Issue Brief | August 2024

Improving FDA's Use and Review of State Food Chemistry Data

State laboratories work in close relationship with the US Food and Drug Administration (FDA) to improve the safety of the food supply and improve public health. This issue brief outlines rationale for five actions FDA could take to improve coordination during review of state laboratory data for chemical contaminants in food, based on feedback collected by the Association of Public Health Laboratories (APHL).

Frequent delays in review of chemistry data packages submitted by states.

State laboratory partners have expressed concern regarding perceived inefficiencies and delays in FDA review of food chemistry data they generate. FDA requests states to assemble and submit a data package comprised of hundreds of pages of information in approximately three days for a sample of concern. States have reported that FDA's internal review of food chemistry data packages can take anywhere from three to 12 months, with states often unaware of the review status even though states are charged with safeguarding the health and safety of their state's food supply and population. Knowing that a likely contaminated product continues to be available for purchase—posing potential short- and/or long-term health effects on consumers—presents a significant ethical burden.

One notable recent example is a class II recall of apple juice due to elevated inorganic arsenic. The state partner collected the sample in September 2023 and reported the results to FDA within two weeks. The FDA subject matter expert (SME) concurrence took only three weeks, but CFSAN/Compliance did not act on these findings for an additional six months. FDA had finalized an Action Level for inorganic arsenic in apple juice in June 2023—one of only two finalized action levels FDA prioritized to protect children. This six-month administrative delay unnecessarily exposed children to a potentially harmful product.

Inconsistent triggers for taking regulatory action.

State partners have described inconsistencies regarding FDA assessment of data package acceptability in relation to FDA's requirement of 12 elevated subsamples (samples from the same manufacturing lot) for subsequent regulatory response. For example, one state was told that FDA would not accept their data packages for review unless 12 subsamples were tested, despite past instances where the elevated contaminant concentration in a single subsample has triggered regulatory action. FDA has informed states that these situations are evaluated on a case-by-case basis as opposed to set rules and that the agency is concerned with contamination at the manufacturing lot level rather than the individual container level. However, states have repeatedly expressed concern that a person may be consuming a full serving of the single contaminated product and therefore be at risk of adverse health events. The presence of *Listeria monocytogenes* or pathogenic *Escherichia coli* in a single sample would trigger a recall on the entire lot based on increased risk of exposure, despite the fact that most retail units would not contain any bacteria. Regulatory action based on chemical data should follow the same logic.

Some examples of where FDA has taken action after a single positive sample include:

- In July 2022, FDA requested a voluntary recall of freeze-dried blueberries based on a single retail unit testing positive for elevated lead. This prudent decision was based on the fact that even 0.245 ppm lead would expose children (to whom these products were targeted) to lead at four times the Interim Reference Level.

- One sample of galanga tested by a state partner showed 14.5 ppm of lead. After analyzing the laboratory data package and sample traceback information, the product was included in the FDA Import Alert 28-13 "Detention Without Physical Examination of Spices and Spice Products Due to Lead Contamination."
- One sample of tesquesquite was tested by a state partner and showed 3.34 ppm of lead, triggering a product recall by another state partner with assistance from the FDA.

Extensive data requests required with quick turnaround times.

FDA requests data packages of concerning results be submitted within three days of detection, creating a burden for state partners who are experiencing workforce shortages and reduced funding. If FDA later determines the risk to human health to be low (e.g., the level detected for a particular contaminant is below a threshold value), then no regulatory action is taken. Data package creation is a labor- and resource-intensive activity for states, and they have expressed frustration with the requirement to submit a full data package when FDA has not conducted a human health evaluation on the result in question. State partners are also required to submit a data package within a set time frame without knowing what specific sample information is crucial for FDA to take regulatory action.

Unclear and burdensome requirements for data packages.

When preparing chemistry data packages for FDA review, states have voiced to APHL their confusion regarding inconsistencies in data element requirements. For example, a state has shared that while a certain set of data elements is sufficient for one sulfite sample, FDA has asked for additional information for a subsequent sulfite sample. Often, more information is requested during subsequent FDA SME reviews—sometimes weeks or months later. This iterative request for data is more burdensome for states to comply with than if they were to gather and share that information with the original data package. In a scenario relayed to APHL, a request for additional data necessitated a state to rerun a sample, requiring them to remake costly standards and adjust their workflow of other samples to prevent wasting the unexpected standard preparation.

A checklist outlining all the information FDA needs to accomplish every stage of the data package review process would remedy these concerns. An excellent model is the Human & Animal Food Regulatory Compliance Review Checklist, created by the Partnership for Food Protection's Laboratory Science Workgroup, which is structured to aid compliance officers in the review of data packages.

A streamlined approach to data package submission should be also considered. After the FDA has reviewed information from accredited state laboratories for several years, it would be beneficial to shorten the review process by submitting relevant information in a few pages. This approach would ease the burden on state partners of submitting hundred-page data packages and on the FDA SMEs who review them.

Undefined test method equivalency.

States have expressed concerns about the resistance they have encountered when using test methods different from those utilized by FDA, even when the methods are scientifically equivalent. States operate under a strong quality management system with many layers of quality assurance to ensure their laboratory data is accurate and defensible; they also understand this stringent quality assurance is necessary for FDA regulatory action. FDA's ability to take action on state data is one of the strongest drivers for state laboratories to become ISO/IEC 17025 accredited. APHL asks that the information required for method equivalency be added to the checklist mentioned above and for FDA to recognize and accept those methods when all stated requirements have been met.

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

For more information, contact APHL at foodsafety@aphl.org

7700 Wisconsin Avenue, Suite 1000, Bethesda, MD 20814 | www.aphl.org | 240.485.2745