ISSC 2009 Biennial Meeting
October 17-23, 2009 – Manchester, New Hampshire
Committee Report

Committee Name : Product Recall Committee

Chairperson: Amy Fitzpatrick

Date of Meeting: October 18, 2009

Roster:

☒ Amy Fitzpatrick	☒ Erin Butler
☒ Bill Dewey	☐ Steve Fleetwood
☒ Jeff French	☐ David Fyfe
☒ David Guilbeau	☐ Clifford Hillman
☒ Lori Howell	☐ Alex Manderson
☐ Chris Nelson	☒ Virginia Olsen
☒ Quincy Boyce	☐ Debbie Rouse
☒ Debra Scoville	☒ Dawn Smith
☒ Kirk Wiles	☒ Marc Glatzer
☒ Michael Antee	☐ Bill Kramer
☒ Calvin Walker	

Charge 1: Proposal 07-200: Requirements to Conduct Product Recall

Findings: The new language in B. (3.) was too restrictive if pathogens were found in shellfish meats below tolerance levels.

Conclusions: Amend text of B. (3.) to strike proposed text which was too restrictive and would require recall of product that may be below pathogen tolerance levels.
Amend text to add a new section B. (4.) for areas when the pathogen levels in the shellfish do not exceed tolerance levels and no recall is necessary.
Re-number new B. (4.) to B (5.).

Recommendations:

B. Growing Area Investigation

(1) The Authority shall….

(2) The Authority shall…

(3) When the Authority determines that the growing area is not properly classified ~~**or that the growing area may be the source of the pathogens**~~ the authority shall take immediate action to:

(a) Change the existing classification to the correct classification; or

(b) Close the growing area until the correct classification can be determined; and

(c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.

(4) When the Authority determines that the growing area may be the source of pathogens the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy title 21 of Code of Federal Regulations Part 7 if the pathogens exceed tolerance levels.

~~(4)~~(5) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7 for all shellfish that may be falsely represented.

C. Distribution and Processing

(1) The Authority shall …

(2) The Authority shall …

(3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulation Part 7.

Charge 2: Immediately address and develop guidance document addressing

	appropriate actions which should be taken by State Shellfish control Agencies in the event of illness outbreaks. The guidance should address epidemiological and etiological determination, closures, reopening and recalls including appropriate timeframes for each.
Findings:	09-236 submitted to conference for consideration
Conclusions:	Minor amendments and editorial changes to recommend to Task Force II
Recommendations:	▪ Under new chapter 5.01A Requirements for the Authority; strike first sentence of paragraph 7. [**~~An immediate closure of a growing area or lease area may not be appropriate when an illness outbreak investigation reveals that the illnesses occurred weeks or months in advance with no subsequent illnesses.~~]** ▪ Under new Chapter 5.01 A Requirements for the Authority; strike first bulleted statement in paragraph 10. [**~~Notification of a confirmed illness outbreak that occurred weeks or months prior to notification with no other illnesses revealed in the preliminary investigation~~]** ▪ Revise paragraph 10 to make one sentence: A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market. ▪ Insert new paragraph 15 under Chapter 5.01 A. Requirements for the Authority; **Pursuant to the Model Ordinance Chapter II @01. (C)(4) and (D)(2) an Authority initiated recall shall include procedures consistent with The Recall Strategy as provided in 21 CFR Part 7.41, 7.42 and 7.50 as listed below: [for purposes of this guidance "the Authority" will be substituted for "the agency for a Food and Drug Administration"]** ▪ Amend old paragraph 15 further to strike duplicate language and create a header for 21 CFR Part 7.41: [**~~"The type of recall needed for any particular situation cannot be specified and is determined by the nature of the recall, as set forth in~~ 21 CFR Part 7.41:** ▪ CFR citations are italicized and in parens. ▪ Strike paragraph 17 [**~~The Recall Strategy as provided in 21 CFR Part 7.42~~]** ▪ Delete paragraph 4 under section B. Requirements for Dealers: [**~~[Press Release Committee – Mike Hickey, Bill Kramer, Kirk Wiles, Lori Howell, Bill Dewey, etc. procedures and states use to respond to public in the case of a recall/illness investigation (get in touch with Mike and Ken].~~** ▪ Add at the end of section B. Requirements for Dealers a note to direct the committee as determined by the Task Force to reconcile guidance with the Reportable Food Registry requirements. ▪ Amend text under section C. 2. Requirements for FDA [**Inform other FDA offices as appropriate ~~the Office of Food Safety and Division of Cooperative Programs~~ as new or pertinent recall information from the Authority becomes available; and** ▪ Revise appendixes A-G to make forms and other examples generic and blank.
Additional Information:	Appendices A-G will be provided to Task Force II.
Recorder:	Michael Antee and Amy Fitzpatrick
Approved by:	