FOOD MARKETING INSTITUTE

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Via Facsimile Transmission and First Class Mail

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: CFSAN Program Priorities for FY 2002 (Docket No. 98N-0359)

Dear Sir or Madam:

As a result of last week's terrible tragedy, the top priority throughout the federal government over the coming year must be to ensure the safety and security of our country. However, in response to the agency's request for comments, the Food Marketing Institute[1] (FMI) offers the following thoughts on the food safety priorities for the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year 2002. 66 Fed. Reg. 37480 (July 18, 2001).

The touchstone for the priority-setting process should be benefit to consumers. With this in mind, we have recommended means to improve food safety, clarify labeling to inform consumers, and increase consumer education programs. In addition, we have made suggestions regarding improvements to the regulatory process. Our recommendations are discussed more fully below and generally follow the outline of CFSAN's 2001 Program Priorities document.

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

I. Food Safety Initiative

A. Irradiation: Clearance of Technology for RTE Foods and Improved Labeling

Irradiation is an important tool in the effort to improve the safety of the food supply. In FY 2002, CFSAN should complete work on the petition to clear irradiation for use with ready-to-eat (RTE) foods and should propose new regulations on labeling for foods that have been treated with irradiation.

Specifically, in August, 1999, the Food Irradiation Coalition (including FMI) submitted a petition to FDA seeking clearance of irradiation for RTE foods. The petition asks the Agency to amend the food additive regulations to permit the use of irradiation in the treatment of certain refrigerated, frozen, or dried food products derived from meat, poultry, fruits or vegetables to help control microbial pathogens and infectious protozoa. We urge the Agency to review and act on the petition quickly so that irradiation will be available as a food safety tool for ready-to-eat food products.

In addition, CFSAN should act in FY 2002 on the information received in response to the 1999 advance notice of proposed rulemaking and propose an amendment to the current irradiation labeling regulations to allow the use of labeling to inform consumers regarding the purpose of irradiation. That is, the regulation should expressly permit the use of labeling that connects the irradiation process with its benefits, *e.g.*, "Irradiated to kill harmful bacteria."

An equally important element to ensuring the ultimate use of irradiation will be educating consumers about the benefits of irradiation and de-bunking the myths that have developed around food irradiation. In this regard, we have welcomed the opportunity to assist the Agency in the development of an educational brochure. However, we recognize that more extensive educational efforts are likely to be necessary before the public will accept irradiation as a food safety tool without reservation. We urge CFSAN to commit to consumer education efforts regarding irradiation in FY 2002.

B. *Vibrio parahaemolyticus* Risk Assessment (CFSAN Strategy 1.3 A and B)

One of CFSAN's significant accomplishments in FY 2001 was the publication of a draft risk assessment on *Vibrio parahaemolyticus* (Vp) in raw molluscan shellfish. See 66 Fed. Reg. 5517 (Jan. 19, 2001). FMI supports CFSAN's efforts in this regard and urges the agency to finalize the risk assessment in FY 2002. As the agency moves toward finalizing the risk assessment, FMI urges CFSAN to adopt interventions that will be most effective in ensuring that raw molluscan shellfish has the lowest possible levels of Vp before it reaches food retailers because, beyond sound sourcing and sanitation

practices, retailers have little ability to eliminate or reduce bacterial hazards associated with the sale of raw molluscan shellfish.

C. *Listeria monocytogenes* (CFSAN Strategy 1.6 A and B,)

As CFSAN has recognized, the agency should continue to focus on the control of foodborne *Listeria monocytogenes* (Lm) in FY 2002. In this regard, the draft assessment and relative risk ranking that the agency released earlier this year is an important first step in addressing the public health implications of Lm. The data gaps that the agencies identified in the draft document must be filled and the next steps in the risk assessment process must be undertaken in an orderly fashion. CFSAN should make these next steps high priorities for FY 2002. Until these steps are completed, CFSAN should not implement the draft action plan but rather modify the action plan in light of new scientific information available to the agency.

In addition, FDA should continue to support the survey of isolates taken from foods purchased at retail that is being conducted jointly by JIFSAN and the National Food Processors Association and is being funded in part by FMI. The data gathered from the study will be important in completing the risk assessment activities that must be conducted in order to establish an effective Lm management plan.

D. Consumer Education (CFSAN Strategy 1.7 A)

Food safety education is an essential component of a strong food safety system. In this regard, FMI is proud to be a founding member of the Partnership for Food Safety Education (Partnership), which is responsible for the FightBAC!™ Campaign, as well as many other food safety initiatives, including two educational programs for children in elementary school. We encourage FDA to continue its involvement with the Partnership in FY 2002 and to pursue additional food safety education programs, such as the secondary school food safety curriculum.

E. Food Code (CFSAN Strategy 1.1 B and Strategy 1.9 B)

The CFSAN 2001 Priorities Program identified several goals related to the Food Code, including tracking and increasing its adoption in the states. CFSAN has also indicated that it will reconsider the definition of "potentially hazardous food" in the Food Code, based on scientifically valid criteria at the retail level.

1. Adoption

FMI supports the goal of widespread Food Code adoption and we are pleased that many states have now adopted some or all of the model Food Code. FMI has had a longstanding commitment to the Food Code and its development; a substantial delegation of our food retailer members and FMI staff regularly attend and participate in Conference for Food Protection meetings. Moreover, through FMI's Food Code Monitoring Project -- a service that we offer to our members -- we have compiled substantial information on the status of Food Code adoption in the fifty states, as well as comparisons of the versions adopted with the model Food Code.[2] We urge FDA to continue its commitment to seeking widespread adoption of the Food Code throughout the U.S. in 2002, and we would be pleased to work with the Agency in this undertaking.

2. "Potentially Hazardous Food" Definition

Several issues embodied within the Food Code have been challenged repeatedly by industry and regulatory agencies as lacking sufficient scientific justification. These issues include cooling and hot holding temperature parameters, time as a controlling factor and the definition of "potentially hazardous food."

The Food Code's definition of "potentially hazardous food" is illustrative of the issue. *See* U.S. Public Health Service, *Food Code* § 1-201.10(B)(61) (1999). The Food Code's definition relies in part on the acidity level and water activity of foods to identify foods that are potentially hazardous. However, the results of recent research and outbreaks indicate that this view does not account for the synergistic effects of additives and preservatives, which may reduce the potential for the food to pose a hazard without otherwise affecting acidity or water activity. The data also suggest that some foods that are currently exempted from the potentially hazardous food definition on the basis of acidity or water activity might, in fact, be hazardous.

In response to the challenges raised by regulators and industry, FDA has expressed an intention to reconsider the issue and to develop position papers that will be incorporated into the Food Code's annex. However, unless the Food Code itself is amended, any recommendations contained in the annex will not likely receive the proper notice from states that intend to incorporate the Food Code. Therefore, to ensure that the highest scientific standards underlie the Food Code, in 2002, the Agency should commit to resolving the controversial issues through the Conference for Food Protection and amending the Food Code itself accordingly.

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[2] We are pleased to note that the Agency intends to work with Association of Food and Drug Officials (AFDO) to survey state and local jurisdictions regarding their adoption of the Food Code. 65 Fed. Reg. 47736 (Aug. 3, 2000). If we may be of assistance via our Food Code Monitoring Project or in any other way, we would be pleased to help.

II. Major Program Areas

A. Assessment of Consumer Warnings and Labeling (CFSAN Strategy 2.2)

Under the current regulations, FDA requires or has proposed consumer warning labels on a variety of different food products, such as unpasteurized juice and shell eggs. In addition, the U.S. Department of Agriculture (USDA) requires warning labels on certain meat and poultry products under the Federal Meat Inspection Act and the Poultry Products Inspection Act. Each of the warning labels is visually and substantively different. Although some element of differentiation is necessary, there is little doubt that the multitude of warnings is confusing to consumers overall. The proliferation of warning labels on food and other consumer products has led consumers to discount or disregard the warnings. Moreover, labeling, in and of itself, does little to protect the public health.

Therefore, the Agency should develop a clear and coordinated policy for when and how warning labels are used on foods. Furthermore, FDA should, in conjunction with the other food safety agencies, develop a more uniform design for warning labels for those instances in which the Agency determines that such a label is appropriate. For example, the Partnership for Food Safety, of which FDA is a member, has developed food safety messages and icons that might form the basis for a uniform food safety labeling system. A consumer education campaign should accompany and reinforce the uniform labeling and warning initiative.

We recommend that CFSAN include a review and evaluation of food safety labeling as a priority for fiscal year 2002.

III. Cross-Cutting Areas

A. Foods Produced through Biotechnology (CFSAN Strategy 3.4. A.1.)

Foods and food ingredients produced through biotechnology have long been part of the U.S. consumer's diet. These foods have always been and continue to be subject to the stringent adulteration and labeling standards set forth in the Federal Food, Drug, and Cosmetic Act, which standards apply to all foods, regardless of the method of production. In response to concern regarding the safety and labeling of foods produced through biotechnology, FDA has taken a number of steps over the past two years, including the issuance of a proposed regulation that would require pre-market notification for bioengineered foods and the publication of draft guidelines for claims made regarding the presence or absence of bioengineering in the production of food.

In FY 2002, we urge FDA to finalize the proposed pre-market notification regulation in the manner recommended by FMI in comments filed earlier this year. The

final rule will enhance consumer confidence and increase the transparency of the system. Moreover, we recommend that FDA finalize the guidance document proposed for a voluntary labeling program and pursue appropriate enforcement action against those who make claims that are false and misleading within the meaning of the FD&C Act.

Perhaps most importantly, FDA must take responsibility for its policy and provide clear information to the public on the safety and regulation of biotech foods. Overall food safety is a primary mission of the Food and Drug Administration, which carefully regulates a majority of the daily American diet. In keeping with its overall mission, FDA has invested significant resources in ensuring that foods produced with biotechnology are likewise safe. In FY 2002, FDA must make a renewed commitment to communicate this information directly to the public in a clear and comprehensive manner.

B. Food Allergens (CFSAN Strategy 3.4. A.2.)

CFSAN identified food allergens as an "emerging issue" priority for 2001 and took some important steps in this area over the previous year. Given the critical nature of food allergen identification and control for a certain segment of the consumer population, we recommend that CFSAN continue to place a high priority on food allergens in FY 2002. FMI stands ready to assist the agency as it moves forward on these issues.

C. Regulatory Process (CFSAN Strategy 3.5. B)

As we did last year, we again recommend that CFSAN add the development of a Retail Advisory Committee to its priorities for the coming fiscal year. As you know, FDA currently receives advice and guidance from several joint advisory committees, some of which serve both FDA and USDA. Given the increased federal focus on retail food safety issues, we recommend that FDA jointly develop a "Retail Advisory Committee" with USDA's Food Safety and Inspection Service (FSIS) to provide guidance to the agencies on the operational and practical issues relevant to food safety at the retail level. The Committee might be comprised of members from the supermarket, distribution, restaurant, and food technology industries, along with federal and state regulators, and consumer group representatives. A body of retail food safety experts would provide important expertise on critical food safety issues such as the Lm action plan and the development of programs for Lm research and control.

Existing advisory committees, such as the National Advisory Committee on Microbiological Contamination of Foods (NACMCF), would also benefit from the insight of the retail perspective. For example, the NACMCF recently considered the merits of gloved and bare-hand contact of food in the retail setting and intends to consider date marking at a future meeting. Although one of the Committee members represents the quick-serve restaurant industry, the food retailing industry – supermarkets, wholesalers, distributors – is not represented on the current committee. In light of the

growing attention that food safety in the retail setting is receiving at the federal level, an increased presence of retail members on the federal advisory committees will help to formulate better food safety recommendations and bring new knowledge and expertise not currently available on the federal committees. Increased expertise will help to ensure that our food safety system will continue to provide safe food for consumers.

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We hope you will find the foregoing suggestions helpful in developing CFSAN's priorities for fiscal year 2002. If we may provide further information on the foregoing or assistance in carrying out these activities, please do not hesitate to call on us.

Sincerely,

Tim Hammonds
President and CEO