MUTUAL RELIANCE PILOT PROJECT

Between

New York State Department of Agriculture and Markets

Division of Food Safety and Inspection

NY State Food Laboratory

And

US Food and Drug Administration

New York District Office

March 2015

Objective:

To use New York State Department of Agriculture and Market's (NYSDAM) analytical results to take U.S. Food and Drug Administration (FDA) regulatory action

Background:

NYSDAM conducts analytical testing of imported food products at the retail and/or distributor level. NYSDAM food laboratory is currently accredited to the ISO 17025 standard for both chemical and biological testing. FDA conducts analytical testing of imported food products as the products are being offered for entry into the US. Currently FDA New York District Office (NYK-DO) is notified via e-mail when a product is found violative by NYSDAM food laboratory analysis. The product, country of origin and violation is reviewed to determine if follow-up is warranted by NYK-DO.

Violative analytical findings by NYSDAM and shared with FDA may result in the FDA collection of the same product and submission to an FDA laboratory for the same analysis. In a very few cases, the NYSDAM analytical worksheets are provided to NYK-DO. NYK-DO interacts with FDA's Office of Regulatory Science (ORS) regarding the acceptability of NYSDAM's analytical worksheets. If the analytical worksheets are acceptable, NYK-DO works with the Division of Import Operations to place the product/manufacturer on Detention without Physical Examination (DWPE) via Import Alert (IA) additions. Placing these products on IA prevents violative products from entering domestic commerce but, additionally, leverages resources for FDA and NYSDAM. FDA does not have to use resources to analyze the products already analyzed by NYSDAM and 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 over and over. Ideally, the product would only be seen on the retail shelves where the firm has provided evidence to overcome the appearance of a violation after being placed on DWPE. As stated, there have been a few instances where FDA has relied on NYSDAM analytical results for FDA regulatory action (e.g. L. mono). However, there has not been a consistent approach to regularly using and relying on state analytical data to directly taking regulatory action.

Violative analytical findings by NYSDAM may result in a recall of the product. NYSDAM will provide FDA with recall information resulting from a recall handled by NYSDAM. Class I recalls received by NYSDAM are processed by the NYK-DO Recall Coordinator.

Proposal:

FDA's New York District and New York State Department of Agriculture and Markets propose to establish procedures for the use of state analytical data, broaden the use of state analytical data to take FDA regulatory action, increase efficiencies in the FDA review of NYSDAM analytical worksheets, provide a mechanism for feedback to NYSDAM regarding questions and/or comments about the analytical worksheets, methodologies used, etc. and to develop a system for continuous improvement in communicating and information sharing (including recall information) between FDA and the NYSDAM.

Activities:

1) NYSDAM and FDA will discuss the specific information needed by FDA from the NYSDAM including analytical package, labels, invoices, etc.

2) NYSDAM Lab is ISO 17025 certified. Any change in their accreditation will be shared with FDA.

3) 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 NYSDAM lab analytical methods for acceptance by FDA.

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

5) NYSDAM and FDA commit to at least quarterly meetings/conference call to discuss pilot progression and to ensure, when appropriate, adjustments are made.

6) A record of the number of state analytical results used to directly place a firm and product on Import Alert will be maintained and tracked by FDA and will be used in the evaluation process of the pilot. This information will be shared with NYSDAM.

Scope:

1) The scope of this pilot is limited to FDA-regulated product.

2) The 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 by both parties and in accordance with the timeframes presented in this agreement.
2) The pilot is for one year from the date of the last signatory
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.

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9/18/15
Date

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