Mutual Reliance Pilot Version 1.0

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Mutual Reliance Pilot Project

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Division of Food Safety and Inspection

Division of Food Laboratory

FDA U.S. FOOD & DRUG ADMINISTRATION

New York District Office

NEW YORK STATE OF OPPORTUNITY. Agriculture and Markets

Objectives (2-year agreement)

Use NYSDAM resources to sample and analyze primarily imported product at the retail level for FDA to take regulatory action. FDA will save resources by not having to duplicate testing of product. The placement of the foreign firm and product on FDA's import alert should prevent future entries of the product from entering the US.

Share FDA imported product analytical results with NYSDAM. NYSDAM will use the results to help guide the state surveillance program. It will allow the state to better focus their resources on higher risk commodities. NYSDAM will save resources by not having to continually sample the same product at manufacturer and retail levels.

Expected Outcomes/Metrics

- Collect data as basis for making recommendations and calculating the Return on Investment (ROI)
- Ability to more defensibly address whether mutual reliance activities conducted during the study promote public health through improved return on investment as described in terms of benefits and costs such as:
  - *Guidelines on data sharing between state and FDA that could be used by other states*
  - *Laboratory paperwork including but not limited to: worksheets, forms and electronic files will be created to efficiently share information between agencies*

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Why New York is participating in this Pilot?

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Division of Food Safety and Inspection

Year	Class I	Class II	Class III	Totals
2011	57 29 Imported 28 Domestic	161 123 Imported 38 Domestic	48 26 Imported 22 Domestic	266 178 Imported 88 Domestic
2012	45 23 Imported 22 Domestic	228 167 Imported 61 Domestic	28 19 Imported 9 Domestic	301 209 Imported 92 Domestic
2013	49 27 Imported 22 Domestic	194 143 Imported 51 Domestic	34 24 Imported 10 domestic	277 194 Imported 83 Domestic
2014	30 21 Imported 9 Domestic	149 99 Imported 50 Domestic	39 26 Imported 13 Domestic	218 146 Imported 72 Domestic
2015	48 16 Imported 32 Domestic	216 159 Imported 57 Domestic	61 37 Imported 24 Domestic	325 212 Imported 113 Domestic
TOTAL 2011- 2015	**229** **116 Imported** **113 Domestic**	**948** **691 Imported** **257 Domestic**	**210** **132 Imported** **78 Domestic**	**1,387** **939 Imported** **448 Domestic**

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Division of Food Laboratory

- ISO 17025 accredited laboratory since 2008
  https://www.a2la.org/scopepdf/2749-01.pdf
  https://www.a2la.org/scopepdf/2749-02.pdf
- Regulatory laboratory (Chemical and Microbiological testing)
- Type of food tested:
  - ❖ Imported and domestic products
  - ❖ Ready-to-eat products
  - ❖ Milk and dairy products
  - ❖ Animal feed
  - ❖ Fertilizers

Food Laboratory Data Sharing

Since 2011, Food Laboratory received 45 requests from FDA to share testing results

Serotype/PFGE

"…I am reviewing a case submitted from NY **district office for recommendation of placing a company on FDA Import Alert**. The worksheet from NY State Dept. of Ag and Markets has been reviewed, the sample chain of custody, testing methodology and QAQC are all satisfactory/acceptable, but there is no documentation provided to ensure that the isolates are different from laboratory process controls…"

Foreign Material

"I forwarded your findings to our Philadelphia **Recall Coordinator. She is requesting the analytical work sheets**. Can you please send them to me and I will forward to PHI-DO."

Listeria monocytogenes

"Can we get a copy of the lab worksheets for the cheese samples, FL-941342-941344? We have the final results but **would like the worksheets to include in our compliance package**."

Antibiotics

"**We would like to submit an Import Alert recommendation based on your analysis.** Can you please provide the full analytical worksheets for this product?"

Colors

"Can you provide your complete analytical package (anything you would use to make a regulatory decision) for the above sample? **We will submit an IA recommendation based on your results."**

Heavy Metals

"**CFSAN would like to get a copy of the analytical worksheets** for the XXX samples"

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NY Mutual Reliance Pilot
Kickoff call – July 25, 2016

Kick off call

Attendees:

- NYSDAM – Food Safety & Inspection
- NYSDAM – Food Laboratory
- FDA – ORA – New York District
- FDA – ORA – Northeast Regional Lab
- FDA – ORA – Office of Partnerships – Integration Staff
- FDA – ORA – Office of Operations – Office of Regulatory Science

Topics	Decisions
What commodity will be used?	Spices (imported)
What type testing?	Microbiological and Chemical
Detection method under ISO scope or not?	*Salmonella* (under the ISO scope) Heavy metals and illegal dyes (*not* under the ISO scope)
Who will be evaluating the data package?	FDA will identify SMEs to talk to NYSDAM Food Laboratory

On-going activities listed in the agreement

"FDA NYK-DO will develop an internal SOP on the review and processing of NYSDAM analytical packages to include DIO, ORS and, if necessary, Center review."

Update:

- **Mutual Reliance Pilot checklist – FDA District was created**

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FDA District Checklist

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Mutual Reliance Pilot

New York State Department of Agriculture & Markets (NYSDAM)

PROPOSED NYSDAM Checklist of Requirements for FDA Import Alert Recommendations

1) Legible shipping documentation (as many of these as possible, if available):
    a. Bill of Lading
    b. Invoice
    c. Purchase Order
    d. Packing slip
    e. Original inbound CBP Manifest
    f. Original importation documentation including CBP Entry Number

2) Complete and legible product labeling
    a. Product labeling – all sides of immediate container
        i. Original label preferred
        ii. Legible photograph acceptable
    b. Case labeling – all sides which bear markings - if available
        i. Legible photograph acceptable

3) Name and Address of manufacturer, if available

4) Name and Address of supplier (to aid with traceback)

Information provided by NYSDAM- Division of Food Safety and Inspection

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FDA District Checklist (cont.)

5) Complete Analytical Worksheets
   a. Collection report (showing method of collection)
   b. NYSDAM Food Laboratory (FL) worksheets
      Add list of lab worksheets when reporting Biological and Chemistry testing

      Biological (method under ISO accreditation scope):
      Bench worksheets
      Raw data from equipment
      Results Report Form

      Chemical (method not under ISO accreditation scope):
      Bench worksheets
      Overview of the Analysis and interpretation
      Raw data from equipment
      Additional information concerning method modification

6) Technical Contact at NYS Laboratory
   a. Name: Maria L. Ishida
   b. Address: 6 Harriman Campus Rd. Albany, NY 12206
   c. Phone number: (518) 457-4478
   d. Email address: Maria.Ishida@agriculture.ny.gov

Information provided by NYSDAM- Division of Food Laboratory

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On-going activities listed in the agreement (cont.)

"NYSDAM will provide written SOP and proficiency material or any information to be in compliance with the data acceptance criteria."

Updates:

- Screening and confirmation for *Salmonella* species and *Listeria monocytogenes*
- Detection of toxic elements (heavy metals)

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On-going activities listed in the agreement (cont.)

"…The NYSDAM analytical package will be submitted to FDA NYK-DO. NYK-DO will submit the analytical package to DIO who will coordinate with ORS and CFSAN on the analytical review. If the analytical package is acceptable, the product and firm will be placed on import alert."

Updates:

- NYSDAM submitted violative findings for spices.
- NYSDAM submitted data package to all violative samples found by the laboratory.
- NYSDAM scheduled sample collection (including import paperwork). Violative samples will have data package submitted to FDA for review.

F/L #	FDA case number (CMS #)	Commodity	Analyte	Country of Origin	Method under ISO scope?	Data package submitted	Date received feedback	Accepted/ Rejected	Import Alert #
385112	No CMS	Cinnamon	Arsenic	China	Not at the time of submission	12/10/2016	01/15/2017	Rejected	Not considered
379444	No CMS	Mace whole	Colors	India	No	5/22/2017	6/1/2017	Rejected	Not considered
385855	**527387**	**Pashupati furandana**	**Allergens**	**Nepal**	**No**	**5/22/2017**	**8/18/2017**	**Accepted information but not lab evidence**	**99-22 (allergens) data triggered FDA investigation (previous data) & 99-39 (misbranded foods)**
374111	No CMS	Turnip pickles	Colors	Lebanon	No	5/22/2017	6/1/2017	Rejected	Not considered
388644	No CMS	Soda water "garnet"	Colors	Russia	No	5/22/2017	6/1/2017	Rejected	Not considered
388168	No CMS	Tomato seasoning	Colors	Senegal	No	5/22/2017	6/1/2017	Rejected	Not considered
387731	**534590**	**Ground cumin**	**Lead**	**India**	**Yes**	**7/21/2017**	**12/13/2017**	**Accepted**	**28-13 (lead in spices)**
387772	**536345**	**Dried butter cake**	**Milk allergen**	**Thailand**	**No**	**8/14/2017**	**9/26/2017**	**Rejected**	**No IA but flagged for 99-22 (allergens)**
386979	**537593**	**Mango gummies**	**Sulfites**	**Malaysia**	**Yes**	**9/14/2017**	**12/8/2017**	**Accepted for colors and not sulfites**	**45-02 (colors) & 99-39 (misbranding)**
375347	No CMS	Dried apricots	Sulfites	Tajikistan	Yes	9/14/2017	9/18/2017	Rejected	Under existent 99-21

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Benefits

- Quick feedback after sending Microbiological SOPs and proficiency from FDA ORS/ORA SME
- Good communication with FDA NYK-DO
  - NYK-DO has better understanding of NYSDAM Food Laboratory capacity and capability
  - NYSDAM has better understanding of FDA process

- FDA checklist for sample information and laboratory result package
- NYK-DO sends monthly a spreadsheet containing what testing FDA labs are performing and their findings

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Challenges

- **Methodology:**
  - How FDA will accept results from a non-FDA method or not under the scope of accreditation?
  - Are the ISO standards sufficient to FDA accept results from a non-FDA method?
    - Single lab validation
    - Number of samples analyzed
    - Method deviation
    - Instrumentation

- **Use of state results to submit recommendation for Import Alert**
- **Have not been enough violative imported samples to test the data sharing process**

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Acknowledgements

NYSDAM

Food Safety and Inspections staff

Food Laboratory staff

FDA/ORA – New York District

FDA/ORA/Office of Partnerships

FDA/ORA/Office of Operations/ Office of Regulatory Science

NY Mutual Reliance Pilot 2.0

Ronald Pace
NY District Director/HAF-E1 Division Director
FDA Office of Regulatory Affairs
Office of Human and Animal Foods
June 10, 2018

Why the reset?

Changes to the Pilot

- Expanded regulatory follow-up options
- More defined activites
- Added section on communication

MRP Pilot 2.0 (June 7, 2018)

- Attendees

FDA-ORA- Office of Human and Animal Food Operations

FDA-ORA- HAF-E1

FDA-ORA- Office of Partnerships

FDA-ORA- Office of Regulatory Science

FDA-CFSAN

NYSDAM- Food Safety & Inspection

NYSDAM- Food Laboratory

Objectives

- Use New York State Department of Agriculture's (NYSDAM) resources to sample and analyze primarily FDA regulated imported products at the retail level. When samples are determined to be violative and result in NYSDAM regulatory action, the goal will be to communicate this information to the Food and Drug Administration (FDA) to trigger, as appropriate, the regulatory follow-up activities.
- Share FDA imported product analytical results with NYSDAM (i.e. ORADSS report in 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.

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.

Activities

- 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, eviscerated fish, and pH
    - 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*

Activities

- Only after NYSDAM and FDA 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 method SOPs from the NY State Food Lab

Activities

- NYSDAM Division of Food Laboratory will provide sample data packages using the following collection criteria to refer to FDA for regulatory action:
  - Attach Mutual Reliance Pilot developed checklist to all data packages – further highlighting that they are part of the Pilot
  - For data packages with toxic elements (metals) results:
    - Provide standard reference material running with sample (independent)
    - Provide proficiency testing results with package
    - Send results > 25 ppm for lead. Continue to explore and share elevated contaminated levels of arsenic, chromium, cadmium and mercury in foods.

Activities

- NYSDAM will follow the steps of package referral for FDA review:
  - Submit through state liaison, who will work with the CO to upload appropriate lab data packages into CMS and assign a task to ORS for assessment.
  - Sample analytical packages will be reviewed following the steps outlined on the FDA ORA ORS SOP and flowchart

Activities

- 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 which FDA can accept from NYSDAM to determine targeted commodities.

Activities

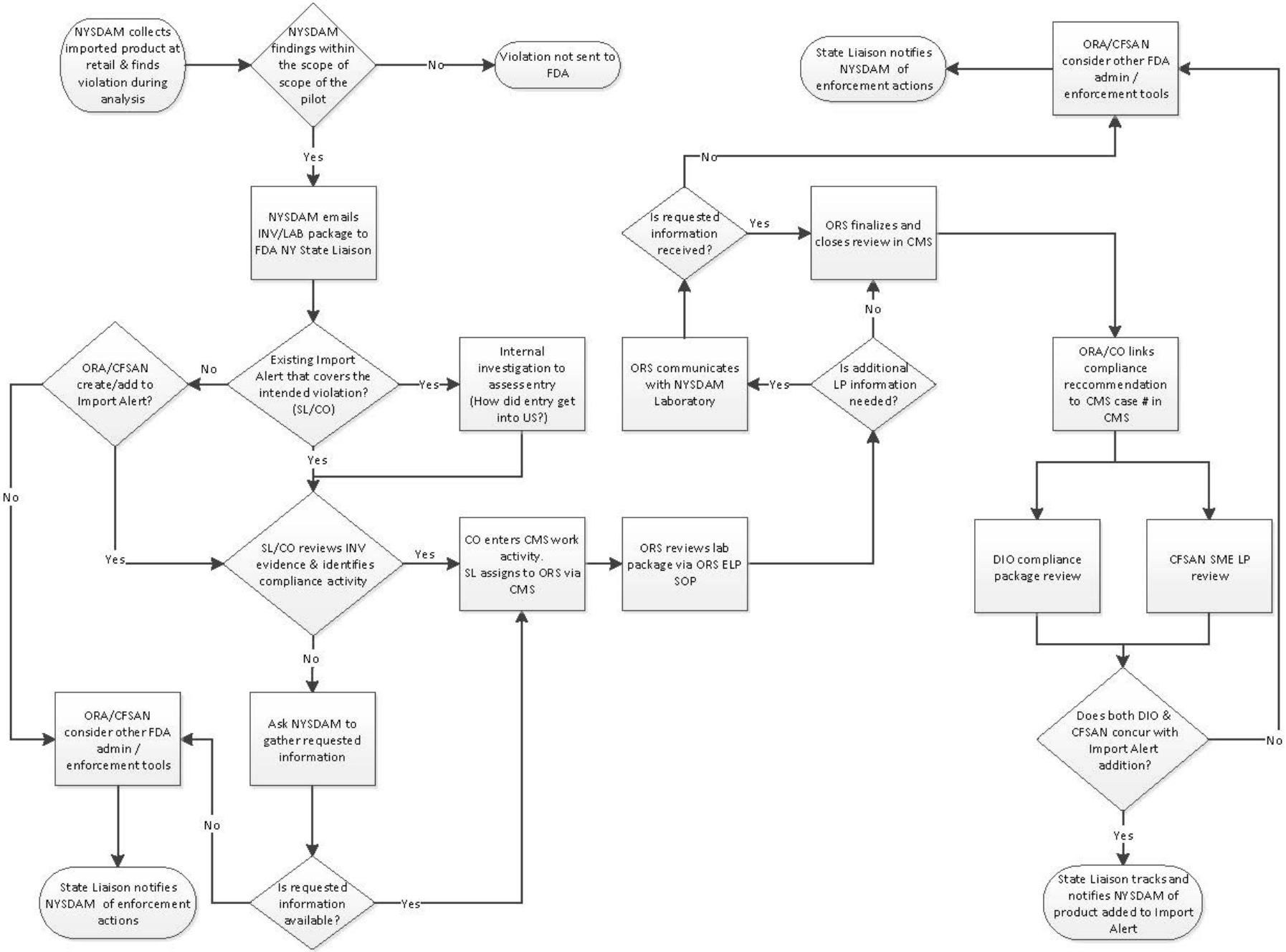
- FDA will share import alert data with NYSDAM
- NYSDAM will maintain the package submission activities (spreadsheet) and share/review with the Mutual Reliance Steering and sub-committee during the applicable recurring calls.
- FDA regulated imported products that are found violative through NYSDAM testing will be submitted to FDA to trigger the appropriate regulatory follow-up activities

Communication

- NYSDAM and FDA commit to at least monthly meetings/conference calls to discuss Pilot progression. Topics to be discussed during calls:
  - Status of collected evidence and sample collections, applicability and appropriateness of sample collections.
  - Status update of on-going data package following up on **Expected Outcomes**.
  - Follow-up on outcomes after data package was submitted.

Communication

- Topics (continued)
  - Discuss which expected compliance outcomes are applicable and ensure appropriate adjustments are made.
  - When applicable, establish timeline for outcomes.


NYSDAM collects imported product at retail & finds violation during analysis
NYSDAM findings within the scope of the pilot
No
Violation not sent to FDA
Yes
NYSDAM emails INV/LAB package to FDA NY State Liaison
Existing Import Alert that covers the intended violation? (SL/CO)
Yes
Internal investigation to assess entry (How did entry get into US?)
No
ORA/CFSAN create/add to Import Alert?
No
Yes
SL/CO reviews INV evidence & identifies compliance activity
Yes
CO enters CMS work activity. SL assigns to ORS via CMS
ORS reviews lab package via ORS ELP SOP
Is additional LP information needed?
Yes
ORS communicates with NYSDAM Laboratory
Is requested information received?
Yes
ORS finalizes and closes review in CMS
No
ORA/CFSAN consider other FDA admin / enforcement tools
State Liaison notifies NYSDAM of enforcement actions
No
Ask NYSDAM to gather requested information
Is requested information available?
Yes
No
ORA/CFSAN consider other FDA admin / enforcement tools
State Liaison notifies NYSDAM of enforcement actions
ORA/CO links compliance reccommendation to CMS case # in CMS
DIO compliance package review
CFSAN SME LP review
Does both DIO & CFSAN concur with Import Alert addition?
No
Yes
State Liaison tracks and notifies NYSDAM of product added to Import Alert

Thank You

Questions and Discussion