

MUTUAL RELIANCE PILOT
PROJECT

Between

New York State Department of Agriculture and Markets

Division of Food Safety and Inspection

New York State Food Laboratory

and

U.S. Food and Drug

Administration

Office of Human and Animal

Food Operations

August 2018

Objectives:

- To use New York State Department of Agriculture and Market's (NYSDAM) resources to sample and analyze FDA regulated imported products at the retail level. When samples are determined to be violative and result in NYSDAM regulatory action, this will be communicated to the Food and Drug Administration (FDA) to trigger, as appropriate, the regulatory follow-up activities ⁽¹⁾. These actions will result in a broader public health impact nationwide by leveraging work done by and shared between state and federal public health officials.
- To share FDA imported product analytical results with NYSDAM (i.e. ORADSS report on Import Alert samples). NYSDAM will use the results to help guide the state surveillance program. It will allow the state to better focus their resources on high risk commodities. NYSDAM will save resources by a reduction in repeat sampling of product distributed at the retail level.

<https://www.agriculture.ny.gov/AD/alertList.asp>

<https://www.fda.gov/Safety/Recalls>

This process will provide mutual benefits to both NYSDAM and FDA. This will allow the leveraging of resources and provide information to both parties to better target sampling of imported products.

Background:

NYSDAM conducts analytical testing of imported food products at retail and wholesale distribution levels. Products sampled by NYSDAM are primarily packaged foods. Most violative food products are due to undeclared ingredients including preservatives, unapproved additives, colors, toxic elements and allergens. NYSDAM conducts traceback of violative products to the furthest extent possible within New York State. The NYSDAM Food Laboratory (NY Food Laboratory) is accredited to the ISO 17025 standard for both chemical and biological testing. Currently, when a product is found to be violative by NY Food Laboratory analysis and determined to be a Class I recall, FDA Human and Animal Foods East Division 1 (HAF-E1) is notified via e-mail. The product, country of origin and violation are reviewed to determine if follow-up is warranted by HAF-E1.

HAF-E1 interacts with the FDA Office of Regulatory Affairs (ORA) Division of Import Operations (DIO) and Office of Regulatory Science (ORS) regarding the acceptability of NYSDAM's inspectional evidence, sample collections and analytical worksheets. If the analytical worksheets are acceptable, HAF-E1 works with DIO to place the product/manufacturer on Detention without Physical Examination (DWPE) via Import Alert (IA) additions.

(1) **FDA Regulatory Follow-up Activities:** domestic import recall (outside NY), domestic follow-up inspections, foreign inspections, imported bulleting surveillance (additional screening), modification of PREDICT Score for the firm or product, adding the firm to an existent Import Alert or a new one, cancel registration, communication with firm competent authority, no further action/unable to investigate.

Placing these products on IA prevents violative products from entering domestic commerce but, additionally, leverages resources for FDA and NYSDAM. In this situation, FDA does not have to use resources to analyze the products already analyzed by NYSDAM. NYSDAM inspectors would not find the same product in retail markets and warehouses and there would be no need for NYSDAM to expend resources by analyzing the same products repeatedly. Under the current system the product should only be seen on retail store shelves after the importing firm had provided evidence to overcome the appearance of a violation after being placed on DWPE. Historically, there have been multiple instances where FDA has relied on NYSDAM analytical results for FDA regulatory action (e.g. detection of *Listeria monocytogenes* contamination). However, there has not been a consistent approach for FDA to use and rely on state inspectional, sample collection and analytical data to directly take regulatory action.

Violative analytical findings by NYSDAM may result in a recall of the product identified as violative by NYSDAM. NYSDAM will provide FDA with recall information resulting from a recall handled by NYSDAM. Class I recalls referred by NYSDAM are processed by the HAF-E1 Recall Coordinator.

Proposal:

HAF-E1 and NYSDAM propose with the Mutual Reliance Pilot (Pilot): To establish procedures for the use of state and FDA inspectional, sample collection and analytical data; to broaden the use of state analytical data to take FDA regulatory action; increase efficiencies in the FDA review of NYSDAM inspectional, sample collection and analytical worksheets; to provide a positive structured mechanism for feedback to NYSDAM regarding questions and/or comments about the inspectional, sample collection and analytical worksheets/methodologies used and to develop a system for continuous improvement in communication and information sharing (including recall information) between FDA and NYSDAM. HAF-E1 and NYSDAM will discuss and determine the specific information needed by FDA including inspectional, sample collections, product labels, invoices, and sample analytical packages. The NY Food Laboratory is accredited to the ISO 17025 standard therefore any change in their accreditation scope will be shared with FDA. NYSDAM and FDA will identify and agree upon the specific analyses that will be accepted for review by FDA. This will include an evaluation of the NY Food Laboratory specific analytical methods for acceptance by FDA.

Activities:

- 1) NYSDAM Division of Food Safety and Inspections will provide sample data using the following collection criteria to refer to FDA action:
 - Imported products
 - Class I recalls as determined by NYSDAM

- Distribution information that can be used for traceback
- Lot number(s) if available
- Information about volume of product if available
- Identify whether product is within its expiration date
- Provide analytical packages for violative samples tested microbiologically for pathogens and non-eviscerated fish
- Provide analytical packages for violative samples tested for toxic elements (metals) and sulfites

Note: For most of the analytes, one sample will be enough to initiate a FDA regulatory activity or be used for signal purposes

- 2) Only after NYSDAM and FDA (ORA ORS, CFSAN ORS and CFSAN Compliance) agree upon which specific testing methods will be part of the Pilot, data packages from those methods will be submitted for FDA review. ORA ORS and CFSAN ORS will review laboratory sample analytical data packages from the NY Food Laboratory. If new testing methods are to be considered after the signing of this agreement, the Pilot may be revised to include these methods.
- 3) NY Food Laboratory will provide sample data packages using the following collection criteria to refer to FDA for regulatory action:
 - Attach the Mutual Reliance Pilot developed checklist (Attachment A) to all data packages to highlight that they are part of the Pilot
 - Submit through the HAF-E1 State Liaison, who will work with the appropriate Compliance Officer to upload appropriate lab data packages into CMS and assign a task to ORA ORS for assessment.
 - Sample analytical packages will be reviewed following the steps outlined on the FDA ORA ORS SOP (Attachment B) and flowchart (Attachment C).
- 4) NYSDAM and FDA will analyze state recall data to determine recurring trends in violative commodities. This information will be used in conjunction with laboratory results that FDA can accept from NYSDAM to determine targeted commodities.
- 5) FDA will share import alert data with NYSDAM.
- 6) NYSDAM will maintain the package submission activities (spreadsheet) and share during the applicable recurring calls specific to the Pilot.
- 7) FDA regulated imported products that are found violative through NYSDAM testing will be

submitted to FDA to trigger the appropriate regulatory follow-up activities (see footnote on page 2 regarding FDA Regulatory follow-up activities).

- 8) Although the focus of this Pilot will be imported products, FDA and NYSDAM will share violative analytical results from domestic products from New York firms using their current process. FDA and NYSDAM will coordinate and determine next steps, including, but not limited to: additional sampling, embargo, voluntary/mandatory recall activities, public notification, and/or other compliance or enforcement actions.

Scope:

- 1) The scope of this Pilot is limited to products regulated by both FDA and NYSDAM.
- 2) The compliance strategy, inspection evidence, sample collections and specific analyses identified for the Pilot will be jointly agreed upon by both NYSDAM and FDA.
- 3) NYSDAM and FDA are committed to supplying the resources necessary to conduct the Pilot.

Implementation:

- 1) FDA and NYSDAM intend for activities under this Mutual Reliance Pilot Project to commence upon signature of both parties and in accordance with the timeframes presented in this agreement.
- 2) The Pilot is for two years from the date of the last signatory on this agreement.
- 3) Should FDA or NYSDAM choose to discontinue activities under this Pilot, intent to discontinue should be conveyed in writing to the other agency at least sixty (60) calendar days prior to Pilot cessation.
- 4) Discontinuation of the activities under this Pilot should not affect the completion of ongoing cooperative activities that were already in practice prior to the commencement of the Pilot project.

Communication:

- NYSDAM and FDA commit to at least monthly meetings/conference calls to discuss Pilot progression. The FDA ORA Office of Partnerships will coordinate calls, develop agendas and generate minutes for each meeting. Topics to be discussed during calls:
 - Status of collected evidence and sample collections, applicability and appropriateness of sample collections.
 - Status update of data packages under review and expected timelines and outcomes.

- Discuss which expected compliance outcomes are applicable and ensure appropriate adjustments are made.
- Establish timeline for outcomes.

Note: HAF-E1 will provide CMS case number to NYSDAM and information will be captured in the spreadsheet

Expected Outcomes:

- Provide an ability to address whether mutual reliance activities conducted during the Pilot improved and promoted public health at both the state and the federal level.
- Provide an ability to address 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.
- Promote public health decision making for regulatory follow-up activities resulting from mutual reliance collaborations.
- Create a process for state food sample laboratory analytical package submission and use by FDA for appropriate regulatory decisions and actions.
- Share regulatory outcomes and information (state and federal) after data package submission.
- As appropriate, use state analytical findings in the PREDICT scoring.
- Contribute to FDA PREDICT Risk Rating of recurring violative products.
- Provide and prepare guidelines on data sharing between state and FDA that could be used by other states to improve federal and state procedures to enable an integrated food safety system.

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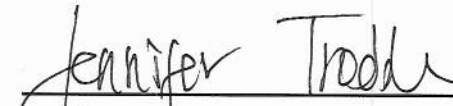
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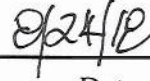
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Date

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Digitally signed by Michael Rogers -S
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08/09/2018

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