

May 8, 2014

BY ELECTRONIC AND FIRST CLASS MAIL

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

Re: Docket No. FDA-2013-N-0013;
Sanitary Transportation of Human and Animal Food –
REQUEST FOR 90-DAY EXTENSION OF COMMENT PERIOD

The undersigned organizations submit this statement requesting that the U.S. Food and Drug Administration (FDA) extend the comment period for 90 days – to August 29, 2014 – on its proposed rule on “*Sanitary Transportation of Human and Animal Food*,” as published in the February 5, 2014 edition of the *Federal Register*.

The proposed rule implementing these provisions of the Food Safety Modernization Act (FSMA) represent the first time FDA has developed regulations that would govern the sanitary transportation of human and animal food. The proposed regulations require significant analysis, given they would encompass a wide and diverse array of human foods, animal feed and feed ingredients, and pet food transported by rail and truck. Further, the proposed rule contains complexities that would affect the interrelated responsibilities of shippers, carriers and receivers that warrant careful examination. In addition, our initial review has identified several sections of the proposed codified language on which we need additional time to develop significant suggested revisions for consideration by FDA. These revisions are needed to avoid unintended consequences and achieve our shared objective of outcome-based rules that are practical and workable, and focus on hazards that truly merit attention in protecting human and animal health. Finally, we believe additional time is needed to analyze the economic impact of the proposed rule on the wide swath of affected industry sectors.

Our organizations have been working diligently to analyze the proposed rule and prepare constructive and meaningful comments that address the significant issues we have identified thus far. However, additional time is needed to complete this undertaking. In addition, several of our organizations have spent extensive time and resources responding to other FDA-proposed foundational rules implementing FSMA. In that regard, we are confronting rapidly approaching comment-period deadlines on two other FSMA-related proposed rules: “*Designation of High-Risk Foods for Tracing and for Scientific Data and Information*” due on May 22, 2014; and “*Focused Mitigation Strategies to Protect Food Against Intentional Adulteration*” due on June 30, 2014.

We also want to take this opportunity to respectfully urge FDA to provide an opportunity for additional stakeholder input if – as we hope – the Agency agrees that significant revisions are needed to the proposed rule after reviewing comments received. In this case, we believe it will be both prudent and necessary for the Agency to reopen such revised codified language for additional public comment before issuing a final rule.

We believe FDA has more than sufficient latitude and time to extend the comment period and reopen comments on new codified language while still meeting the new March 31, 2016 deadline for issuing a final rule on sanitary transportation of human and animal food pursuant to the settlement agreement reached between the Agency and the Center for Environmental Health and Center for Food Safety, as approved by the U.S. District Court for the Northern District of California.

We commend FDA for its significant outreach to stakeholders on this and other rulemakings implementing FSMA. We believe this request for an extension in the comment period on this rulemaking is consistent with the Agency's oft-repeated desire to obtain meaningful and substantive comments.

We appreciate the Agency's timely consideration of this request.

Sincerely,

Agricultural Retailers Association
American Farm Bureau Federation
American Feed Industry Association
American Trucking Associations
Corn Refiners Association
Fresh Produce Association of the Americas
Grocery Manufacturers Association
Idaho Trucking Association
Institute of Shortening and Edible Oils
National Barley Growers Association
National Association of Manufacturers
National Chicken Council
National Cotton Council
National Council of Farmer Cooperatives
National Grain and Feed Association
National Oilseed Processors Association
National Renderers Association
National Turkey Federation
North American Millers' Association
Pet Food Institute
Transportation Intermediaries Association
United Fresh Produce Association

cc: Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine, FDA
Michael E. Kashtock, Center for Food Safety and Applied Nutrition, FDA
Mr. Donald Kraemer, FDA
Dr. Bernadette Dunham, Director, Center for Veterinary Medicine, FDA
Dr. Daniel McChesney, Director, Office of Surveillance and Compliance, CVM, FDA
Mr. Shannon Jordre, Consumer Safety Officer, Office of Surveillance and Compliance,
CVM, FDA