

**FDA Food Safety Modernization Act
Lessons from
Implementation of Seafood
HACCP 1995-2005**

**Caroline Smith
DeWaal**

**Center for
Science in the
Public Interest**

July 21, 2011

CSPI/SFI and IACFO

- **The Center for Science in the Public Interest (CSPI) is a bi-national NGO representing over 850,000 consumers in both the U.S. and Canada.**
- **Safe Food International (SFI), a CSPI project, partners with consumer organizations in other regions of the world on food safety issues.**
- **The International Association of Consumer Food Organizations provides representation in Codex for consumer organizations on five continents.**

ELEMENTS OF EFFECTIVE FOOD SAFETY SYSTEMS



SEAFOOD HACCP: IMPLEMENTATION & REVIEW

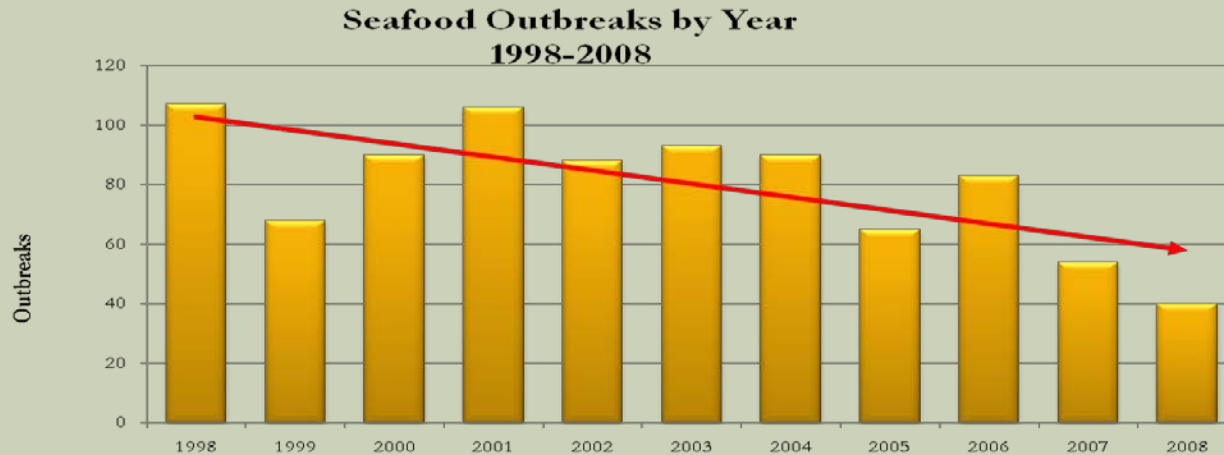
- Seafood HACCP Rule proposed March 3, 1994.
- Compliance phased-in over 2 years.
 - Dec. 18, 1995 – Final rule published.
 - Dec. 18, 1997 – All seafood firms required to have HACCP plans.
- Progress evaluations.
 - 1998-99 – Only 44% of inspected firms have adequate plans.*
 - 2000-01 – FDA ceased assessment of overall implementation.
 - 2002-03 – Spike in firms without plans blamed on warehouse inspections.
 - 2004-05 – Only 77% of histamine firms had adequate monitoring.†
- Completion of implementation?
 - 2005 – Only 86% of inspected firms had plan when needed.



* Does not include facilities that had no risk and, therefore, did not need plans.

† Histamine (scombroid poisoning) is a temperature abuse/monitoring issue.

APPARENT PROGRESS? BASELINES AND TRACKING



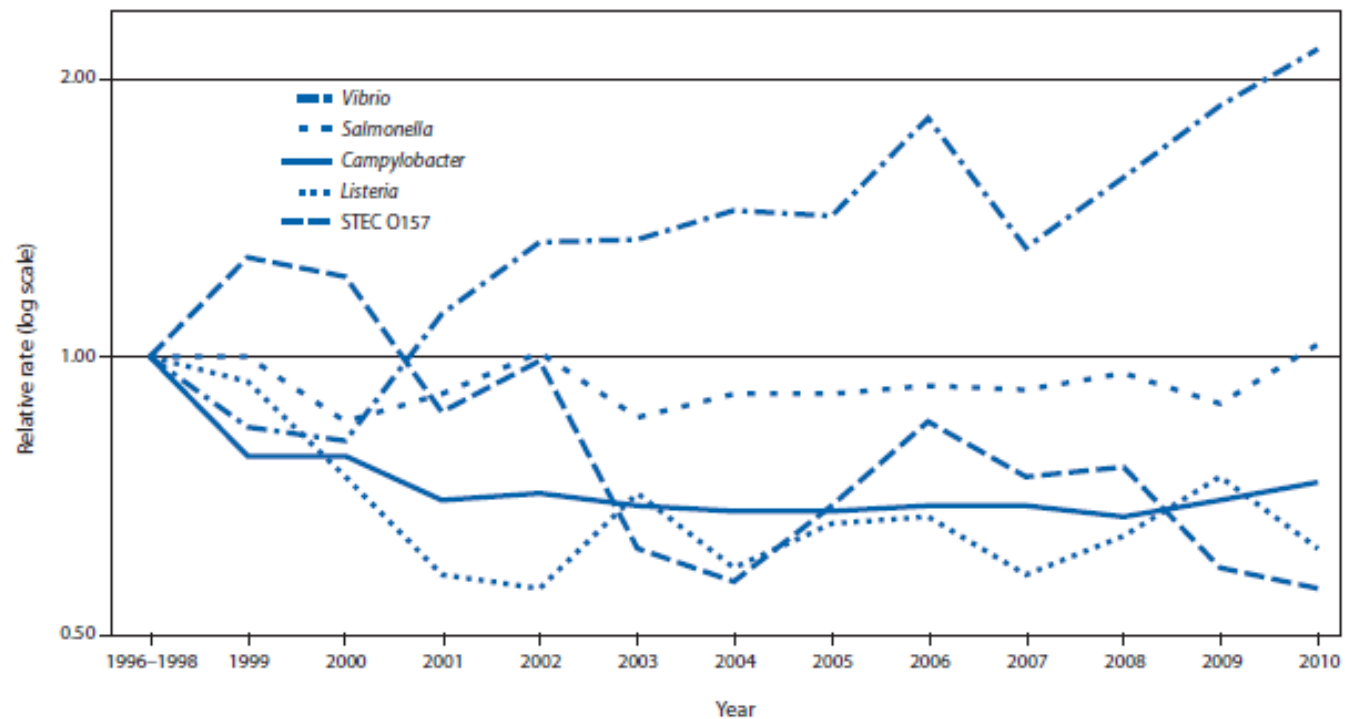
- No baseline for measuring progress.
 - 1992 study of 3 segments of industry.
- FoodNet does not track most common seafood hazards other than vibrio
- Verification testing made optional.

Source: CSPI's Outbreak Alert!.

TRACKING ONE COMMON SEAFOOD HAZARD

- FoodNet indicates HACCP has not controlled Vibrio.

FIGURE 1. Relative rates of laboratory-confirmed infections with *Campylobacter*, STEC O157, *Listeria*, *Salmonella*, and *Vibrio*, compared with 1996–1998 rates, by year — Foodborne Diseases Active Surveillance Network, United States, 1996–2010*

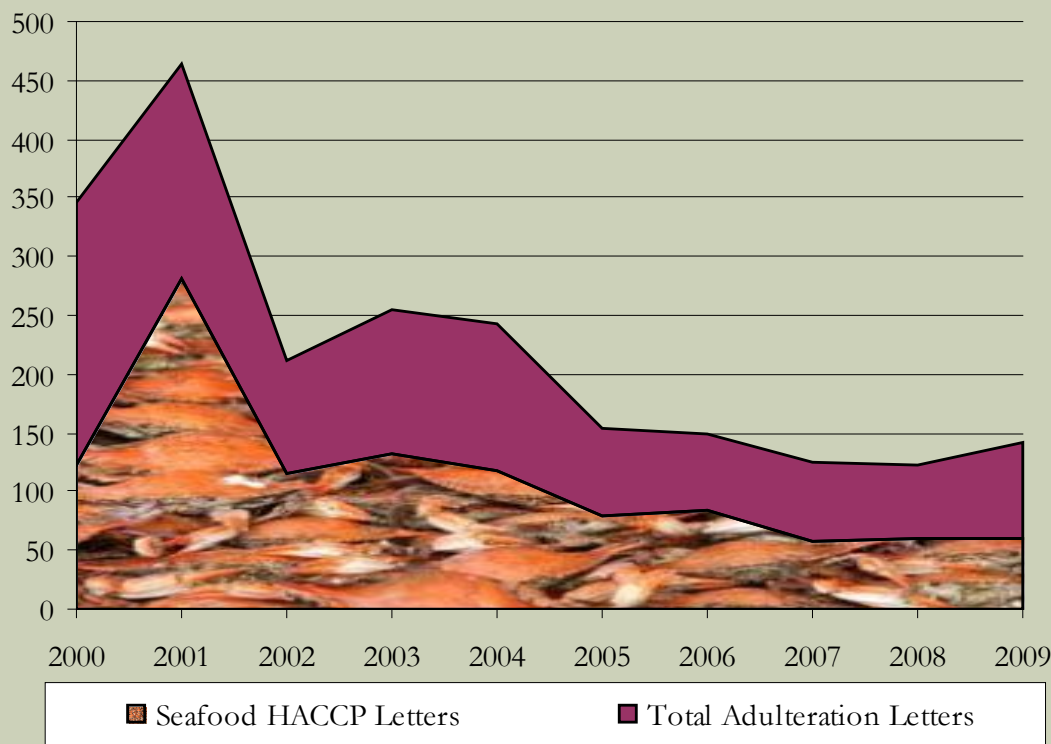


Source: CDC, MMWR 2011

MISSING OR INADEQUATE HACCP PLANS

Adulteration Warning Letters 2000-2009

N=2210



- CSPI reviewed warning letters from 2000-2009.
 - On average 50% of warning letters are for missing or inadequate seafood HACCP plans.
 - 10 years after first evaluation, 43% of warning letters reference seafood HACCP compliance issues.

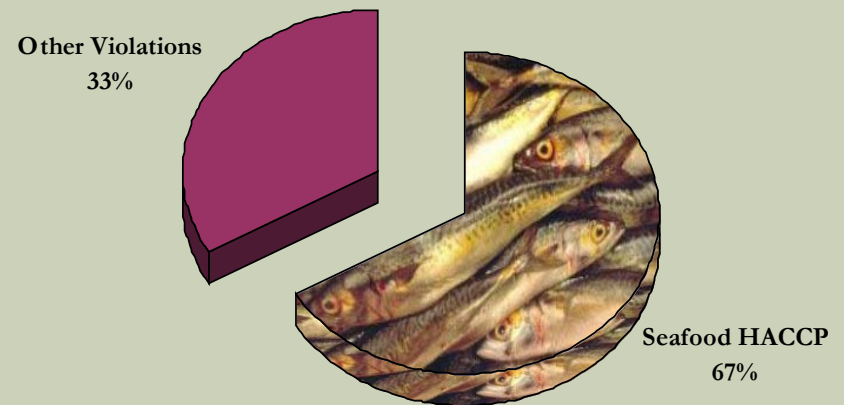
Source: Compiled from FDA warning letters.

SEAFOOD PROCESSORS MORE LIKELY TO REPEAT

- Compliance Rates.
 - Rule was fully effective in 1997
 - Over 80% compliance achieved by 2001 (4 years)
 - Moderate gains in compliance rates after that time (peaked in 2005 at 86%).
 - FDA indicated in 2002 “regulatory action may be necessary to correct much of the remaining non-compliance.”
 - Repeat violations are evidence of weak follow-up.

Seafood HACCP More Likely to be Topic of Repeat Warnings, 2000-2009

N=93



Source: Compiled from FDA warning letters, repeat warnings for all food categories.

LESSONS FROM SEAFOOD HACCP IMPLEMENTATION

■ Problems:

- 10 years after rule published, full implementation (95%+ of industry) still not achieved.
- Without baseline & consistent/appropriate metrics, progress is hard to assess.
- No apparent follow-up to close gap on non-compliance.

■ Solutions:

- Greater assistance and insistence on compliance.
- Identify baseline studies; develop tracking system that allows firms to recognize their progress.
- Evaluate performance and take actions against firms that fail to comply.
- Avoid silos and make links between authorities.
 - Environmental testing (§ 418(f)(4)) – Specify as a requirement.
 - Test reporting (§ 422(b)(2) & (d)) – Require labs to forward results of positive tests.

FSMA: IMPLEMENTATION OF PREVENTIVE CONTROLS

- President Obama signed FSMA into law on Jan. 4, 2011
- Compliance phased-in over 3 years.
 - July 4, 2012 – Facilities other than small and very small must have food safety plans and preventive controls in place.
 - ~Jan. 4, 2013* – Small facilities must have food safety plan and preventive controls in place.
 - ~Jan. 4, 2014 – Very small facilities must have food safety plan and preventive controls in place.



* Deadlines for small and very small facilities dependent on date final regulations are issued.

THANK YOU!

Caroline Smith DeWaal

Center for Science in the Public Interest

1220 L St., N.W. Suite 300

Washington, D.C. 20005

Phone: (202) 332-9110

Fax: (202) 265-4954

E-mail: cdewaal@cspinet.org

**On the internet: www.cspinet.org and
www.safefoodinternational.org**

