0910-0500
FDA's Rapid Response Survey
Summary of Survey Conducted

FDA's Center for Food Safety and Applied Nutrition (CFSAN) sought to investigate the presence of disease-causing bacteria in select foods as part of its mission to keep contaminated foods off of the market. CFSAN used the FDA Rapid Response Generic Survey to obtain information and perspectives from the food industry and regulatory representatives to help inform FDA's decisions regarding which food-hazard pairs the Agency should target, share specific assignments to investigate these products with external partners, and allow FDA to communicate final assignment details to external stakeholders.

What was the problem to be investigated? In 2011, the FDA Food Safety Modernization Act was enacted to help prevent food-based problems before they occur and as a complement to the Agency's work in the service of foodborne illness outbreak response. To develop prevention-based systems, FDA needs data and other information to help identify hazards in commodities that must be addressed and minimized. FDA used sampling as an important part of the Agency's proactive approach, and used a microbiological surveillance sampling model to identify patterns that will help predict and prevent future contamination by disease-causing bacteria.

The FDA held two calls (one for regulatory partners and one for industry representatives) to discuss a list of 11 hazard-commodity pairs under consideration for large-scale surveillance sampling. This was done because industry stakeholders asked FDA to engage with industry earlier and more frequently throughout the assignment development and execution process. FDA asked stakeholders to take part in an outreach call and provide their feedback by email, which the agency indicated should involve no more than two hours to complete.

The microbiological surveillance sampling model ensures the FDA collects sufficient data to determine contamination rates for each of the hazard commodity pairs; CFSAN specifically issued assignments to FDA field whereby field staff collected a large number of samples of a given commodity over a short time span of 12 to 18 months. With this sampling, FDA was able to more fully consider given commodities and the associated bacterial prevalences, apparent trends (such as those pertaining to seasonality, product variety, and geographic origin), and conduct follow-up activities based on the findings.

We chose this generic collection so the information would be collected extremely fast, as this allowed FDA to conduct follow-up activities and prevent foodborne illnesses. More specifically, the food product sampling has led to recalls and previously (in 2015) helped to stop an outbreak of listeriosis in the Midwest while the case count was small in number.

The method used to obtain the convenience sample. The FDA engaged external stakeholders by phone and email to obtain information from industry and other stakeholders to inform which hazard-commodity pairs to sample as well as the design of related sampling assignments. Once the information was collected, the Agency shared specific assignment details with external partners and asked follow-up questions when needed. FDA then provided final assignment details to external stakeholders for their awareness.

Burden imposed. As stated previously, FDA engaged external stakeholders by phone and email in two calls for information, allowing each stakeholder respondent 2 hours (1 hour for the call, and 1 hour for the follow up) to provide information in a free-form way to inform the Agency which hazard-commodity pairs to sample and to provide input on the design of the sampling assignments. Each hazard-commodity group had up to 25 potential respondents, for a total of 50 hours for each of the 11 pairs of hazard-commodities. The total burden for this collection of information was estimated to be 550 hours (50 hours x 11 hazard-commodity pairs.)

FDA ended up using a two call approach - one for industry (domestic, international, and importers) and regulatory (state, local, and federal) and covered all 11 hazard-commodity pairs at once. The Agency's estimate was based on FDA's expertise and the knowledge that most stakeholders involved with this collection of information are experts in their fields, resulting in their ability to answer all questions presented to them very quickly.