



The Association of Food, Beverage
and Consumer Products Companies

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February 4, 2008

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

Re: Docket No. 2007N-0489; Request for Comments on the Science and Technology Report; Establishment of Docket; Request for Comments; 73 Federal Register 869; 4 January 2008.

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The Association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of fifty-two chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over \$1 trillion in added value to the nation's economy.

GMA commends FDA staff for the remarkable job they have done and are continuing to attempt to accomplish with the limited resources available. Clearly the time has come for Congress and the Administration to recognize the important contribution this agency provides both nationally and internationally toward ensuring the safety of the food supply.

While the ultimate responsibility for the safety of food rests with the food industry, FDA provides the oversight necessary to ensure that all parties meet that responsibility based on the best available scientific information and processing technologies. FDA must be in a position to continue to pursue strong, science-based regulatory policy.

In reviewing the FDA Science Advisory Board report we can only say that we agree with their findings with respect to agency funding. The FDA and specifically the Center for

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GMA Comment
Docket No. 2007N-0489
February 04, 2008
Page 2 of 3

Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) are significantly underfunded to the point that their core function is in jeopardy.

Over the years, FDA's ability to provide its basic food system inspection, enforcement, and rulemaking functions has severely eroded as has its ability to respond to outbreaks in a timely manner. Likewise, it is less able to develop and keep pace with developments in regulatory science and to address future problems of both novel (GMO's, nanotechnology, processing technologies, packaging systems) and traditional sources of contamination (microbial resistance, chemical contamination, risk assessment), as well as address deliberate contamination of the food supply. This condition can be traced directly to the lack of funding to maintain agency resources and cannot be allowed to continue. This past year, the agency responded quickly to multiple product recalls (melamine, *E. coli* O157:H7, *Salmonella*, *Clostridium botulinum*) but was stretched to the limit and likely had to cut back in other areas to meet this challenge. The agency deserves to be funded at a level sufficient to maintain and expand its regulatory oversight and scientific expertise without compromising other essential activities to address crises.

There has been a dramatic increase in and diversification of Agency responsibilities, reflecting the sharp increase in FDA regulatory mandates from Congress and the challenges of a globalized food supply. These changes require additional FTE's with corresponding scientific expertise to meet the challenges of today and the future. At the same time, lack of adequate resources has reduced the ability of FDA to retain key personnel in an aging workforce, made it more difficult to attract new career oriented staff and reduced the opportunity for the new staff to interact with and learn from veteran FDA staff.

Likewise, FDA needs adequate funding to update its information technology to enhance communication between its field offices and Headquarters as well as counterparts in other countries. An updated system will further ensure that FDA District offices can maintain essential communications with its field staff and other Federal Agencies (USDA, EPA, DHS) as well as coordinate with State and local authorities during times of crisis (hurricane, flood, pandemic, bioterrorism). It will also provide timely, accurate information to the legislative and executive branches of government and to the regulated industry.

Enhanced IT will also enable scientific staff to access information globally to better identify and prepare for emerging issues. FDA must be in a position to keep pace with a global economy using the most current scientific tools. CFSAN and CVM should have the ability to access and work closely with other research programs (NCTR, ARS, CSREES, CDC, NIC, DHS) to address food and cosmetic safety priorities in toxicology, microbiology, human and animal nutrition, and issues of emerging science. A commitment to upgrading and maintaining a state of the art information acquisition and processing system will provide FDA staff with access to the most current information to

GMA Comment
Docket No. 2007N-0489
February 04, 2008
Page 3 of 3

support both its scientific and regulatory mission. FDA must maintain its scientific capability if it is to continue to provide leadership for global food safety. GMA applauds the effort and dedication of FDA staff to maintain FDA's leadership role in supporting global food safety initiatives. But insufficient funding and staffing constrain these efforts and have a negative effect on attracting promising young scientists to the Agency. This does not bode well for the future. If FDA cannot attract new talent and provide those individuals with the incentives (professional development, collaborative programs with external scientists, equipment, and a clearly defined career ladder) to remain with the Agency it will no longer be able to fulfill its food safety mission.

The need to maintain FDA's scientific capability was further advanced in a separate report by the Interagency Working Group on Import Safety (IWGIS). The recommendations made in the IWGIS November 2007 Report to the President "Action Plan for Import Safety" would require a strong, science-based, IT-oriented FDA. It would also require FDA to work closely and cooperatively with other Federal, State, local and foreign regulatory agencies and the regulated industry to ensure continued availability of a safe, secure, and wholesome food supply.

CFSAN is responsible for regulating over \$420 billion in domestic food products representing 133,798* individual domestic facilities and \$49 billion in imported foods representing 188,946* individual foreign facilities. The current budget for CFSAN and its related field activities to regulate this industry is \$449 million (2007 budget). To have any realistic expectation of achieving and retaining the objectives set forth in the Report of the Subcommittee on Science and Technology, this budget should be doubled for 2008 and indexed for inflation in subsequent years with additional funding for any new programs mandated by Congressional or Presidential action in future years. Clearly the time has come for Congress and the Administration to recognize the important contribution this agency provides both nationally and internationally toward ensuring the safety of the food supply.

Thank you for providing this opportunity to comment on the Science and Technology Report.

Sincerely,



Robert Brackett, Ph.D.
Senior Vice President and Chief Science and Regulatory Affairs Officer

*As of July 3, 2007, FDA had received 322,744 facility registrations, of which 188,946 are foreign facilities and 133,798 are domestic facilities.