THE VOICE OF FOOD RETAIL
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March 31, 2014

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

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

Dear Sir or Madam:

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/Animal 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 proudly advocates on behalf of the food retail industry. FMI's U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

The Purpose of the FDA Qualitative Risk Assessment (RA) is to satisfy requirements of the Food Safety Modernization Act (FSMA) which requires a science-based risk assessment to determine which activity/animal food combinations conducted on farm mixed-type facilities are low risk. These combinations may be used to exempt or modify the impact of FSMA on small or very small farms that manufacture, process, pack or

hold certain types of animal food. Two metrics—must satisfy the first or both parts of the second—are used to determine if the combinations are low risk: 1) activity/animal food combination has inherent controls such as pH or a_w or combinations of, 2a) activity/animal food combination is not reasonably likely to introduce (or increase the potential for) a hazard for which there is a reasonable probability that use of or exposure to the food will cause Serious Adverse Health Consequences or Death to Humans or Animals (a SAHCODHA hazard) and 2b)activity/animal food combination does not minimize or prevent a SAHCODHA hazard.

The RA follows the typical risk assessment structure (Hazard ID, Hazard Characterization, Exposure Assessment and Risk Characterization) used in a quantitative risk assessment; however, it lacks quantitative data such as hazard levels in food, food consumption quantity/frequency and a dose-response metric. Instead, hazards reasonably likely to cause or prevent a SAHCODHA (metric #2 from above) are qualitatively concluded using Reportable Food Registry (RFR) and Recall Enterprise System (RES) data. Data from RFR are based on self-reported contamination events and such events are likely under-reported. RFR contains reports of food contamination that are not consistently associated with health outcomes as food is often recalled before entering the marketplace to prevent illness. Additionally, RFR reports are generally associated with companion animals, not considered in this RA, and not food animals. Data should be collected to link animal food (produced by small or very small farm mixed-type facilities if possible) exposure to illness; this is demonstrated for human exposure linkage to illness via the Centers for Disease Control and Prevention (CDC) Foodborne Disease Outbreak Surveillance System (FDOSS). Using epidemiological methodology versus a voluntary reporting database, those illnesses reasonably likely to occur along with the corresponding animal food source-hazard combinations could be more accurately estimated and used in a risk assessment.

As noted by external reviewer #4, a precedent in literature for a qualitative risk assessment used to estimate the risk of activity-food specific combinations is not available.[1] Quantitative data should be employed in the risk assessment as much as possible.[2] Examples of incorporating quantitative data into a risk assessment follow: 1) sampling of animal food—produced by small or very small farm mixed-type facilities if possible—should be conducted to identify hazards and their corresponding levels in

[1] http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366907.pdf

[2] http://www.codexalimentarius.org/input/download/standards/13322/CXG_080e.pdf

food, 2) data should be collected to estimate animal and human exposure (e.g., consumption practices, biotransformation and handling) to animal food and edible products developed from the exposed animals, 3) these data could then be used to increase the likelihood of identifying a hazard that may not have been accurately represented in the RFR and to more accurately estimate exposure values through the combination of hazard levels and consumption/handling practices and 4) the resulting exposure values could be compared to a corresponding health based guidance value yielding an estimation of risk.

Low risk activity/animal food combinations gleaned from the RA might be written into the regulation and cannot be easily changed in the future. We recommend that combinations be written into a guidance document that can be updated. For example, if one of the low risk activity/animal food combinations is linked to an animal or human illness, the combination remains exempt from FSMA oversight. If FDA creates a guidance document that can be easily modified, the list of low risk combinations could be adjusted to account for food safety events and quantitative data, such as foodborne illness outbreaks and regulatory surveillance data, respectively.

We acknowledge and appreciate that FDA had limited data in order to develop a QRA to estimate low risk activity/animal food combinations. FMI encourages FDA to move the low-risk activity/animal food combinations to a dynamic guidance document until quantitative data is available in which a more robust risk assessment can be performed.

We appreciate your consideration of these comments. Please do not hesitate to contact me at elieberman@fmi.org or (202) 810-4044 if you have any questions.

Sincerely,

Erik R. Lieberman
Vice President and Chief Regulatory Counsel