

August 17, 2012

Submitted Electronically

Docket No. FDA-2012-N-0547
Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville MD. 20852

RE: Proposed Collection; Comment Request; Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2022)

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On June 19, 2012, the Food and Drug Administration (FDA) published in the Federal Register a notice soliciting comment on a survey entitled “Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2022)” (Information Collection Request or ICR). FDA invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of FDA’s functions
- The accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and,
- Ways to minimize the burden of the collection of information on respondents.

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the request of FDA for comments on the ICR.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI’s members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI’s retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI’s associate members include the supplier partners of its retail and wholesale members.

Food safety is of the highest priority to the retail grocery industry. Food retailers employ a number of food safety programs at retail, including training programs for sanitation and safe handling practices, and implementation of best practices for preparing, serving and storing food. Retailers are subject to thorough oversight by federal, state and local inspectors. In addition to working with suppliers, retailers continually reach out to consumers with education about the importance of food safety and by providing guidance on proper food handling, preparation, cooking, and cleaning practices.

1. FDA appears to have underestimated the amount of time needed at 15 minutes per event. Based on the retail industry's experience during the last survey (2008), the time spent collecting and monitoring data points took up 120 minutes per event per retail grocer. This caused an undue interruption to business operations and passed on unnecessary costs to those surveyed.
2. The FDA is not aligned with the CDC in the development of the study. According to CDC data, most foodborne illness outbreaks occur in restaurants (39% compared to <1% foodborne illness events occurring in grocery stores as well as 21% compared to <1% actual foodborne illnesses occurring in grocery stores).¹ Based on the data, it seems to put an unnecessary burden on retail grocery stores as retail grocery stores will be surveyed at a 4:1 ratio. The study should be more balanced between the restaurants and grocers.
3. We believe the study fails to meet FDA's Information Quality Guidelines and the requirements of the Data Quality Act because its structure will not provide information of utility to the public or the Agency as it is disproportionately focused on retail food stores when statistics indicate that far more foodborne illness events occur in restaurants.

Unless new scientific evidence clearly justifies the paperwork burden imposed on the retail grocery industry by the ICR, FMI believes FDA should not move forward with the ICR. If FDA does decide to proceed with the ICR, it should consider reducing the number of retail food operations surveyed related to the number of recorded foodborne illnesses and adjusting the time estimate per survey to a more realistic number.

FMI appreciates the opportunity to comment on this important matter.

Sincerely,

Terry Levee
Director, Food Safety Programs

¹ Information is based on data from 2008-2010 from the CDC Foodborne Outbreak Online Database <http://wwwn.cdc.gov/foodborneoutbreaks/>