



Kraft Foods

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<http://www.fda.gov/dockets/ecomments>

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

**Re: Prior Notice of Imported Food
Docket No. 02N-278**

Dear Sir or Madam:

Kraft Foods is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. We have plants located just over both the Canadian and Mexican borders. We import roughly 200 ingredients from almost 100 countries. We also sell in the US products made in our facilities around the world. Thus, we have a substantial interest in the rules governing the importation of food products, which are now being developed by the Food and Drug Administration (FDA).

Kraft commends the FDA personnel who are working to implement the Bioterrorism Act so quickly. We understand the pressure under which the agency's officials have been operating, the long hours they have invested and we appreciate their service. We also share the government's goal of protecting the food supply, since our products are found in 99.6% of American households and are sold in 150 countries around the world, and have spent considerable resources, both in time and dollars in upgrading already strong food safety systems to further protect our products. We have also spent considerable time learning the new proposed regulations and implications on our business.

In spite of our efforts and those of our suppliers, the myriad logistical implications of the proposed rules have not yet all been identified, especially for trade across the Canadian and Mexican borders. In these comments, we highlight the most significant issues we have identified to date and attempt to suggest solutions in addition to pointing out concerns. From afar we cannot appreciate all the systems constraints imposed on FDA, so solutions that seem straightforward to us admittedly may be less viable than we anticipate. Nevertheless, if FDA were to adopt the rules as proposed, confusion at US

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borders would be inevitable in December, so changes must be made to avert that outcome, but without compromising food safety.

I. More focused data collection would be consistent with the direction given by Congress and result in overall process improvement.

For each prior notice of entry, FDA proposes to collect much more information than is required by the Bioterrorism Act, without explaining why the information is needed for day to day entry screening. The information items in the proposed rule are listed below, with those required by Congress shown *in bold type*. All of the other information items were added by FDA, apparently in an effort to compile a comprehensive list of information that potentially might be of interest, although not necessarily for entry screening.

- Submitter
 - individual, firm
 - address, email address
 - phone, FAX
 - registration number
- Customs entry type
- ACS entry number
- Hold information
- **Growers, if known**
- **Originating country**
- **Shipping country**
- Anticipated arrival
 - **port of entry**
 - date & time
- **Article Identity**
 - FDA product code
 - common name
 - trade or brand name
 - quantity (smallest package size to largest container)
 - lot, code, identifying numbers
- **Manufacturer**
 - address, email address
 - phone, FAX
 - registration number
- **Shipper**
 - address, email address
 - phone, FAX
 - registration number
- Customs port of entry

- Customs date of entry
- All carriers
 - names
 - address, email address
 - phone, FAX numbers
 - Standard Carrier Abbreviation Codes (SCAC)
- Importer
 - address, email address
 - phone, FAX
 - registration number
- Owner
 - address, email address
 - phone, FAX
 - registration number
- Consignee
 - address, email address
 - phone, FAX
 - registration number

The need for gathering some data beyond the minimum required by law, such as the manufacturer's registration number, is easily understood. Not so readily apparent is the need for gathering less relevant and less certain information, like the Customs date of entry. FDA recognizes that entry for Customs purposes may take place several to many days after the prior notice is filed. 68 Fed. Reg. 5441.

Not all products have brand names, so brand name information could not possibly be considered essential for proper entry screening. A requirement to provide brand names also would be confusing to implement. Many products carry several brand names. For example, on the label for OSCAR MAYER brand LUNCHABLES brand lunch combinations one also might see the brand KRAFT for cheese or RITZ for crackers, TOMBSTONE brand Pizza Sauce, NABISCO brand OREO brand or CHIPS AHOY brand cookies, and a CAPRI SUN brand juice drink. The Customs brokers who most likely will be completing the prior notice are not typically familiar with the fine distinctions between the various types of common names and brand names on a label. Indeed, we have encountered both FDA inspectors and our own internal personnel who find this area of law confusing. Brand name manufacturers should not be required to assume greater risk that the broker will complete the data screen incorrectly than generic manufacturers. If it ever becomes necessary, the manufacturer or importer can identify brand names for FDA upon request. Common or usual name information should be sufficient for the entry screening process.

Additionally, the proposed requirement for a "lot, code or other identifying number" is unclear, perhaps so vague as to be unenforceable. Many products have code and lot

numbers. Some products have neither. Certainly, the language “other identifying number” could confuse the importer or agent completing the notice. Whatever “other identifying information” is entered, it is difficult to discern how the information could be meaningful to FDA or how the agency could check for accuracy. Therefore, we recommend that this requirement also be dropped from the final rule.

Before requiring data beyond that mandated by Congress, FDA should challenge itself to explain how the additional data will be used to improve import screening decisions. Every additional piece of required information will consume both FDA and industry resources. Requiring more information inevitably also will increase the number of data entry mistakes. For example, under the proposal six different registration numbers would need to be provided, each one increasing the chance of a typographical error that could lead to detention of the shipment. Moreover, not all of the six entities may even be required to register, since registration is triggered by actual possession of the food.¹ The person submitting the notice, the importer, and the owner may not ever take possession of the shipment. By focusing on information that is useful for entry screening, FDA could redirect the resources the agency would otherwise spend tracking irrelevant information and detaining shipments of goods that comply with the law but for an inadvertent paperwork mistake. Then, the agency could concentrate on activities more likely to improve security and improve the process overall.

The more focused on relevant information, the more successful the new process will be, both for FDA and industry. We note that the FDA analysis of economic impacts omits the costs of changing business systems used by processors, brokers, and carriers. Not only must programming changes be made to accommodate the new requirements, contracts and pricing must be renegotiated. Additionally, personnel throughout the entire supply chain must be trained to comply with the new rules. All of these activities take time and cost money. The more precisely FDA identifies the information actually necessary for routine import screening, the more quickly industry will be able to comply with the new requirements and the more cost effective the system will be for FDA as well as for industry.

II. However long the notice period FDA adopts, the required notice should be a fixed number of hours, not tied to a time on a calendar day.

The new notice system would operate much more smoothly, if FDA were to adopt a constant number of hours as a required notice period, instead of the proposed notice deadline of noon on the calendar day before arrival. By tying the notice to noon of the calendar day before arrival, the agency’s proposal, in effect, would establish a notice requirement of just over 12 hours for entries processed in the morning, but a

¹ The registration provision in the Bioterrorism Act, section 415, applies to facilities that manufacture, process, pack, or hold food for consumption.

requirement of over 36 hours for entries processed during the afternoon. This disparity would cause shippers, brokers, and carriers to try to avoid the 24 hour "afternoon penalty," distorting allocation of resources throughout the supply chain and creating formidable logistical challenges. With a rolling notice period, supply chain labor could be spread throughout the day, rather than peaking with accelerated demand as people try to avoid the penalty imposed by missing the noon deadline.

We ask that FDA consider the effect of tying the notice period to a calendar day on the traffic patterns flowing across the border. Like the flow of notices that would peak just before noon, the traffic across the border would be likely to peak just after midnight, at a time when the agency's offices may be less than fully staffed. A rolling notice period would eliminate the potential traffic jam.

III. In selecting the notice period, FDA should balance the desire for early notice with the practical limits on availability of accurate information.

Today, two streams of information flow separately from the shipper, one to the US Customs broker and another to the carrier. North American carriers usually do not contact the Customs broker until the truck arrives at the US border. The level of detail FDA proposes to require would force significant changes in business systems to bring the two separate streams of information together in time to meet whatever prior notice requirement FDA adopts. Ability to file the notice is determined by the availability of the last piece of required information, which may be the quantity, the last carrier, port of entry, or estimated time of arrival.

The proposed 12 to 36 hour notice period is so long that the number of required amendments to identity information and updates to arrival data would drain both FDA and industry resources. With a shorter prior notice period, the information collected by FDA would be more accurate and less likely to change significantly, reducing the number of required amendments and updates that must be processed and evaluated for each entry. A rolling notice period of 4 to 8 hours, not tied to a calendar day, would drastically reduce the need for repetitive submissions associated with the same entry.

IV. The rules for amending and updating data should foster full compliance and efficient trade.

With regard to product identity, we ask FDA to clarify in the preamble to the final rule that as long as the basic nature of the food is properly identified on the prior notice, the amendment process may be used for minor changes to product variety, flavor, or size. For example, if a piece of manufacturing equipment breaks down or a different type of truck arrives, adjustments should be allowed so long as an amendment is filed in the following example situations:

1. the mix of different flavors of JELL-O brand gelatin dessert on a truck needs to be adjusted;
2. the quantities of macaroni and cheese dinners in different size boxes or with different noodle shapes needs to be adjusted;
3. different varieties of ready to eat pudding need to be loaded to "top off" a truck.

Identity amendments should be limited only when the fundamental nature of the product changes. For example, pudding could not be used to "top off" a truck of macaroni and cheese dinners. Allowing reasonable amendments would improve the agency's resource allocation as well as industry's.

The requirement to amend identity information, including precise quantity information, at least 2 hours prior to entry easily could be replaced with a requirement to amend the data by the time of entry, without compromising security. Eighty percent of our Canadian plants are located less than two hours from the border. Although approximate quantities ordinarily would be known the day before a shipment, the exact quantities on a truck often are not known until the truck is sealed and ready to leave for the border. As only minor adjustments to identity and quantity are allowed through the amendment process, allowing more time to file accurate information ultimately would reduce the FDA resources devoted to immaterial paperwork changes. Approximate quantity information certainly should be accurate enough for the agency's import screening inspection decisions.

Additionally, the requirement that a shipper predict whether an amendment will be needed sometime in the future at the time the prior notice is filed probably will cause shippers to check the "Amendment to follow" box "Yes" routinely just in case a change becomes necessary. Then, both the shipper and the agency would end up processing numerous unnecessary amendments, a true waste of resources. So long as the circumstances under which amendments are permitted remain narrowly defined, whether the shipper does or does not commit to filing an amendment at the time the prior notice is filed should not cause FDA to make a different screening decision. Thus, we recommend that the proposed requirement be dropped and amendments be allowed as necessary.

Even when most of the information required for the prior notice is known at least by the day before shipment, the exact identity of all carriers and the time of arrival at the border often are not yet known. Estimating the time of arrival at US Customs from Mexico is especially challenging. The Mexican carrier must first arrive at the Mexican Customs broker for administration of the paperwork, then must clear Mexican Customs. Mexican carriers currently cannot complete a delivery to our warehouses in the US. Therefore, the Mexican carrier stops to do a mechanical inspection of the trailer and then transfers

the trailer to a drayman. The draymen takes the shipment across the border to US Customs. Delays may occur with any of these exchanges, making arrival time difficult to predict accurately.

Making the rules on updating estimated arrival time more flexible would reduce unnecessary cost associated with the proposed new system. For example, FDA could drop the requirement for updating arrival time 2 hours before entry, if the truck might arrive one hour earlier than anticipated. A requirement to notify FDA at least one hour before reaching the border would be more workable. Instead of requiring updates to arrival time if the truck is more than three hours late, the agency could require an update only if the truck will be more than eight or twelve hours late, significantly reducing the unimportant data FDA is expected to process. FDA inspectors do not need to be present when the truck arrives at the border; the agency only needs to notify Customs if a truck must be detained. Thus, establishing too tight a window for arrival time is unnecessary.

Incidentally, we also request that FDA explain how the agency proposes to determine arrival time, especially when there are lines at the border. The arrival time window FDA proposes is quite narrow: one hour early or three hours late. FDA should provide notice of how the agency plans to regulate compliance during busy periods, when a truck could wait in line a long time before reaching the US Customs official. In considering the guidance to be provided, FDA should be mindful that Congress expressly directed, in section 307 of the Bioterrorism Act, "Nothing in this section may be construed as a limitation on the port of entry for an article of food." Therefore, the notice requirements should not prevent a truck from leaving a long line at one port and entering through a less congested, nearby port.

V. The FDA Analysis of Economic Impacts actually shows that the four hour advance notice option is most cost effective.

FDA quite correctly acknowledges that "a four hour minimum prior notice requirement would be less likely to change current food importing practices than would a longer minimum time requirement for prior notice submission." 68 Fed. Reg. 5443. FDA also accurately recognizes that many foods are sourced close to the US border, making the four hour notice requirement most consistent with current business systems. *Id.*

The agency's analysis derails when FDA concludes, at least tentatively, that the information required in the prior notice would be fixed at the time an order is placed and that at least 75% of the time the invoice date or date of sale would precede the arrival date by at least 1 day. 68 Fed. Reg. 5433. FDA based this tentative conclusion on examination of 64 packets of entry documents, but the agency did specifically invite comment on the "representativeness of this sampling." *Id.*

We were able to examine redacted copies of the entry documents FDA reviewed and compare them with some of our entry packets. We can now confirm that the packets upon which FDA relied do not reflect the typical circumstances we encounter importing bulk and finished products from our plants across the Canadian and Mexican borders. Typical entry documents for our products show invoicing the same day the shipment arrived at the border or the day before. From the information that is legible in the 64 packets of entry documents FDA reviewed, it does not appear that any examples of intra-company cross-border shipments were considered, although we cannot reach this conclusion with complete certainty due to the redaction. The result of our analysis is not especially surprising. As is implicit in the agency's request for comments on the sampling, 64 packets can hardly be expected to represent 4.7 million entry lines of food, even when some of the packets have multiple entry lines.

Our plants usually do not ship in response to individual customer orders; instead, we make products according to a plan that is based upon a forecast. Often we import finished foods ready for retail sale that are shipped to our distribution centers, but we also import bulk components from Canada or Mexico, then process and package what we import in the US. The exact quantities available for shipment across the border frequently depend upon factors like whether a machine malfunctions, packaging is delivered late, or personnel call in sick on a particular day. Similarly, the exact time the carrier will arrive at the border is influenced by a multitude of factors, such as how long the driver has been working, weather conditions, and traffic.

According to the agency's analysis of economic impacts, noon the calendar day before arrival (option five) turned out to be the most cost effective prior notice option, but FDA allowed amendments and updates until two hours before arrival only for that option, not for any of the other options considered. If the same assumptions about amendments and updates had been incorporated into the analysis of the other options, the four hour advance notice option (option two) would have been the most cost effective.

In fact, careful examination of Table 17 and the accompanying text shows that the agency's economic analysis is driven entirely by assumptions about timing of acceptable amendments and updates. 68 Fed. Reg. 5453. For example, in evaluating the four hour notice option, FDA assumed that 20% of all entries would need to be resubmitted, resulting in at least another four hour delay and consequent loss of value for perishable items. 68 Fed. Reg. 5443. In contrast, FDA estimated that only 5% of entries would need to be resubmitted in the noon of the calendar day before entry option, due to the amendment and update provisions. Consequently, the agency reduced the assumed loss in value of perishable goods accordingly. Yet, if the same amendment and update possibilities had been allowed in all the different scenarios being evaluated, the shortest notice period would have been identified as the lowest cost option. Actually, the four hour notice period would require far fewer amendments and updates than would the day before entry notice requirement, since the data

submitted to FDA would be more certain, further reducing overall cost and improving efficiency.

In the analysis of economic impacts, FDA considered the cost of delayed shipments only for shipments of highly perishable foods. The cost of delay is quite real for all food products; moreover, delayed shipments incur additional transportation charges. Both of these costs should be recognized as the agency considers the prior notice period requirements. The shorter the notice period, the lower the cost of delayed shipments.

VI. It is important to integrate the Prior Notice, OASIS, and Customs systems as soon as possible.

We are concerned that FDA is not planning from the outset to integrate the new prior notice information collection system with the existing OASIS system--or with existing Customs Service systems. Much of the information FDA proposes to gather already is collected through the existing FDA OASIS and Customs systems. In fact, FDA acknowledges, "Most of this information is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process....." 68 Fed. Reg. 5435. Instead of moving forward the time FDA receives entry information from the FDA OASIS system, the agency proposes to establish a second entirely separate "prior notice" data collection system. Under the FDA proposal, an importer would have to feed data to the new prior notice system, but also still would have to continue to enter data independently to the existing FDA OASIS system and, incidentally, have to pass through two potential FDA inspection points rather than one. The productivity opportunity for both FDA and industry is readily apparent. The duplicative systems should be combined into a single import screening system as soon as possible.

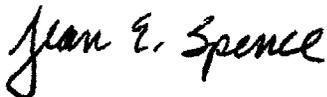
In addition to the duplicative proposed information requirements, we also are concerned about the implications of disrupting essential systems links that now exist, such as between the FDA and Customs systems. In particular, we plan to participate in the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Free And Secure Trade (FAST) programs, both of which expedite processing of shipments, especially intra-company shipments, for low risk importers like Kraft. Perhaps we misunderstand the FDA proposal, but it appears that the new requirements would supercede, and hence defeat, the forward looking government-industry partnership that has been developing to improve security, a result that would be exceptionally unfortunate. We recommend that FDA recognize the low risk status of C-TPAT certified importers and reduce inspection delays accordingly.

Conclusion

If government and industry are to assure the safety of the food supply, without at the same time imposing unnecessary costs on American citizens, deploying resources as effectively and efficiently as possible is critical. In summary, we recommend that FDA focus information collection requirements to improve import screening decisions, adopt a rolling four hour notice period, and provide greater flexibility in the rules for amendments and updates. Adjusting the prior notice requirements for food imports as we have suggested will enable FDA and industry to comply with Congressional directives without wasting or misdirecting resources that could be better used for more targeted security measures.

Kraft always stands ready to work with the government to protect the safety of the food supply. Please do not hesitate to contact me at (847) 646-6125, if we can provide additional information that might be helpful.

Sincerely,



Jean E. Spence
Senior Vice President
Worldwide Quality, Scientific Affairs and Compliance