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May 17, 2021

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types [Docket No. FDA-2012-N-0547]

Dear Dr. Woodcock:

The Academy of Nutrition and Dietetics (the "Academy") appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) related to its request for comments on its recently issued "Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (Docket No. FDA-2012-N-0547)" (the "information collection"). Representing more than 107,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to accelerating improvements in global health and well-being through food and nutrition and to providing medical nutrition therapy (MNT) and nutrition research and counseling to enhance America's food safety.

The Academy supports the proposed information collection of a survey as part of a 10-year study on the occurrence of foodborne illness risk factors in various facility types. Our members look forward to utilizing forthcoming research results to enhance members' ongoing efforts working with clients, patients, and policymakers to improve and protect health through evidence-based food safety initiatives.

A. Academy of Nutrition and Dietetics' Commitment to Food Safety

Foodborne illness is preventable, yet the United States experiences significant economic costs, loss of productivity and reduced quality of life as a result of people becoming ill in the U.S. from food safety concerns. The Centers for Disease Control and Prevention "estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases."[1] Updated modeling of these CDC estimates show the resulting aggregate of medical costs, productivity losses, and illness-related mortality is between "$77.7 billion (90% CI, $28.6 to $144.6 billion) and $51.0

[1] Burden of Foodborne Illness: Findings. Centers for Disease Control and Prevention. November 5, 2018. Available at https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html. Accessed May 15, 2021.

billion (90% CI, $31.2 to $76.1 billion)"[2] annually. Our members "are encouraged to participate in policy decisions, program development, and implementation of a food safety culture."[3] "Registered dietitian nutritionists and dietetic technicians, registered, have unique roles in promoting and establishing food safety cultures in foodservice settings, clinical practices, community settings, and in public venues because their training integrates food; science; and health, both preventive and therapeutic."[4] In addition, "RDNs and DTRs have unique roles in promoting and establishing food safety cultures when practicing with high-risk populations, which include children younger than age 5 years, seniors aged 65 years or older, pregnant women, and individuals who have compromised immune systems due to health conditions or their treatment, such as diabetes, human immunodeficiency virus/acquired immune deficiency syndrome, kidney failure, and cancer."[5]

B. Enhancing the Quality, Utility, and Clarity of the Information to Be Collected

1. Generally

The proposed new information collection has the potential to expand the ongoing surveys on food safety behaviors conducted by the FDA and can be complemented and extended by the observational studies conducted by the USDA's Food Safety and Inspection Service. The survey here seeks to obtain data relevant to many of the steps the "retail marketing of foods include[s] . . . to prevent, reduce, or eliminate contamination of foods and to keep perishable foods safe. [But,] appropriate time and food temperatures must be maintained *throughout* the food supply chain to reduce pathogen growth in perishable foods."[6] Although outside the scope of this survey, efforts during transit to maintain and ensure healthy food safety practices are highly relevant to retailers and foodservice operators. Temperature monitoring while in transit can be a significant challenge. Package indicators that register temperatures outside of the desirable range are available but are not in routine use.[7] We note that surveyors' review of time and temperature controls are important, but question whether the ninety minutes during which surveyors may be on-site is adequate for larger facilities. The FDA should evaluate the impact of survey times on the results and whether conducting the surveys at non-peak times may lead to a greater

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[2] Scharff, Robert. (2012). Economic Burden from Health Losses Due to Foodborne Illness in the United States. Journal of food protection. 75. 123-31. 10.4315/0362-028X.JFP-11-058.

[3] Cody MM, Stretch T. Position of the Academy of Nutrition and Dietetics: food and water safety. J Acad Nutr Diet. 2014;114(11):1819-29.

[4] *Ibid* (internal citations omitted).

[5] *Ibid* (internal citations omitted).

[6] *Ibid*, citing US Food and Drug Administration. FDA Food Code 2013. http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm. Updated November 21, 2013. Accessed January 12, 2014.

[7] US Food and Drug Administration. Food facts from the U.S. Food and Drug Administration. Fresh and frozen seafood: Selecting and serving it safely. http://www.fda.gov/food/resourcesforyou/consumers/ucm077331.htm. Updated November 15, 2017. Accessed April 8, 2018. (Emphasis added.)

propensity for false or incomplete results. If that is the case, surveyors should adjust to conduct visits at peak survey times.

Although referenced in two sections in the Marking Instructions for the Data Collection Form,[8] respectfully suggest that the use and impact of gloves is not adequately addressed in the survey, and we encourage the FDA to assess the relationship of glove use to excessive or insufficient handwashing and whether glove use observes reflects proper use or not, such as using the same pair of gloves when moving from task to task. We recognize the importance of noting the use of hand antiseptics as handwashing in areas outside kitchens in lieu of traditional soap and water handwashing and the extent to which this represents conformity with food safety standards in various facilities.

We support and appreciate the FDA's inclusion of a food allergy component in its survey. Although not a traditional food safety issue, similar policies and procedures can apply with regard to glove use, hand washing, securing and protecting food against cross-contact, and suitable equipment cleaning. For those with food allergies, this is a food safety issue, and training in food allergen awareness is a critical part of the solution.

Members continue to report confusion and frustration arising from differences between manufacturer dates, use by dates, and other expiry dates. For example, one may have to denote three dates on thawed meat: received date from distributor, thaw date (date moved from freezer to refrigerator), and use-by date. We look forward to continued efforts with industry, the FDA, and the U.S. Congress to simplify and standardize expiration dates.

2. *Retail Settings*

In retail settings, personnel are responsible for following food safety procedures,[9] and public health inspections monitor this compliance. As in food production settings, personnel in foodservice and other retail operations can contaminate foods when they do not practice recommended hygiene behaviors. In addition to public monitoring, third-party audits are used by many retailers to check their food safety processes for continuous implementation and improvement. We support surveying to identify the effectiveness of these efforts. Facilities are inspected regularly by a variety of agencies, and depending upon the facility, may include inspectors at the local, state, and federal levels. We support the inclusion of local inspectors who already inspect facilities for other purposes when practicable and appreciate the FDA's recognition of the potential issues arising if local inspectors were to conduct simultaneous regulatory compliance inspections. Observation of incorrect procedures should inform educational efforts, which should be culturally-guided, provided in multiple languages, and include photos or illustrations to facilitate remediation.

We also suggest that the FDA consider modifying the survey to account for new foods and

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[8] FDA Retail Food Program Foodborne Illness Risk Factor Study: Marking Instructions for the Data Collection Form. FDA Website. June 6, 2016. Available at https://www.fda.gov/media/98232/download. Accessed May 15, 2021.

[9] US Food and Drug Administration. FDA Food Code 2013. Available at http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm. Updated February 2, 2018. Accessed April 8, 2018.

new means of securing food access in the retail environment, including grab-n-go, meal delivery services and kits, salvage stores, department and discount stores, farms with on-site retail, and sales of new exotic produce.

3. Pandemic-Related Considerations

The FDA's New Era of Smarter Food Safety blueprint outlines new approaches and processes to reduce the *costs* of foodborne illness by reducing the *number* of foodborne illnesses.[10] We strongly support inclusion of Core Element Three of the blueprint relevant to this information collection, "New Business Models and Retail Food Modernization," which "is intended to address how to protect foods from contamination as new business models emerge and change to meet the needs of the modern consumer."[11] The pandemic has coincided with and catalyzed an evolution of restaurant food service processes and procedures, and we encourage the FDA to update survey questions to capture and reflect these changes, elucidating (a) whether and how restaurants have made changes and (b) whether they intend to keep the changes or revert to pre-pandemic models. In particular, we encourage questions related to hot holding during the pandemic and online delivery models, with a focus on their effects on time and temperatures, because they would add significant utility to the data collection.

4. Statistical Analysis and Data Sharing

The data collected in the surveys is presently utilized substantially by the FDA and other federal agencies, and we note the value of the published Occurrence Reports and Trend Analyses used to produce educational materials as part of the FDA's ongoing efforts to improve food safety and reduce the effects of foodborne illness. Risk-based analysis has significant practical utility even when imperfect; correlations in activities help identify future areas for consideration as risk factors. The data as applied can also help inform appropriate training requirements and standards, and we encourage the FDA to underscore the identified added value of having certified food production managers in the surveyed establishments.

The survey data is used for common statistical analysis with descriptive statistics, correlations, and regressions. However, we encourage the FDA to consider an opportunity for additional analyses as well, including comparative studies across types of foodservice operations (*i.e.*, commercial vs. on-site). Our members report they would benefit from additional data sharing and dissemination of information collected in these surveys, and accordingly we encourage the FDA to make the dataset public to the extent possible for further analysis, similar to the manner in which the NHANES data is available.

Additional understanding of conclusions drawn from the survey data, including both identified knowledge gaps and the work being done to bridge them, would also enhance the quality and utility of the information. We respectfully note potential limitations in the data collection methodology (*e.g.*, arising from the regional collections) and statistical analysis, including the absence of statistics in several past reports that limit researchers' ability

[10] New Era of Smarter Food Safety Frequently Asked Questions. FDA website. July 13, 2020. Available at New Era of Smarter Food Safety Frequently Asked Questions | FDA. Accessed May 15, 2020.

[11] *Ibid*.

either to independently assess or validate the data. Finally, we recognize the enhanced value brought to the 2020-2025 Dietary Guidelines for Americans from federal agency scientists' peer review of data and encourage the FDA to consider the added utility of similar processes here.

Conclusion

The Academy appreciates the opportunity to submit comments related to the information collection, "Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types" and to support the FDA's important work to minimize the incidence of foodborne illness. Please contact either Jeanne Blankenship by telephone at 312-899-1730 or by email at jblankenship@eatright.org or Pepin Tuma by telephone at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information; we would welcome the opportunity to provide whatever assistance we can in this endeavor.

Sincerely,

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