Making Mutual Reliance and Information Sharing Happen
Session Objectives

• Understand mutual reliance pilot projects
  – Objectives of projects
  – Most successful areas and best practices developed
  – Barriers and solutions
  – Sustainability and resources required
Session Objectives

• Outline proposed new funding approach to support mutual reliance and information sharing

• Receive your input on future funding approach
  – Pros
  – Cons
  – Suggestions
  – Concerns
  – Questions
Panel Discussion

• Overview of pilot projects
  – California
  – New York
  – Wisconsin
Panel Questions

• Which areas of the pilot were most successful? Why?
Panel Questions

- What were barriers to success? How were they overcome?
Panel Questions

• What effective coordination and data sharing efforts were included in your pilot?
Panel Questions

• Is the sustainability of the best and successful practices and activities of your project an operational reality? What resources would be required? If not, why?
Panel Questions

• Questions from the audience
Proposed Funding Approach to Support Mutual Reliance & Information Sharing

• Very early stages of discussion and looking several years ahead into the future

• Concept only

• Feedback is critical
Current Issues

• Current funding mechanism (food contract) limits information sharing

• Contracts primarily benefits FDA
  – Critical to assist FDA meeting performance goals
  – Work is very prescriptive
  – Little flexibility

• Alignment of contract size with District inventory and workplan
Goals of Funding Approach

• Promote mutual reliance and 2-way information sharing between States and FDA

• Legal funding approach beneficial to all stakeholders

• FDA can obtain State assistance in meeting inspection goals

• Support PFP initiatives
Proposal

• Use a combination of the food contract and a new cooperative agreement

• Cooperative agreement: Primarily benefits grantee and the public, greater flexibility, funding provided upfront

• Contract: Primarily benefits Federal government, rigid, reimbursement basis
Proposal

• Combination of cooperative agreement and food contract may allow for:
  – Improved information sharing to protect public health and promote compliance
  – Increased reliance upon each other’s work
  – State assistance FDA in meeting performance goals
Cooperative Agreement Objectives

• Promote two-way regulatory information sharing between States and FDA:
  – Inspection reports
  – Consumer complaints
  – Compliance and enforcement actions
  – Recall investigations and audit checks
  – Natural disaster response follow-up
  – Laboratory testing results and follow-up
  – Foodborne illness outbreak investigations
Cooperative Agreement Objectives

• Infrastructure to share regulatory information

• Generate new ideas and best practices to incorporate into MFRPS

• Support PFP best practices and priorities
Eligibility Requirements

- Conformance with the MFRPS
- Maintaining food contract in satisfactory condition with minimum # of inspections
- Active manufactured foods program
Funding

• Tiered funding based on program size and activities

• Funding levels TBD
  – Input is critical to determine resource requirements and funding
Allowable Costs

• Employee salaries and fringe expenses
  – Develop and implement SOPs, templates, protocols
  – Develop systems for sharing information
  – Conduct work prioritized by the grantee and FDA
  – Coordination of activities, such as joint inspections, training, meetings
  – Workplanning
Allowable Costs

• Travel
  – Attend agreed upon training courses and meetings to promote goals of cooperative agreement
  – Conduct work prioritized by the grantee and FDA

• IT systems, ideally to allow for automated data exchange
Items to Consider

• Future of State food contract inspection program:
  – Inspections that meet FDA performance goals must be completed under the food contract
  – More alignment of the contract with the District inventory and workplan
Items to Consider

- State must have an active manufactured food regulatory program outside of FDA funded activities

- Districts and States must decide upon critical reporting procedural elements for data acceptance
  - Flexibility will be required
  - Focus on equivalent outcome
Pros

• Greater access to States and FDA for sharing of regulatory information
  – Risk-based decision making
  – States counting FDA inspections

• Reliance upon each other’s work

• Implement and improve upon PFP resources
Pros

• Greater recognition for States that achieve conformance with the MFRPS

• Sustainable systems supporting mutual reliance

• More flexibility with reporting requirements
Cons & Challenges

• Impact will be variable based upon relative size of contract and State regulatory activities

• State program in conformance with the MFRPS

• Inspections that meet FDA performance goals must be excluded from cooperative agreement
Group Exercise

Working at each table, participants as a group will:

1. Provide input on pros/cons of introducing an alternative funding approach using a cooperative agreement and food contract to support mutual reliance and information sharing

2. Provide input for recommendations and solutions on how this funding approach might best work (including resources/FTEs needed)

3. Have an opportunity to hear each other’s (State and FDA) concerns and challenges
How Integrated is Your Table!?

Total your points – one point for each of the table combinations:

- At least one FDA and one State
- At least one State Program and their District
- At least one State Liaison and their MFRPS Coord.
- At least one State program manager and another District manager
- At least one State, and at least one FDA District and FDA HQ or Center representative
- More than one State, and more than one FDA District, FDA HQ or Center representative
Group Exercise

1. Based on today’s presentations and the proposed funding approach, identify:
   a. Pros
   b. Cons
   c. Recommendations/ Suggestions

2. For each response identify source – S (state) F (federal)

3. Prioritize responses and report out on the top one or two priorities for a-c. (along with your table integration score!)

4. Hand in responses on flipchart to Wendy
Report Out

• Top pro

• Top con or challenge

• Top recommendation or concern

• Integration score