Joint Efforts on Seafood Safety

Case Study

FDA THIRD PARTY CERTIFICATION OF AQUACULTURE SHRIMP “PILOT”

Consumer Goods Forum

Feb 5, 2010

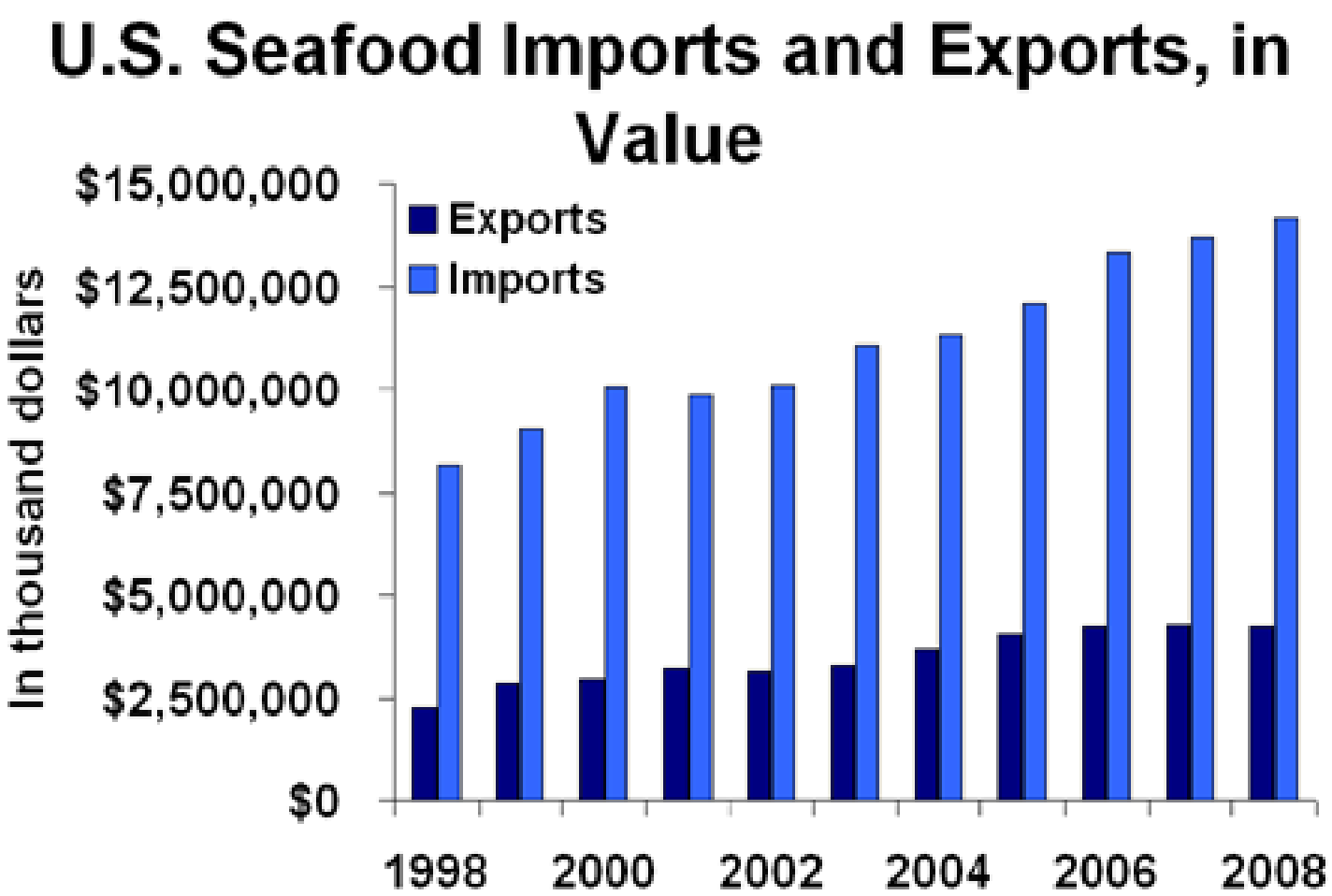
WHEN YOU NEED TO BE SURE

SGS

TOPICS

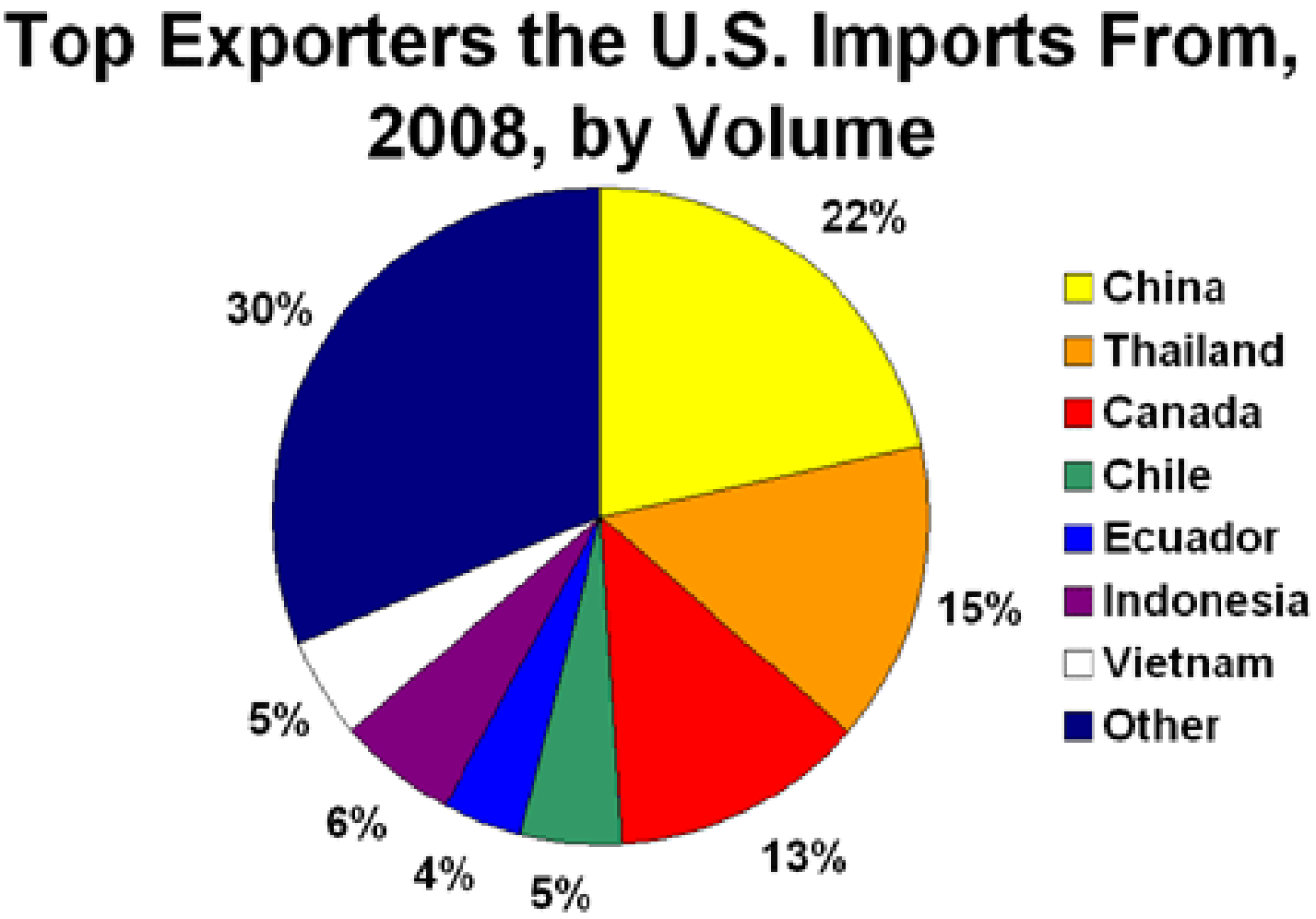
1. Statistics that are relevant to US Seafood
2. Rationale for the joint effort in seafood safety
3. Focus on Aquaculture Shrimp
4. Pilot Program Logistics
5. Lessons Learned
6. Questions

SEAFOOD TRADE DATA 1



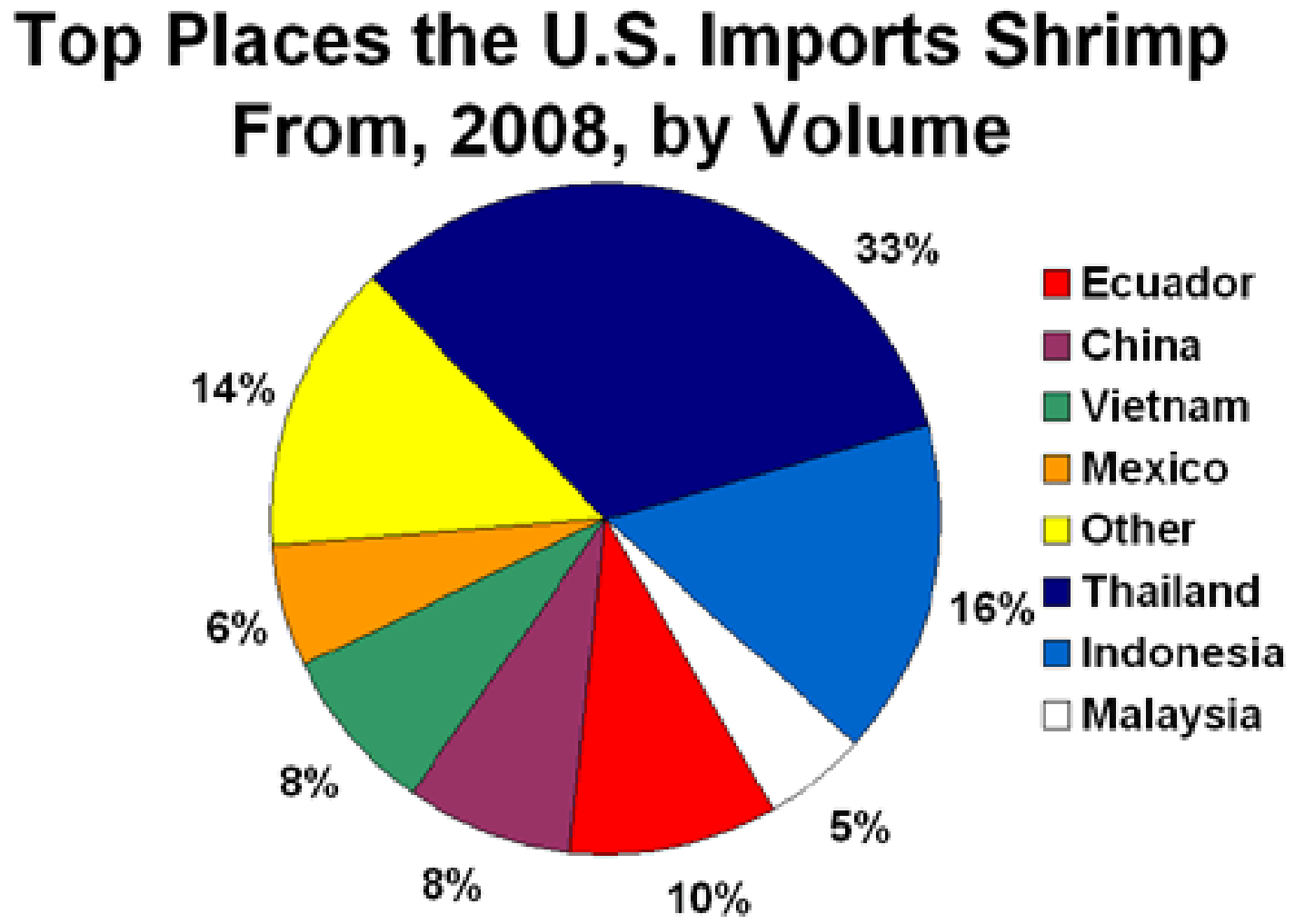
NMFS NOAA Fish Watch

SEAFOOD TRADE DATA 2



NMFS NOAA Fish Watch

SEAFOOD TRADE DATA 3



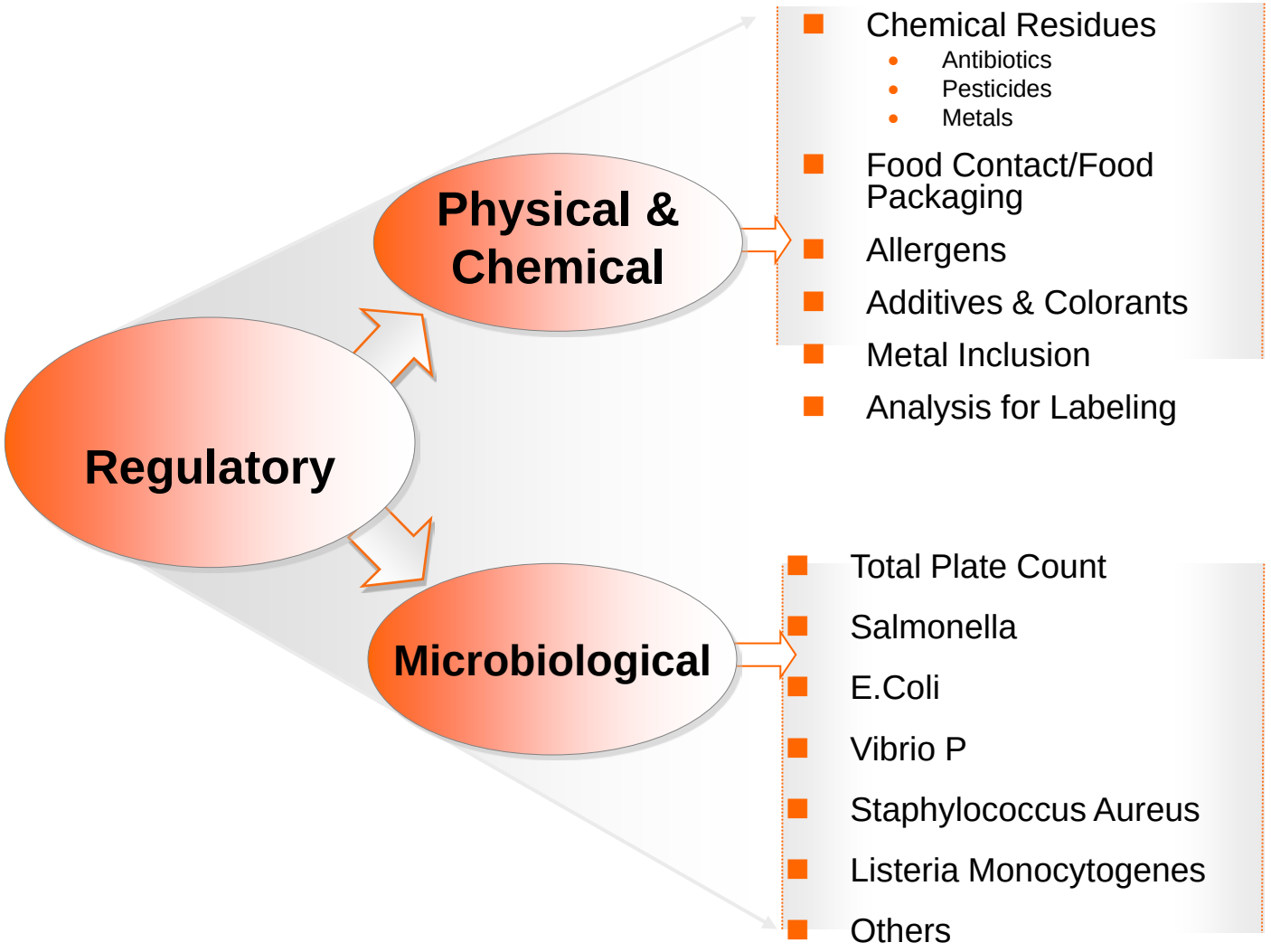
NMFS NOAA Fish Watch

FDA CHALLENGES DRIVING THE JOINT EFFORT

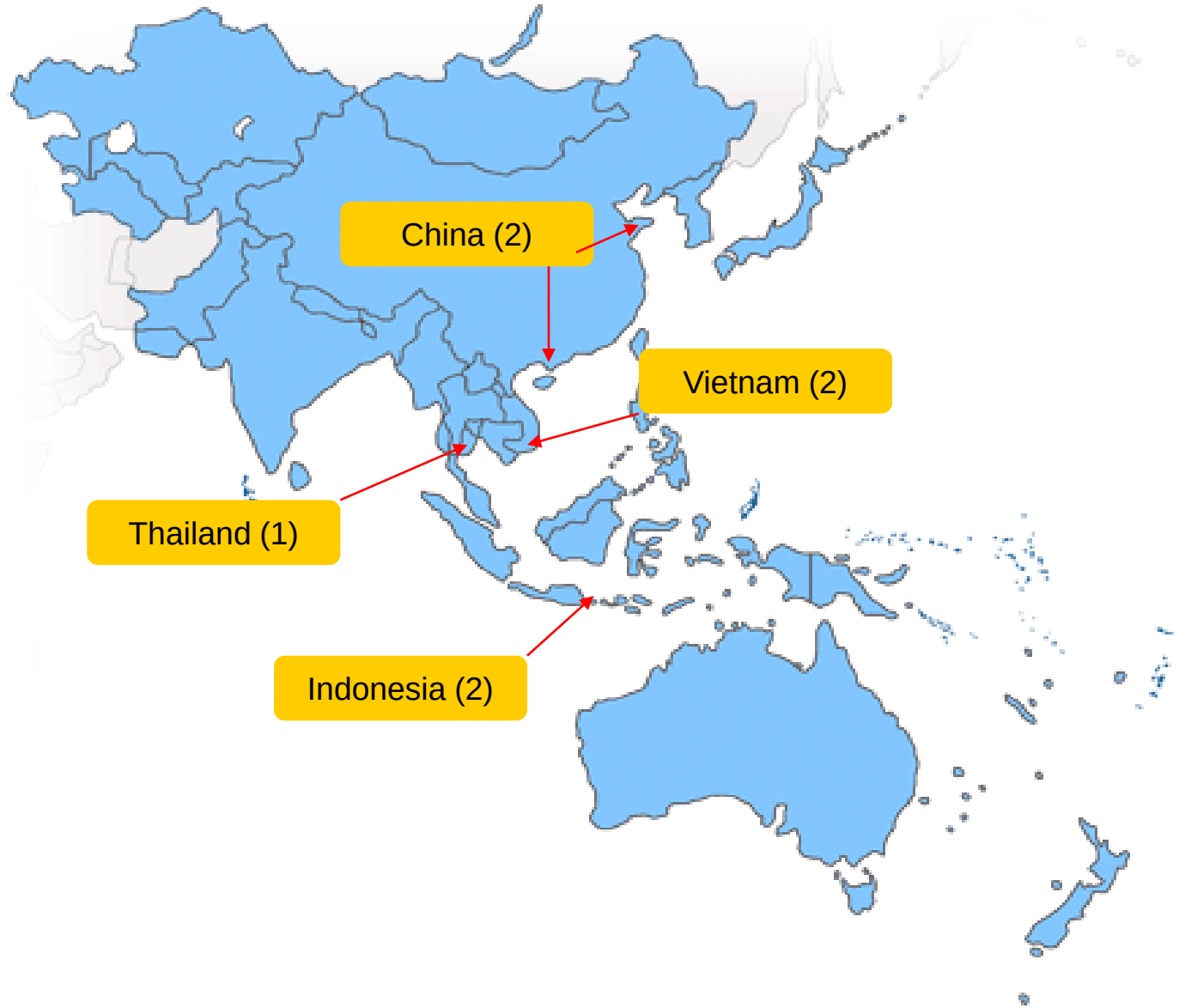
- The US seafood import records indicate over 900,000 lines of imports per year into its Oasis/Predict
- ‘It could take 30 years for the FDA to visit and audit all the factories’
- The FDA continues to update and issue Import Alerts against products, facilities and countries.
- The need to reach out to third parties was clear and justified.
- The FDA challenge was to study certification providers, different certification schemes and then “audit the auditor” to that specific certification scheme.

US SHRIMP SAFETY ISSUES (overview)

- 21 CFR 123 Seafood HACCP
- Fish & Fisheries Products Hazards and Controls Guidance 3rd Edition
- Low Acid Canned Food 21 CFR 113 and 21 CFR 114
- Economic Adulteration
- Country of Origin - Species Identification



LOCATIONS FOR THE SGS FDA PILOT PROGRAM



PILOT PROGRAM LOGISTICS

UNITED STATES

- Dedicated Project Management
- Pre-requisite SGS Body Self Assessment
- FDA visits to the UK, and Asia
- Certification & Laboratory Documentation
- Manage cultural expectations

INTERNATIONAL

- Coordinate Shrimp Processor information across four countries
- Address processor fears/concerns
- Coordination of visas, lodging and local travel
- Provide language & logistics support
- Schedule & execute audits and laboratory visits

BRITISH RETAIL CONSORTIUM CERTIFICATION AUDIT

The BRC Scheme was chosen as a globally accepted certification scheme - to enable comparison to FDA Seafood HACCP.

Process:

1. Senior Management Commitment and Continual Improvement
2. The Food Safety Plan – HACCP
3. Food Safety & Quality Management System
4. Site Standards
5. Product Control
6. Process Control
7. Personnel

LAB PROCESS BY LIMS

Opening Meeting

Quality Management System

LIMS

Sample Track – US Client

Witness Testing

Method & Report Analysis

Customer Feedback

Continuous Improvement

Bar-coding system / tracking status

LIMS system

“LESSONS TO LEARN & UNLEARN”

1. Concerns for the evaluation of Certification Standards
    a. Independent of processor size, we were asked to complete two audits per week, including location travel, because “the other providers” were doing that. Size varied by 100%.
    b. We understood that the other participants were performing their inspections in one day.
    c. The FDA team commented that do get their job done, they may spend up to five days in a plant.
    d. Plant scheduled client visits and additional audits during the FDA visit which disrupted the audit completion and integrity – in Vietnam, a government official was also present.

“LESSONS TO LEARN & UNLEARN”

2. Concerns for Auditor
    - Every audit had an FDA interpreter; they differed in linguistic skill.
    - Confusion over technical terminology and clarity of communication occurred daily – distracting the auditors.
    - Attitude: If the auditor did not state what he saw – he was penalized.
    - Dual Role part teacher and part auditor in the certification process.
3. Concerns on the off-site Laboratory ‘Inspection’
    - Two day audit was not intended to cover all relevant lab methods
    - No coverage of Microbiology, etc.
    - Tremendous organization cost with incomplete “take-away”

“LESSONS TO LEARN & UNLEARN”

4. Concerns for Holistic Integration with Product Inspections

- Private industry may treat facility certification audits, product inspection, product testing and environmental testing as separate services – still falling under GFSI certification.

- Separate product inspections as part of the “certified” quality system were declined due to FDA budget constraints. Why not?

“LESSONS TO LEARN & UNLEARN”

5. Open concerns for Stakeholders

    a. Forensic / Criminal Investigations by the auditor
    b. FDA Adulteration
        a. When does soaking time > Adulteration?
        b. Antibiotics – known and unknown?
    c. Attention to Allergens – guidance from FDA.
    d. Upstream supply chain review – brokers.
    e. Package Labels – consistent declaration of ingredients
    f. Product versus process certification?

PROVOCATIVE QUESTIONS ON THIS JOINT EFFORT

- If not a GFSI scheme, then what & how will the FDA implement to cover their own, revised Seafood HACCP and Fish & Fisheries Hazards & Controls Guidance throughout the import supply chain?
- How & when will the legislation in the House and Senate affect the pilot outcome and ongoing certification process in the shrimp/seafood industry?
- Different export and import governments have different seafood regulations – will the FDA override local legal requirements?
- What are the political and economic consequences when or if import - export governments become de-facto certification bodies?

TRIBUTE TO THE US FDA TEAM

Field Comments

- The FDA sent a very competent team of food safety professionals
- They were intelligent, and empathetic.
- They were faithful to the their role in observing and gathering information
- There were surprises every day, and they adapted very well
- We are all human!!!

Thank you!

WHEN YOU NEED TO BE SURE

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ABOUT US

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- Experts at:
  - Providing competitive advantage
  - Driving sustainability
  - Protecting brands
  - Delivering trust
- 59,000 employees, including:
  - Scientists, engineers, doctors, chemists, auditors and inspectors
- 1,000 offices and laboratories globally

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