

# FDA Compliance Issues

Kathleen M. Sinninger

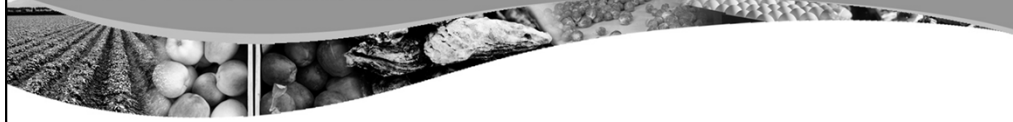
Director of Investigations, Florida District, FDA

Michael W. Roosevelt

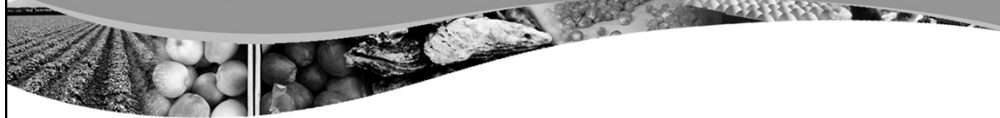
Acting Director, Office of Compliance, FDA/CFSAN

116<sup>th</sup> AFDO Annual Educational  
Conference

June 4, 2012

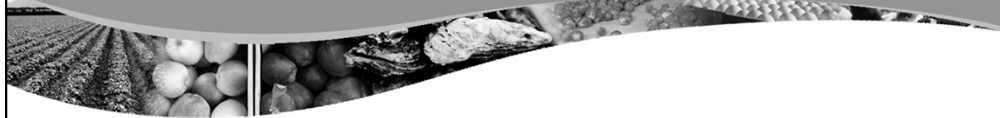


# FSMA Changes



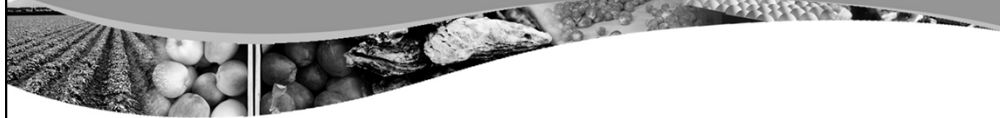
## FSMA Changes

- Domestic
  - Domestic inspection frequencies
  - Risk prioritization
  - State contract inspections of high risk firms
- Foreign
  - Increased foreign inspections by FDA



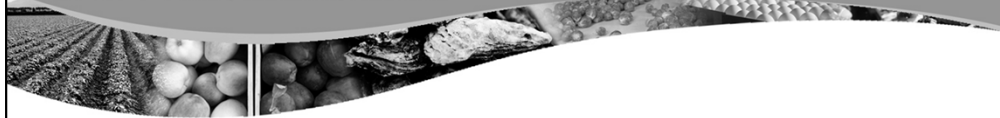
## FSMA Changes

- Facility registration changes



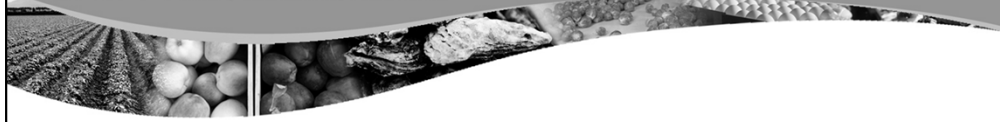
## FSMA Changes

- User fees for compliance re-inspections



## FSMA Changes

- **New enforcement tools**
  - Administrative detention
  - Mandatory Recalls



## Recent & Emerging Compliance Issues

- Orange juice and carbendazim
- Arsenic in rice and rice products
- Imports
- Produce
  - Cantaloupe
  - Papaya