, e.g., "Sell By" dates or "Use By" dates.

c.

While a zero tolerance exists in the U.S. for L.m. the industry acknowledges that findings of L.m. in RTE PHF have been documented and L.m. found in the retail environment (Ref 2 and 3). It is also known that an infectious dose for this pathogen has not been determined, but that hasn't stopped other countries outside the control of the U.S. public health service from establishing an allowance of up to 100cfu/g in RTE foods as a safe level. Because *L. monocytogenes* is capable of slow growth at –0.4°C (31°F), quantifying the maximum time/temperature requirements (shelf life) may not reflect the number of organisms found on the food at the time of handling by the food establishment or at the time of consumption by the consumer.

The time/temperature guidance provided in the same section is based on predictive growth curves utilizing the USDA Pathogen Modeling Program (Ref. 4). The use of this Pathogen Model on all RTE PHF "should be considered as initial estimators of microbial behavior and guides for evaluating potential problems." However, the current FDA Food Code does not recognize the built-in limitations of the Pathogen Modeling Program and insufficient science exists to classify all RTE PHFs into a 4 days @ 45°F and 7 days @ 41°F scenario for maximum shelf life for food safety. The use of the USDA Pathogen Modeling Program has inherent limitations that do not solely support food safety time/temperature relationships (shelf life) in Section 3-501.17. The current USDA Pathogen Modeling Program, clearly notes:

> "CONCLUSION: The progress in microbial modeling has been impressive and models are becoming a standard research tool and a valuable aid in evaluating and designing food processes. However, it is not possible to rely solely upon models to determine the safety of foods and process systems. Laboratory testing is still necessary to unequivocally determine the propensity for pathogen growth of survival in the food product." (Ref. 5)

This same Pathogen Modeling Program warns that results from the model must be validated against studies for particular food products prior to use. At this time the results from the Model are unproven, insufficiently studied and non-supportive due to a lack of scientific data validating the Model prior to implementation by industry, research and regulatory agencies. The use of the USDA Pathogen Modeling Program is a valuable tool, but is recognized as a small portion of a complete quantitative risk assessment approach to food safety.

The general reference of predictive growth curves for 4 days @ 45°F and 7 days @ 41°F for all RTE PHFs needs to take into account the presence of extrinsic variables. The food industry utilizes a variety of approved ingredients and preservatives within RTEs as secondary control mechanisms or in combination with other ingredients to achieve a synergistic effect to ensure food safety. According to the current Pathogen Modeling Program "growth models do not usually include factors such as anion effects from the acidulent used, phosphates, sorbates, and bactrocins, and humectants other than sodium chloride. No broth models include competition from other microorganisms."

FDA has already gone on record in the area of RTE cheeses that "in addition to refrigeration, there are several factors in certain cheeses that may further control growth of pathogenic organisms. These factors may include the presence of organic acids, preservatives, or competing flora; pH; water activity; or salt concentration. When two or more of these are combined, the resultant effect is an additional hurdle to the outgrowth of pathogens of concern" (Ref 6). This resulted in exemptions for hard or semi soft cheeses that did not support the growth of L.m.

USDA has also allowed "exemptions" to RTE PHF meat when the original casing is left intact after the slicing process. Therefore natural or artificial (synthetic) materials left intact are exempted from the date marking requirements without increase of risk from L.m. While this interpretation helps, it falls short in proving the science that states that other "hurdles" already existing in many of these RTE PHF's will reduce the risk of L.m over a 10-day period with temperatures not exceeding 45°F. In this case, enforcement to reduce the risk of L.m. in RTE PHF's should come through assuring proper cleaning and sanitizing of food contact surfaces and cleaning of non-food contact surfaces are in place; not an arbitrary across the board 4/7 @ 45°F/41°F rule based only on a model!

Until such time as risk assessment studies are completed to validate the concern for L.m growth in RTE PHF's in the retail industry, exemptions should be made to allow RTE PHF with secondary barriers beyond refrigeration be sold up to 10 days @ 41°F and 7 days @ 45°F provided the RTE PHF is sliced to order or sliced and packaged to assure surface protection.

REFERENCES:

1. National Institute of Standards and Technology, Handbook 130 (http://www.nist.gov)

2. Humphrey, T.J., Worthington, D.M. *Listeria* Contamination of Retail Meat Slicers. PHLS Microbiol Digest. 1990;3:57.

3. Schuchat, A., Deaver, K., Wenger, J.D., Plikatytis, B.D., Mascola, L., Pinner, R.W., Reingold, A.L., Broome, C.V. and the Listeria Study Group. Role of Foods in Sporadic Listeriosis. JAMA. 1992:267:2041-2045.

4. USDA ARS Eastern Regional Research Center, Pathogen Modeling Program, Version 4.0, 1994. Microbial Food Safety Research Unit, Philadelphia, PA.

5. USDA ARS Eastern Regional Research Center, Pathogen Modeling Program, Version 5.1. Microbial Food Safety Research Unit, Philadelphia, PA.

6. FDA Letter, December 15, 1999, Subject: Date Marking Cheese

Recommended Solution: [State as precisely as possible what action you would like the Conference to take to address this Issue. Cite the **specific** type of change, location (page and line), and exact wording to be changed in a document, such as the Food Code or Conference document.]

The Conference should direct the Chair to send a letter to the FDA Commissioner to urge the revision of Section 3-501.17, pages 64-66 of the of the 1999 FDA Food Code to:

1. Clarify the language of ¶ 3-501.17(A) and (C) to include date marking terminology currently used by the supermarket industry, e.g. "Sell By", "Best If Use By" date, "Prepared on" "Pull on" dates. Example of rewording for ¶ 3-501.17(A) with bracketed example for ¶ 3-501.17(C) could read:

   "Except as specified in ¶ (E) of this section **[or exempt under in ¶ (F**)], refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD prepared and held refrigerated for more than 24 hours in a FOOD ESTABLISHMENT shall be clearly marked at the time of preparation to indicate the a date by which the food shall be sold or used, which is , including the day of preparation. ***Date marking may be accomplished***

through use of identification stickers or tags, color codes or other effective means commonly used in the industry."

2. Re-categorize Section 3-501-17 as non-critical by removal of the asterisk (*) at the end of the tagline due to insufficient and non-supportive food safety shelf life data until scientifically validated quantitative risk assessments of RTE PHFs are completed.

(iv)

3. Allow commercially prepared RTE PHF that remain cased per USDA MPI Guideline No.6, "A Glossary of Meat and Poultry Industry Terms be allowed to be sold or used within 10 days if held @ 45^{o}F or less if the remaining portions are maintained with the casing on.

(v)

4. Expand 3-501.17(F) to include products exempt from the date marking requirements to include:

(vi)

a. Hard cheeses that meet the aging standards of 21 CFR Part 133, or as already identified in reference 6.

(vii)

b. RTE PHF commercially processed meats that contain other barriers aside from refrigeration to control the growth of pathogens . These include acidulents, phosphates, sorbates, nitrates, salts or other ingredients and/or processes known to control the growth of pathogenic bacteria.

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Attachment A

YEAR 2000

CONFERENCE FOR FOOD PROTECTION

ISSUE SUBMISSION FORM

Issue No. 2000–I-15
Internal # 79

Title: Date Marking

Council Action:	**No Action**	_____	**Accepted**	_____	**Amended**	_____
Delegate Action:	**No Action**	_____	**Accepted**	_____		

Issue you would like the Conference to consider: [Explain in detail the Issue that concerns you. List relevant references.]
PAGE 1 OF 2

Date marking is a mechanism in the Food Code to limit the growth of Listeria monocytogenes (L.m.) in refrigerated, ready-to-eat, potentially hazardous food. Implementation of the Food Code provision has been difficult, indicating that alternative methods of addressing this provision are needed.

FDA recommends that the Conference address the following concerns:

1. Address the control of L.m. by creating a standard in the Food Code that growth of L.m. in refrigerated, ready-to-eat potentially hazardous food must be controlled and suggest alternatives for accomplishing that goal. Consider the use of date marking as the "safe harbor" Food Code provision, and the use of a HACCP plan specific to L.m. as an alternative for compliance.

2. What constitutes "cellulose casings" with respect to the exemption in §3-501.17 and what food safety difference does it make if products in casings are sliced, i.e.,
   a. A natural casing is more permeable and you eat it; and
   b. A cellulose casing is not permeable and you don't eat it?

3. Implementation practicality, manageability
   a. Logistics with rewrapping, such as lunchmeats
   b. Sausage casings not labeled as cellulose
   c. Milk and soft serve dispensing.

4. Limitations of the phrase "consume by', especially as it applies to food that is not consumed on the premises. Consider alternatives such as "sell by" or "use by."

Reference: FDA Food Code

Public Health Significance: [Completely describe what impact this Issue will have on food service, retail food or vending.]

d. **Date marking is the mechanism by which the Food Code addresses time, in addition to temperature, as a control for the growth of L.m. in refrigerated, ready-to-eat, potentially hazardous food. Controlling the L.m. hazard must be achieved in a valid manner that is practical, can be reasonably implemented by industry, and can be enforced by regulatory agencies.**

Recommended Solution: [State as precisely as possible what action you would like the Conference to take to address this Issue. Cite the **specific** type of change, location (page and line), and exact wording to be changed in a document, such as the Food Code or Conference document.]

Taking into account the on-going risk assessment initiatives, particularly with respect to L.m., the Conference should evaluate the date marking provision found in the 1999 Food Code at Section 3-501.17 and recommend Code language that reflects current science, provides adequate consumer protection, and provides guidance on the concerns listed above.

FDA will offer a proposal for the Conference to consider.

Submitter's Name: Retail Food and Interstate Travel Team (Jeanette Lyon)

Agency/Company: CFSAN, Food and Drug Administration

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Attachment A

YEAR 2000
CONFERENCE FOR FOOD PROTECTION
ISSUE SUBMISSION FORM

Issue No. 2000-I-16
Internal # 098

Title: PHF, expiration date labeling

Council Action:	**No Action**	_____	**Accepted**	_____	**Amended**	_____
Delegate Action:	**No Action**	_____	**Accepted**	_____		

Issue you would like the Conference to consider:
Section 3-501.17 (A) and (E) "Ready-to-Eat, Potentially Hazadous Food, Date Marking", requires that all PHFs held over 24 hours be labeled with a 7 calendar day or 4 calendar day expiration date. Many restaurant chains, and other food service establishments, have long established systems of quick use, and product rotation, labeling and marking, that do not exactly match the requirements but that that do meet the purpose and spirit of the section code.

There is no provision for allowance for the use of these long standing rotation and identification systems in place of the expiration date requirement.

Public Health Significance:
It is believed that the recommended addition will positively affect public health protection as the systems used will be simplified and more easily delivered, while still allowing easy oversight by regulatory officials and establishment management. Rather than specify a "one system fits all" approach, this lets the restaurant chain or establishment identify to both the employees and regulatory officials the means of rotation and age identification.

Recommended Solution:
Modify the wording of section 3-501.17 (E) to include a new paragraph as follows:
A food service establishment shall also meet the provisions of Paragraphs (A)-(D) of this section by submitting an alternative identification method that 1) easily identifies the preparation or opening date of each container, and 2) details the system to assure all specified products are less than 7 or 4 days.

Submitter's Name: Francis Ferko, Co-chair, NCCR Food Safety Task Force

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Attachment B

Date Marking Committee
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Attachment A to Issue 03-11 follows on next page

Please note: This document is scanned. Digital images may be viewed at
www.kenkut.com/bacteria.html

KENKUT®
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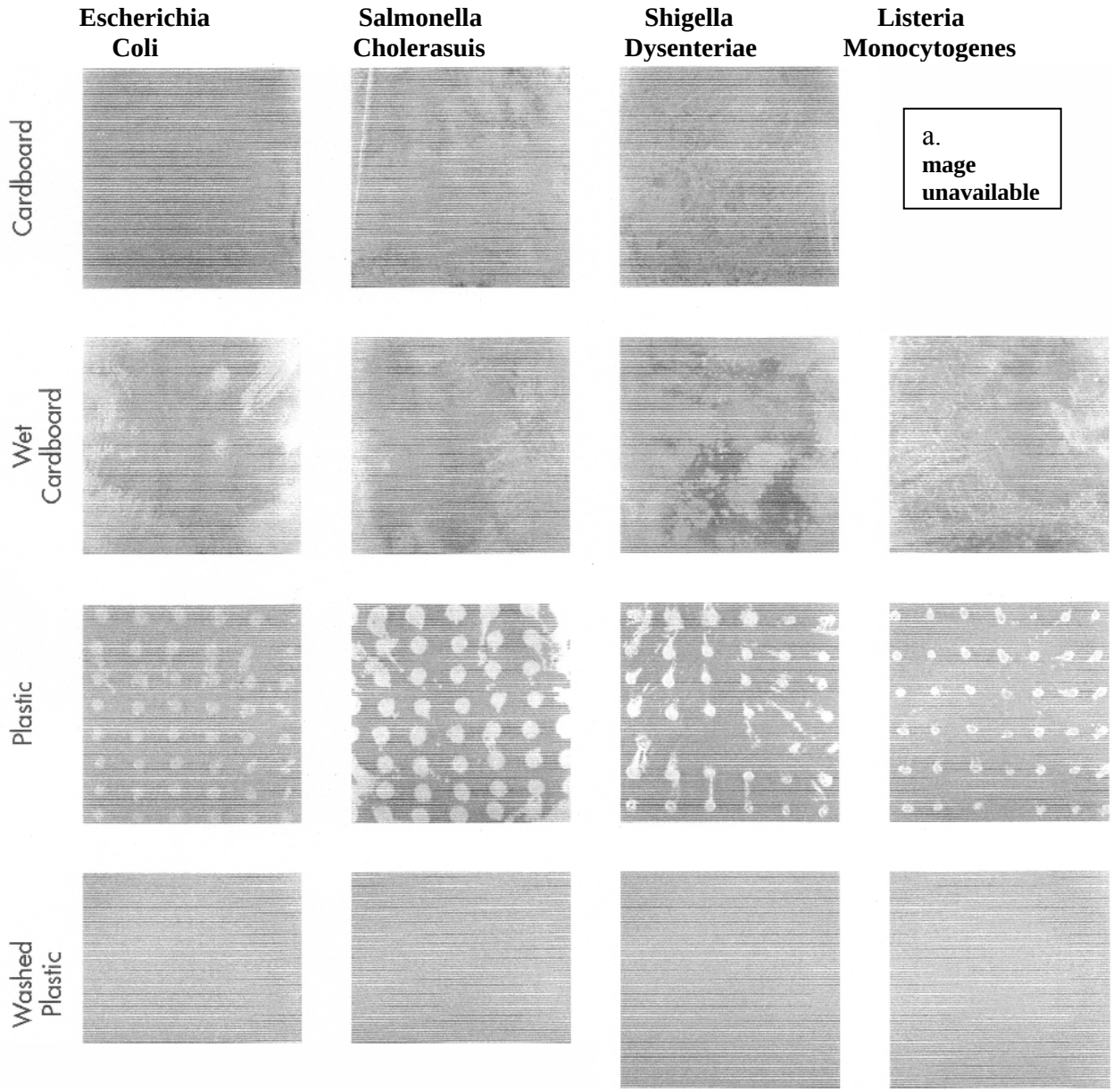
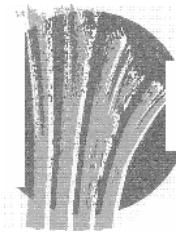
PATHOGEN CROSS CONTAMINATION ALERT

(viii) *Independent laboratory study proves that E. Coli, Salmonella, Shigella and Listeria grow and flourish in the cardboard cutter boxes for commercial plastic film and aluminum foil under normal kitchen environmental conditions.*



Images provided by Marin Biologic, Tiburon, CA

KENKUT Products Inc. P.O. Box 704, San Anselmo, CA 94979
Contact: Ken Krall Email: Ken@chefmall.com 800- 248- 6172



FOOD DEVELOPMENT CENTER

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CERTIFICATE OF ANALYSIS
FOOD MICROBIOLOGY

May 14, 1997

Ken Krall
Kenkut Products Inc.
P.O. Box 704
San Anselmo, CA 94979
ph:(415)454-2311
fax:(415)459-2311

Dear Ken,

Please find below the microbiological results of the cardboard samples received on April 24, 1997
nd analyzed on April 28, 1997. Condition of the samples received - dry and sealed

I I

Client Identification number	**FDC sample number**	**SPC (CFU/g)***	***E. coli* (CFU/g)**	***Salmonella* spp. (/25 g sample)**	***Listeria* spp. (/25g sample)**
item #1	971156	94,000	<10	negative	negative
item #2	971157	350,000	<10	negative	negative
item #3	971158	7400	<10	negative	negative
item #5	971159	27,000,000	<10	negative	negative

* CFU/g = colony forming units per gram of sample

Item #5 is 27 times the minimum amount of bacteria to begin food spoilage

Method:	Reference:
SPC method SOP-MICR-104	Health Protection Branch method MFHPB- 18
E. coli SOP-MICR-107	Health Protection Branch Method MFHPB-27
Salmonella method SOP-MICR- 110 -*Salmonella* in Eggs	Health Protection Branch MFO-6
Listeria monocytogenes isolation from food	Health Protection Branch MFBPB-30

Thank you for the opportunity to be of service. If you have any questions, please do not hesitate to call.

Sincerely,

Mavis McRae
Supervisor - Food Microbiology
Analytical Services

Dr. Jurek Zawistowski
Manager
Analytical Services

H.\,MICRO\PROJECTS\1244\REPMY24.WPD

Project 1244

Analytical results relate only to the items tested. This certificate of analysis may not be reproduced for any purpose except in full without the written approval of FDC.

Box 1240 - 810 Phillips Street - Portage la Prairie, Manitoba 0 R1N 3J9

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MARIN BIOLOGIC
CONTRACT RESEARCH LABORATORIES

Quantitation of Growth of Shigella Dysenteriae, Salmonella choleraesuis, Listeria monocytogenes, Esherichia coli on Cardboard and ABS Plastic Surfaces

Final Report Submitted to:

Mr. Ken Krall
President
KenKut Products, Inc.
P.O. Box 704
San Anselmo, CA 94979

PH: 415-454-2311
FAX: 415-459-2311

Submitted by:

Tania L. Weiss, Ph.D.
Marin Biologic
3152 Paradise Drive
Tiburon, CA 94920

DATE: June 10, 1998

3152 PARADISE DRIVE TIBURON, CALIFORNIA 94920
PHONE: 415-435-6636 FAX: 415-435-9299

SUMMARY:

Five infectious bacteria commonly found as kitchen/food contamination were tested to determine whether growth on ABS plastic was inhibited compared to cardboard and whether washing the plastic with kitchen antibacterial soap inhibited bacterial growth. The experimental design was to transfer an array of bacteria as discrete drops on to the plastic or cardboard. The plastic and cardboard materials were incubated overnight then blotted onto a sterile agar plate that would support bacterial growth. Data show that although the bacteria grew little on plastic, if at all, they were still present. Even though the bacteria were dried on the plastic, when the plastic was blotted onto sterile agar growth medium, the inoculate was able to sustain growth. However, data show that the antibacterial soap reduced/eliminated the bacterial contamination on the plastic, so that when plastic was blotted onto sterile agar growth medium, there was no bacterial growth. Data also show that moist/wet cardboard is a rich medium for bacterial growth. The results demonstrate that a "lawn" of bacteria grew on the sterile agar growth medium when the cardboard was blotted on the surface.

METHODS and RESULTS:

1 . Organisms:

Shigella dysenteriae	ATCC #13313
Escherichia coli	ATCC #15922
Salmonella choleraesuis	ATCC #13311
Listeria monocytogenes	ATCC #51414
Campylobacter jejuni	ATCC #49943

2. Lyophilized bacteria were resuspended in LB broth and incubated at 37°C overnight to achieve a growing culture. The Campylobacter did not grow. To determine the concentration of bacteria which would grow as discrete,individual colonies, serial dilutions of the E. coli were made (1 /10, 1 /100,1 /1000, 1 /10,000, 1 /100,000, 1 /1,000,000) and 1 00ul of culture were plated onto 100CM² agar plates. The plates were incubated overnight at 37°C. The two concentrations resulting in individual colonies were 1/100,000 and 1/1,000,000. The optimum concentration was approximately 1/500,000.

3. All the bacteria were diluted to 1/500,000 and 1 /1,000,000 and 100ul of culture were transferred to the agar plates and incubated overnight at 37°C. Depending upon the bacterial strain, the concentration was appropriate, but there was uneven distribution of colonies. Some colonies were very close together.

   A blot of the bacteria colonies was made by laying the plastic or cardboard upon the agar plate in order to transfer the bacteria to the test material. The cardboard was pretreated by applying water to all surfaces including between the two faces in the corrugated portion. The plastic and cardboard were grown in a moist atmosphere, at 37°C overnight. The bacteria were present on the plastic but did not grow. The cardboard contained a lawn of bacteria. These plates were kept at 4°C until they were digitally imaged.

4. A different approach was used to minimize the visual bacterial detection on the plastic. Using a multichannel pipettor, less than I ul was applied as individual spots directly onto the plastic and dried cardboard. The plastic was incubated overnight at 37°C, in a moist atmosphere that was allowed to dry out. The cardboard was "floated" on water, and incubated in a moistatmosphere overnight at 37°C. The bacteria appeared as dried spots on the plastic. On some of the cardboard pieces, the bacteria could not be visualized. On others, the drops of bacteria were remained as drops rather than soak into the cardboard. One replicate set of plastic samples was washed with a dilute antibacterial soap. The washing process included squirting the samples five times with soap then squirting with purified water to rinse off the soap. The samples were air dried before blotting ontothe agar plates.

   The plastic and cardboard pieces were blotted onto a sterile agar plate. The plates were incubated at 37°C overnight and imaged using a digital camera imaging system. The photos were touched-up in Adobe Photoshop and replicated in floppy discs and hard copy. The agar plates blotted with the unwashed plastic materials resulted in the growth of small individual spots of bacteria replicating the pattern of the bacterial application to the plastic. The agar plates blotted with the washed plastic materials supported no growth of bacteria. The agar plates blotted with some of the cardboard showed a "lawn" of bacteria. In agar plates blotted with other cardboard samples a replicate pattern of the bacterial application to the plastic was observed, however, the colonies were larger than that on plastic indicating growth.

CONCLUSIONS

The ABS plastic did not support the growth of the various bacteria, however, the bacteria remained viable after 24 hours even after the medium in the drop dried out. The wet cardboard is a rich medium supporting vigorous growth of the bacteria. Washing the ABS plastic with antibacterial soap was an effective means to reduce the organisms. In this case, all the bacteria were eliminated. In the cardboard samples where the bacteria were applied to wet cardboard rather than dry cardboard, and incubated in a moist atmosphere overnight at 37°C, a thicker "lawn" of bacteria was observed. This suggests that either wet cardboard supports better growth than moist cardboard or the results may be due to the fact that the bacteria spread out during the application process, rather than soak into the cardboard as discrete spots.

FOOD ALLERGY

WHAT WE NEED TO KNOW

Customers allergic to some foods need our special attention. Understanding the food allergy basics on this chart will help us ensure our customers have a pleasant and safe dining experience. When a customer asks whether a certain food or ingredient is included in a menu item, you *must* answer their questions carefully and accurately. If you are unsure of the exact ingredients of a particular food, say so and refer the question to the manager on duty.

MOST COMMON ALLERGENS

The foods most likely to cause serious reactions in people with allergies are:

MILK

EGGS

FISH, SHELLFISH

WHEAT

SOY

PEANUTS

OTHER NUTS

SYMPTOMS OF ALLERGIC REACTIONS

Sometimes an allergic reaction can be so severe it may even cause death.

Call 911 and notify management if a customer experiences any of the following symptoms:

Note: Spanish language version of poster printed on reverse of original

- ✖ loss of consciousness
- ✖ wheezing and hoarseness
- ✖ shortness of breath
- ✖ tightening of the throat (difficulty swallowing)
- ✖ swelling of the face, eyelids, lips, hands or feet
- ✖ hives (welts)
- ✖ itching in and around the mouth, face, scalp, hands and feet

WHAT WE NEED TO DO

We can help prevent serious allergic reactions if we:

- ✖ Carefully clean utensils, containers, and grills (to avoid cross-contamination between foods)
- ✖ When in doubt, refer customers' food allergy questions to management

FOR MORE INFORMATION

American Academy of Allergy, Asthma and Immunology
611 East Wells Street
Milwaukee, WI 53202
1-800-822-2762

The Food Allergy Network
10400 Eaton Place
Suite 107
Fairfax, VA 22030
1-800-929-4040
http://www.foodallergy.org/

International Food Information Council Foundation
1100 Connecticut Avenue, N.W.
Suite 430
Washington, D.C. 20036
http://ificinfo.health.org

National Restaurant Association
1200 Seventeenth Street, NW
Washington, DC 20036

Bacillus cereus Fact Sheet

compiled by M. Ellin Doyle, Ph.D.
Food Research Institute, December 2001

Introduction

Bacillus cereus was reported as the cause of 14 outbreaks and 691 cases of foodborne illness in the USA during 1993–1997. Improper holding temperature was identified as a contributing factor in 11 outbreaks (*9*). Since *B. cereus* usually causes mild to moderate symptoms, the true incidence of foodborne infections is probably much higher than the reported incidence and is estimated at 27,360 cases yearly in the USA (*30*). *Bacillus cereus* has been identified as the cause of 42% of foodborne disease outbreaks in canteens serving the German military (*21*).

Bacillus cereus spores occur in soil, air, and dust. The spores are commonly detected in spices and herbs, suggesting their presence in foods containing these ingredients. *Bacillus cereus* is also a problem in the dairy industry and is infamous for multiplying in cooked rice left at room temperature (*3*). A survey of ready-to-serve moist foods from a cafeteria in Washington D.C. revealed that *B. cereus* spores were present in 88–100% of noodles, mashed potatoes and rice, in 50–83% of cooked vegetables, and in 25–75% of gravies sampled (*18*). Lower levels of contamination were reported from a similar survey in Italy (*2*).

Bacillus cereus grows in the presence and absence of oxygen (aerobically and anaerobically) at temperatures of 39–122°F, with optimal growth at 82.4–95°F. Growth rates at particular temperatures depend on acidity and concentrations of sodium chloride, sodium nitrite, and other inhibitors and nutrients in food or growth medium (*5, 6, 7*). Some other species of *Bacillus* grow at temperatures exceeding 140°F (*14*).

Cooking destroys vegetative bacteria, but spores of foodborne bacterial pathogens such as *B. cereus* are very heat-resistant and usually cannot be completely destroyed by heat without compromising the nutritional value and/or organoleptic properties of foods. There is a wide range of natural heat resistance of *B. cereus* spores (*13*). Heat resistance of spores is decreased by acidity (*8, 11, 17, 24, 26*). Heat resistance is increased by low water activity (e.g., high salt concentrations) (*27*) and by gradual heating, which allows some adaptation to heat (*10, 15, 27*). *Bacillus cereus* spores are also more heat resistant in phosphate buffer than in soybean oil (*31*).

Spores may be activated by heat and can germinate and grow if the food is maintained at a permissive temperature. Studies have demonstrated that some warmers do not always keep all parts of food hot enough to prevent growth and toxin production by activated spores (*7*).
To prevent the growth of undesirable microorganisms of public health significance in foods that can support their growth, the Food Code recommends that hot foods be maintained at a temperature of 140°F or above (*1*).

Spore Germination and Growth in Laboratory Media

Exposure to heat during cooking may activate spores but can also injure them, and germination will only occur if the damage is repaired. Heat activation is not required for all *B. cereus* strains. The optimal temperature for germination appears to be 86°F although germination has been reported to occur at a wide range of temperatures (*12*).

Acidity (pH <6.7) and a low water activity (<0.98) inhibit germination and growth of *B. cereus* after heating (*10, 11*).

Initial stages of germination have been reported to occur in laboratory media at temperatures as high as 138°F (*22*).

Spore Germination and Growth in Foods

In cooked rice, *B. cereus* spores germinated and grew at temperatures as high as 122°F. However, percent germination decreased and generation time increased as temperatures increased above 40°F (*20*). No germination or growth was observed in cooked rice maintained at 140°F (*28*).

Sodium chloride, at concentrations of 2 and 4%, inhibited growth of *B. cereus* in mashed potatoes, but this effect was stronger at lower temperatures (*25*). Some organic acids, such as lactates, can prevent growth of *B. cereus* in beef goulash at 50–68°F (*4*). Powdered lacticin 3147 (a bacteriocin produced by *Lactococcus lactis*) reduced by 80% the number of *B. cereus* in soup (*32*).

Models for Spore Germination and Growth

Several research groups have accumulated experimental data and developed models to predict:

- Heat resistance of *B. cereus* spores as affected by pH (*11, 17*)
- Heat resistance and germination of *B. cereus* spores as affected by isothermal and nonisothermal heating (*15, 16*)
- Growth from *B. cereus* spores in boiled rice (*29*)
- Growth of *B. cereus* as affected by eight organic acids at pH 5.25 (*19*)
- Recovery and lag time to growth of *B. cereus* as a function of duration and temperature of heating (*23*)

Data from these papers and others on the growth of *B. cereus* were used by USDA researchers to develop interactive pathogen modeling programs available on the internet. Several parameters, including temperature, pH, sodium chloride and sodium nitrite concentrations, can be varied and growth curves generated (*33*).

Summary

Viable, activated spores may be present in cooked foods and may start growing if temperature decreases to 122°F. Generation times of some *B. cereus* strains are as short as 11 minutes. Therefore, it is important to maintain the holding temperature of all parts of a food above the maximum temperature that allows growth. If these foods are to be kept for another day, they must be cooled rapidly through the permissible temperature range for growth (41–122°F) to prevent multiplication and toxin production. There are some strains of *B. cereus* which can grow at refrigeration temperatures, but lag times are as long as 9–10 days (*6, 13*).

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Attachment B to Issue 03-16

Clostridium botulinum Fact Sheet

compiled by M. Ellin Doyle, Ph.D.
Food Research Institute, December 2001

Introduction

Clostridium botulinum was reported as the cause of 13 outbreaks and 56 cases of foodborne illness in the USA during 1993–1997. Improper holding temperature was identified as a contributing factor in nearly half of these outbreaks (*3*). When these bacteria grow in foods they produce a neurotoxin, and this toxin frequently causes death or severe symptoms requiring long periods of hospitalization before recovery. The true incidence of foodborne botulism poisonings has been estimated at 58 cases yearly in the USA (*17*). Although the number of cases is small, effects on health and economic costs of outbreaks are substantial.

Clostridium botulinum is commonly present in the environment and grows in the absence of oxygen (anaerobic). Proteolytic strains (Types A, B, and F) produce more heat-resistant spores than non-proteolytic strains (Types B, E, and some F); only non-proteolytic strains grow and produce toxin at refrigerator temperatures. The generally accepted maximal growth temperatures for proteolytic and non-proteolytic strains are, respectively, 118.5 and 113°F. However, these numbers vary somewhat depending on the acidity and composition of the food or growth medium.

Cooking destroys vegetative bacteria, but spores of foodborne bacterial pathogens such as *C. botulinum* are very heat-resistant and usually cannot be completely destroyed by heat without compromising the nutritional value and/or organoleptic properties of foods. Thermal destruction of *C. botulinum* spores does not follow first-order kinetics, indicating that some spores are more heat resistant than others (*15, 20*). Heat resistance of spores is greater at higher pH values (*14, 16*) and fat content (*18*) and lower water activity values (*19*) and sodium chloride (*11, 14*) and sodium pyrophosphate concentrations (*14*). Generally, spores are more resistant to heat in foods than in test solutions used in the laboratory (*12*).

Spores are activated by heat and will germinate and grow if cooked food is maintained at a permissive temperature. In laboratory experiments, exposure of *C. botulinum* spores to 176°F for 10 min activates them. If the hot-holding temperature of cooked foods is not hot enough to prevent germination and growth, then activated spores may grow and produce toxin in foods.

To prevent the growth of undesirable microorganisms of public health significance in foods that can support their growth, the Food Code recommends that hot foods be maintained at a temperature of 140°F or above (*1*).

Spore Germination and Growth in Laboratory Media

Following heat activation, spores go through a process of germination and then start outgrowth and produce toxin if environmental conditions are suitable. Experiments have demonstrated that germination of some non-proteolytic strains of *C. botulinum* proceeds rapidly at 122°F (*8*) and germination of some proteolytic strains can occur at temperatures up to 158°F (*21*). Germination kinetics of proteolytic strains of *C. botulinum* spores have been studied as a function of temperature (59–86°F), pH (5.0–6.5), and sodium chloride (0.5–4.0%). Increasing sodium chloride concentrations inhibited germination, especially at low temperatures and/or pH values. Germination was also very slow or undetectable at pH 5.5 (*22*).

Although spores germinate at higher temperatures, there appears to be no appreciable growth until temperatures have fallen below 119°F (proteolytic strains) or 113°F (non-proteolytic strains). Proteolytic *C. botulinum* strains grow in laboratory media at 118.4°F but not at 122°F (*13*). Lower pH and higher sodium chloride concentrations inhibited growth of non-proteolytic *C. botulinum* at lower growth temperatures (<59°F) (*6*). Other factors also inhibiting growth and toxin production include sodium lactate (*10*), sodium nitrite, sorbates, and some other preservatives (*9*). Some of these compounds are commonly used in preserved meats, and it may or may not be feasible to use them to limit growth of *C. botulinum* in some cooked foods.

Heat may injure spores and then germination occurs only if the damage is repaired during growth in a nutrient-rich medium. It is important to note that there is some variability in tolerance to environmental conditions in a population of spores and that certain conditions, such pH 5.5, may retard germination but do not significantly affect growth of vegetative cells (*2*). Therefore, the cells arising from the few spores that germinate at this pH will, in time, grow and produce toxin.

Spore Germination and Growth in Foods

Foods are complex systems which encompass important variables that may not be tested in carefully controlled laboratory experiments. Therefore, it is important to study pathogen survival in foods under realistic cooking and hot-holding conditions. However, there is little relevant data available on potential for germination and outgrowth of *C. botulinum* in foods at hot holding temperatures.

Addition of some inhibitory substances to a food may provide a hurdle to bacterial growth if temperature control is inadequate. Bacteriocin-producing lactic acid bacteria can inhibit growth of *C. botulinum* in gravy at 59°F, but experiments have shown that they may not be effective at higher temperatures (77–95°F) (*5*).

Models for Spore Germination and Growth

Several research groups have accumulated experimental data and developed models to predict:

- Germination kinetics of proteolytic *C. botulinum* spores as a function of incubation temperature, pH, and sodium chloride concentration (*4*).
- Growth of proteolytic *C. botulinum* at 53.6–118.4°F in laboratory media (*13*).
- Growth from spores of non-proteolytic *C. botulinum* as a function of temperature, pH, and sodium chloride concentration (*7*).

Data from these papers and others on the growth of *C. botulinum* were used by USDA researchers to develop interactive pathogen modeling programs available on the internet (*24*, *25*). Various combinations of preservatives, salts and acid may effectively inhibit growth of *C. botulinum* (*23*).

Summary

Vegetative cells of *C. botulinum* are killed by cooking temperatures but spores survive and can germinate, grow, and produce toxin if environmental conditions are suitable. Since the maximum temperature for growth in laboratory media has been measured as 118°F, hot holding at the recommended temperature of 140°F should prevent outgrowth of cells from spores. However, experimental data indicate that spores can start germinating at temperatures at or below 150–170°F. If the temperature of a part of hot-held food declines to about 118°F, then the germinated spores could start outgrowth. It is important to note that heat resistance of *C. botulinum* is often greater in foods than in laboratory media and is greater in foods that are less acidic, have higher concentrations of fat or lower levels of salts. As yet there are not published studies which report the potential for growth of *C. botulinum* in cooked foods maintained for several hours at temperatures above 118°F and below 140°F.

Food Research Institute, University of Wisconsin–Madison, 1925 Willow Drive, Madison, WI 53706 www.wisc.edu/fri/

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Clostridium perfringens Fact Sheet

compiled by M. Ellin Doyle, Ph.D.
Food Research Institute, December 2001

Introduction

Clostridium perfringens was reported as the cause of 57 outbreaks and 2,772 cases of foodborne illness in the USA during 1993–1997. Improper holding temperature was identified as a contributing factor in 46 outbreaks (*10*). Since *C. perfringens* usually causes mild to moderate symptoms, the true number of cases of foodborne infections is probably much higher than the reported incidence and is estimated at 248,520 cases yearly in the USA (*19*).

Although *C. perfringens* is widespread in the environment, most of the strains involved in foodborne illness are more heat resistant than strains isolated from the general environment. *Clostridium perfringens* grows in the absence of oxygen (anaerobic) at temperatures ranging from 53.6 to 125°F. Growth is rapid, even at high temperatures, with a reported generation time of 6.6 min at 109.4°F in beef cubes. Growth rates depend on the acidity and the concentrations of sodium chloride, sodium nitrite, and other inhibitors and nutrients in a food. Usually, meat is the vehicle for *C. perfringens* food poisoning because this bacterium requires the presence of 13 amino acids that it cannot synthesize (*2, 6, 7, 17*). However, an outbreak of *C. perfringens* poisoning associated with tofu (soy bean curd) was reported from Japan (*20*).

Cooking destroys vegetative bacteria, but spores of foodborne bacterial pathogens such as *C. perfringens* are very heat-resistant and usually cannot be completely destroyed by heat without compromising the nutritional value and/or organoleptic properties of food. Spores can survive several hours of boiling and are activated by heat, so that they can germinate and grow if food is maintained at a permissive temperature. This may present a problem for hot-held cooked foods: if the holding temperature is not hot enough, activated spores can grow and produce toxins.

To prevent the growth of undesirable microorganisms of public health significance in foods that can support growth their growth, the Food Code recommends that hot foods be maintained at a temperature of 140°F or above (*1*).

Spore Germination and Growth in Laboratory Media

A temperature of 221°F injures spores, but, if the medium contains enough nutrients, repair can occur as the temperature decreases (*4*).

Cell growth has been reported at temperatures up to 125°F. When *C. perfringens* is heated to temperatures just above 122°F, it may appear to die off. But if incubation is continued for several hours longer, viable cells reappear. This has been dubbed the "Phoenix phenomenon." During the stage when no viable cells can be cultured, the heat-injured cells are repairing themselves and then they grow and increase in number (*24*).

If cells grow at higher temperatures (113 vs 98.6°F), they are more likely to survive short cooking at modest temperatures (*23*). Curing salts, in concentrations used commercially, prevent growth of *C. perfringens* at pH ≤6.2 (*12, 22*).

Spore Germination and Growth in Foods

Effects of various factors, including holding temperature, pH, Eh, water activity, curing salts, other additives, protein supplements, and presence of other bacteria, on growth of *C. perfringens* in foods have

been reviewed. Growth generally does not occur in meat at temperatures ≤59°F or >122°F (*11*).

Generation times in ground beef can be very rapid, with one report of 6.6 min at 109.4°F (*17*).

Surface layers of cooked meat are of particular concern when foods are being held hot prior to serving customers. When meat loaf slices were kept uncovered in an incubator at 140°F, *C. perfringens* was able to grow slowly on the surface because evaporative cooling reduced the temperature on the surface (*18*). Surfaces of gyros (beef or lamb broiled on a spit) were heated sufficiently during cooking to kill vegetative bacteria, but after cooking and cooling high concentrations of *C. perfringens* were recovered from samples taken just underneath the surface of the meat (*9*). This points out the necessity for rapid cooling if meat is to be kept overnight for serving the next day.

Clostridium perfringens grew on beef cubes at 124°F but not at 128°F (*7*). Heating of beef cubes (8×8×8 cm) for 24 hours (as a tenderizing method) at 131°F did not allow growth of *C. perfringens*. But some growth did occur if beef cubes were larger (*16*).

Germination and growth of heat-activated *C. perfringens* occurred in chili within 2 hours of incubation at 118.4°F (*5*).

Heat resistance of vegetative cells can be increased up to three-fold by a short sublethal heat shock. If such temperature abuse has occurred then foods may need to be cooked longer or at higher temperatures to destroy vegetative *C. perfringens* (*13, 15, 21*).

Some organic acids, such as lactates, can prevent growth of *C. perfringens* in beef goulash at 59–77°F (*3*).

Hazard analysis of roast beef preparation in foodservice establishments was investigated, and it was found that vegetative organisms could have survived in the center of some roasts. In about 25% of cases, roasts were held in hot storage devices with inadequate temperature control, which would have allowed spore germination and significant bacterial growth (*8*).

A review of several studies on hot holding of meats and other cooked foods concluded that careful maintenance of temperatures greater than 140°F would assure safe foods (*25*). Even though *C. perfringens* apparently does not grow on meat at temperatures above 124°F, there is some variability in heat resistance of different strains grown under different conditions and some variability in the efficiency of hot-holding devices.

Models for Spore Germination and Growth

Several research groups have accumulated experimental data and developed models to predict:

- Growth rate as a function of temperature (*26*)
- Interactive effects of temperature, pH, sodium chloride, and sodium phosphate on growth rate (*14*)

Data from these papers and others on the growth of *C. perfringens* were used by USDA researchers to develop interactive pathogen modeling programs available on the internet. Several parameters, including temperature, pH, sodium chloride and sodium nitrite concentrations, can be varied and growth curves generated (*27, 28*).

Summary

Clostridium perfringens may pose the greatest threat of bacterial foodborne illness from foods which are kept hot for several hours before serving. Not only do its spores survive cooking, but vegetative cells grow rapidly at relatively high temperatures (up to about 123°F). However, *C. perfringens* requires 13 amino acids for growth and therefore is most likely to be a problem in protein-rich foods, particularly those containing meat or soy proteins. Cooking can activate spores, which may germinate and grow if the holding temperature of any part of a food decreases enough to permit growth. The activated spores can also grow if food is to be saved for the next day and is cooled slowly during refrigeration.

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Attachment A to Issue 03-17

2002 Conference for Food Protection
Council III
Potentially Hazardous Food (PHF) Definition Committee Report - Final

In 2000, the Conference for Food Protection recommended the PHF Definition Committee of Council III be formed for deliberation of the definition of PHF and that the committee report back to the CFP Executive Board at the Board's next regularly scheduled meeting in September 2000.

The co-chairs of the PHF Definition Committee report that the committee did not have the opportunity to meet its charges assigned in 2000. The committee was aware of the work being performed by the Institute of Food Technologists (IFT) during 2001 under a contract with CFSAN. In lieu of repeating that work, the committee attempted to devise strategies for inspectors and operators to measure scientific criteria that would be fostered by the IFT report. The co-chairs of the PHF Definition Committee had the opportunity to review and comment on 2 early drafts prepared by IFT. —

The IFT report has been finalized and received by CFSAN in early January. The PHF Definition Committee believes it is extremely important for CFP to review and comment on the IFT report and to keep the CFP involved in the ultimate resolution of this complex issue.

The PHF Definition Committee should be continued and charged with responding in a timely manner to the Executive Board of the CFP with comments on the IFT report. This input from the CFP will ensure that the broad considerations that the regulators, food service and retail food industries face when considering which foods must be temperature controlled for safety will be conveyed to FDA. The IFT report is attached electronically with the committee's Issue submission.

Rationale for issue submission:

The PHF Definition Committee has submitted an issue to CFP 2002 for the CFP to recommend that the PHF Definition Committee be continued beyond the April 2002 meeting for the purposes of reviewing the IFT report, deliberating the definition of PHF, and making recommendations for actions by the CFP Executive Board and/or the 2004 CFP.

Respectfully Submitted By:

Council III PHF Definition Committee
Carl Custer & Alfred Bugenhagen, Co-chairs

January 14, 2002

Attachment B to Issue 03-17 can be found by going to the CFP website located at www.foodprotect.org and locating the IFT Report under "Other Documents"

CALCULATING THE TOTAL GROWTH OF BACTERIA IN COOKED FOOD USING THE FDA CODE CONTROLS

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Hospitality Institute of Technology and Management

Click here to view a copy of this paper in PDF.

h. The FDA Food Code tells us that cooked food can be held at 41ºF for 7 days or at any temperature between 41 and 140ºF, if the time is limited to 4 hours. This, of course, is scientifically wrong, because pathogen growth actually starts at about 29.3ºF and stops, for all practical purposes, at 125ºF.

Using the well-established Radkowsky bacterial growth predication equation (Radkowsky, 1983), and setting 30ºF as the start point, 41ºF for 7 days as a second point, putting 4 hours at about 115ºF (because it fits the equation), and setting the upper growth limit at 125ºF, I calculated the equivalent growth times from 30 to 125ºF (Snyder, 1998). Remember, the FDA does not refer to specific bacteria. This is based on FDA code time-temperature controls. The FDA has never cited a source for the numbers in the code. It appears to be 10 generations of *Listeria monocytogenes* at 41ºF and 10 generations of *Salmonella* / *Staphylococcus aureus* at 115ºF. (See Table 1.)

Table 1. Maximum Holding Times at Specified Temperatures

°F	°C	1 Multiplication of Pathogens	SAFETY LIMIT* 10 Multiplications of Pathogens
<30	<-1.1	Safe	Safe
30	-1.1	297.14 hours	123.8 days
35	1.7	46.34 hours	19.3 days
40	4.4	17.99 hours	7.5 days
41	5.0	15.55 hours	6.5 days
45	7.2	9.49 hours	4.0 days
50	10.0	5.85 hours	2.4 days
55	12.8	3.96 hours	1.7 days
60	15.6	2.86 hours	1.2 days
65	18.3	2.16 hours	21.6 hours
70	21.1	1.69 hours	16.9 hours
75	23.9	1.36 hours	13.6 hours
80	26.7	1.12 hours	11.2 hours
85	29.4	0.93 hour	9.3 hours
90	32.2	0.79 hour	7.9 hours
95	35.0	0.68 hour	6.8 hours
100	37.8	0.59 hou	5.9 hours
105	40.6	0.52 hour	5.2 hours
110	43.3	0.47 hour	4.7 hours
115	46.1	0.46 hour	4.6 hours

120	48.9	0.56 hour	5.6 hours
125	51.7	3.10 hours	31.0 hours

Now, how does a foodservice operator use this? I have developed a simple calculation sheet so that the operator can find the equivalent growth in a process between 30 and 125ºF. First, the operator must collect times and temperatures for a process and put it in the blank table (Table 2). Then, for each temperature, the operator looks up the growth / hour from Table 3, fills in this information on Table 2, and calculates the growth for each step in the process. When the growth reaches 10 generations, the operator must have used up the food. This is exactly equivalent to what the FDA allows with 41ºF for 7 days or 4 hours at 115ºF.

Table 2. Calculation Worksheet

Description	Temp. (F)	Time(hr.)	Multiplication rate / hr	Multiplication	Accumulated multiplication

Table 3. Calculated Rates at Specified Temperatures

Temp. (F)	Multiplication rate / hr.	Temp. (F)	Multiplication rate / hr
<30	Safe	82	0.965
30	0.003	83	1.000
35	0.022	84	1.036
40	0.056	85	1.073
41	0.064	86	1.110
42	0.074	87	1.148
43	0.084	88	1.186
44	0.094	89	1.225
45	0.105	90	1.265
46	0.117	91	1.305
47	0.130	92	1.346
48	0.143	93	1.387
49	0.157	94	1.429
50	0.171	95	1.472
51	0.186	96	1.515
52	0.202	97	1.558
53	0.218	98	1.602
54	0.235	99	1.647
55	0.252	100	1.692
56	0.271	101	1.737
57	0.289	102	1.782
58	0.309	103	1.827
59	0.329	104	1.872
60	0.350	105	1.917

61	0.371	106	1.961
62	0.393	107	2.004
63	0.416	108	2.045
64	0.439	109	2.083
65	0.463	110	2.119
66	0.487	111	2.149
67	0.512	112	2.174
68	0.538	113	2.190
69	0.565	114	2.196
70	0.592	115	2.188
71	0.619	116	2.163
72	0.648	117	2.115
73	0.676	118	2.038
74	0.706	119	1.927
75	0.736	120	1.775
76	0.767	121	1.573
77	0.798	122	1.319
78	0.831	123	1.013
79	0.863	124	0.668
80	0.897	125	0.323
81	0.931	126	0.058
		>127.5	Safe

References:

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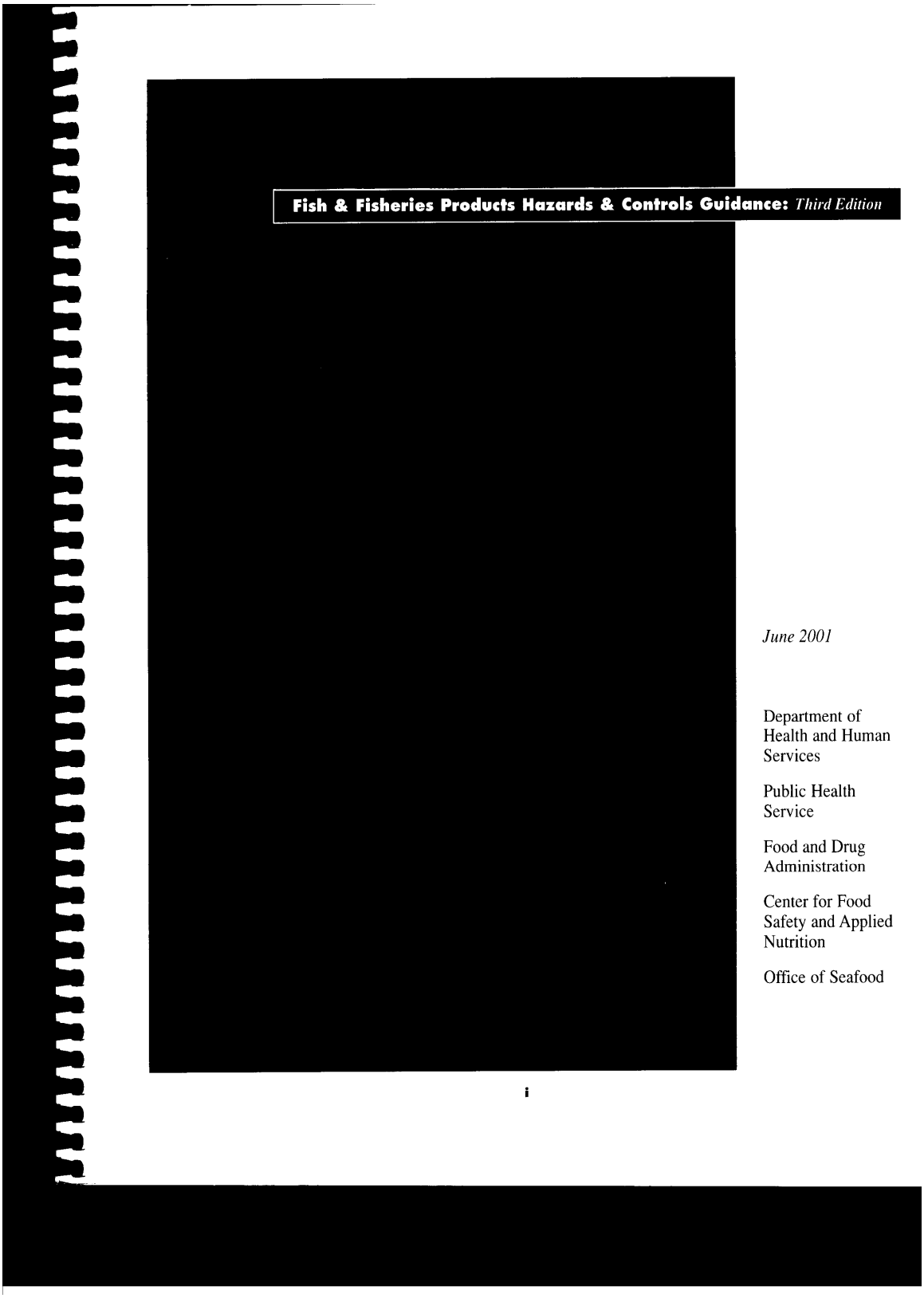
Snyder, O.P. 1998. Updated guidelines for use of time and temperature specifications for holding and storing food in retail food operations. Dairy Food Environ. Sanit. 18(9):574-579.

To HITM home page



Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*

June 2001

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Seafood

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Attachment B to Issue 03-23:

Fish and Fisheries Products Hazards and Controls Guidance: Third Edition Excerpt from page 2:

Scope & Limitations

The control and practices provided in this guidance are recommendations and guidance to the fish and fishery products industry. This guidance provides information that would likely result in a HACCP plan that is acceptable to FDA. However, it is not a binding set of requirements. Processors may choose to use other control measures, as long as they provide and equivalent level of assurance of safety for the product. However, processors that chose to use other control measures (e.g. critical limits) are responsible for scientifically establishing their adequacy.

The information contained in tables in Chapter 3 and in Steps #10 and 11 in Chapters 4-21 provide guidance for determining which hazards are "reasonably likely to occur" in particular fish and fishery products under ordinary circumstances. The tables should not be used separately for this purpose. The tables list potential hazards for specific species and finished product types. This information must be combined with the information in the subsequent chapters to determine the likelihood of occurrence.

Attachment C to Issue 03-23

Market Names	Latin Names	Hazards				
		Biological	Chemical			
		Parasites CHP	Natural Toxins CHP 6	Histamine CHP 7	Chemical CHP 9	Drugs CHP 11
SALMON AND roe (WILD) (FRESHWATER)	*Oncorhynchus spp.* *Salmo salar*	T4 T4				
SALMON AND roe, (WILD) (OCEAN)	*Oncorhynchus spp.* *Salmo salar*				T T	
SANDDAB	Citharichythys sordidus				T	
SANDPERCH	*Mugiloides chilensis* *Parapercis spp.*					
SARDINE	*Harengula spp.* *Sardinella spp.*			T T		
SAUGER	*Stizostedion canadense*					
SAURY	*Cololabis saira* *Scomberesox saurus*			T T		
SCAD	*Caranx mate* *Decapterus spp.* *Selar crumenophthalmus* *Trachurus spp.*	T4 T4 T4 T4				
SCULPIN	*Hemitripterus americanus* *Myoxocephalus polyacanthocephalus* *Scorpaenichthys marmoratus*					
SEA BREAM	*Archosargus rhomboidalis* *Chrysophrys unicolor* *Pagellus spp.*					
SEAROBIN	*Chelidonichthys spp.* *Persistedion niniatum* *Prionotus carolinus* *Pterygotrigla picta*					
SEATROUT	*Cynoscion spp.*	T4				
SHAD and roe	*Alosa spp.*			T	T	

Attachment A to Issue 03-27

REPORT OF THE COUNCIL III BARE HAND CONTACT COMMITTEE
February 1, 2002

Issue Number: 00-01-07
Issue Title: Preventing Contamination from Hands, Section 3-301.11
Recommendation: The Conference recommends a committee be established to develop a report based on review of the statement "when other approved" and to consider the following items:

1) Those risk factors associated with transmission of foodborne illness related to bare hand contact (e.g., direct contact with wet foods, ill workers, etc.)
2) Identify potential examples of the following:
   a) Tasks where bare hand contact cannot be practically avoided; and
   b) Incidental contact where bare hands do not appear to present appreciable risk to consumers.

The committee shall present its report at the 2002 Conference, including its rationale for making recommendations relative to the above issues and guidelines for regulatory approval.
Council Action: Accepted as Amended
Delegate Action: Accepted

The Bare Hand Contact Committee of Council III of the Conference for Food Protection has been in existence since March 2001. Several avenues of communication have taken place via the internet and Yahoo Groups and through conference calls provided by the FDA and by CFP.

The deliberations of the group have not resulted in the consensus sought through the charge to the committee from Council III to review the "except when otherwise approved" clause of the Food Code, but substantive discussions have occurred and some consensus has been achieved among the group.

Neither the concept of regulating via minimizing bare hand contact nor strictly prohibiting bare hand contact was agreeable to all parties. However, there was general agreement that neither of the aforementioned approaches was sufficient as a single means of contributing to an improvement in public health. The group subscribed in general to the opinion of the National Advisory Committee for the Microbiological Criteria for Food that is included within this report.

The Committee dealt with the CFP charge by separating into two subcommittees to look at charges one and two independently. It was hoped that after these two subcommittees dealt with their respective areas, the entire committee could discuss the main point of concern; how the Food Code will be interpreted at the state / local level with regard to No Bare Hand Contact with RTE foods.

The Committee feels that additional discussions should occur to look at practical ways to both protect the public and have multiple barriers to transmission of human pathogens via the food. The Committee requests that the 2002 Conference for Food Protection charges this committee to continue the discussion during 2002 and 2003.

Food Safety and Inspection Service

United States Department of Agriculture
Washington, D.C. 20250-3700

National Advisory Committee on
Microbiological Criteria For Foods (NACMCF)

Updated November 21, 2001

Recommendations on Bare Hand Contact with Ready-to-Eat Foods

National Advisory Committee on Microbiological Criteria for Foods
September 24, 1999

Based on data presented, the National Advisory Committee on Microbiological Criteria for Foods (the Committee) finds that bare hand contact with ready-to-eat foods can contribute to the transmission of foodborne illness. In principle, this transmission can be interrupted.

Available data suggest that a preventable cause of foodborne illness related to bare hand contact is the handling of ready-to-eat foods by foodworkers with a disease or medical condition as defined in section 2-201 in the 1999 Food Code.

The first preventive strategy to interrupt transmission of foodborne illness is the exclusion/restriction of ill food workers from contact with ready-to-eat foods and food contact surfaces. This prevents not only transmission to the public, but also to other employees who, if infected, further extend the chain of transmission.

Exclusion/restriction of ill workers by itself is not sufficient to halt transmission of foodborne pathogens from infected food workers. Persons who are infected but asymptomatic can also transmit foodborne pathogens. Hence, proper handwashing is an essential and integral component of a strategy (such as that outlined in 2-3 of the 1999 Food Code) aimed at interrupting transmission of foodborne pathogens through bare hand contact with ready-to-eat foods. In addition, handwashing helps control cross contamination from other sources.

The Committee concludes that minimizing bare hand contact with ready-to-eat food provides an additional means, of interrupting disease transmission, when used in combination with the exclusion/restriction of ill foodworkers and proper handwashing. However, most members of the Committee deemed the available scientific data insufficient to support a blanket prohibition of bare hand contact with ready-to-eat foods.

Implementation of all three interventions outlined above will require education and motivation of food workers and managers.

The Committee noted that additional research is needed on the benefits, disadvantages, and public health outcomes of bare hand contact with ready-to-eat foods.

CFP Bare Hands Committee
Sub-Committee on Risks

Charge: Summarize current knowledge about bare-hand contact of foods, identify processes and practices that appear to carry more risk, evaluate whether available data are adequate to support or modify existing FDA Food Code provisions regarding bare hand contact with ready-to-eat foods.

Background: Hands can be a source of microbial contamination for ready-to-eat (RTE) foods. There are three primary pathways for contamination of RTE foods by hands:

1. Stool to Hand to Food
2. Raw food to Hand to Food
3. Contaminated surface to Hand to Food

Much of the discussion around the issue of bare hand contact with RTE foods has centered around the issue of infected foodhandlers and contamination of foods by pathogens found in stool. For pathogens with no animal reservoir, such as hepatitis A, Norwalk-like virus, or *Shigella* sp., such a focus is warranted, since human feces provide the primary source of contamination, and infected foodhandlers have frequently been implicated as the cause of outbreaks. For agents such as *Campylobacter* or *Salmonella*, barriers that prevent fecal contamination of hands may not be sufficient to prevent hands playing a role in cross-contamination from raw foods to RTE foods.

This report will summarize current knowledge about bare-hand contact of foods, provide a qualitative ranking of risks and evaluate the adequacy of available data to support or modify existing FDA Food Code provisions.

Data Sources: Both experimental and observational studies bear on the issue of bare-hand contact with RTE foods. Experimental studies include feeding trials to establish infectious doses, inoculation studies to determine the potential for growth and survival of various agents on different types of food, and studies designed to measure the efficiency with which pathogens can be transferred from hands to foods. These studies are typically conducted by University-based researchers and published in peer-reviewed journals.

Observational studies include the results of foodborne disease outbreak investigations conducted by public health officials, and environmental assessments of food processing or food service operations conducted by industry. Results of some outbreak investigations are published in the peer-reviewed medical literature, if the outbreak was very large, important, or novel. A review of this literature can provide valuable insights into the factors associated with foodborne disease outbreaks, but published reports are not representative of most foodborne disease outbreaks.

Foodborne outbreak investigations are primarily conducted by local and state health departments. Each state compiles records of outbreak investigations and CDC compiles these reports on a national level. The most recent data published by CDC covers outbreaks reported from 1993-1997. While these data are national in scope, the completeness of the reports and the quality of the investigations varies markedly from state to state. Several states, including Minnesota, New York and Washington have

systematically compiled and published foodborne outbreak data over long time periods. Thus, reviewing outbreak data from these states provides a more consistent basis for evaluation than does the less well characterized national data.

Observational studies conducted by industry are generally considered proprietary and are not generally available for review.

Outbreak Data:

i. CDC: Since 1973, CDC has maintained a collaborative surveillance program for collection and periodic reporting of data on the occurrence and causes of foodborne disease outbreaks (FBDOs) in the United States. Outbreaks of foodborne disease are reported to CDC by state and local health departments using a standardized report form. The current was approved in 2000, and collects information on multiple contributing factors associated with contamination (15 factors), proliferation/amplification (12 factors), pathogen survival (4 factors), and method of preparation (16 factors). Before this, the report form only collected information on five factors:
j.

1. Improper storage or holding temperatures,
2. Inadequate cooking,
3. Contaminated equipment or working surfaces,
4. Food from an unsafe source,
5. Poor personal hygiene of food handler.

k.
l. The most recently published surveillance reports cover 1988-1992 and 1993-1997. These reports were based on use of the "five factor" reporting form. During this time period, 5,174 outbreaks were reported (Bean, 1996; Olsen, 2000). Contributing factors were reported for 58% of all outbreaks; 67% of outbreaks with a laboratory confirmed etiology and 52% of outbreaks with an unknown etiology. Poor personal hygiene of food handler was implicated in about a third of all outbreaks for which contributing factors were reported (1004 of 2993; 34%). Among outbreaks of hepatitis A virus, poor personal hygiene was identified as a contributing factor in 47 of 54 outbreaks (87%). It was also reported as a contributing factor in 213 of 627 (34%) of Salmonella outbreaks and 629 of 1729 (36%) outbreaks for which the agent was considered unknown because it could not be confirmed by laboratory testing.
m.
n.Whether poor personal hygiene actually contributed to transmission or was merely documented during the investigation of these outbreaks can not be determined. The tabular presentation of the data do not lend themselves to cross-tabulations with implicated vehicles, or multivariate analyses including outbreak setting. Of note, in the FDA baseline environmental health surveys of retail establishments, poor personal hygiene was noted in 37% of observations in fast food restaurants, and 53% of observations in full service restaurants.
o.
p.Detailed analyses of national foodborne outbreak data reported on forms with more detailed contributing factor information will not be available for several years.

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r. **Minnesota:** Outbreak surveillance data in Minnesota have been compiled since 1981.
s.
t. The number of outbreaks, by agent reported in Minnesota from 1981-2000, are shown in the following table.
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Agent	No. (%) Outbreaks
Norwalk-like Virus	166 (48)
Salmonella	43 (12)
C. perfringens	40 (11)
E. coli O157	14 (4)
S. aureus	14 (4)
B. cereus	11 (3)
Campylobacter	11 (3)
Shigella	8 (2)
Hepatitis A	8 (2)
Other/Unknown	31 (9)
Total	346 (100)

v.
w. Among 120 foodborne outbreaks caused by Norwalk-like viruses from 1981-1998, an ill food worker was identified in 53 (44%). Ill household members of food workers were identified in 21 (18%). More than one ill food worker was identified in 29 (58%) of 50 outbreaks of Norwalk-like viruses in restaurants. Recently, sequencing of PCR products have confirmed identical sequences of Norwalk-like viruses among patrons and food workers. From 1997-2000, 16 outbreaks of salmonellosis have occurred in Minnesota, 11 in restaurants. In these restaurants, 64 (10%) of 646 food workers tested were infected with the outbreak strain of Salmonella. Of these, 34 (53%) denied having any symptoms of gastrointestinal illness. Outbreaks have been associated with salads, sandwich items and apparent bare hand contact with curly-fried potatoes and ice.
x.
y.Although these data suggest that ill and infected foodhandlers are important sources of food contamination leading to outbreaks, food handler hygiene, hand washing practices, and bare-hand contact with foods have only recently been systematically evaluated in Minnesota.
z.
aa. Selected Contributing Factors Reported, Minnesota 1999-2000

bb. cc. dd. gent type	ee. ff. o. gg. utbreaks	hh. o. (%) Infected Food Workers	ii. o. (%) Hand Contact	jj. o. (%) Cross-Contamination	kk. ll. o. (%) Unknown
mm. AV	nn. 2	oo. 2 (100)	pp. (100)	qq.	rr. 0
ss. iral Gastroenteritis	tt. 47	uu. 2 (47)	vv. (11)	ww.	xx. 23 (49)
yy.	zz.	aaa.	bbb.	ccc.	ddd.

almonella	10	3 (30)	0	4 (40)	3 (30)
eee. ther fff. acterial	ggg. 16	hhh. 1 (6)	iii. 0	jjj. 0	kkk. 4 (25)
lll. nknown	mmm. 8	nnn. 0	ooo. 0	ppp.	qqq. 6 (75)

rrr.

sss. In addition to the summary data on food borne outbreaks, a series of individual outbreaks provide insights on the relationship between hand contact with RTE foods and transmission of foodborne disease. There have been two foodborne outbreaks of parasitic diseases in Minnesota during this time period, one outbreak of Giardia and one of Cryptosporidium. Both involved foods (salmon dip, chicken salad) that required extensive hand manipulation and immersion of the hands in the food. Neither food preparer was ill at the time of preparing the food. Both had changed babies diapers before preparing the implicated food.

ttt.

uuu. Immersion of contaminated hands in foods also contributed to the occurrence of a large outbreak of campylobacteriosis in Minnesota. Forty-two confirmed and 110 probable cases of Campylobacter infection were associated with eating lettuce at a restaurant (odds ratio 91. 95% confidence interval 27-321). The outbreak occurred after a chicken prep cool was assigned to prepare lettuce for salads. The lettuce was washed in a prep sink filled with water. The food worker stirred the lettuce with immersed hands and forearms. The lettuce was subsequently drained, bagged, and stored in the cooler until needed. The food worker had no history of illness and apparently contaminated his hands working with chicken. Thus, his hands contributed to a cross-contamination event.

vvv.

www. In an outbreak of Norwalk gastroenteritis caused by an ill baker who immersed his hands in frosting, 60% of persons who ate the frosted products became ill. In an outbreak of Norwalk-like viral gastroenteritis caused by an ill baker who handled hamburger bums and oatmeal cookies, only 30% of persons who ate them became ill. Thus, the degree of hand contact with RTE foods may affect the attack rate and size of the outbreak. These factors are also related to the likelihood that the outbreak will be recognized, investigated and reported.

xxx.

yyy. Although foodborne outbreaks of hepatitis A infections are uncommon, infection of foodhandlers with hepatitis A virus is not. From 1996-2000, 883 cases of hepatitis A were reported in Minnesota. Foodhandlers accounted for 61 (7%) cases. Also, during this time period there were four foodborne outbreaks involving 57 cases; 38 cases were associated with one outbreak. No infected foodhandlers were identified in two hepatitis A outbreaks that occurred during 1997. These outbreaks were associated with 11 cases. Infected foodhandlers and bare-hand contact with ready-to-eat foods were identified in both hepatitis A outbreaks reported in 2000. These outbreaks were associated with 46 cases.

zzz.

aaaa. Hennepin County Health Department summarized data on hepatitis A virus infections among foodhandlers from 1997-2000. Over that 4-year period, 19 (7%)

of 250 hepatitis A infections reported in Hennepin County were in foodhandlers. No foodborne outbreaks of hepatitis A were reported during this time period. A more detailed follow-up of nine foodhandlers reported during 1999-2000 was conducted. Two foodhandlers reported only working with hot foods. Among the other seven, five were reported to have good handwashing practices and 5 reported wearing gloves when handling cold foods. All seven reported practicing at least one of the prevention measures.

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eeee.

ffff. **New York:** Outbreak surveillance data in New York have been compiled since 1981.

gggg.

hhhh. The number of outbreaks, by agent reported in New York from 1981-1999, are shown in the following table.

iiii.

Agent	No. (%) Outbreaks
Norwalk-like Virus*	504 (23)
Salmonella	317 (14)
C. perfringens	123 (6)
S. aureus	70 (3)
B. cereus	57 (3)
Campylobacter	36 (2)
Hepatitis A	27 (1)
E. coli O157	20 (1)
Shigella	17 (1)
Other	374 (17)
Unknown	650 (30)
Total	2195 (100)

• includes 78 Norwalk virus, 3 calicivirus, 4 Snow Mt. virus and 419 viral gastroenteritis.

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kkkk. In contrast to Minnesota, results of environmental health investigations have been systematically categorized and maintained a part of the outbreak database in New York.

llll.

mmmm. Selected Contributing Factors Reported, New York 1995-1999

nnnn. oooo. pppp. gent type	qqqq. rrrr. o. ssss. utbreaks	tttt. o. (%) Infected Food Workers	uuuu. o. (%) Hand Contact	vvvv. o. (%) Cross-Contamination	wwww. xxxx. o. (%) Unknown
yyyy. AV	zzzz. 4	aaaaa. 3 (75)	bbbbb. 0	ccccc.	ddddd. 1 (25)
eeeee. iral	fffff. 99	ggggg. 3 (33)	hhhhh. 2 (22)	iiiii.	jjjjj. 60 (61)

Gastroenteritis					
kkkkk. almonella	lllll. 58	mmmmm. 8 (14)	nnnnn. 3 (5)	ooooo. 0 (17)	ppppp. 17 (29)
qqqqq. ther rrrrr. acterial	sssss. 75	ttttt. 1 (1)	uuuuu. 1 (1)	vvvvv. 4 (5)	wwwww. 26 (35)
xxxxx. nknown	yyyyy. 19	zzzzz. 9 (8)	aaaaaa. 6 (5)	bbbbbb.	ccccc. 07 (90)

dddddd.

eeeeee. These data suggest that infected food workers are frequently identified as the source for outbreaks of viral foodborne diseases, which is consistent with the fact that most foodborne viruses have a human reservoir. In contrast to the national data, contributing factors were not identified for most outbreaks with an unknown etiology. This suggests that results of environmental health investigations are actively evaluated in New York, and only those factors that are plausibly associated with the known agent are reported as contributing factors. In this regard, however, it is also apparent the hand contact with RTE foods is only reported as a subset of outbreaks in which infected food workers are identified. Thus, for example, an outbreak such as Minnesota's Campylobacter outbreak would likely be attributed to cross-contamination in the New York database, without cross referencing the hand contact as a source of the contamination.

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gggggg. **Washington:** Outbreak surveillance data in Washington have been compiled since 1990.

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iiiiii. The number of outbreaks, by agent reported in Washington from 1990-1999, are shown in the following table.

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Agent	No. (%) Outbreaks
Norwalk-like Virus*	146 (16)
Salmonella	59 (7)
C. perfringens	57 (6)
B. cereus	28 (3)
E. coli O157	22 (2)
Other bacterial	59 (7)
Hepatitis A	5 (<1)
Other/Unknown	530 (58)
Total	906 (100)

• includes 3 Norwalk-like virus, 143 viral gastroenteritis.

kkkkkk.

llllll. Contributing factor data were summarized for 695 (77%) reported outbreaks during this time period. Inadequate hand washing was cited as a contributing factor in 31% of outbreaks. Cross-contamination was cited in 18% of outbreaks, bare hand contact with implicated foods and ill or infected employees were cited in 13% of outbreaks. Overall, contamination introduced by the worker was responsible for 13% of outbreaks and 26% of outbreak associated cases from 1990-1999.

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nnnnnn. In contrast to New York, in Washington, bare hand contact was evaluated independently of the presence of ill or infected employees, and contributing factors were identified for the majority of outbreaks in which the agent was unknown.

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ppppp. Selected Contributing Factors Reported, Washington, 2000

qqqqqq. rrrrrr. ssssss. gent type	ttttt. uuuuuu. o. vvvvvv. utbreaks	wwwwww. o. (%) Infected Food Workers	xxxxxx. o. (%) Hand Contact	yyyyyy. o. (%) Cross-Contamination	zzzzzz. aaaaaaa. o. (%) Unknown
bbbbbbb. AV	ccccccc. 1	ddddddd. 0	eeeeeee. 1 (100)	fffffff.	ggggggg. 0
hhhhhhh. **iral Gastroenteritis**	iiiiiii. **16**	jjjjjjj. **4 (25)**	kkkkkkk. **7 (44)**	lllllll.	mmmmmm **7 (44)**
nnnnnnn. **almonella**	ooooooo. **2**	ppppppp. **0**	qqqqqqq. **0**	rrrrrrr.	sssssss. **0**
ttttttt. **ther** uuuuuuu. **acterial**	vvvvvvv. **11**	wwwwwww. **0**	xxxxxxx. **1 (9)**	yyyyyyy. **(9)**	zzzzzzz. **4 (36)**
aaaaaaaa. **nknown**	bbbbbbbb. **31**	ccccccccc. **7 (23)**	ddddddddd **9 (29)**	eeeeeeee. **(16)**	fffffffff. **4 (45)**

ggggggggg.

hhhhhhhh. In addition to the summary data, the experiences of several outbreaks highlight the relationship between hand contact with RTE foods and transmission of foodborne disease.

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jjjjjjjj. In an outbreak of hepatitis A, an ill foodworker with reportedly good handwashing practices prepared guacamole and salsa with bare hands. At least four patrons became ill. Although this outbreak may have been preventable had the ill employee been excluded, another hepatitis A outbreak occurred as a result of an infected foodhandler who was not ill. This employee prepared sliced meats, cheeses, and vegetables and refilled serving line containers for two submarine sandwich shops. The shops had a policy requiring glove use for making sandwiches, but not for prep work or refilling containers. The implicated foodworker did not have good handwashing habits and did not wear gloves. The outbreak involved 35 cases and litigation resulting in a $1.6 million settlement.

kkkkkkkk.

lllllllll. Two outbreaks of Norwalk-like virus further highlight the difficulties in preventing outbreaks by exclusion of ill foodworkers. In one outbreak 22 of 30 people became ill after eating cold, grilled pineapple slices that were served on a variety of dishes as a garnish. The worker, who placed each pineapple piece on the plate with bare hands, became ill 3 hours after preparing the dishes.

mmmmmmmm. The worker claimed to have good handwashing habits, but details of handwashing before handling the pineapple are not known. In a second outbreak, a foodworker at an assisted living facility developed a gastrointestinal illness and stayed

home for 2 days. After recovering from this illness, the worker returned to work and prepared melons and salads with bare hands. Subsequently, 34 residents became ill, and attack rates were 17% among residents and 12% among staff. A number of secondary cases occurred after the initial foodborne transmission.
nnnnnnnn.
oooooooo. Similarly, an outbreak of shigellosis occurred after a foodhandler returned from a trip to Mexico. The foodworker developed a diarrheal illness upon returning and stayed home while ill. After returning to work, the foodworker resumed duties including preparing romaine lettuce for the salad bar. The romaine was washed and "sanitized" with a vegetable wash. The restaurant had good handwashing policies and required that food workers wear gloves all the time, except when preparing romaine lettuce. Nine confirmed Shigella infections and many probable cases of shigellosis were associated with eating romaine from the salad bar.
pppppppp.
qqqqqqqq. A final outbreak of Norwalk-like virus highlights the fact that bad management practices can undermine the effectiveness of food protection systems that may be in place. In this outbreak a foodworker called in sick, but the manager made the worker report for duty anyway, believing the foodworker was lying. The foodworker was ill at work, but the manger requested that the foodworker prepare lettuce and tomatoes before going home. The foodworker did this with bare hands. At least 143 patrons became ill after eating hamburgers prepared with the contaminated lettuce and tomatoes. In this situation, the restaurant had good written policies regarding handwashing and exclusion of ill employees. Furthermore, the employee attempted to remain home because of an illness. However, the manager violated the company's policies and a large foodborne outbreak occurred as a result.
rrrrrrrr.
sssssss. These outbreaks highlight the challenges of establishing and maintaining effective barriers to the contamination of food by foodworkers. The Washington Department of Health has concluded that no outbreaks from lack of hand washing have occurred in establishments with barriers in place to prevent bare hand contact with RTE foods. Furthermore, they conclude that no outbreaks from lack of hand washing have occurred in jurisdictions served by Local Health Departments that require such barriers. Finally, they concluded that no cross-contamination outbreaks occurred in establishments when using barriers to prevent bare hand contact with RTE foods. While the data, as presented, do not establish these claims, Washington appears to have a foodborne outbreak data system that could produce such data.
ttttttt.
uuuuuuuu. Summary: Foodborne outbreak surveillance data from Minnesota, New York and Washington are similar in many respects to the national foodborne outbreak surveillance data with respect to the distribution of outbreaks by likely agent. However, there are systematic differences in the way data have been collected and reported that make direct comparison of the data difficult. Existing data in Washington appears to be more complete and free of bias than data from New York, Minnesota or CDC.

vvvvvvvv.

wwwwwwww. Selected Contributing Factors Reported, MN, NY, and WA

xxxxxxxx.

yyyyyyyy. zzzzzzzz.	bbbbbbbbb. ccccccccc.	eeeeeeeee. o. (%) Infected	fffffffff. o. (%)	ggggggggg. o. (%) Cross-	hhhhhhhhh. iiiiiiiii.

aaaaaaaaa. gent type	o. ddddddddd. utbreaks	Food Workers	Hand Contact	Contamination	o. (%) Unknown
jjjjjjjjj. AV	kkkkkkkkk. 7	lllllllll. 5 (71)	mmmmm 3 (43)	nnnnnnnnn.	ooooooooo. 1 (14)
ppppppppp. iral Gastroenteritis	qqqqqqqqq. 62	rrrrrrrrr. 9 (36)	sssssssss. 4 (21)	ttttttttt.	uuuuuuuuu. 90 (56)
vvvvvvvvv. almonella	wwwwwww 70	xxxxxxxxx. 1 (16)	yyyyyyyy 4 (6)	zzzzzzzzz. 4 (20)	aaaaaaaaa. 19 (27)
bbbbbbbbb. ther ccccccccc. acterial	ddddddddd. 02	eeeeeeeee. 2 (2)	fffffffff. 2 (2)	ggggggggg. 5 (5)	hhhhhhhhh 34 (33)
iiiiiiiii. nknown	jjjjjjjjj. 58	kkkkkkkkk. 6 (10)	lllllllll. 5 (9)	mmmmmmmm 5 (3)	nnnnnnnnn 27 (80)

ooooooooo.

CFP Bare Hands Committee
Sub-Committee on Risks

This is not a complete listing and additional examples were given by the retail grocer representatives that could generate a much longer listing of hand contact with RTE Foods

2) Identify potential examples of the following:

a) Tasks where bare hand contact cannot be practically avoided; and

b) Incidental contact where bare hands do not appear to present appreciable risk to consumers.

Bakery tasks

delicate pastry assembly (cream puff swan, eclairs, napoleons)
handling meringue
handling chocolate filigree, leaves, delicate chocolate shapes
cake decorations (placement of frosting roses on cakes)
forming pulled sugar designs
assembly of layer cakes
assembly of petit fours
forming marzipan decorations
plating a piece of cake or pie
removing hot baked breads, rolls, etc. from baking sheets

Garnishes

Fresh fruit twists, squeezes for drinks
parsley, kale, and other edible garnishes on plate
intricate plate design

Centerpieces

Ice carvings,
chocolate carvings
pastiallage
whole fresh fruit displays

Miscellaneous

Rolling sushi, seaweed sheets
Composing salads (Cobb, Nicoise, Chef)
Mixing large quantities of delicate foods like pasta salad, tender salad greens, delicate seafood like scallops
"shingling" platters of deli meats and sliced cheeses
handling fruits, vegetables for fresh squeezed juice
turning quesadillas on hot grill
folding tortillas
handling hot deep fried tortilla shells
placing french fries in take out containers
portioning tortilla, taco, potato or other chips on plates
filling baskets or bowls with snack items such as peanuts, chips, pretzels

Meats

Sectioning portions of cooked pork, beef ribs, cooked poultry, pulled pork
Raw oyster shucking
peeling cooked shrimp
placing cured sausages (e.g. hard salami) into deli case
butcher handling cooked, bone-in ham, cooked, smoked pork chops
vacuum packaging area in grocery store.

Breakfast Items

removing toast (or bagels, English muffins, etc.) from toaster
"shingle" or "fan" pancakes on plate
rolling or folding crepes

Equipment

bare hand assembly of equipment which comes into contact with rte's.
(e.g. frozen dessert machine, slicer, vegetable slicer, chopper)

CFP Council III Bare Hand Contact Committee

Janet	Anderberg	Washington Department of Health
Angeline	Benjamin	Tricon Global
Ronnie	Call	Arkansas Department of Health
Jerry	Chesser	California State Polytechnic University, Pomona
Bruce	Cords	Ecolab, Inc.
Larry	Decker	New York State Dept. of Agriculture and Markets
Michael J.	Dolan	GOJO Industries, Inc.
Wendy	Fanaselle	FDA-CFSAN DCP RFITT
Mary	Fandrey	Missouri Department of Health
Francis	Ferko	Brinker International
Susan C.	Grayson	NC Dept. of Environment & Nat. Resources
Steve	Grover	National Restaurant Association
Craig	Hedberg	University of Minnesota
Chuck	Higgins	National Park Service
Thaddeus J.	Koeune	Lake County Health Department
Cynthia C.	Kunkel	Food & Drug Administration
Laurie	Leis	Wyoming Department of Agriculture
David	Ludwig	Maricopa County Environmental Services
Jim	Mann	Infocus Learning
John	Marcy	University of Arkansas
Carlota	Medus	Minnesota Department of Health
Ken	Rosenwinkel	Jewel-Osco
Mary	Sandford	Burger King Corporation
Lacie	Thrall	FoodHandlers
Keith	Winkler	Kings County (CA) Environmental Health Services
Lisa	Wright	Jack in the Box Inc.

(ix) FDA report on progress of investigation of reported allergic reactions related to Heavea natural rubber latex products when used in contact with food

Food & Drug Administration
Center for Food Safety & Applied Nutrition
Office of Premarket Approval
Office of Field Programs

This report to the 2002 Conference for Food Protection contains the progress of FDA's investigation of reports of allergic reactions related to Heavea natural rubber latex products (NRL) when used in contact with food, pursuant to the 2000 Conference recommendation regarding (Issue 00-03-22) Latex gloves, proscription.

We have been actively searching for peer-reviewed research and case report documentation of reported allergic reactions to NRL when used in contact with food. We are still in the process of gathering such documented medically diagnosed allergic reactions resulting from consuming food that had been in contact with NRL products.

To date, we have been unable to locate peer-reviewed, published research, that provides the documentation. Several papers and reports exist that document or assess reactions to food exposed to latex gloves. Case reports have appeared in separate letters to *The New England Journal of Medicine, The Journal of Allergy and Clinical Immunology* and *The Medical Journal of Australia*.[10, 11,12]: -

The Center for Food Safety and Applied Nutrition has received about 75 self-reported cases of food-mediated latex allergies from consumers in late 2000 and early 2001. The reports raise concern that latex protein from gloves worn by food workers may contribute to serious allergic reactions in latex-sensitized individuals. However, these reports are not clinically verified through medical records and it is possible that some of the reactions described could have been due to consumption of foods that cross react to latex protein (e.g., kiwi, bananas, buckwheat, stone fruits, potatoes, tomatoes, sweet pepper, chestnuts, spinach, etc.).

One published research paper by Beezhold, 2000, attempts to quantify the amount of latex allergens that are transferred from latex gloves to food during food handling.[1] Using a specific protocol, the authors of this study concluded that an average of 50 ng of latex protein was transferred to lettuce per finger contact with a NRL glove. The study also demonstrated latex proteins from gloves can transfer to cheese. Their protocol employed gloves with a high residual protein content, and used the gloves inside out to enhance the amount of protein transferred to the food (the corn starch donning powder that binds the protein is applied mainly on the inside of the glove). The authors report that as little as 70 pg/ml of latex protein may induce a response in the skin prick test.

FDA Position on Gloves used in Food Service

CFSAN is concerned with the potential food-mediated Type 1 or *Immediate type hypersensitivity* latex allergic reactions to those sensitized individuals that may react to ready-to-eat foods, which have been handled by a food worker wearing latex gloves.

Our current position on the use of NRL gloves in food service can be found in regulation and has been affirmed through CFSAN policy interpretation letters for many years. NRL gloves are deemed repeat-use items, and as such, may be considered in compliance with 21 CFR 177.2600 *Rubber articles intended for repeated use*. Under this regulation, natural rubber is acceptable as an indirect food additive.

ppppppppppp. In accordance with section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA), food-contact articles, such as food service gloves, are subject to regulation as indirect food additives whenever they enter interstate commerce in the U.S. Title 21 of the Code of Federal Regulations (CFR), section 177.2600, prescribes conditions of safe use for substances that are permitted to be used as components of repeat-use rubber articles intended to contact food. Natural rubber is listed in 21 CFR 177.2600 for use as a component of any repeat-use, food-contact, rubber article. Food service gloves are repeat-use, food-contact articles because each pair of gloves will contact many articles of food during its useful lifetime. Consequently, natural rubber is currently permitted by federal regulation to be used as a component of food service gloves. Importantly however, neither 21 CFR 177.2600, nor section 3-301.11 of the Food Code, which restricts bare-hand contact with ready-to-eat foods, mandates latex as a component food-service gloves. The use of any single-service glove in food service is not mandated in section 3-301.11 of the Food Code.
qqqqqqqqqq.
The FDA has been charged by Congress to review this position on latex glove use in food service, and is currently reviewing the issue through a CFSAN Latex Work Group, under the direction of the Office of Premarket Approval. The Office of Premarket Approval will submit a report on the review to Congress by September, 2002.

FDA Position on Latex Gloves used in Health Care

The Center for Devices and Radiological Health (CDRH) has reviewed the occupational use of latex gloves and subsequent exposure to latex gloves in health care, related to the use of patient examination and surgical gloves. That review determined that experimental and clinical data demonstrate that: NRL proteins can be allergenic, NRL proteins bind to cornstarch, and aerosolized powder from NRL gloves is allergenic and can cause respiratory allergic reactions.

Published studies support the conclusion that airborne glove powder represents a threat to people allergic to NRL and may be an agent for sensitizing non-allergic individuals. In general, prolonged, chronic exposure is required to become sensitized to NRL, although genetic predisposition plays a role. One report concludes that NRL proteins may be rapidly transferred to objects by contact with powdered latex gloves.

On July 30, 1999, CDRH proposed new regulations to reclassify all surgeons' and patient examination gloves as Class II medical devices because it believes that general controls currently

in place are insufficient to provide a reasonable assurance of safety and effectiveness of latex gloves. The proposed rule is intended to reduce the adverse health effects from allergic and foreign body reactions caused by the NRL protein allergens and glove powder found on surgeons' and patient examination gloves, and to reduce the adverse health effects from defects in the barrier integrity and quality of surgeon's and patient examination gloves. The reclassified gloves, including those made of NRL or synthetic material, will be regulated in four categories: Powdered and powder-free surgeon's gloves, and powdered and powder-free patient examination gloves. The proposed special controls are in the form of a proposed guidance document entitled A *Medical Glove Guidance* at http://www.fda.gov/cdrh/dsma/135.html which includes recommended protein and glove powder limits, and new label caution statements including protein and powder labeling requirements. FDA is also proposing to require expiration dating.

Food Mediated Latex Allergy
Immediate type hypersensitivity reaction is a Type I, or systemic reaction that is IgE-mediated and linked to several latex proteins. Immediate type hypersensitivity reactions exhibit a range of symptoms including urticaria, rhino conjunctivitis, asthma and, rarely, anaphylaxis. These type I allergic reactions to NRL proteins require previous sensitization, usually a prolonged cumulative exposure to NRL. Immediate type hypersensitivity reactions to NRL protein are the potential adverse health effects associated with latex food-service glove use, which is the subject of this issue submission and referred to herein simply as latex allergy.

Occupational or Health Care Exposure to NRL
Irritant contact dermatitis is a breakdown of the skin that is exposed to NRL gloves and is a response that is not mediated by the immune system. Latex proteins do not generally cause this response. *Delayed type hypersensitivity* (Type IV allergic reaction) is a T-cell mediated sensitization to certain constituents of the glove, usually accelerators used to hasten the cross linking of the polymers during manufacture of the glove. This reaction is limited to the site of direct contact with the glove. The Occupational Health and Safety Administration (OSHA) regulates occupational exposure to latex.

Prevalence and High Risk Groups

Many screening surveys have been conducted to determine the prevalence of latex allergy in the general population as well as within specific risk groups[3]. Taken together, these surveys suggest that latex allergy is rare in the general population but may affect 17% or 1.4 million operating room physicians and persons within other high-risk groups associated with the health care profession in the United States[4]. The incidence of acquired allergy to natural rubber latex proteins and chemicals has been increasing in recent years among health care workers, dental workers, children with spinal bifida, and with health care patients that have frequent mucosal contact with various natural rubber products[3,4].

An increase in prevalence of reported latex allergies among health care workers has coincided with the increased NRL gloves use that followed the issuance of CDC guidance on the prevention of transmission of bloodborne pathogens in 1987[4]. No data were found regarding prevalence of latex allergy among housekeepers, hairdressers, or food-service workers. However, the risk of developing latex allergies may be greater in individuals from these groups due to the extensive use of NRL gloves.

rrrrrrrrrr. Considerable information now exists regarding risks to workers and patients associated with the occupational use of natural rubber latex gloves within the healthcare community. There is much less information available regarding the occupational use of latex gloves by the food service industry, however, to the extent that the food service use patterns are similar to those found in the healthcare setting, one might expect the risks to food service workers to be similar.

Importantly, the use of natural rubber latex gloves by the food service industry raises a separate question regarding food safety that is not an issue in the healthcare setting. Specifically, can food that has been handled with natural rubber latex gloves be allergenic when consumed by individuals that have been previously sensitized to latex allergens? As stated above, CFSAN has received reports implicating food that was handled with latex gloves as the cause of allergic reactions to latex. CFSAN is reviewing this information to determine whether there is sufficient credible information to establish that food is a vehicle in the transmission of latex allergens from worker's gloves, and what actions this information may justify.

FDA recognizes the concern over potential food-mediated, latex allergic reactions in consumers. Because of the complexity of this issue, CFSAN intends to use its Food Advisory Committee (specifically, the Food Ingredient subcommittee of its FAC) to gather information from all interested stakeholders and to provide input to specific questions that have been raised regarding this issue.

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REPORT TO COUNCIL III, SCIENCE AND TECHNOLOGY, CONFERENCE FOR FOOD PROTECTION

Ready-to-Eat Fruits and Vegetables Committee

CFP Issue 00-03-10

Committee Members:

H. Wayne Derstine, Chair
Wendy Fanaselle, Member
Keith Winkler, Member
Larry Kohl, Member
Melissa Tucker, Member
Gail Prince, Member
Richard Ramirez, Member

Committee's Function:

Develop guidance for minimizing the potential of contamination and growth of pathogens in ready-to-eat fruits and vegetables in retail food operations.

Progress Report:

The committee was established in late August 2001 with the appointment of a chair for the committee. Members were contacted and asked to share ideas and reference documents with the Chair. Members provided documents for review and ideas for consideration. An annex (enclosed) to the Food Code was drafted and submitted to all of the members for comments, additions, and suggestions. Comments have been received. Additions to the document are being worked on to improve the annex. The annex being developed is intended to provide operational guidelines for the retail operator who sells ready-to-eat fruits and vegetables. The guidelines will assist the operator in minimizing contamination and pathogen growth in produce. The annex should provide a ready available source of guidelines without having to search various other documents. This annex should also sort out references and help avoid duplication, i.e., finding the same information in different documents. The annex will provide the retail operator with the best practices for his retail operation.

The following individual was also recommended for membership to our committee: Jim Gorny, Technical Director, International Fresh-cut Produce Association. The recommendation was submitted to Council III for approval.

Recommend committee be allowed to continue to work on document for future submission.

Submitted by Wayne Derstine, Chair
December 26, 2001

NSF COMMERCIAL FOOD SERVICE OVEN MITT PROTOCOL CERTIFICATION PROGRAM

Since 1944, NSF has developed standards and provided third-party certification services to government, consumers/users, and manufacturers of products and systems related to environmental and public health safety. In the area of commercial food equipment, NSF is the most widely accepted and recognized certification provider in the industry and is responsible for developing the majority of public health safety standards available today. NSF Certifications are accredited by the American National Standards Institute (ANSI), the Raad voor Accreditate (Dutch Council for Accreditation) and the Standards Council of Canada (SCC). NSF is a Collaborating Center in Food Safety and Drinking Water Safety and Treatment with the World Health Organization (WHO).

In 1997, in response to an industry request, NSF developed a document which set forth test methods and requirements for reusable oven mitts for use in commercial food service operations. NSF Protocol P149 "Oven Mitts used in Commercial Food Service" was developed with the assistance of an expert panel consisting of representatives from state health departments, national trade associations, risk managers from restaurant chains, and technical experts in thermal protection. Although not an ANSI-approved document, NSF P149 reflects the basic requirements as set forth in NFPA/ANSI 1971 "Standard on Protective Ensemble for Structural Fire Fighting" which is ANSI-approved. NSF added requirements to deal with issues specific to food safety including cleanability and durability.

Certification to NSF P149 involves qualification testing covering heat resistance, wet and dry thermal protective performance, flame resistance, durability and cleanability. In addition, manufacturing facilities are audited on an annual basis to verify continued conformance with the requirements of the Protocol. Products meeting the requirements of the Protocol may bear the NSF Certification Mark as shown below:

NSF

NSF Protocol P149
Oven Mitts used in Commercial Food Services – Class I (or Class II) Mitt

Further information on NSF Protocols can be obtained through the NSF website (www.nsf.org) or by contacting:

Bruce Low
NSF International
Engineering & Research Services
789 N. Dixboro Road
Ann Arbor, MI 48105
Phone: 734-769-5250
Email: low@nsf.org

NSF International Engineering & Research Services
January 28, 2002

ADDENDUM:

SECTIONS OF THE 2001 FOOD CODE THAT REFER DIRECTLY TO USE OF TEXTILES, GLOVES, UTENSILS, ETC. BUT ONLY INDIRECTLY TO PPE (Personal Protective Equipment, or Protective Apparel such as thermal gloves—Oven Mitts)

EXECUTIVE SUMMARY

The 2001 Food Code does not directly address the subject of documented health hazards presented by textile "PPE" (Oven Mitts, Hot Pads, etc). It does, however, provide specific guidelines for proper design, construction, performance characteristics, cleanability, cleaning and sanitization methods and storage of related products (utensils, linens, multiuse articles and food contact surfaces). These guidelines do not adequately address risks presented by PPE.

"Standard" PPE in the foodservice industry consists of commodity (usually quilted cotton or terrycloth cotton) PPE. These products are constructed in a manner consistent with the definition of "*single-use articles*" but in fact are used in a manner consistent with multi-use articles. These products cannot realistically conform to existing FDA guidelines. In order to conform to existing FDA guidelines, foodservice operators ostensibly have two choices:

(a) implement *single-use* commodity PPE, and throw them away after each and every use;

or

(b) implement PPE that can be constantly washed and sanitized upon any possible instance of contamination and used wet without fear of burns, establishing them as functional *multi-use* articles.

A definition of PPE that can be maintained in a constantly sanitary state has been established by the National Sanitation Foundation International (NSF) under its Certification P-149 (NSF Protocol 96/011/480/2480). This NSF Certification is based on NFPA (National Fire Protection Association) Standards which are ANSI-based and are therefore deemed to be FDA-compliant.

It is therefore urged that, with regard to PPE, the CFP formulate and submit to the FDA a recommendation that the Food Code be amended so as to permit the use of one of the following classes of PPE only:

(a) *single-use* items which must be thrown away after each and every use; or

(b) *multi-use* items Certified by a recognized, third-party Certifying body whose criteria relate specifically to foodservice and sanitation (such as NSF); or

(c) products capable of performing in a manner equivalent to PPE that is certified by a recognized, third-party Certifying body whose criteria relate specifically to foodservice and sanitation (such as NSF).

Permitting the use of products which perform to a lesser standard will not resolve the serious recurrent problem of bacterial contamination emanating from PPE.

The vast majority of Foodservice Operations in the United States commonly use commodity textiles (quilted cotton or terrycloth cotton Oven Mitts and Hot Pads, cotton aprons, etc) as thermal PPE (Personal Protective Equipment) for the prevention of burns. This type of product constitutes the "standard" in use in most restaurants throughout the United States today. Examination will reveal that these commodity products are inadequate in burn injury prevention and in fact cause bacterial cross-contamination.

Current Food Code (2001) does not provide specific guidelines regarding the use of such products. Several Sections of the Code treat related subjects, but none specifically addresses the dangers uniquely attributable to thermal textiles.

The following is an enumeration of Sections of the 2001 Food Code that treat related subjects.

PREFACE: DEFINITIONS (1-201.10)

97**.** **"Utensil"** is defined as "a food-contact implement or container used in the storage preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; food temperature measuring devices; and probe-type price or identification tags used in contact with food."

50. **"Linens"** is defined as "fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves."

23. **"Easily Cleanable"** is defined as "a characteristic of a surface that:

(i) Allows effective removal of soil by normal cleaning methods;
(ii) Is dependent on the material, design, construction, and installation of the surface; and
(iii) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

(b) "Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified under Subparagraph (a) of this definition to different situations in which varying degrees of cleanability are required such as:

(i) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

(ii) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area."

34. **"Food-Contact Surface"** is defined as "

(a) A surface of equipment or a utensil with which food normally comes into contact; or

(b) A surface of equipment or a utensil from which food may drain, drip, or splash:

(i) Into a food, or

(ii) Onto a surface normally in contact with food."

42. **"Hazard"** is defined as "a biological, chemical, or physical property that may cause an unacceptable consumer health risk."

45. **"Imminent Health Hazard"** is defined as "a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(i) The number of potential injuries, and

(ii) The nature, severity, and duration of the anticipated injury."

19. **"Critical Item"** is defined as "a provision of this Code, that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard." In this Code, it is denoted with an asterisk *. "

89. **"Single-Use Articles"** "

(a) means utensils and bulk food containers designed and constructed to be used once and discarded.

(b) Single-Use Articles" includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse utensils."

I. PPE DEFINED

According to definitions of the 2001 Food Code, PPE (including thermal oven mitts) must be considered to be a "Utensil". By definition, PPE must also considered as a "Linen" and because these articles are not thrown away after every single use, as a "Multiuse Article". Because of its ubiquitous use in the kitchen, should also considered to be a "Food Contact Surface".

II. CONSTRUCTION & PERFORMANCE

According to the Food Code (Section 4-101.11), "Materials that are used in the construction of *utensils* and *food-contact surfaces* of *equipment* may not allow the migration of deleterious substances or impart colors, odors, or tastes to *food* and under normal use conditions shall be:

(A) Safe;

(B) Durable, *corrosion-resistant*, and nonabsorbent;**N**

(C) Sufficient in weight and thickness to withstand repeated *warewashing*;**N**

(D) Finished to have a *smooth, easily cleanable* surface;**N** and

(E) Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.**N"**

As a "Utensil", PPE must be "designed and constructed to be durable and to retain their characteristic qualities under normal use conditions" (4-201.11).

III. CLEANABILITY

As "Multiuse Articles" that come into constant contact with food ("*Food Contact Surface*"), PPE must be easily cleanable (4-202.11).

The "Good Repair" clause of the Food Code (4-502.11) requires that "*Utensils* shall be maintained in a…condition that complies with the requirements specified under Parts 4-1 and 4-2 or shall be discarded."

Section 4-6 "Cleaning of Equipment and Utensils" (Subparts 4-601/Objective, 4-602/Frequency and 4-603/Methods) enumerates cleaning guidelines for these products:

Objectives of cleaning Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils (Section 4-601.11):

"(A) *Equipment food-contact surfaces* and *utensils* shall be clean to sight and touch.
(B) The *food-contact surfaces* of cooking *equipment* and pans shall be kept free of encrusted grease deposits and other soil accumulations.**N**"

Frequency of cleaning Equipment Food-Contact Surfaces and Utensils (Section 4-602.11):

"(A) *Equipment food-contact surfaces* and *utensils* shall be cleaned:

(1) Except as specified in (B) of this section, before each use with a different type of raw animal *food* such as beef, *fish*, lamb, pork, or *poultry*;

(2) Each time there is a change from working with raw *foods* to working with *ready-to-eat foods*;

(3) Between uses with raw fruits and vegetables and with *potentially hazardous food*;

(4) Before using or storing a *food temperature measuring device*; and

(5) At any time during the operation when contamination may have occurred."

"(C) Except as specified in ¶ (D) of this section, if used with *potentially hazardous food*, *equipment food-contact surfaces* and *utensils* shall be cleaned throughout the day at least every 4 hours."

Methods of cleaning Equipment Food-Contact Surfaces and Utensils (Section 4-603)
Several methods of cleaning various Equipment Food-Contact Surfaces and Utensils are listed depending on the type of surface or utensil. For linens, the most practical and logical cleaning method among these options is "Wet Cleaning", defined as follows (Section 4-603.14):

"(A) *Equipment food-contact surfaces* and *utensils* shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices."

"(B) The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed."

For linens, the preferred method of washing or "Wet Cleaning" is Laundering (specified in Section 4-8, Subparts 4-801/Objective, 4-802/Frequency and 4-803/Methods:

The objective of laundering linens is to obtain Clean Linens (Section 4-801.11):
"Clean *linens* shall be free from food residues and other soiling matter."

The recommended frequency of such laundering is also specified (Section 4-802.11)

"(A) *Linens* that do not come in direct contact with *food* shall be laundered between operations if they become wet, sticky, or visibly soiled.

(B) Cloth gloves used as specified in ¶ 3-304.15(D) shall be laundered before being used with a different type of raw animal *food* such as beef, lamb, pork, and *fish*.

(C) *Linens* and napkins that are used as specified under § 3-304.13 and cloth napkins shall be laundered between each use.

(D) Wet wiping cloths shall be laundered daily.

(E) Dry wiping cloths shall be laundered as necessary to prevent contamination of *food* and clean serving *utensils*."

Likewise, a method of storing linens is prescribed:
Storage of soiled linens (Section 4-803.11)
"Soiled *linens* shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of *food*, clean *equipment*, clean *utensils*, and *single-service* and *single-use articles*."

Methods of Mechanical Washing are also defined (Section 4-803.12)

"(A) Except as specified in ¶ (B) of this section, *linens* shall be mechanically washed.

(B) In *food establishments* in which only wiping cloths are laundered as specified in ¶ 4-301.15(B), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a *warewashing* or *food* preparation sink that is cleaned as specified under § 4-501.14."

When mechanical laundering is implemented, facilities must be as follows (4-803.13)

"(A) Except as specified in ¶ (B) of this section, laundry facilities on the premises of a *food establishment* shall be used only for the washing and drying of items used in the operation of the establishment.

(B) Separate laundry facilities located on the premises for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering *food establishment* items."

Rinsing Procedures are also defined (Section 4-603.16)
"Washed *utensils* and *equipment* shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-*sanitizer* solution by using one of the following procedures:

(A) Use of a distinct, separate water rinse after washing and before sanitizing if using:

(1) A 3-compartment sink,

(2) Alternative manual *warewashing equipment* equivalent to a 3-compartment sink as specified in ¶ 4-301.12(C), or

(3) A 3-step washing, rinsing, and *sanitizing* procedure in a *warewashing* system for CIP *equipment*;

(B) Use of a detergent-*sanitizer* as specified under § 4-501.115 if using:

(1) Alternative *warewashing equipment* as specified in ¶ 4-301.12(C) that is *approved* for use with a detergent-sanitizer, or

(2) A *warewashing* system for CIP *equipment*;

(C) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a 2-compartment sink operation;

(D) If using a *warewashing* machine that does not recycle the *sanitizing* solution as specified under ¶ (E) of this section, or alternative manual *warewashing equipment* such as sprayers, use of a nondistinct water rinse that is:

(1) Integrated in the application of the *sanitizing* solution, and

(2) Wasted immediately after each application; or

(E) If using a *warewashing* machine that recycles the *sanitizing* solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the *sanitizing* solution."

Sanitization methods are discussed and enumerated (Section 4-701/Objective, 4-702/Frequency and 4-703/Methods)
The Objective is that "Equipment food-contact surfaces and utensils shall be sanitized." (4-701.10)
Frequency requirements stipulate that "*utensils* and *food-contact surfaces* of *equipment* shall be *sanitized* before use after cleaning" (4-702.11).

Methods of sanitization are described as follows (4-703.11)
"After being cleaned, *equipment food-contact surfaces* and *utensils* shall be *sanitized* in:

(A) Hot water manual operations by immersion for at least 30 seconds and as specified under § 4-501.111;

(B) 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; or

(C) Chemical manual or mechanical operations, including the application of *sanitizing* chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under § 4-501.114 by providing:

(1) Except as specified under Subparagraph (C)(2) of this section, an exposure time of at least ten seconds for a chlorine solution specified under ¶ 4-501.114(A),

(2) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F),

(3) An exposure time of at least 30 seconds for other chemical *sanitizing* solutions, or

(4) An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields *sanitization* as defined in Subparagraph 1-201.10(B)(79)."

Standards are defined for the Storage of Equipment, Utensils, Linens and Single-Service and Single-Use articles to assure cleanliness (4-903.11)

"(A) Except as specified in ¶ (D) of this section, cleaned *equipment* and *utensils*, laundered *linens*, and *single-service* and *single-use articles* shall be stored:

(1) In a clean, dry location;

(2) Where they are not exposed to splash, dust, or other contamination; and

(3) At least 15 cm (6 inches) above the floor.

(B) Clean *equipment* and *utensils* shall be stored as specified under (A) of this section and shall be stored:

(1) In a self-draining position that allows air drying; and

(2) Covered or inverted.

(C) Single-service and single-use articles shall be stored as specified under ¶ (A) of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used."

Finally, the 2001 Food Code addresses the question of Acceptability of Food Equipment, Certification and Classification.
Section 4-205.10 states that "Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program will be deemed to comply with Parts 4-1 and 4-2 of this chapter."

SUMMARY COMMENTS

- Commodity* PPE *does* allow migration of deleterious substances.
- Commodity* PPE is not safe.
- Commodity* PPE is not durable.
- Commodity* PPE is not nonabsorbent.
- Commodity* PPE does not withstand repeated washing.
- Commodity* PPE is not easily cleanable.
- Commodity* PPE is not resistant to decomposition.
- Commodity* PPE does not remain free of construction imperfections.
- Commodity* PPE does not remain clean to sight and touch.
- Commodity* PPE cannot be kept free of encrusted grease deposits and other soil accumulations.
- Commodity* PPE cannot be reasonably sanitized.
- Evidence indicates that commodity* PPE is not cleaned at least every 4 hours.
- Evidence indicates that commodity* PPE is not wet-cleaned (laundered) between operations if it becomes wet, sticky, or visibly soiled.
- Evidence indicates that commodity* PPE is not laundered every time it is used with a different type of raw animal food.
- Evidence indicates that commodity* PPE is rarely, if ever, sanitized.
- If commodity* PPE is not cleaned on a regular basis, evidence indicates that, not only do these products become a "Hazard", they become "Imminent Health Hazards". In fact, they not only become "Imminent Health Hazards", they become a "Critical Item" (see independent laboratory data, attached).

Unfortunately, in the case of commodity* PPE, foodservice operators chronically fail to comply with cleaning requirements. This is because cleaning means washing, and wet commodity* PPE will not protect against burns. Likewise, commodity* PPE is simply too expensive for operators to realistically discard after every single use. Instead, operators place commodity* PPE in service, and continue to use it for extended periods (usually for weeks or months) until a manager or an employee arbitrarily elects to replace these items. In addition to bacterial transmission, as these products age, they decompose, and insulation (cotton batting, etc.) falls out into food and elsewhere throughout the food preparation area.

Occasional (weekly or even daily) machine washing is not sufficient to ensure constant sanitation. PPE must be washable at every moment. Every time a textile (linen) Oven Mitt is used, if it comes into contact with any organic (food) matter, it must be washable on the outer surface. Similarly, every time a textile Oven Mitt is used, if the wearer places soiled hands into the mitt's interior, the mitt must be washable on its inner surface. It must then be possible to sanitize the entire Mitt (exterior and interior) in a sanitizing solution. Finally, in order to retain the "multiuse" mitt in service, it must be usable (i.e., deliver protective qualities) while wet. Commodity* PPE simply cannot perform to this necessary standard.

**The term "Commodity* PPE" indicates protective apparel that does not effectively protect against burns when wet. Because of this characteristic, evidence indicates that these products are neither frequently nor adequately washed.*

CONCLUSIONS

The 2001 Food Code does not directly address the subject of documented health hazards presented by textile PPE (Oven Mitts, Hot Pads, etc).

"Standard" PPE in the foodservice industry consists of commodity (usually quilted cotton or terrycloth cotton) PPE. These products are constructed in a manner consistent with the definition of "*single-use articles*" but in fact are implemented in a manner consistent with multi-use articles. When so-used, these products do not conform to specific existing FDA guidelines. In order to conform to existing guidelines, foodservice operators ostensibly have two choices:

(a) implement *single-use* commodity PPE, and throw them away after each and every use;

or

(b) implement PPE that can be constantly washed and sanitized upon any possible instance of contamination and used wet without fear of burns, establishing them as functional *multi-use* articles.

A definition of PPE that can be maintained in a constantly sanitary state has been established by the National Sanitation Foundation International (NSF) under its Certification P-149 {NSF Protocol 96/011/480/2480}. (See NSF Addendum, attached.) This NSF Certification is based on NFPA (National Fire Protection Association) Standards which are ANSI-based and are therefore deemed to be FDA-compliant.

It is therefore urged that, with regard to PPE, the CFP formulate and submit to the FDA a recommendation that it modify its Food Code in order to permit *only* the use of one of the following classes of PPE:

(a) single-use items which must be thrown away after each and every use; or

(b) multi-use items Certified by a recognized, third-party Certifying body whose criteria relate specifically to foodservice and sanitation (such as NSF); or

(c) products capable of performing in a manner equivalent to PPE that has been certified by a recognized, third-party Certifying body whose criteria relate specifically to foodservice and sanitation (such as NSF).

[Note: The NSF has determined that, in order to be effective, PPE must include the following critical elements:

sssssssss. (a) LIQUID-VAPOR BARRIER: PPE must prevent burns from surface contact, boiling water, steam, oil, grease, spills and splatters. In order to achieve this, the product must be equipped with an approved "liquid-vapor barrier". A liquid-vapor barrier is a material which prevents the penetration of liquids and steam into the PPE. "Approved" must be defined as the documented ability of the barrier to withstand oven-range temperatures (500 °F.) for 24 continuous hours. This criterion is necessary to outlaw the use of inferior materials that might burn or melt at oven temperatures, resulting in

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uuuuuuuuuu. (i) emission of noxious and potentially dangerous fumes, or (ii) destruction of the barrier itself.

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wwwwwwwww. (b) "WASHABILITY": PPE must demonstrate the ability of being used wet or dry, thereby offering the ability of being washed regularly both inside and out *while in service* without risk of steam burns.

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yyyyyyyyy. (c) CLEANABILITY: Not only must the PPE be "washable" (i.e., demonstrate the ability to protect wet as well as dry), it must become clean and sanitary when washed. (NSF requires that spiked levels of E. Coli and S. Aureus be placed on the PPE, and in a single machine washing according to AATCC Standard 135, that 99% of the bacteria be removed.)

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aaaaaaaaaa. (d) DURABILITY: The PPE must withstand a minimum of 25 machine launderings. This durability also contributes to extremely long life of the product, helping to assure that this change to the Food Code will not prove cost-prohibitive for Operators.

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ccccccccc. (e) CONDUCTIVE HEAT RESISTANCE: PPE must adequately protect the wearer against burns, defined as 15 seconds to pain and 26 seconds to second-degree burn injury.

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eeeeeeeeee. (f) FLAME-RESISTANCE: Whenever necessary, PPE must be able to resist damage when exposed to open flame (according to established NFPA Standards which are ANSI-based).

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ggggggggg. *(NOTE: The NSF created two levels of Certification: Class I products are not flame-resistant; Class II products are flame-resistant.)*

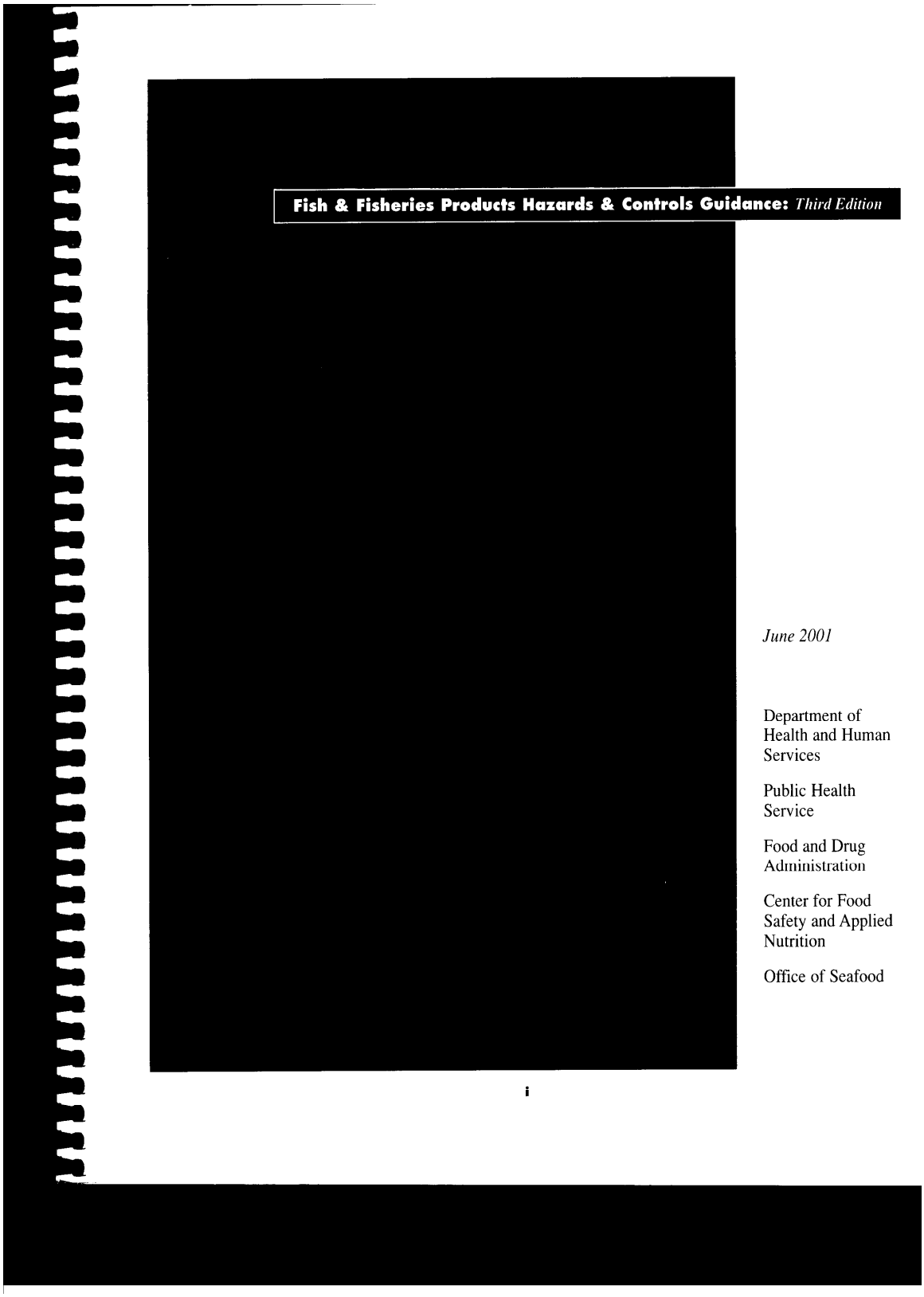
Permitting the use of products that perform to a lesser standard will not resolve the serious recurrent problem of bacterial contamination emanating from PPE.

FOOTNOTE: PPE and HACCP

Clearly, periodic facility inspections by regulatory agencies and periodic enforcement of the above regulations has not created a common practice with regard to linen PPE that safeguards the public health.

Rather, what is necessary is a practical, logical set of regulations that is achievable by operators and that is cost-effective (to entice operator conformity).

If and when the CFP prevails upon the FDA to modify its Food Code as recommended above, the net result will be the implementation of guidelines which are practical and logical, which conform to all precepts of the Food Code relating to Food-Contact Surfaces, Equipment and Linens, and which—when properly and fully implemented—are cost-effective. Furthermore, these guidelines can be implemented under a program which conforms to the Principles of HACCP.



Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*

June 2001

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Seafood

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Fish and Fisheries Products Hazards and Controls Guidance: Third Edition
Excerpt from page 173:

Control in frozen, reduced oxygen packaged fishery products

If your product is immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use"), then formation C. *botulinum* toxin may not be a significant hazard.