North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner

FSMA, HACCP, on-farm Inspections

NC Aquaculture Association

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Food Safety Modernization Act

Signed into law January 4, 2011

- Focus on risk-based preventive controls and provides new enforcement authorities
- Directs the creation of an integrated food safety system in partnership with State and local authorities.

Why is this law necessary?

- Globalization
- Food supply more high-tech and complex
- Shifting population demographics

Proposed Rules

- Produce Safety
- **Preventive Controls for Human Food**
- **Preventive Controls for Food for Animals**
- Foreign Supplier Verification Program
- Third Party Accreditation
- Intentional Adulteration
- Sanitary Transportation of food

Key Aspects of Rules

- Confirms industry role in food safety
- Focus is on prevention, not reaction
- Address small business issues (Tester Amendment)
- Extensive government, stakeholder input

Compliance Dates

Compliance Dates (After Effective Date)	Preventive Controls (Human and Animal)	Produce Safety
Final Rule Issued	Aug 30, 2015	Oct 31, 2015
Effective Date	60 days	60 days
Other	1 year (2016)	2 years (2017)
Small	2 years (2017)	3 years (2018)
Very Small	3 years (2018)	4 years (2019)

(+ 2 additional years for some water requirements)

Timeline/Next Steps

- FDA will re-release key portions of some rules for public comment in summer 2014
- Final Rules scheduled for release 2015 and 2016
- Compliance begins 1 year after final rule; smaller facilities have additional time

Education before regulation

Preventive Controls for Human Food Rule

- Applies risk-based preventive principles to the manufacturing, processing, packing and holding of food for humans
- **Facilities,** unless otherwise exempt, would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Updated Good Manufacturing Practices

Impact on Aquaculture Farms

- Farms are not subject to the preventive controls rule if all activities are conducted under “farm” definition with no additional processing.
- Facilities (seafood processors) are subject to the GMP provisions of the rule but are exempt from preventive controls provisions if in compliance with FDA seafood HACCP.

Definition of "Farm"

Farm definition at present: 21 CFR 1.227:

"(3) *Farm* means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting.

Other regulatory topics

- Mandated by 2014 Farm Bill, primary regulatory oversight of domestically produced and imported Siluriformes fish and fish products will transition from FDA to USDA.
- MOU between agencies signed on April 30, 2014, a coordinated and phased transition process is underway.

Thank You!

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