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Global Quality, Scientific Affairs & Nutrition

July 8, 2004

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

Re: Prior Notice of Imported Food—Docket No. 2002N-0278

Dear Sir or Madam:

Introduction

Kraft Foods Global, Inc. (Kraft) is a \$30 billion global company, the largest food manufacturer in North America and the second largest worldwide. We have plants located in both Canada and Mexico. In the United States, we sell products made in our facilities around the world; we import roughly 200 ingredients from almost 100 countries. Thus, we have a substantial interest in the rules governing the importation of food products and substantial experience with the new prior notice system established by the Food and Drug Administration (FDA).

Kraft commends FDA personnel for their efforts in quickly implementing the prior notice requirements of the Bioterrorism Act. We recognize the challenging timeframe and difficult issues faced by the agency. Fortunately, the long hours devoted by FDA staff have borne fruit. In Kraft's experience, the prior notice system works consistently and efficiently, with a minimum of unnecessary delays and confusion. Kraft appreciates the agency's pledge to further reduce the prior notice timeframes and to integrate its advance electronic notification processes with the Bureau of Customs and Border Protection (CBP) and looks forward to the completion of those tasks.

Kraft's products are found in 99.6% of American households and are sold in 150 countries around the world. Accordingly, Kraft has a substantial and continuing stake in protecting and improving the safety of the food supply. Based on its

experience, Kraft believes further enhancements to food security and efficiencies in the food importation process can be achieved, beyond what may accrue through better integration with CBP. As discussed more fully below, Kraft believes this opportunity for greater security and efficiency lies in better integration of the resources devoted to the agency's 801(a) and 801(m) review processes.

I. Better Integration of Current Import Programs is Logical Next Step

To build on the progress FDA has already made in improving food security and import efficiency, Kraft urges FDA to take the next logical step and begin integrating the prior notice (Section 801(m)) information collection system with the existing OASIS (Section 801(a)) information management system as fully as possible. Currently, these systems seem to function separately, essentially creating two sequential FDA reviews. Merging these systems and the resources they involve into a more simultaneous import review step offers a significant opportunity to enhance food security and improve productivity for both FDA and industry. Such a merger would also be a natural extension of the integration efforts already underway with CBP.

Moreover, better integration of the 801(a) and 801(m) review functions would assist the agency in meeting its statutory obligations under the Bioterrorism Act.

Pursuant to the Act, FDA must:

give high priority to making necessary improvements to the information management systems . . . that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this chapter.¹

A well-conceived, streamlined importation information management system would fulfill this mandate by helping FDA better allocate import resources and facilitate the importation of food that is in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA).

II. Importance of Integration

The unnecessary delays caused by the duplicative nature of the current FDA importation information management systems place the nation's food supply at greater risk. Currently, many shipments offered for import are cleared for purposes of Section 801(m) but are held pending Section 801(a) review. Kraft acknowledges

¹ 21 U.S.C. § 381(h)(2).

the enforcement discretion enjoyed by FDA personnel in deciding whether to sample a shipment, but believes the current, two-step system can be unduly slow, duplicative, and lead to unnecessary holds on shipments. In many cases, FDA eventually releases shipments held for 801(a) review without any examination or sampling of the product, or review of the accompanying documents.

It appears that a substantial portion of the 801(a)-related delays now experienced by Kraft and other importers are attributable to the absence of FDA personnel at ports of entry on evenings and weekends. Often shipments arriving at a port of entry late in the day that are “flagged” by OASIS must be held overnight for review and release the following morning, at the earliest. Regrettably, shipments that are held for review on Fridays often must be placed on hold until FDA personnel devoted to the 801(a) review process arrive on Monday. Delays of this sort, particularly when no actual review is conducted prior to release, serve no discernable interest.

They also inevitably diminish security. Anytime shipments are delayed, security suffers. The chain of custody lengthens and becomes more complex as the cargo is exposed to the additional sets of handlers necessary to transport, store, or hold the delayed shipments until FDA personnel become available for review or release. In short, unnecessary 801(a) holds reintroduce the very same types of security risks FDA and companies such as Kraft have labored to eliminate.

III. Ways to Address Integration and Improve Efficiency

Because the bifurcated 801(a)/801(m) review process degrades import security and efficiency, Kraft urges the agency to pursue integration of its 801(a) and 801(m) information management systems. Working from a single system, FDA could combine the personnel resources it now expends on separate 801(a) and 801(m) reviews and devote them to a single, integrated review program that, ideally, is staffed 24 hours a day, 7 days a week at ports of entry. FDA could couple this reallocation of existing agency resources with efforts to transform the integrated information management system into a more sensitive, risk-based tool, as discussed more fully below.

A. Continuous Coverage at Ports of Entry

Kraft is confident FDA would conserve time and resources by integrating the Section 801(a) and 801(m) review processes into a more seamless whole. Under the current, divided system, the agency often expends entry review and import inspectional resources trying to confirm information that is already available through the Section 801(m) program. Eradication of this type of duplicative effort,

together with realization of other economies of scale, should free critical financial and personnel resources for reallocation.

First priority in reallocating these freed resources should be given to achieving 24-hour, 7 day per week coverage by FDA personnel at ports of entry. Continuous agency staffing, capable of conducting 801(a) and 801(m) reviews simultaneously, would enhance shipment security and further facilitate trade at the borders. If existing resources, reallocated as necessary, still are not sufficient to achieve 24-hour, 7 day per week coverage, Kraft stands ready to support the agency in legislative efforts necessary to obtain the additional funds needed to make continuous coverage possible.

Kraft also suggests that FDA consider deputizing CBP personnel to assist in carrying out Section 801(a) review. The Bioterrorism Act requires FDA to “improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety.”² Collaboration with CBP on the 801(a) review process would further this goal.

Collaboration with CBP is, of course, already in place with regard to 801(m) review, as evidenced by the December 2003 Memorandum of Understanding (MOU) signed by the agencies. Kraft notes that the MOU commissions CBP officers to conduct 801(a)-type functions like “collect[ing] samples upon FDA’s request, and ... forward[ing] those samples to FDA for analysis.”³

In short, FDA and CBP have laid the groundwork for cooperation in carrying out both the 801(a) and 801(m) functions. Kraft urges FDA to extend this working relationship on a formal basis to cover 801(a) review, thereby ensuring more comprehensive coverage at the nation’s ports of entry.

B. Improved Risk Profiling

Kraft also suggests that the agency devote freed resources to improving data collection and, thus, improving risk profiling. An integrated 801(a)/801(m) system that allows for submission and consideration of additional types of data and information will produce more refined, risk-based sampling selections. Such a modified system might, in addition to assigning risk by product category, distinguish among existing and new products, as well as take account of the higher risk inherent in some types of products and the lower risk inherent in others.

² 21 U.S.C. § 381(h)(3).

³ Memorandum of Agreement Between Customs and Border Protection and the Food and Drug Administration, signed December 3, 2003.

To sharpen the risk sensitivity of FDA's import review process still further, Kraft suggests that the agency incorporate information about the particular importer or manufacturer offering a shipment into its assessment. Relevant considerations might include the manufacturer's (or importer's) compliance history, its implementation of risk-management principles, and participation in other risk-management programs sponsored by the U.S. government.

IV. Recognizing Low Risk Shippers

Development of a formal, FDA-sponsored "low risk" importer program, similar to that adopted by CBP to facilitate efficient trade across the borders, would be a logical adjunct of the 801(a)/801(m) integration process. In Kraft's view, however, the development of such a program need not, and should not, be delayed pending total 801(a)/801(m) integration. Both FDA and industry would benefit from the immediate development of such a program.

Accordingly, Kraft urges FDA to begin working with all interested parties to identify criteria for qualification and participation in a program like C-TPAT, FAST, and others. Participation might hinge on the submission and verification of documentation evidencing the implementation of, and continued adherence to, validated supply chain risk management techniques.

The mutual benefits of such an arrangement are obvious. FDA could reallocate its resources to closer review and examination of shipments from those importers that do not participate in the program and, thus, have not demonstrated the same level of commitment to food safety and shipment security as participating importers do.

Program participants would benefit from the agency's recognition of their commitment to safety and security, which presumably would be reflected in more efficient and timely processing of their entries at the border. In that regard, Kraft suggests that the agency consider extending to participating low risk importers the option of submitting a single prior notice for all entries in a mixed load container or truck. FDA product codes for all line entries would continue to be available to FDA through the existing OASIS system.

This option would substantially lessen the prior notice paperwork burden for importers and FDA. Yet, by limiting its availability to recognized low risk importers, FDA would not compromise safety and security. In fact, the option would give importers not participating in the low risk importer program a strong incentive to improve their supply chain security and qualify, thereby enhancing overall safety and security.

Conclusion

Kraft recognizes that the integration of FDA's existing importation information management and review systems is a major undertaking. Our experience tells us, however, that the current system is duplicative and riddled with unnecessary delays, heightening food security risks and hindering the efficient movement of fully compliant foods across the borders. Integration of the 801(a) and 801(m) review steps will allow FDA to redirect valuable resources toward more targeted security enhancing activities, while facilitating importation of food that complies with the law, as required by the Bioterrorism Act.

Kraft is committed to working with FDA on this important next step in the agency's efforts to enhance the safety and security of the food supply. Kraft looks forward to what it hopes will be a cooperative effort among all interested stakeholders, led by FDA.

Sincerely,

A handwritten signature in black ink that reads "John Ruff". The signature is written in a cursive, slightly slanted style.

John Ruff
Sr. Vice President
Global Quality, Scientific Affairs & Nutrition