# NY Mutual Reliance Pilot After Action Report

## Office of Partnerships/Division of Integration
## NY Department of Agriculture and Markets
## Division of Human and Animal Food, East 1
## Division of Northern Boarder Import Operations

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# MUTUAL RELIANCE PILOT PROJECT Between the New York State Department of Agriculture and Markets Divisions of Food Safety and Inspection and Food Laboratory, and the U.S. Food and Drug Administration Office of Human and Animal Food Operations (June 2016 and August 2018)

### Purpose

The primary purpose of this pilot was to increase integration in sample collection, product information components (e.g., traceback documentation), and laboratory review and analysis of imported products. The pilot will provide the FDA with the basis to initiate appropriate compliance actions against foreign manufacturers and violative imported products based on state analytical data.

### Scope

The scope of this pilot was the sampling and evaluation of imported foods, primarily those sampled by the state at retail facilities. (Note: Objectives taken from the MOA)

Objective 1: Laboratory analysis, sample information, sample follow-up, traceback documentation (when available), and data sharing.

Activity: NY AGM Food Safety and Inspection provided sample and traceability information with data package submissions.

NY AGM Food Laboratory provided violative sample data packages to the FDA for regulatory action and included the mutual reliance pilot checklist, which was modified as needed during the pilot, for all data packages.

Observations

- Sample information was captured in a timely manner when feasible.
- Some traceability information (i.e., invoices, receipts, and import documents) was not available at the state level.
- State had limited jurisdiction when acquiring documentation from out-of-state importers.
- Violative data packages were submitted to FDA in a timely manner when feasible (e.g., traceability documentation available for collection by the state).
- Some relevant FDA offices were not included (e.g., DIO and CFSAN) during the initial planning phase of the pilot.

- Sample invoices required for FDA regulatory follow-up were collected at time of sample collection, if available.

Analysis: Strengths

- The robust NY AGM sampling program resulted in a high number of recall level violative samples to test the pilot workflow.
- Information sharing improved the FDA's ability to enforce regulations and protect public health.
- Leveraged import alerts or screening criteria by adding manufacturers and products when NY AGM found positive product samples.
- Efficient and transparent processes were developed and enabled the following:
    - Provided all the necessary laboratory information required for the FDA review.
    - Allowed for full development of the FDA's review process in a timely manner.
    - Developed a process between NY AGM and the FDA for discussing methodology issues affecting the acceptance of the laboratory data.
    - Developed NY AGM's internal processes for obtaining the necessary sample information to allow the FDA to identify the correct entity to be added to the Import Alert.

Analysis: Areas for Improvement

- All relevant stakeholders were not included during the planning phase of the pilot.
- Laboratory analyses under the pilot were limited in scope.
- The pilot was not fully structured with specific, clear, and achievable objectives for both agencies such as required documentation from NY AGM and reducing time for FDA package review.

Recommendations

- Expand program to include more regulatory laboratory interactions.
- Share this pilot model with other states and the FDA Divisions to facilitate access to lessons learned.
- Identify point of contacts for DIO, CFSAN, and ORA/ORS prior to initiation of the pilot for advanced awareness that allows package reviews to be tracked and processed in a reasonable amount of time.
- Consider further discussion with internal stakeholders on where and how to reduce the FDA review time of analytical packages received from states (e.g., conduct ORA/ORS and CFSAN/ORS review concurrently).

Activity: NY AGM Food Laboratory will provide violative sample data packages of imported samples resulting in state Class 1 recalls to the FDA for regulatory action and include the mutual reliance pilot checklist to all data packages.

Observations

- Some NY AGM laboratory methodologies were not accepted as equivalent by the FDA (e.g., allergens).
- Violative data packages were submitted to FDA in a timely manner when feasible (i.e., traceability documentation available for collection by the state).

- Discussions were held between the NY AGM and the FDA related to methodology for allergen testing. The specific testing of allergens was removed from the list of possible hazards analyzed under the pilot reset, and allergen results were reported either as supplemental information or supported through the normal reporting process outside the pilot.

Analysis: Strengths

- Collaborated to create a checklist that was modified and improved during the pilot.
- The FDA created a flowchart to assist in communication, decision-making, and agency involvement with state data package reviews.
- The FDA used CMS case numbers to track data packages submitted by the pilot, which made the packages easy to locate by all the FDA reviewers.
- State-submitted data packages evaluated through the pilot were also recalled at the state level under Class 1 or 2 and products were removed from grocery shelves.
- NY AGM submitted a total of 29 analytical packages for evaluation. Three of the 29 packages represented the same product/firm but different lot numbers. Thirteen of these packages were positive for sulfites, lead, *Listeria monocytogenes*, allergens, and colors. In most of the cases the laboratory results were used as evidence under the pilot and added to import alert. An additional six packages were positive for sulfites, lead, and allergens, resulting in the screening criteria for the suspect firms (responsible party was not verified).
- The FDA did not have to collect and analyze product samples during the pilot, which showed a benefit of mutual reliance.
- The FDA added products to import alerts which greatly minimized duplicative efforts on the part of many states that were potentially impacted.
- Products successfully held by import alert did not end up in retail facilities locally or nationally where state inspectors may have difficulty in identifying violations (e.g., undeclared sulfites in brightly colored packaged foods and undeclared food colorings).

Analysis: Area for Improvement

- Decisions were not clearly established for what type of noncompliance (Class 1) NY AGM should submit evidence (invoice and type of testing).
- There was no written operational process for state analytical package submission and use by the FDA to support appropriate regulatory decisions and actions.
- Repeated documents were required for each data package submission creating an undue burden on the state participants.
- After each FDA technical feedback, NY AGM personnel had to be re-trained on what documentation was necessary as part of the data packages submitted to the FDA for regulatory follow-up.
- There was an insufficient number of FDA reviewers to complete all package reviews in a timely manner.
- FDA regulatory limits for certain violative analytes were not clear to NY AGM.
- In some circumstances, there appeared to be a lack of trust in equivalency of state laboratory analyses due to process differences.

Recommendations

- Train more ORA/ORS and CFSAN reviewers to help evaluate state data packages to improve timeliness of package reviews.
- Provide training to state personnel on gathering information for data package submissions to the FDA.
- State partners should discuss how to reduce the FDA review time of analytical packages.
    - Define what is acceptable from both agencies concerning data sharing for regulatory action (e.g., types of samples, number of samples collected, sample traceback information, chain of custody, methodology, quality assurance, and laboratory proficiency).
    - Full FDA review should not be required for similar violative samples.
    - Meet with subject matter experts (technical and compliance) and identify what key elements are required to be included in a data package and checklist prior to submission of a data package.
- Reduce sending same documents for each package submission by creating a repository where states can share methods and any relevant information that does not need to be incorporated in each data package.
- Initiate discussion about regulatory action limits and how they can be used between agencies to allow future collaborations.
- Understand resource limitations and compromise when possible.
- Develop a written draft procedure or SOP prior to initiation of the pilot for all inspectional documentation required for FDA regulatory follow-up actions which can be updated based on knowledge and experiences gained through the pilot.
- Overcome agency processes differences and use available tools to establish method equivalency and trust regarding state laboratory results (e.g., method under ISO 17025 accreditation, proficiency testing results, and compliance with the managerial and technical requirements of ISO/IEC 17025 and AOAC ALACC criteria).
- Articulate the importance of having an efficient and transparent package review process with state partners, which promotes data sharing and mutual reliance.
- Establish strong communications and feedback loops to provide updates on actions that occurred as well as improvements needed for future pilots or operational activities.

Objective 2: Regulatory Action (Import Alerts and Screening Criteria)

Activity: The FDA will share import alert data with NY AGM on violative analytical packages received from NY AGM.

Observations

- FDA shared import alert data with the NY AGM when one of the state's violative packages was added to a specific import alert.
- FDA evaluated the use of screening criteria for manufactures/importers of interest when evidence was insufficient to identify the responsible party of violative sample package submissions.

Analysis: Strengths

- 13 analytical packages positive for sulfites, lead, *L. monocytogenes*, allergens, and colors under the pilot were added to import alert.

- 6 analytical packages positive for sulfites, lead, and allergens resulted in the addition of screening criteria for suspect firms.

Analysis: Area for Improvement

- There was no plan of action from DIO and CFSAN OC for cases where there was insufficient evidence for issuing import alerts on violative state analyzed samples.
- In some cases, it took approximately four months from NY AGM initial submission of the analytical package to adding the product to the import alert.
- Understanding the limitations faced by each agency in the pilot (i.e., state agencies generally may not be able to identify an actual place/address of manufacture of an imported product) were not identified during the planning phase of the pilot.

Recommendations

- Assess issues and successes throughout the entire lifecycle of the pilot.
- Consider other follow-up activities such as FSVP inspections/foreign inspections if an import alert is not feasible.
- Identity where regulatory delays may occur and establish a mechanism to address delays where feasible when adding product/manufacturer to import alert.
    - Note: Traceback investigations required to identify the responsible party conducted by other HAF divisions/foreign offices added to some of the delays.
- Consider expansion of the program to include Class 2 recall products.
- DIO, CFSAN, and the HAF Divisions should collaborate on the development of an evidence-based compliance checklist for import sample collections at retail establishments.
- DIO and CFSAN should establish a written strategy for addressing violations where sufficient evidence is unavailable for placement of the product on import alert.
- Establish a transparent vetting of methods prior to the submission of laboratory packages to work out any pre-existing or outstanding method deficiencies affecting the acceptance of the data.
- Finalize a workflow process based on the lessons learned from this pilot to be used in other proof of processes.
- Identity limitations for all stakeholders early on in the planning process.
- Establish agency limits that may be encountered prior to initiation of the pilot for a better understanding of the expectations of compliance actions.

Objective 3: Communications

Activity: NY AGM and the FDA will hold at least monthly meetings/conference calls to discuss pilot progression.

Observations

- Held regular monthly calls, post pilot reset, between NY AGM and the FDA to discuss pending and new analytical packages as well as identifying any action item(s).
- Held ad-hoc calls between NY AGM and the NY Division Offices (HAF East 1 and DNBI), and ORA/ORS, CFSAN and DIO, as needed, to

obtain additional information or discuss sampling/laboratory questions and product traceback issues.
- Identified primary FDA POCs for this pilot (e.g., state liaison, HAF Division, and Import Division).

Analysis: Strengths
- Post pilot reset, frequent and regularly scheduled meetings provided the opportunity to exchange information and provide timely feedback that kept the pilot moving forward and met expectations.
- Action items were identified for follow-up during these meetings.
- The FDA used CMS case numbers to track data packages submitted by the pilot that enabled the FDA to provide updates to NY AGM.
- Information from the pilot was provided to the FDA PREDICT system for recurring violative products.

Analysis: Area for Improvement
- Initially, DIO and other stakeholders such as recall and emergency response coordinators, were not included on scheduled calls.
- State liaison and POC backups (e.g., emergency response coordinators and other POCs) were not trained on sharing regulatory outcomes and information after data package submission.
- There were no clear instructions on when to hold ad hoc calls with the NY AGM to quickly identify and correct information gaps and technical barriers.
- DIDP was not included in early discussions to ensure appropriate guidance on information sharing was conveyed and understood by all parties.

Recommendations
- Assess issues and successes throughout the entire lifecycle of the pilot.
- Consider establishing ad-hoc technical calls between state, ORA/ORS, DIO and CFSAN before submitting any data package to identify gaps and what is acceptable for FDA regulatory action concerning sampling and laboratory testing.
- Consider sharing an ORA/ORS and CFSAN data package review checklists with state.
- If available, state could share information as expected by the FDA data package review checklist.
- Include DIDP in drafting of MOA/MOU for data sharing language between state and the FDA that could be used by other states to improve federal and state procedures to enable an integrated food safety system.
- Promote public health decision making policies regarding appropriate regulatory follow-up activities based on information gained from collaborative information such as those resulting from the mutual reliance pilot.
- Develop a process and timeline for providing feedback/information to state laboratory and other applicable stakeholders on regulatory actions or additional information required to proceed forward.
- Evaluate whether mutual reliance activities conducted during the pilot provided an opportunity to reduce the duplication of resources at both the state and the federal level.

- Ensure all parties are included in calls between state and the FDA partners, including recall and emergency response coordinators, to provide a seamless discussion on possible topics

**Conclusion**

The expected outcomes of the NY mutual reliance pilot were met during the life cycle of the pilot. These included reduced duplication of resources at both the state and federal level, promoting public health decision making for regulatory follow-up activities through state and federal collaboration, leveraging product analyses conducted by the state for FDA regulatory decision making, contributing to FDA PREDICT Risk Rating for reoccurring violative products, and developing guidelines and checklists for analytical data sharing between the state and FDA to improve integration of food safety activities between other state and federal partners.

Additionally, there were several key takeaways from the NY mutual reliance pilot. Some of these included: (1) Identify all stakeholders at the start of the program to ensure proper feedback and engagement in program development (2) Identify outcomes sought by all parties and the criteria required to achieve those outcomes (3) Document processes to be used and shared with all stakeholders (4) Regular follow-up and feedback loops are critical to ensure continuous improvement of the program.

Working collaboratively and strategically with the FDA's regulatory partners is key to ensuring a safer food supply and advancing the integrated food safety system mandated by FSMA. Working with our state partners in a cooperative endeavor increases the capacity of both agencies. Mutual reliance pilots are key to harmonizing efforts between strategic partners and optimizing the ability of each agency to leverage resources through increased information sharing and recognition of partner agency sample collection and laboratory analyses as well as other regulatory activities. This improves efficiencies, avoids duplication of activities, and results in long-term cost savings.

Following the activities and outcomes from previous pilots, the NY mutual reliance pilot provided a framework for increased engagement with state partners. The pilot went beyond the routine joint work planning or quarterly meetings typically held by federal and state partners. It challenged the agencies to continue to push toward domestic mutual reliance, allowing for creativity and developing solutions to operations and policies that benefit the unique needs of the state and the FDA.

Mutual reliance pilots' outcomes are sustainable. The pilots provide a roadmap for the strategic partners to develop best practices that optimize coordination, information sharing and resources and align regulatory programs. While the pilots themselves occur for a definitive amount of time, these best practices* will be carried forward as a way of doing business in the future to improve the overall quality of operations.

*As of this final writing, the Lab Flexible Funding Model (LFFM) is using some of the pilots' practices such as using CMS to track samples, one POC, sample guide for regulatory actions, instructions and communication.

If you have any questions or would like to discuss additional opportunities, please reach out the Office of Partnership at: OP.Feedback@fda.hhs.gov

## Acronym List

ALACC - Analytical Laboratory Accreditation Criteria Committee
AOAC - Association of Official Agricultural Chemists
CFSAN - Center for Food Safety and Applied Nutrition
CMS - Compliance Management Services
DIO - Division of Import Operations
DIPDP - Division of Information Disclosure
DNBI - Division of Northern Border Imports
FDA - U.S. Food and Drug Administration
MOA - Memorandum of Agreement
MOU - Memorandum of Understanding
FSMA – Food Safety Modernization Act
FSVP - Foreign Supplier Verification Programs
HAF - Division of Human Animal Food
IEC - International Electrotechnical Commission
ISO - International Organization for Standardization
NY AGM - New York State Department of Agriculture and Markets
OC - Office of Compliances
ORA – Office of Regulatory Affairs
ORS – Office of Regulatory Sciences
POC – Point of Contact
PREDICT - Predictive Risk Based Evaluation for Dynamic import Compliance Targeting
SOP - Standard Operating Procedure

## Appendix

NY Mutual Reliance Pilot MOA 2018


NYS_MRP_MOA_Signed.2018.pdf

NY Mutual Reliance Pilot MOA 2015


Mutual Reliance Pilot_NYK final signed

NY Mutual Reliance Pilot Compliance Checklist

MRP Checklist 07312018.pdf

NY Mutual Reliance Pilot Final Collection/Analysis Numbers (2015 and 2018 MOA)

NY MRP Final Package Numbers an

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