Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell
Leigh G. Barcham

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Re: FSMA Update: FDA Launches "FDA-TRACK: Food Safety Dashboard" to Track FSMA Progress

The U.S. Food and Drug Administration (FDA) has launched two new online dashboards that track key metrics reflecting the impacts from the FDA Food Safety Modernization Act (FSMA) regulations. 1/ The dashboards are part of FDA-TRACK, an agency-wide performance management program. There are separate dashboards for: (1) Preventive Controls and Current Good Manufacturing Practice (CGMP) Measures, and (2) Imported Food Safety Measures.

The release of these new data dashboards is consistent with one of FDA's longstanding goals for FSMA implementation: to establish and analyze metrics to track the outcomes for the FSMA regulations. FDA's intends to eventually release data tracking compliance with all seven major FSMA rules. This memorandum provides an overview of the information included in the two new dashboards and identifies some of the key takeaways from the data currently available.

Overview of the Preventive Controls and CGMP Measures Dashboard

The Preventive Controls and CGMP Measures Dashboard includes data intended to measure progress toward two desired outcomes: increased compliance with the Preventive Controls for Human Food (PCHF) and the Preventive Controls for Animal Food (PCAF) regulations and more rapid and effective recall actions by facilities subject to the Preventive Controls rules. The metrics used to track these outcomes include:

- The percentage of inspections in which the facility had a written food safety plan and, among those, the percentage of facilities whose food safety plan included a written hazard analysis;
- The respective percentages of facilities that identified process preventive controls, allergen controls, and sanitation controls, including additional data broken down by requirement (i.e., adequate procedures, validation, monitoring, corrective actions, and verification);
- The percent of facilities in compliance with supply-chain program requirements;
- The number and percent of Preventive Controls inspections by classification (i.e., No Action Indicated, Voluntary Action Indicated, Official Action Indicated) for both human and animal food. (This data also can be broken down further by full and limited scope inspections.);

1/ The two new dashboards are available at https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-food-safety-dashboard.

- The number and percent of animal food CGMP inspections by classification;
- The number of Class I and Class II recalls attributed to facilities subject to the PCHF and PCAF rules. For human food, this data set also is broken down by the cause of the recall (e.g., labeling/allergen, microbiological); and
- For Class I recalls, the time between initiation of the recall and the firm's press release announcing the recall.

Users have the option to view the data broken down by fiscal year, as well as to download the source data for the metrics provided on the dashboard (i.e., the raw data, rather than the percentages presented in the dashboard). FDA is collaborating with the Centers for Disease Control and Prevention (CDC) to establish metrics to track a third desired outcome: reduced risk of illness attributed to food from facilities subject to the PCHF rule.

Overview of the Imported Food Safety Measures Dashboard

The Imported Food Safety Measures Dashboard includes metrics related to imported human and animal food and the Foreign Supplier Verification Programs (FSVP) rule. The data sets measure progress toward increasing foreign supplier compliance with U.S. food safety standards and more effective oversight of foreign suppliers by importers (through the FSVP rule).

The metrics used to track these outcomes include:

- The number and percent of foreign Preventive Controls inspections classified NAI, VAI, or OAI for both human and animal food. (This information can be broken down by both full and limited scope inspections.);
- The number of Class I and Class II recalls attributed to imported human food and imported finished animal food that is not intended for further manufacturing or processing; and
- The number and percent of FSVP inspections classified by NAI, VAI, or OAI for both human and animal food.

As with the Preventive Controls and CGMP Measures Dashboard, the data can be broken down by fiscal year, and the source data for these metrics is available for download. Likewise, FDA currently is working with the CDC to develop metrics to measure progress toward a third desired outcome: reduced risk of illness or injury attributed to imported food.

Key Takeaways

When considering the key takeaways from the data, it is important to recognize the factors that are influencing them. For instance, the data begin with fiscal year (FY) 2017 when, because of staggered compliance dates, only large businesses had reached their compliance dates. Some of the data also reflect only full scope inspections (i.e., inspections for compliance with both the Preventive Controls and CGMP requirements), which FDA prioritizes based on risk, and exclude limited scope inspections focusing only on CGMP requirements. As a result, FDA cautions that the data are not representative of all human food facilities subject to the Preventive Controls regulations. Additionally, because of FDA's "educate before and while we regulate" approach, the agency's inspections have primarily focused on food safety problems that could pose a public health risk.

The relatively limited scope of the data currently available also should be taken into account when considering any trends in the data. The data will be continuously updated on a quarterly basis, and FDA states it is expected to take several years to establish baselines and identify meaningful trends in FSMA compliance. Data from state inspections also are not included in the dashboards.

Notwithstanding these limitations, the data provided in the two dashboards provide an excellent tool for facilities preparing for inspections. The dashboards identify causes of recent Class I and Class II

recalls, as well as areas where FDA has found deficiencies in previous inspections (and likely will focus its inspections going forward). For instance, monitoring appears to be an area where FDA has found the most deficiencies across all types of preventive controls, and especially for allergen and sanitation controls. Among the categories of preventive controls, FDA so far has found the greatest rate of deficiencies in sanitation preventive controls, and in particular for the monitoring and verification of sanitation controls.

The categories of metrics also are indicative of FDA's priorities. It is noteworthy, for example, that FDA is tracking the amount of time it takes firms to issue a press release for a Class I recall, reflecting FDA's desire to see press releases issued more quickly. So far the average time to issue a press release for human food in FY 2019 is 2.05 days (among 63 recalls), down from 2.96 days in 2017 (among 196 recalls).

In sum, it will be worthwhile to monitor the dashboards as FDA continues to add new metrics and to supplement the existing metrics with new data.

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We will continue to track FDA's implementation of the FSMA regulations. Please contact us if you have any questions or if we can be of assistance.