FDA Criticality Work Group Report
Conference for Food Protection
Columbus, Ohio
April 7-12, 2006

Shirley B. Bohm
Chair, FDA Criticality Work Group
U. S. Food and Drug Administration
Retail Food Protection Program

FDA Criticality Work Group Report

- Background
  - Efforts to reclassify Food Code provisions on-going since 2000
  - Charge to FDA in 2004-I-011
    - Remove “critical item” & replace with more appropriate term/terms
    - Redesignate Food Code provisions in terms of risk factors that contribute to foodborne illness
    - Seek review & comment from CFP on draft proposal of these charges

FDA CFSAN

FDA Criticality Work Group Report

- Reclassification System
  - Complex systems must be considered
    - Food preparation
    - Food Code
  - Contribution to FBI must be considered
    - Direct or indirect
    - Measurable (critical limits)
  - Consistency with other documents and science
    - HACCP, HACCP Guides, CDC's FBI Reporting Form
    - Epidemiological investigations & research

FDA CFSAN

FDA Criticality Work Group Report

- Qualitative Risk Assessment*
  - Helps organize very complex concepts
  - Enhances the scientific basis for decisions
  - Can be done as a risk ranking
  - Characteristics of a risk assessment
    - Transparency
    - Well documented
    - Credibility & defensibility
    - Based on good science
    - Peer reviewed with stakeholder input

FDA CFSAN

FDA Criticality Work Group Report

- Definition #1
  - "Priority Item means an item in the Food Code whose application contributes to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury."
    - Is there a measurable critical limit?
    - Do other provisions more directly control the hazard?
    - Examples include cooking, cooling, handwashing

FDA Criticality Work Group Report

- Definition #2
  - "Priority Foundation Item means an item whose application supports, facilitates or enables the active managerial control of one or more priority items."
    - Examples include hand sink, documentation to execute a priority item (records), labeling

FDA Criticality Work Group Report

- Definition #3
  - "Core Item means all provisions that are not Priority Items or Priority Foundation Items such as but not limited to general sanitation, operational controls, facilities and structures, equipment design, etc."

FDA Criticality Work Group Report

- Decision making process (Excel Risk Assessment Spreadsheet)
  - Identify the general and specific hazard associated with provision
  - Make a preliminary classification (P, PF, C)
  - Assess the characteristics of the hazard
  - Assess the size &/or numbers of outbreaks
  - Identify contributing factors (C, P, S)
  - Revise classification if necessary
  - Provide rationale, additional comments & references for decision making

FDA CFSAN

FDA Criticality Work Group Report

- Example #1 of Risk Assessment Process
  - Provision: 3-501.14(A)(1-2) Cooling
  - Hazard – General: Spore-forming bacteria
  - Hazard – Specific: *Clostridium perfringens*
  - Initial Assessment: Priority Item (see def. – prevents germination of spores, critical limits are provided)
  - Characteristics of Hazard: (H, M or L)
    - shed at high levels
    - Spores survive cooking
    - Germinate & multiply during improper cooling
    - Sporulation in gut releases toxin

FDA CFSAN

FDA Criticality Work Group Report

- Example #1 Risk Assessment Process – Cont'd

  Size &/or Number of Outbreaks*:* (H, M, L) Large outbreaks – often associated with preparation and cooling of large volumes of food

  Contributing Factors:

  P2 – Slow cooling,

  P4 – Preparing food 1/2 day or more before serving

  M2 – Solid masses of PHF

  M6 – Roasted meat, poultry

  M8 – Liquid/semi-liquid mixtures of PHF

  Final Category: Priority Item

  Rationale: Meets the risk assessment criteria for Priority Item

FDA CFSAN

FDA Criticality Work Group Report

- Example #1 Risk Assessment Process – Cont'd

  Additional Comments: Measurable critical limits included (2 hrs. from 135°F to 70°F and to 41°F in total of 6 hrs.)
- References: #4, #15, #18

FDA Criticality Work Group Report

- Example #2 Risk Assessment Process

  Provisions: Date Marking

  3-501.17(A)

  3-501.17(A)(1-2)

  3-501.17(A)(2)(a)

  Hazard – General: Vegetative bacteria

  Hazard – Specific: *Listeria monocytogenes*

  Initial Assessment:

  3-501.17(A) – Priority Foundation – DM system

  3-501.17(A)(1-2) – Priority – measurable CLs

  3-501.17(A)(2)(a) – Core – operational conditions: equipment in place and in use

FDA CFSAN

FDA Criticality work Group Report

- Example #2 Risk Assessment Process Cont'd

  Characteristics of Hazard: (H, M, L)
  - Low infectious dose
  - Multiplies at refrigeration temperatures
  - Targets immunocompromised
  - High case fatality rate

  Size &/or Number of Outbreaks: (H, M, L)
  - Few outbreaks
  - Mostly sporadic cases

FDA CFSAN

FDA Criticality Work Group Report

- Example #2 Risk Assessment Process Cont'd

  Contributing Factors:

  P3 – Inadequate cold holding temperatures

  P5 – Prolonged cold storage for several weeks

  M11 – Commercially processed foods

  M12 – Sandwiches

  M 14 – Salads with raw ingredients

  Final Category:

  3-501.17(A) – Priority Foundation

  3-501.17(A)(1-2) – Priority

  3-501.17(A)(2)(a) – Core

  Rationale: Meets the criteria for definitions

FDA CFSAN

FDA Criticality Work Group Report

- Example #2 Risk Assessment Process Cont'd

  Additional Comments:

  3-501.17(A) – Specific criteria to establish DM system (foundation to enable DM)

  3-501.17(A)(1-2) – Measurable critical limit (7 days @ 41°F or 4 days @ 45°F) to determine disposition based on anticipated Lm growth

  3-501.17(A)(2)(a) – Equipment is available and in use

  References: #4. #15, #18

FDA Criticality Work Group Report

- Completion of the Charges to FDA
  - New definitions
  - Risk assessment process
  - Initial comments from (CFP DM Committee)
  - 1st review of all Food Code provisions
  - Validation by CFSAN and other scientists
  - Full review and open comment – stakeholders
  - Incorporate necessary changes from comments
  - Develop final report, finalize Excel document
  - Submit issue to 2008 CFP

FDA Criticality Work Group Report

- Expected Outcomes
  - More consistent, uniform and defensible re-designation of criticality in Food Code
  - Documented decision making process, open to examination
  - Recommendations for potential uses of designations
    - Focus training
    - Focus inspections and active managerial control
    - Guide regulatory enforcement for immediacy of correction