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

Preventative Process Controls
Registration
Import Controls
Inspections
Research and Education

Performance Standards
Federal/State Cooperation
On-Farm Controls
Enforcement

SAFER FOODS

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

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.*
- 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.
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!.
FoodNet indicates HACCP has not controlled Vibrio.

Source: CDC, MMWR 2011
MISSING OR INADEQUATE HACCP PLANS

- 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.
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.

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.
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!

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