FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF RAPID RESPONSE SURVEYS (0910-0500)

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

TITLE OF INFORMATION COLLECTION: Surveillance Sampling Outreach

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **What is the problem to be investigated:**

   The proposed collection will investigate the prevention of future foodborne illness. This will collect qualitative feedback on routine food safety activities implemented by the Agency to better understand the prevalence of pathogens in select food commodities and prevent foodborne illnesses.

   Signed into law in 2011, the FDA Food Safety Modernization Act (FSMA) is based on preventing problems before they occur, rather than solely responding to outbreaks of foodborne illness. However, in order to develop prevention-based systems, CFSAN needs insights and feedback from industry as well as other stakeholders to ensure the food safety activities are performed as effectively and efficiently as possible. CFSAN also needs other information to help identify hazards in commodities that must be addressed and minimized. Sampling is an important part of the agency's preventive approach, and CFSAN will use a surveillance sampling model to identify patterns that may help predict and prevent future contamination by disease-causing bacteria.

   In our efforts to prevent future foodborne illness as directed under FDA's FSMA, the Agency analyzes historical data and emerging issues. Accordingly, FDA has recently received several reports of foodborne illness, and needs to conduct this to promptly fill knowledge gaps related to these emerging food safety trends. The results of the survey will help FDA meet the immediate need for addressing recent food safety concerns, and will help prevent future illness by helping us develop prevention-based systems by providing data and other information to help identify hazards in commodities that must be addressed and minimized.

   A key element of this model is working collaboratively with industry partners, during the development of sampling plans, by gaining their qualitative feedback and insight on these types of activities, including if our communication strategies and sampling activities are effective and efficient. This collaboration is a two-way street; by providing input to CFSAN, the industry helps CFSAN fulfill its mission while also serving their own interest in terms of rationale, effectiveness and efficiency of a sampling program that already has buy-in from the industry, which in turn facilitates our and industry's operations without sacrificing product safety. To ensure the success of this model, it is imperative that there exists a communication channel for CFSAN to obtain input from its partner as well as customers (i.e., the industry) so CFSAN can consider and respond to

their needs as much as possible. In addition, it is useful for CFSAN to collect similar feedback from other stakeholders (e.g., government/regulatory partners and academia).

To obtain relevant and useful feedback from its customers, the industry, CFSAN continues to establish and maintain ongoing, collaborative, and actionable communication between CFSAN and its stakeholders, primarily the industry. This type of communication channel will provide useful input to the Agency on how to continue to improve our services and information so that our collaboration is useful, effective, and efficient.

The FDA intends to follow a plan that features three phases. During the preliminary "Engage" phase, the FDA seeks information to inform which hazard-commodity pairs to sample as well as the design of related sampling assignments. In the "Validate" phase, the agency shares specific assignment details with external partners and asks follow-up questions. The "Communicate" phase is primarily a one-way communication during which the FDA provides final assignment details to external stakeholders to facilitate the assignment, minimize possible disruption to the operations of any food facility, and further efforts to prevent possible future foodborne illnesses.

The FDA intends to hold industry calls, expected to begin in August 2018.

It is important to note that industry stakeholders have asked the agency to conduct this outreach. The FDA estimates the burden for each stakeholder to be three hours in all, with the outreach call(s) taking about an hour and the questionnaire completion taking about two hours.

The FDA's Center for Food Safety and Applied Nutrition microbiological surveillance sampling model ensures that the agency will collect sufficient data to inform decision making in the near term; it specifically involves issuing assignments to FDA field whereby field staff (and possibly State Partners) collect a comparatively large number of samples of a given commodity over a comparatively short time span of 12 to 18 months. This model allows the FDA to more closely consider given commodities, determine contamination rates, look for trends (such as those pertaining to seasonality, product variety, region, country of origin, or domestic versus import), and conduct follow-up activities based on the findings.

A key aspect of the FDA's model is "External Stakeholder Engagement," the process that the FDA employs to communicate with industry, states (those commissioned to collect samples, and those non-commissioned), foreign governments, consumer groups, and other stakeholders about upcoming sampling assignments to enhance FDA transparency and leverage resources.

The feedback received from this data collection will help inform the development of more effective and efficient assignments, guidance materials, educational outreach activities and materials, and collaboration opportunities that leverage the industry's expansive knowledge as well as enhance our communication strategies. The feedback will help the Agency better utilize its resources and decrease adverse impact on the

industry, our partners and customers. The information will not be used to develop any quantitative measures such as prevalence of certain practices.

This data collection is targeted at industry associations, government/regulatory partners, academia, and participation is completely voluntary. Participants will be invited to participate according to the food industries which would be affected by subsequent sampling efforts. For example, if the Agency is soliciting feedback on sampling assignments for leafy greens and frozen berries, produce associations, frozen food associations, grocer associations, etc. will be invited to participate. The FDA maintains a list of industry associations and representatives and asks participants to provide additional industry association points of contact for their inclusion in the voluntary data collection.

2. **Please describe the method to obtain the convenience sample:**

   The FDA plans on engaging external stakeholders via the three-phase process mentioned above. During the preliminary "Engage" phase, the FDA seeks information from industry and other stakeholders to inform which hazard-commodity pairs to sample as well as the design of related sampling assignments. In the "Validate" phase, the agency will share specific assignment details with external partners and may ask follow-up questions. The "Communicate" phase will be primarily a one-way communication during which the FDA provides final assignment details to external stakeholders.

   Appendix A lists the questions to be asked for each hazard/commodity group, and a list of stakeholders for each hazard/commodity group is in Appendix B.

3. **Are there any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2017 Justification Statement:**

   No

4. **If yes, please describe:**

   N/A

5. **Burden Chart and Description:**

   The FDA estimates that the outreach call(s) and questionnaire for each hazard/commodity pair group will take approximately 1 hour and 2 hours, respectively, for a total estimated burden of 3 hours per stakeholder. Each call is anticipated to have up to 40 potential respondents, and the total burden hours for each call are as follows:

Validate call	120 hours
Engage call	120 hours
Total Estimated Burden Hours	240 hours

The FDA has arrived at this estimate based on its expertise and its knowledge that most of the potential respondents are experts in their fields. Therefore, the total burden for this collection of information is expected to take 240 hours.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Validate	40	180	120
Engage	40	180	120
Total			240

6. **Attach Questions**

Appendix A contains the questions asked of each category or respondent.

REQUESTED APPROVAL DATE: August 6, 2018

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