

May 5, 2011

Submitted Electronically

The Honorable Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
White Oak Building 1
10903 New Hampshire Avenue, Room 2217
Silver Spring, MD 20993

**RE: Executive Order 13536 and Implementation of the Food Safety
Modernization Act**

Dear Commissioner Hamburg:

The U.S. Chamber of Commerce Food Safety Working Group (the “Working Group”) represents many of the food industry stakeholders affected by the Food and Drug Administration’s (“FDA”) rules and guidance implementing the Food Safety Modernization Act (“FSMA”). As you know, the FSMA marks the most sweeping change to our nation’s food safety laws since the enactment of the Federal Food, Drug and Cosmetic Act in 1938. This landmark legislation, passed with the support of a broad coalition of Working Group members, retailers, producers and non-governmental advocacy organizations, clearly reflects a Congressional commitment that administrative flexibility and innovation will be the cornerstones for modernization of the U.S. food safety regulatory system.

We understand and fully appreciate the scope of the task facing FDA as it implements the FSMA and look forward to working with the Agency in a constructive and effective manner as the process moves forward. To that end, we urge the Agency to integrate and apply the principles of Executive Order 13563 and the Regulatory Flexibility Act (“RFA”)¹ in every step of the FSMA guidance and rulemaking process. We believe Executive Order 13563 and RFA together provide the tools and principles needed to modernize the food safety regulatory system in a balanced and cost-effective manner, consistent with Congressional intent.

Executive Order 13563 provides in relevant part:

Our regulatory system...must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends...each agency must...propose or adopt a regulation only upon a reasoned determination

¹ See 5 U.S.C. §601 et seq.

that its benefits justify its costs...[and] tailor its regulations to impose the least burden on society.²

The Office of Management and Budget has explained that the basic tenets of the Executive Order are for agencies to consider costs and to reduce burdens for American businesses and consumers; to expand opportunities for public participation and stakeholder involvement; to seek the most flexible, least burdensome approaches; and to ensure that regulations are scientifically-driven, among other things. This “smarter approach” to regulatory policy purportedly builds on the best practices of the past, “while adapting to serious economic challenges the country faces today.”³

Similarly, the RFA commands federal agencies to consider the needs of small business when new regulations are written, to analyze and understand the potential economic impacts of proposed regulatory actions, and critically to identify and consider less burdensome regulatory alternatives.⁴ Among other things, the RFA requires that when an agency proposing a rule is required to provide notice of the proposed rule, it must also produce an initial regulatory flexibility analysis that includes discussion of significant alternatives. Significant alternatives include the use of performance rather than design standards; simplification of compliance and reporting requirements for small businesses; establishment of different timetables that take into account the resources of small businesses; and exemption from coverage for small businesses. Congress commanded these measures in an effort to counteract the deadening impact of “one-size-fits-all” regulations and guidance on jobs, economic growth, and innovation.⁵

² Executive Order 13563 (January 18, 2011).

³ See Jack Lew, OMB Director, “Regulatory Strategy” (January 18, 2011), <http://www.regulationwriters.com/downloads/OMB-Regulatory-Strategy-Statement-01-18-11.pdf>.

⁴ See Office of the Press Secretary, Presidential Memoranda - Regulatory Flexibility, Small Business, and Job Creation (January 18, 2011) <http://www.regulationwriters.com/downloads/ObamaMemo-RegFlex-SmallBusiness-Jobs-01-18-11.pdf>; see generally Holman, THE REGULATORY FLEXIBILITY ACT AT 25: IS THE LAW ACHIEVING ITS GOAL? 33 Fordham Urban L. J. 1119, 1121 (2006) (citations omitted).

⁵ According to the Small Business Administration Office of Advocacy:

Both Houses [of Congress] built, in a number of hearings over 10 years, a conclusive record of disillusionment and discontent among the regulated. Small businesses and small entities repeatedly claimed that uniform application of the same regulations to them and to larger entities produced economic injustice. Four congressional committees (the Senate and House Small Business and Judiciary Committees), among others, heard damage reports from small businesses, small cities and towns, and small non-profit associations. Federal regulations, it was argued, imposed a disproportionate economic burden of compliance on them. In the business sector, there is considerable evidence that uniform application of regulatory requirements increases the minimum size of firms that can compete effectively in that regulated market.

Office of Small Business Advocacy, THE REGULATORY FLEXIBILITY ACT: BETTER FEDERAL TREATMENT FOR SMALL ENTITIES 5 (1980).

We believe that the “smarter approach” to regulatory policy enshrined in the Executive Order and the RFA ought to substantially inform and guide the FDA’s promulgation of FSMA guidance and rules. In practical terms, this means the Agency should take the following steps.

A. FDA Should Formulate Guidance and Rules Using a Scientifically Sound, Risk-Based Approach.

We believe that FSMA guidance and regulations should address the risks of greatest magnitude and highest probability. Furthermore, the risk assessments used to formulate policy and support Agency actions should be based on high-quality, up-to-date science and fully comply with all of the provisions of the Information Quality Act, § 515 of Public Law 106–554 and the relevant OMB Guidance.⁶ It is important that risk-based policies are incorporated into all guidance and rules and not as an additional layer of obligation above a base of deterministic regulations. Also, we believe that it is critically important for FDA to ensure its limited resources are focused on scientifically sound and properly defined high-risk concerns. Over-precaution in lower-risk areas will leave the Agency with insufficient resources to deal with the greatest threats to public health.

B. FDA Should Continue to Involve Stakeholders in the Regulatory Process.

We believe food businesses ought to have a major role in the evaluation and management of risk to promote innovation and regulatory flexibility as Congress has directed. The Working Group and the food industry have a tremendous store of practical knowledge and expertise, and are eager to play a constructive role in FDA’s implementation of FSMA. Cooperation and coordination will benefit all stakeholders.

⁶ 67 Fed Reg 8452 (Feb. 22, 2002). Notably, the information quality standards for human health risk information are clear and precise:

With regard to analysis of risks to human health...maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g– 1(b)(3)(A) & (B)).

67 Fed. Reg. at 8460. Under 42 U.S.C. 300g– 1(b)(3)(B), the Agency is directed, “to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable.” The Agency is further directed, “in a document made available to the public in support of a regulation” to specify to the extent practicable (i) each population addressed by any estimate of applicable risk; (ii) the expected risk or central estimate of risk for the specific populations affected; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific data. 67 Fed. Reg. at 8458.

Therefore, we are pleased that the Agency has demonstrated it will aggressively solicit stakeholder input regarding FMSA implementation. We are very appreciative of the FDA's efforts to date and look forward to robust participation and partnerships in the coming months and years. Going forward, we are confident that FDA will ensure comment periods are of adequate length for industry and other stakeholders to fully evaluate regulatory proposals and respond completely, solicit the views of Working Group members in advance of the issuance of proposed guidance or rules, and allow a thorough opportunity for public comment on scientific and technical findings.

C. FDA Should Ensure Inter-agency Integration and Promote Innovation.

The food and agricultural sectors are highly regulated and food businesses often face redundant, inconsistent and overlapping rules and regulatory regimes. As directed by Section 3 of the President's Executive Order, FDA should coordinate with other agencies to the maximum extent possible to harmonize FSMA guidance and regulations with existing regulatory schemes. Also, FDA's internal deliberations should be predicated on the identification and implementation of innovative regulatory approaches. The food industry is constantly innovating food processing and manufacturing methods and American consumers enjoy an unmatched bounty of healthful, convenient and affordable food choices as a result. The Agency must ensure this culture of innovation is promoted and not stifled by FSMA rules and guidance, and that the food industry and American consumers are not chained to a regulatory regime that mandates or promotes outmoded processing or manufacturing methods.

D. FDA Should Adopt the Least Burdensome and Most Flexible Regulatory Approaches.

As directed by the Executive Order, FDA should at all times identify and employ the least burdensome regulatory approaches, or at least explain why the least burdensome alternative was rejected in any given case. Also, FDA ought to broadly apply RFA analyses and principles to ensure FSMA guidance and rules are as flexible as possible to protect and promote small businesses. Improvident regulation of the food industry will mean higher consumer prices at a time when most Americans are struggling to make ends meet as it is.

E. FDA Should Ensure All Guidance and Rules are Based on a Reasoned Determination that Costs Justify Benefits.

The Administration directs agencies to propose or adopt regulations "only upon a reasoned determination that its benefits justify its costs."⁷ Therefore, we

⁷ A test for the term "reasoned determination" can be found in the exhaustively long line of cases interpreting similar language in the National Environmental Policy Act, 42 U.S.C. §4331. Specifically, a

believe FDA should conduct comprehensive cost-benefit analyses on all rules and guidance issued to implement FSMA to ensure the benefits exceed the costs to the maximum extent practicable.

F. FDA Should Develop and Employ Objective Metrics for Regulatory Efficacy.

We believe that FDA must have appropriate metrics to evaluate the efficacy of FSMA guidance and regulations. Therefore, we suggest FDA should develop with robust transparency and participation by affected stakeholders and then employ objective and scientifically sound metrics for regulatory efficacy at the earliest practicable time. FDA’s goal should be to assure that guidance documents and regulations demonstrate a measurable and sustained reduction in the incidence of foodborne disease. The failure to meet this goal ought to trigger retrospective analysis and withdrawal, as appropriate.

G. FDA Should Implement FSMA as Congress Intended.

FMSA grants FDA new legal authorities. However, Congress granted those authorities with the understanding the Agency will implement the law in a common-sense manner that promotes innovation, flexibility and cost-effectiveness and with due regard for the protection of trade secrets and intellectual property. Congressional intent, as manifest in the FSMA’s plain language, ought to drive the Agency’s regulatory approach and choices.

We appreciate your consideration of these important matters and thank you for your attention and your Agency’s efforts to keep America’s food supply safe, healthy and affordable.

Sincerely,

American Bakers Association
American Farm Bureau Federation
American Feed Industry Association
American Frozen Food Institute
American Peanut Council
The Coca-Cola Company
Flavor and Extract Manufacturers Association of the United States
Food Marketing Institute
Grocery Manufacturers Association
International Dairy Foods Association

“reasoned determination” that social benefits justify regulatory costs is one in which the agency has accurately identified and characterized the scope of the regulatory initiative, taken a “hard look” at the regulatory costs and alternatives, and then made a convincing case for its finding. *See e.g. Grand Canyon Trust v. FAA*, 290 F.3d 339 (D.C. Cir. 2002).

International Association of Color Manufacturers
National Confectioners Association
National Grain and Feed Association
National Grocers Association
National Renderers Association
Pet Food Institute
Produce Marketing Association
Snack Food Association
United Fresh Produce Association
U.S. Chamber of Commerce