



Lab and Program Success Stories:
NYS Mutual Reliance Pilot

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NYS Department of Agriculture and
Markets

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11:15 am – 12:00 pm



Mutual Reliance Pilot Project



**Division of Food Safety and Inspection
Division of Food Laboratory**

and



New York District Office

MFRPAlliance



Objectives

- **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*





**Department of
Agriculture and Markets**

Why New York is participating in this Pilot?



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Department of
Agriculture and Markets

Division of Food Safety and Inspection

The Food Safety Unit regulates the State's food industry which processes, distributes and sells food and feed products.

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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





Division of Food Laboratory

- ISO 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 44 requests from FDA to share testing results

Sent: Monday, October 17, 2011 9:42 AM
To: Rice, Daniel (AGR); Oglesby, Debra (AGR)
Subject: FW: FL 323579
Attachments: Document.pdf

Sulfites

The FDA is looking for the bench notes for FL 323579. They would like to use our sample results in order to request an import alert on the product.

Sent: January 20, 2012 3:56 PM
To: Sawyer, Erin (AGR)
Subject: FW: FL325045 Honey Ginger Candy Class 2.pdf

Colors

Hi Erin,

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.

Thanks

Sent: Friday, January 11, 2013 3:43 PM
To: Oglesby, Debra (AGR); Sheridan, Robert (AGR); Stephani, Karen (AGR); Greene, Virginia (AGR)
Subject: FW: Chicken Jerky Pet Treats

Antibiotics

Please accommodate FDA requests for data associated with the chicken jerky treat recall. There was a high level FDA call today and will be another one next week. It will help the cause (the recall and pet treat issue) on other fronts if we provide this information. We (our group) should use this as a teachable moment in our interactions w/FDA for the goal of integrating our food safety system.

I can fill you in w/more next week.

Dan Rice
Director, Food Laboratory Division

Sent: Thursday, July 03, 2014 10:32 AM
To: Sawyer, Erin (AGRICULTURE)
Cc: Greene, Virginia M (AGRICULTURE); Oglesby, Debra V (AGRICULTURE)
Subject: 14C-747 & 754
Attachments: 3-31-14 chromat test c.jpg; 747 & 754 ICP-MS data.pdf; FLS 747 & 754.pdf

Heavy Metals

Erin,

Attached are worksheets supporting the detection of lead and chromium by ICP-MS in the two turmeric samples (Calibration curve, blank, 747 & 747 dilution, 754 & 754 dilution). I also included the FL sample reports, and a photo of the results of the lead chromatate test we are now running. If FDA needs anything else on these please refer them to me!



Kickoff call – July 25, 2016

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?	<i>Salmonella</i> (under the ISO scope) Heavy metals and illegal dyes (<u>not</u> 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

- NYSDAM and FDA commit to at least quarterly meetings/conference calls to discuss pilot progression and to ensure, when appropriate, adjustments are made.
- **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. The draft **APHL data acceptance checklist** currently under FDA review will be used as a guide. However, additional items will be included for data acceptance, if necessary.



FDA District Checklist



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
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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.

Update:

- Screening and confirmation for *Salmonella* species (data package accepted)
- Screening and confirmation for *Listeria monocytogenes* (data package accepted)
- Heavy metals detection (under discussion). Method not under ISO scope.



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

- FDA regulated imported products that are found **violative through NYSDAM testing will be submitted for import alert recommendation**. 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.

Update:

- Under discussion... Current violative findings are related to a method that is not under the ISO scope.





Benefits

- Quick feedback after sending Microbiological SOPs and proficiency from FDA 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 laboratory result package
- Good communication with FDA (OP, ORA, ORS)





Challenges

- **Method not under ISO scope**
 - How FDA will accept results from a non-FDA method ?
 - Are the ISO standards sufficient to FDA accept results from a non-FDA method ?
- **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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- Don Burr
- Terri McConnell
- Sean Linder



Contact Information

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