

August 9, 2004

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

RE: Program Priorities in the Center for Food Safety and Applied  
Nutrition; Request for Comments  
*69 Federal Register* 35380 (June 2, 2004)  
Notice  
**Docket No. 1998N-0359**

Dear Sir/Madam:

For over 100 years, Americans have trusted the well-known brands Kraft Foods Global, Inc. (Kraft) sells. Today, our brands are found in more than 99% of all U.S. households and are sold in 150 countries around the world. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. We distribute over 18 billion packages of food each year. We have followed and participated with FDA in the creation and implementation of the programs and priorities of CFSAN. Accordingly, Kraft has a very substantial interest in the development and implementation of effective food regulatory programs.

Kraft commends FDA for utilizing the CFSAN priority list as an effective management tool and the report card as a timely tracking method in an environment of limited resources. Further, we applaud CFSAN's continued efforts to involve all stakeholders in the priority process. We support the emphasis on the broad categories of food safety and security as consistent with the mission and goals of CFSAN. We also recognize the importance of continuity between fiscal year workplans in areas such as food security and initiatives to address obesity and consumer health as these are issues of a long-term nature.

For the Agency's FY 2005 plan, Kraft recommends that CFSAN include the following items among its highest priorities.

**Food Bioterrorism.** Increasing the security of the nation's food supply is among the most important priorities for the Agency. Kraft urges FDA to complete the issuance of final regulations as the foundation of a basic food security system. FDA should continue to develop other prevention measures, in concert with the Department of Homeland Security and other relevant agencies, to strengthen the barriers against potential threats through the food supply.

**Food Safety.** Along with food security, food safety occupies a premier position in any list of Agency priorities. Among the many food safety issues facing the Agency, we think three deserve special consideration:

- 1) action on the Citizen Petition to amend regulations to establish a regulatory limit for *L. monocytogenes* in foods that do not support its growth;
- 2) promotion of research to establish thresholds for major food allergens;
- 3) development of revised Good Manufacturing Practices (GMPs) that encourage industry to invest in and implement the best practices to reduce foodborne illness.

Regarding GMPs, we support FDA's approach to GMPs which sets overall goals and requirements as a foundation for food safety, but allows manufacturers the flexibility to achieve these goals using the most current and efficient techniques suited to their individual environments. Indeed, consistent with the current GMP framework, Kraft has continued to successfully develop numerous improved food safety programs. Kraft suggests that flexible GMPs, supplemented with guidance documents for specific products and/or processes for which more detailed information could improve consumer protection, provide the best approach.

**New Technology.** Kraft notes that advances in food processing techniques and ingredient technologies that would result in significant improvements in food safety, quality and cost, are often thwarted by barriers in existing food standards. The continued ability of U.S. companies of all sizes to participate in world trade will often depend on a regulatory environment favoring adoption of such innovations. FDA needs to update and modernize or repeal many outdated food standards not only to acknowledge new technology, but also to fulfill its regulatory function to maintain and administer the food standards program. We are encouraged that FDA will work with USDA to develop approaches to address the food standards administered by both agencies. As a further step to encouraging new technologies, Kraft asks the Agency to consider application of the principles of the Critical Path Initiative to areas such as food additives so that sound science may drive timely regulatory approvals.

**Improving Nutrition.** Kraft applauds the Agency's initiatives to provide more information to improve consumer nutrition. In particular, suggestions in the Obesity Working Group report will provide action items for several years. Of the many opportunities available, Kraft would like to see four areas considered during the next year:

- 1) changes in the nutrition label to alert consumers to calories, as part of the Calories Count program; and changes in the nutrition label to alert consumers to focus attention on serving size, as critical to understanding how individual foods fit into a total diet. For example, for some products providing data on a per serving and per package basis simultaneously may be particularly helpful to consumers;

- 2) proposal to delete the “low fat” requirement in several heart–related health claims as recommended by the Nutrition Subcommittee of the Food Advisory Committee;
- 3) timely response to all petitions on nutrient content claims and health claims;
- 4) issue an ANPR on mandatory nutrition label facts panel to begin the long process to update the macronutrient definitions in accordance with National Academy of Science recommendations and other best available evidence.

**Biotechnology.** The Agency has addressed several issues in biotechnology as priority items over the last several years. Many of these priorities continue from year to year. Kraft notes that bioengineering has now extended to the production of pharmaceuticals or other chemicals in plants. This non-food use of bioengineered plants is a cause of great concern to the food industry, since many of these plants are also important food crops. We ask FDA to move the issue of plant-made pharmaceuticals from the “B” to the “A” priority list for FY 2005.

**International Trade.** The global marketplace is a reality for companies large and small. We recommend that CFSAN continue to contribute to the leadership role of the U.S. in international venues, such as Codex and WTO, which can influence world trade. Thus, U.S. positions must be grounded in sound science and reflect current best practices as a basis for negotiations. In particular, we continue to advocate for cooperation among NAFTA countries for better coordination on food regulations concerning nutrition labeling, ingredient approvals, inspection practices, and contaminants.

Kraft recognizes that food security and safety have a pre-eminent position among CFSAN’s priorities. We urge the Agency to consider these comments as priorities consistent with other important Agency functions. Simply, we encourage FDA to advance new science and technology to expedite applications that will improve food security, safety, quality and cost. In addition, we encourage strong cooperation to enable seamless trade.

Respectfully submitted,



John Ruff  
Sr. Vice President  
Worldwide Quality, Scientific Affairs & Compliance