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Submitted Electronically

Division of Dockets Management (HFA–305)
U.S. Food and Drug Administration,
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket No. FDA–2012-N-1258

RE: Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on the "Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm." We commend FDA for completing a risk assessment to support decisions made during the rulemaking process.

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.

The FDA qualitative risk assessment models risk from certain activity/food combinations conducted at small farm mixed-type facilities. Modeling these activities is a challenge due to the lack of specific small farm consumption data and other model inputs and known and unknown variability, such as infectious dose of pathogen/toxin and extrinsic and intrinsic growth conditions. The FDA risk assessment employs a definition of a low risk activity/food combination as: 1) has inherent controls, such as a low A_w for boiling honey; or an activity that 2) is not likely to introduce or increase potential of a Serious Adverse Health Consequence or Death (SAHCOD) hazard; or 3) an activity that doesn't minimize or prevent a SAHCOD hazard.

When performing a quantitative risk assessment, it is important to estimate the dose of a substance ingested, while comparing that dose to a level of human health concern. For instance, one would estimate the quantity of food consumed and multiply that by the concentration of the substance in that food, yielding consumer exposure to the ingested substance. Then, the exposure would be compared to a dose-response value that characterizes the presence/absence of an adverse human health effect at different levels of consumption of that substance. A simple quantitative risk assessment model, excluding growth conditions, might include sampling farm mixed type facility cracked peanuts (activity/food combination shown to be a low risk activity on Table 17) in order to develop a distribution of salmonella levels in peanuts that could be used in conjunction with quantity/frequency data from a dietary study in order to determine a distribution of consumer exposure. A dose-response value, generated from a determination of the level of salmonella that does/doesn't cause an adverse human health effect could be developed as a reference to compare to the distribution of consumer exposure.

While the standard for risk assessments is quantitative, FDA instead conducted a qualitative risk assessment. The risk assessment acknowledges a lack of exposure calculation data, which includes food consumption data, levels of contamination in the foods, as well as dose-response data necessary to do a risk characterization. We are concerned that the conclusions drawn regarding risk categories, and exemptions made based on this qualitative risk assessment do not quantitatively account for consumer risk from consumption of activity/food products.

The FDA qualitative risk assessment combined certain activity/food combinations in order to assess whether or not each one should be deemed low risk and excluded from additional food safety oversight of FSMA. Additionally, these activity/food combinations should be subjected to a more robust quantitative risk assessment, such as described above, before assessing risk and assigning exclusions or exemptions from food safety regulations.

We encourage FDA to continue to update this risk assessment and input more data into the model as it becomes available. We also encourage FDA to utilize this risk assessment as a dynamic tool for determining the risk of foods and on farm activities when enough data is available to perform a quantitative risk assessment.

FMI appreciates the opportunity to comment on this draft risk assessment and we look forward to working with FDA on the implementation of FSMA.

Sincerely,

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