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

Re: Current Good Manufacturing Practices for Foods
Docket No. 2004N-0230

Dear Sir or Madam:

With net 2003 revenues exceeding \$31 billion, Kraft Foods Global, Inc. (Kraft) is the largest food manufacturer in North America and the second largest worldwide. Our well-known brands are found in 99% of U.S. households and are sold in 150 countries around the world. The consumer trust we have built over more than 100 years is priceless and critical to our company's continued success. That trust, of course, depends upon the quality and safety of our products, which are of paramount importance to us. Public trust also depends, in large part, upon the credibility of the entire food industry. Thus, we commend the efforts of the Food and Drug Administration (FDA) to update the Good Manufacturing Practices (GMPs) regulations governing the food industry.

The current GMPs have worked well for over a quarter century, yet Kraft agrees the time has come to build upon the existing solid regulatory foundation. We suggest that the goal of the present proceeding should be to update current regulations to take advantage of the lessons we all have learned since the GMP regulations were last amended, without eroding the flexibility at the heart of the successful umbrella scheme that has served the country well for so long.

Recognizing that GMPs apply to all types of food products, processes, and processors, in preparing these comments we began by thinking carefully about the diverse attributes of our operations and those of our suppliers, for those operations form the base of experience upon which we rely in making these recommendations to FDA. To help agency personnel appreciate the diversity of our operations, we note that in materials for the financial community we are described as competing in 25 different food categories.¹ We mention here as examples a few of our major products lines: Maxwell House coffees; Capri Sun, Country Time, and Kool Aid beverages; Nabisco cookies,

¹ More information is available at <http://www.kraft.com/>.

crackers, and snacks; Kraft cheeses, dressings, and dinners; Post cereals; Planters nuts; Jell-O desserts and Cool Whip toppings; Baker's chocolate; Tombstone, Jack's, and DiGiorno pizzas; Boca meatless burgers and sausages; and Oscar Mayer Lunchables meal kits regulated by FDA as well as the many Oscar Mayer and Louis Rich meat and poultry products regulated by the Food Safety and Inspection Service (FSIS). Some of these products are dry and distributed at ambient temperatures, while others must be refrigerated, and still others are frozen. In fact, we sometimes think of our operations as a microcosm of the food industry.

In addition to reviewing our own portfolio of products and processes, in preparing these comments we reviewed both the study of recalls that FDA conducted, dated August 3, 2004 ("FDA Recall Study"), as well as the external review of food GMPs FDA received from the Eastern Research Group, Inc., dated August 9, 2004 ("ERG Report"). We also considered the summaries of presentations made at the public meetings FDA held this past summer.

Fundamental Premises

After participating in scores of internal and industry debates about how to enhance existing GMPs, we have concluded that a few fundamental premises could help constructively to focus further discussion. Accordingly, we recommend that FDA recognize the following underlying premises as the proceeding continues:

- The first premise is that GMPs provide the basic controls that are the foundation for safe food production, but they are not the only set of controls for assuring food wholesomeness and safety. FDA's modernization effort should retain this focus on basic sanitation and related controls that assure conditions favorable to the manufacture of wholesome and safe food.
- The second premise is that, along with the breadth in kinds and types of food products that Kraft and other members of the food industry process and sell comes an equal breadth in the types and degrees of risk presented by the products. The food GMP regulations need to embody this wide range of risk, and not become either overly prescriptive or driven by requirements that would only apply properly to the products presenting the highest level of risk.
- Some of the issues identified in the FDA Recall Study and the ERG Report reflect the failure of certain companies to comply with existing requirements, a deficiency that will not be cured by imposing additional requirements upon the industry as a whole, but rather requires an increase in targeted enforcement actions.

Specific Comments

With these premises and the diversity of our operations in mind, the comments below address four specific subjects that Kraft recommends for particular attention: written sanitation practices, targeted environmental monitoring, allergen control practices, and record keeping. Many of the trade associations in which Kraft participates are filing comments addressing in detail the eleven questions FDA posed in the Federal Register, so we will try to avoid repeating here what others are suggesting.

I. THE FOOD GMPs SHOULD ADDRESS WRITTEN SANITATION PRACTICES

Effective sanitation practices have always served as a foundation for FDA's current good manufacturing practices. The existing GMPs are based upon the expectation that food manufacturers will implement comprehensive procedures designed to ensure that the manufacturing environment and equipment are cleaned regularly and protected from contamination both during processing operations and post-processing, that employees are trained in and adopt personal hygiene practices compatible with a clean processing environment, and that compliance with these practices is monitored.

One especially important practice that has become standard in our facilities and elsewhere is the development and use of written sanitation programs tailored to the specific equipment and processes employed at each production site. The current regulations have a number of provisions covering different aspects of food sanitation, but there is no explicit requirement or reference suggesting that each facility develop a detailed written set of practices or procedures for how the facility will comply with the GMP sanitation requirements.

To facilitate GMP compliance, Kraft recommends that the regulations be amended to provide that every food manufacturer should document its sanitation practices, update those practices as circumstances dictate, and train its employees accordingly. Accordingly, Kraft recommends that the current regulations be amended to include the following provision:

“Each manufacturer, regardless of size or products produced, should document practices that it will employ to ensure adherence to these requirements. In addition, each manufacturer should review and update these practices to reflect developments in technology. Employees should be trained to comply with the specific manufacture’s practices as well as these requirements.”

II. THE FOOD GMPs SHOULD PROVIDE FOR ENVIRONMENTAL MONITORING

One of the most significant advances in food processing controls since the original promulgation of the food GMP regulations is the development of environmental monitoring programs which include appropriate microbial testing. These programs help processors evaluate the effectiveness of sanitation programs and guide the development of improved sanitation programs. From our point of view, requiring an environmental monitoring program for each facility would fill one of the key gaps in FDA's food GMP regulations, but the flexibility to develop programs tailored appropriately for each product, process, and facility is imperative.

The need for environmental monitoring programs is most apparent in the production of ready to eat food products that support the growth of undesirable microorganisms. In particular, products that both support the growth of *Listeria monocytogenes* and are exposed to the processing environment beyond the lethality step require increased surveillance. Based upon our experience, Kraft recommends that every manufacturer of processed ready to eat products institute an environmental monitoring program that includes microbial testing to evaluate sanitation effectiveness, detect potential harborage sites, and guide corrective actions.

Environmental testing programs are appropriate in other circumstances as well with other target organisms. As noted above, the GMP regulations need to accommodate the full breadth of products and degrees of risk. In concert with the type of product/risk involved, Kraft supports a requirement for a science-based implementation of environmental control programs. Accordingly, Kraft recommends that the regulations be amended by adding the following provision:

“Each manufacturer should monitor the production and processing environment, including microbial testing as appropriate, to evaluate the effectiveness of its sanitation practices, detect potential microbial harborage sites, and guide corrective actions.”

III. THE FOOD GMPs SHOULD REQUIRE ALLERGEN CONTROL PRACTICES

The food industry has become increasingly sensitive to the need for proper labeling of allergens and plant practices designed to prevent cross contact which might inadvertently introduce an unlabeled allergen into a product. Kraft recognizes that consumers with food allergies need to be constantly vigilant to avoid certain foods or food ingredients. It is the industry's responsibility to label its products accurately so they contain what is listed on the label and—just as importantly—do not contain food allergens that are not so listed.

The current regulations contain a number of provisions that relate to preventing contamination in the food processing environment, but there is no explicit mention of food allergens. Moreover, the current regulations focus primarily upon the control of contaminants that would cause the product to become adulterated. Food allergens, though potentially hazardous to susceptible individuals, are otherwise wholesome ingredients that may legally be added to foods; they are not considered adulterants..

To update the food GMPs by enhancing the focus on allergens, Kraft recommends that the regulations require food processors to develop and adopt allergen control practices within their facilities. Kraft recommends that FDA keep the regulations at the “general principles” level, and allow individual processors the flexibility to design and implement an allergen control plan in a way tailored to their individual circumstances. In general terms, the required plan should address production scheduling, cleaning of equipment, ingredient control, and labeling control and compliance. Accordingly, Kraft recommends that the regulations be amended to include the following provision:

“Each food manufacturer should adopt and implement practices designed to prevent the presence of unlabeled allergens in food products.”

IV. KRAFT SUPPORTS MAINTENANCE OF RECORDS TO ACHIEVE AND MONITOR ADHERENCE TO GMP REQUIREMENTS

As a general proposition, FDA does not have the authority to mandate that food manufacturers maintain records or, except in carefully circumscribed situations, make records accessible to the agency. The current food GMP regulations in Part 110 do not contain records access requirements, though FDA inspectors will frequently ask to see food manufacturing records on a voluntary basis during an inspection. Other existing FDA regulations go further than Part 110 in this regard. In particular, current FDA regulations have recordkeeping requirements, in varying degrees, for: (a) low acid canned foods (processing and production records, 21 CFR 113.100); (b) acidified foods (records, 21 CFR 114.100); (c) juice products (records, 21 CFR 120.12); and (d) seafood products (records, 21 CFR 123.9), but these have been adopted in accordance with specific and narrow statutory or regulatory provisions. In addition, the recent Bioterrorism law contains limited requirements, and new FDA regulations are now pending to implement those requirements.

Although FDA’s legal authority to mandate records retention or seek access to them is very limited, Kraft’s position is that manufacturers should be expected to maintain records as necessary to achieve and monitor their basic adherence to GMPs. Absent specific statutory authority, however, FDA should not routinely demand access to a manufacturer’s records

Manufacturers typically maintain records necessary to monitor their effectiveness in achieving compliance with the GMP requirements and the current regulations could reasonably be interpreted implicitly to require recordkeeping. Kraft recommends, however, that the regulations be amended to specifically address the need to maintain adequate records to assure compliance. Accordingly, Kraft recommends that the regulations be amended by including the following provision:

“Each manufacturer should maintain such records as are necessary to achieve and self-monitor adherence to these requirements.”

CONCLUSION

Kraft appreciates the approach the FDA is taking in looking for the most efficient and effective ways to modernize the food GMP regulations. From our point of view, the current GMP regulations generally have worked well. Thus, the task at hand is to improve upon a sound foundation by enhancing current requirements selectively where “gaps” exist. These include the key areas of documenting sanitation practices and updating them as appropriate, facilitating allergen control and environmental monitoring, and maintaining records necessary to monitor and achieve GMP compliance. In addressing these areas, Kraft urges FDA to keep the regulations themselves at the “general principles” level, to allow industry needed flexibility to implement the regulations as best fit particular circumstances and to keep the scope of the regulations within the traditional GMP framework.

Kraft looks forward to continuing to work with FDA as the agency moves ahead with this initiative. Please do not hesitate to contact me, if we can be of assistance.

Respectfully submitted,



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