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Kraft Foods Global, Inc.

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

Re: Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 2004G-0381]

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) appreciates the agency's ongoing efforts to implement the food-related provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and welcomes the opportunity to comment on the recently issued draft guidance. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells. Today, Kraft brands are found in more than 99% of all U.S. households and are sold in 150 countries around the world. Kraft, therefore, has a substantial stake in the continued safety of the food supply.

Kraft commends FDA for the actions the agency has taken to address intentional contamination and other third party threats to food safety, and to improve the agency's own responsiveness to those threats. Kraft recognizes that the success of these efforts depends in part on the agency's ability to access necessary records expeditiously. Accordingly, Kraft stands ready to cooperate fully with the agency in response to requests for records under the Bioterrorism Act.

To ensure that FDA receives the most rapid and complete cooperation possible in response to a records request, Kraft respectfully suggests that FDA submit those requests directly to the "emergency contact" named in our company's registration. FDA required facilities to submit emergency contact information as part of the registration process to expedite the agency's response to emergency situations. 68 Fed. Reg. 58894, 58922 (October 10, 2003). The circumstances that would justify a request for records under the Bioterrorism Act (namely, information suggesting that a food is adulterated and presents a threat of serious adverse health consequences or death) seem to fall squarely within that category.

Moreover, for Kraft and other companies that operate multiple facilities in multiple geographic locations, directly notifying the emergency contact will ensure that the agency's records request receives upper management's attention immediately, and that individuals empowered to extend the company's fullest possible cooperation are involved from the outset. A system that notifies personnel at the facility level only will unnecessarily slow response times, creating additional and entirely unnecessary layers of communication between FDA and a company.^{1/}

For these reasons, Kraft urges FDA to modify the draft guidance to provide for direct and immediate notification of a facility's emergency contact in the event of a request for records under the Bioterrorism Act. Once again, we applaud the agency's efforts in implementing the Bioterrorism Act and appreciate the opportunity to comment on this important issue.

Respectfully submitted,



Sheryl A. Marcouiller
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^{1/} FDA acknowledged the importance of notifying a company's upper management in the preamble to the interim final rule on registration. Specifically, the agency observed that "[i]f an emergency occurs with respect to a particular facility or group of facilities, FDA will need to alert the parent company, as well as the affected facilities, because the parent company has ultimate responsibility for the facility. Moreover, in terms of inspections, the relationship between a facility and its parent company is vital for FDA in tracking and investigating incidents." 68 Fed. Reg. at 58922.