The International Trade Association of Greater Chicago

Import Operations Strategic Plan

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Overview of Presentation

- **Import Operations Strategic Plan**
  - ✓ Present an overview of the import operations strategic plan
  - ✓ Describe the actions taken to this point
  - ✓ Discuss the 19 initiatives and the 6 selected as the first tier
  - ✓ Discuss next steps
  - ✓ Answer any questions that you may have regarding the project

What have we learned through our recent work?

- **We have major challenges**
  - ✓ Public is at risk
  - ✓ Substantial increases in volume; product diversity and complexity
  - ✓ Resources primarily focused on intervention and response activities
  - ✓ Need valid, accurate, accessible data and tools
  - ✓ Need to engage stakeholders in a different way
  - ✓ Suffer from morale and management issues

- **Our system is in need of dramatic improvement**
  - ✓ Divergent processes across nation
  - ✓ Insufficient hard data for understanding performance capability or informed decision-making
  - ✓ Poor structure for intelligence-driven decisions
  - ✓ Lack a unified model for doing work

- **We must continue to leverage the work of others (e.g. CBP)**

The Operations Model puts the Agency in a strong position to take import operations forward

- Our new operations model is aligned with Congressional legislative intent and all key strategies (i.e., White House, HHS/FDA, ORA)
- The model includes 19 key activities distributed across the business areas of prevention, intervention and response – we have started detailing six of these activities
- Key stakeholders continue to be engaged in the development of the operations model (Industry, OGA, Field, OMOP)
- The creation of uniform policies and procedures across all types of ports of entry will greatly improve import operations and help create efficiencies and improve effectiveness across food, drugs, medical devices, biologics, cosmetics radiation emitting devices and tobacco
- We have commitment from Commissioners Hamburg and Bersin to harmonize our operations to improve import security and safety and fix current gaps (ex: MIDs, enforcement, procedures, sharing of data) – an import Safety Conference, hosted by CBP, CPSC and FDA will be held in October

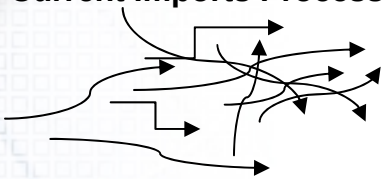
We are designing a global approach to imports

ORA's Import Operations Program protects consumers and enhances public health by minimizing the risk associated with imported FDA-regulated products and maximizing compliance along the global supply chain of those products.

Guiding Principles ("What")	*Design Criteria ("How")*
Prevention Orientation	…sustained through a global focus, active alignment with foreign and domestic inspections and leveraging relationships with other stakeholders
Intelligence Based Decision-Making	...readily available through innovative technology, informed by science and prioritized through risk analysis
Higher Levels of Compliance	...through authorities, enforcement actions and education and outreach
Effective and Efficient Processes	...maintained through partner collaboration, mutually agreed upon standards and monitored performance levels
Systemic Accountability	…demonstrated through adherence to performance standards and maximizing national resources and authorities

A new "whole system" approach is more effective and efficient

Current Imports Process

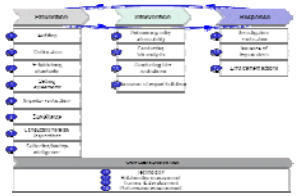


Today each unit operates at its own pace, process and style - resulting in a lack of uniformity, efficiency, effectiveness – and increased risk to public health

Issues

- No linkage between foreign inspections/intelligence and domestic inspections
- Limited capacity management capabilities
- Structural inflexibility
- Reactive based inspections
- Local SOPs guide work
- Each district and region executes the process differently
- Gaps in the system exposes imports to harmful situations
- Fragmented operations are ineffective to meet current and future challenges and complexities
- No organized and documented enforcement strategy

Future Operations Model



A whole systems approach aligns and connects the moving parts of the system so that they work together in a coherent fashion to produce the desired outputs

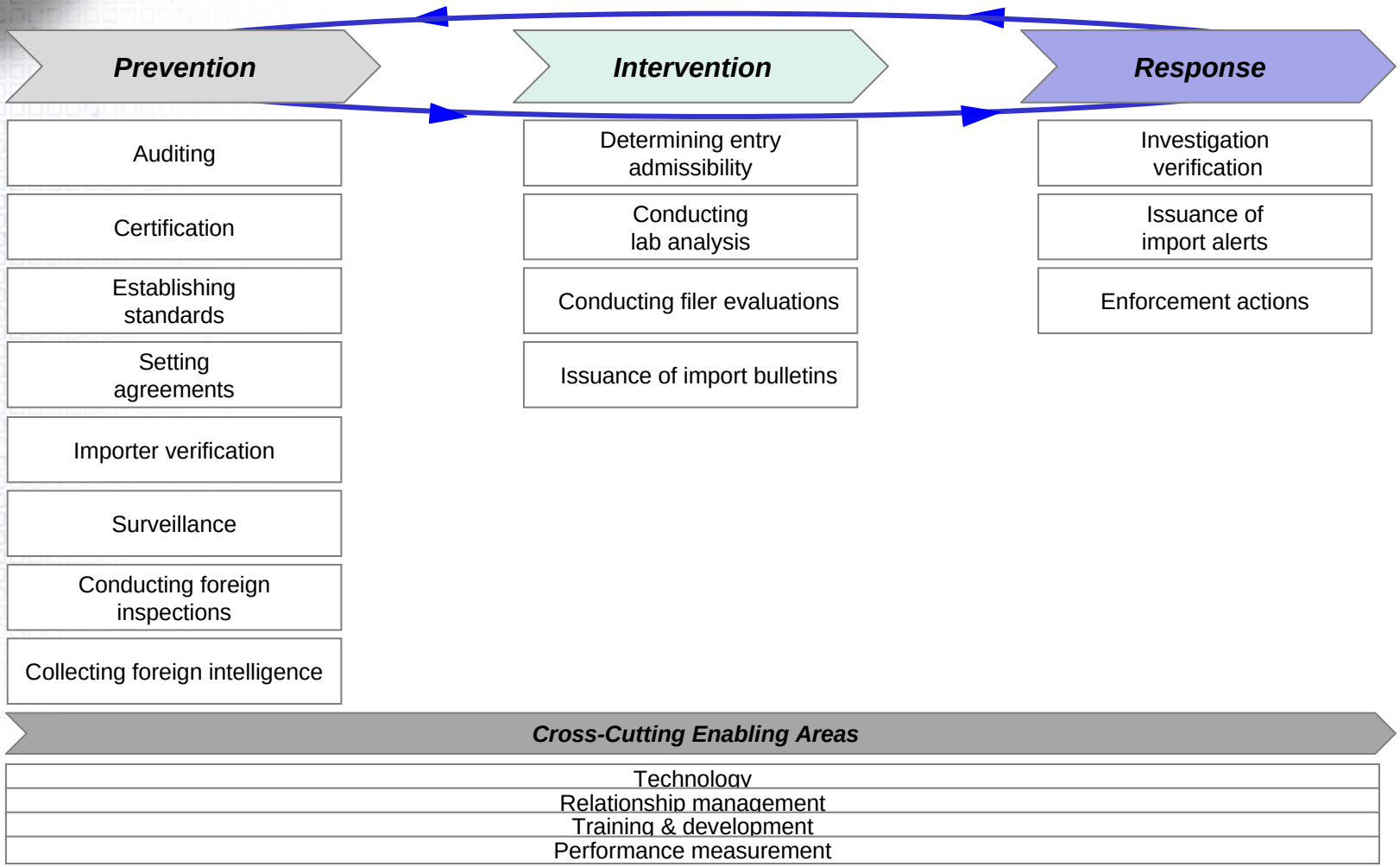
Features

- Increased focus on prevention and proactive management of risk before harm happens
- Uniform process
- Efficient use of resources
- Effective allocation and management of resources
- Flexible capacity to meet changing needs
- Smarter inspections

Benefits

- Boost in performance
- Reduction of risk to Public Health
- Increased public confidence
- Increased industry compliance
- Ability to exceed stakeholder expectations
- Address GAO concerns before critical reports issued
- Harmonize procedures with CBP

The “whole system” approach to import operations has three business areas



We are proceeding across four work streams

1 **Program Management**

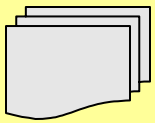
2 **Operations Model Development & Implementation**

2a *Detailed Design Requirements*

- Categorize data by operating model activity
- Review all themes, issues, actions and recommendations in the context of system level requirements
- Develop kickoff packages for Detailed Design Teams

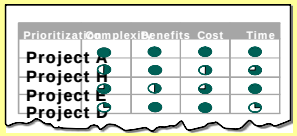
We are here

2b *Detailed Design*



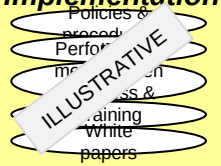
- Establish Detailed Design Teams, lead by Core Team members to:
  - Develop detailed process flows
  - Identify technology, infrastructure and people needs
  - Identify performance measures (input, activity, output and outcome)

2c *Project Prioritization*



- Prioritize resources and effort based on impact, complexity, stakeholder interest, etc.
- Feed cross-cutting needs to additional groups as appropriate

2d *Design Implementation*



- Establish additional teams
- Develop project plans
- Implement projects
- Document results

3 **Communications**

4 **Performance Measurement**

Note: Workstreams 1-4 are underway

Priorities have been established and activity design teams are being developed

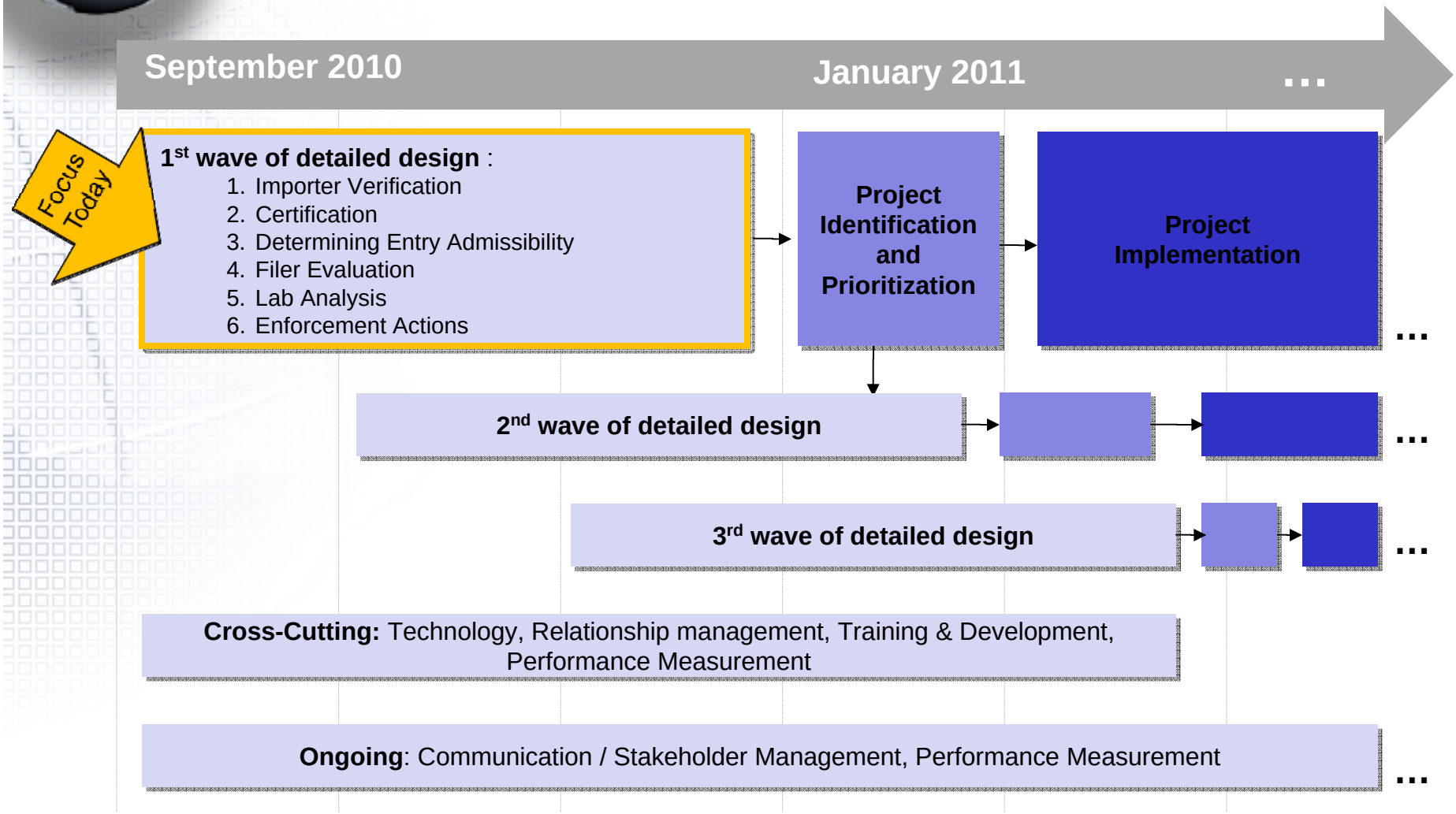
- **We received guidance from members of the ORA's Senior Management Team to:**
  - ✓ Focus on the hard problems
  - ✓ Be innovative in our analysis and expansive in our problem solving
  - ✓ Move quickly but be thorough and use defensible approaches (i.e., pass any OMB, GAO test)

- **In early September, the Core Team validated all 19 import operations activities to be designed, weighing each against the following criteria:**
  - ✓ **Strategic Impact:** public health impact achieved, key stakeholder impacted, risk minimization, addresses operational pain points, impacts efficiency/effectiveness/uniformity, forward thinking
  - ✓ **Level of Complexity:** degree of difficulty moving from current to future state, level of complexity for implementation, level of dependence on others, level of effort
  - ✓ **Level of Maturity:** readiness of ORA to implement (e.g.,: high= 80% of the way – we have everything we need; low=immature process)

- **Using these criteria, six activities rose to the top for the first wave of development**
  - Importer Verification
  - Certification
  - Determining Entry Admissibility
  - Filer Evaluation
  - Lab intergration
  - Enforcement Actions

- **The remaining activities will be prioritized and completed on an on-going basis and any activity that other initiatives have started we will play a supportive role**

Detailed design is proceeding on a rolling, integrated basis starting with six activities



Summary of next steps

- **September-November 2010:**
  - ✓ Continuing stakeholder dialogue regarding key requirements
  - ✓ Meeting with Core Team and Design Activity Teams (October 13-14)
  - ✓ Creation of the detailed design
  - ✓ Project prioritization
- **December-January 2011:**
  - ✓ Development of project plans
  - ✓ Establishment of project implementation teams
  - ✓ Begin project implementation

QUESTIONS?