**Conference for Food Protection**

**2012 Issue Form**

**Internal Number: 048**

**Issue: 2012 I-024**

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| **Council Recommendation:** | Accepted asSubmitted |  | Accepted as Amended |  | No Action |  |
| **Delegate Action:** | Accepted |  | Rejected |  |  |  |

*All information above the line is for conference use only.*

**Title:**

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

**Issue you would like the Conference to consider:**

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

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

**Public Health Significance:**

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

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

The only guidance in the Food Code is located in **Annex 3, 3-201.15 Molluscan Shellfish** (pages 374-375) which specifically identifies Listeria monocytogenes (and others) as a pathogen of concern at harvest, a position that is elaborated on in recently published research (Moustafa A. et. al Listeria spp. in the coastal environment of the Aqaba Gulf; Suez Gulf and the Red Sea. Epidemiol. Infect. 2006; 134; 752-757) (Colburn KG et. al. Listeria monocytogenes in California coast estuarine environment. Applied Environ Microbiol 1990; 56; 2007-2011).

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

Once received by a FOOD ESTABLISHMENT, raw live in-shell SHELLSTOCK are typically cold held longer than 24 hours due to the quantity received. And while the Food Code does not specify the number of days raw, live in-shell SHELLSTOCK can be cold held, Annex 3 estimates a shelf-life up to fourteen (14) days [**Section 3-203.12** **Shellstock, Maintaining Identification**; page 382]. This presents a serious potential challenge to REGULATORY AUTHORITIES that adopt and enforce date marking as recommended in the Food Code since date marking for commercially processed RTE PHF/TCS FOOD limits shelf-life to seven (7) days [**Section 3-501.17 Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Date Marking**; and **Section 3-501.18** **Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food) Disposition].**

SHELLSTOCK served in a raw, live in-shell form to the CONSUMER are currently subject to a CONSUMER ADVISORY [**Section 3-603.11 Consumption of Animal Foods that are Raw, Undercooked or Not Otherwise processed to Eliminate Pathogens**; pages 97-98] and have been identified by FDA as a potential source of pathogen contamination, including Listeria monocytogenes [Annex 3; **Section 3.201.15** **Molluscan Shellfish**; page 375]. Further, raw, live in-shell SHELLSTOCK can be harvested, transported and delivered to the FOOD ESTABLISHMENT at temperatures above 41o F [**Section 3-202.11 Temperature**; page 54] which can encourage the growth of pathogens such as Listeria monocytogenes.

Further, SHELLSTOCK are PACKAGED and shipped in netted bags or other non-reusable shipping containers, none of which are air-tight. Some of the non-reusable containers are opened at receiving to allow the FOOD ESTABLISHMENT to verify the condition and temperature of the raw, live in-shell SHELLSTOCK and the porous nature of the shipped non-reusable bags/containers does not discourage or prevent possible further contamination of the SHELLSTOCK under refrigerated storage in the FOOD ESTABLISHMENT.

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

**Recommended Solution: The Conference recommends...:**

...the language of the 2009 FDA Food Code (as modified by the Supplement issued in 2011) be changed to clearly reflect that date marking provisions apply to raw, live in-shell SHELLSTOCK served to CONSUMERS upon request without cooking or other treatment. (new language is in underline format; language to be deleted in strike-thru format)

**3-501.17(B)** **Ready-to-Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food), Date Marking.**

(B) Except as specified in ¶¶ (D)-(F) of this section, refrigerated, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) prepared and PACKAGED by a FOOD PROCESSING PLANT shall be clearly marked, at the time the original container is opened in a FOOD ESTABLISHMENT and if the FOOD is held for more than 24 hours, to indicate the date or day by which the FOOD shall be consumed on the PREMISES, sold, or discarded, based on the temperature and time combinations specified in ¶ (A) of this section and:PF

(1) The day the original container is opened in the FOOD ESTABLISHMENT shall be counted as Day 1~~;~~:Pf ~~and~~

(a) Except for containers of raw, live in-shell SHELLSTOCK, Day 1 shall be the date or day the SHELLSTOCK are receiving in the FOOD ESTABLISHMENT if the SHELLSTOCK will be served upon CONSUMER request in a raw, RTE PHF/TCS form; Pf and

(2) The day or date marking by the FOOD ESTABLISHMENT may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on FOOD safety.Pf

**Submitter Information:**

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**Attachments:**

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

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