

April 2, 2003

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

Dear Sir or Madam:

Re: Docket No: 02N-0278: Prior Notice

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The Food and Consumer Products Manufacturers of Canada (FCPMC) is pleased to have the opportunity to provide comment on the above sections of the Bioterrorism Act. We believe it is important to the free flow of trade across our mutual borders that appropriate mechanism are in place to ensure the security of our food supply chain, while taking into account the unique circumstances of traffic across our mutual border.

FCPMC is the industry association representing over 150 Canadian-operated member companies that manufacture and market retailer and national brand food and consumer products that are integral to daily life at home, work and leisure. A list of our member companies is attached. These companies provide Canadians with safe, nutritious and high quality products sold through retail grocery, drug, convenience, mass merchandise and foodservice distribution channels. Last year, the industry generated over \$24 billion annually in GDP (15% of the Manufacturing Gross Domestic Product), employed 312,000 Canadians directly in every region in Canada, contributed \$33 million to charitable causes and donated over 4.5 million bags of groceries to needy Canadians. The industry has a record of embracing world-class regulatory standards and is governed by 442 federal and provincial pieces of legislation, as well as thousands of regulations and self-imposed standards.

FCPMC supports the objective of the Prior Notice proposal as a step toward improving security of the supply chain. However we believe there are some fundamental problems with the execution as set out in the above docket. While it is obvious that The Food and Drug Administration (FDA) has devoted much effort and thought to the Prior Notice proposal, FCPMC has serious doubts that affected industries will be able to adjust their business practices and procedures to implement the proposed prior notice system without significant cost and disruption to the smooth flow of product across our borders.

Some of the requirements in the Prior Notice are practically impossible to fulfill without delaying shipment. Economic impact due to unprecedented changes to normal business practices resulting from Prior Notice requirements will ripple across all trading partners in the supply chain right down to the ultimate consumer.

As a result, FCPMC recommends FDA re-evaluate the following:

***Who Submits Prior Notice (Proposed 1.285)***

The proposed rule, under Section 1.285, would require the Prior Notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States, acting on behalf of the U.S. purchaser or importer. FCPMC believes that this proposal will not provide FDA with the most accurate and timely information in prior notices as the information will be submitted by a third party. The U.S. agent is not in the best position to provide accuracy, especially when it pertains to possible amendments. In transactions involving perishables or just in time deliveries or transactions involving companies located near to each other across the border, this will introduce errors and make it more difficult to comply with the minimum time for advance notice. It is the Canadian exporter will know the soonest and with the highest degree of accuracy precisely what is being shipped in an order.

If only resident U.S. parties or their agents are permitted to submit the notice, FDA will be creating obstacles to its objectives.

When the shipment may be the subject of an inadequate notice and held at the border (or sent to a secure facility), it is the Canadian exporter that owns the product. According to the proposal, FDA will be requiring the U.S. agent to rectify the situation. In reality, the U.S. agent/customer does not yet have any financial interest in the shipment and might well abandon said shipment to the loss of all concerned.

From an operational standpoint, FDA is requiring detailed and extensive information for the Prior Notice. The level of detail is consistent with the information normally submitted by U.S. Customs brokers acting as agents for importers of record. As previously stated, it is the Canadian exporter that hires such a customs broker and provides this information to the broker acting as the exporter's legal agent. The proposed rule would result in this information continuing to be submitted by Canadian exporters and their U.S. customs brokers for Customs Service purposes yet, at the same time, requiring for the same transaction the submission of essentially the same data by a resident U.S. party (hiring the same or different broker) solely to comply with FDA Prior Notice requirement. This will inevitably introduce complications, delays and inaccuracies for FDA.

FCPMC recommends FDA amend the rule to include food exporters in the requirements for who must submit the notice. Trade between Canada and the U.S. provides some unique opportunities, and where possible, flexibility should be provided to ensure a smooth flow of trade as well as meet the FDA required objectives.

***When Must Prior Notice Be Submitted to FDA (Proposed 1.286)***

The proposed rule, in Section 1.286 requires that Prior Notice be submitted to FDA no later than noon on the calendar day before the article of food is to arrive at the border crossing point. In addition, Prior Notice, except for two specific product identity amendments, cannot be submitted until all the extensive required information exists (i.e. lot numbers, production code). The proposed rule allows a two-hour period for one amendment for product identity and quantity only.

In the case of food products produced in Canada, the time between the completion of production, loading and transportation to the U.S. port of entry is often considerably less time than the time proposed in the Prior Notice. Given the short distances between many Canadian facilities and the U.S. border, the notice can't be submitted in time to permit the vehicle to clear Customs unimpeded.

FCPMC recommends the notice period be a rolling 4-8 hour period before the product is expected to arrive at the port of entry. The shorter notice should apply in the case of product arriving from contiguous countries, especially by truck or rail and the 8-hour period should apply to product arriving by other means or from other places. Shortening the notice period will enable facilities to better ensure that the notice that is provided is complete and accurate and will minimize the need for amendments and updates.

FCPMC recommends the data and information required in Prior Notice should be limited to the seven items specified in the Bioterrorism Act. Duplication with Customs information should be avoided. The data needed to identify the article of food to be imported should be narrowed. The purpose of the Prior Notice can be achieved if the notice contains a general description of the article being imported (canned soup) rather than the incredibly detailed identification called for in the proposal.

The FDA proposal does not take into consideration bulk commodities shipments such as seafood and produce which are likely to require amendments 100% of the time. Bagged and cased product will also likely require amendments 100% of the time due with shorter distances to the border and 2 hour windows for amendments. The business risk associated with rendering a Prior Notice inadequate due to short shipping an order consequently resulting in the re-scheduling of the order 24 hours later will prove to be too arduous for the industry. As a safeguard, initial notifications will always require amendments under the current proposal with effectively less than 10% of the amendments actually adjusting the quantity originally reported and 90% of the final amendments only confirming the original quantity reported. This will prove to be burdensome to FDA who will be flooded with needless amendments and to industry as a whole. It is recommended FDA consider an acceptable load tolerance of +/- 10 % for bulk commodities. If within these ranges then updates would not required.

FCPMC recommends FDA provide for an optional<sup>1</sup> notice for regular recurring shipments of essentially the same article of food. If, for example, FDA allowed a monthly notice for shipments from a facility that produces an array of snack foods/confectionery with the dates and approximate times of anticipated arrival at the U.S. border (and, of course, a description of the products to be imported), companies would not need to prepare daily notices and amendments, and FDA would receive even more advance notice of imports than even the Bioterrorism Act contemplates.

For example, if a company knows that during a coming month, it will have four trucks per day, every Monday and Wednesday and Thursday of the month, leave a facility for the United States, it should be able, if they so desire, to file a single “monthly” notice instead of the 48 notices that would otherwise be required. Such a company could then use the amendment and update process to account for changes in the scheduled deliveries that occur during the month. If adopted, this approach would substantially ease the burdens of the daily notice requirement without impeding the functioning of the notice system.

FCPMC recommends FDA provide for an additional optional advanced notice to handle the less frequent but periodic shipments of the same article of food such as an ingredient that is imported four times per year from the same supplier, entering through the same port of entry and destined for the same U.S. facility. It is recommended the FDA allow a single annual notice, subject to necessary amendment or update, to satisfy the Prior Notice requirement. As in the case of the frequent, ongoing shipments during a month, this approach will also provide FDA will more notice than is contemplated under the Bioterrorism Act.

FCPMC recommends FDA consider reducing the update window by 1 hour.

FCPMC recommends FDA allow quantity changes to fall under updates thereby reducing the amount of incomplete Prior Notices subject to amendments and subsequent amendment receipts. This will greatly enable the exporter who has most of the information available at the time the order is placed, leaving only the final loading quantity to be determined.

Since many of our companies participate in the CTPAT and FAST programs we ask FDA to give preferred recognition to registered exporters participating in these US Customs initiatives. It would be useful to have a “short form” Prior Notice for the registered exporters.

FDA must take this into account when assessing admissibility of goods for a “low-risk” importer as well as affording greater flexibility to an import in good standing.

As an added consideration to CTPAT/FAST participation, FCPMC recommends FDA exercise some flexibility where exceptions can occur. FCPMC recommends FDA provide business

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<sup>1</sup> The Bioterrorism Act does not permit FDA to require prior notice more than five days before the food is offered for import (section 801(m)(2)(A) of the FDC Act). There is nothing in the Bioterrorism Act, however, that precludes FDA from providing for an optional notice period that exceeds five days.

“exception” provisions for exporters in good standing to be able to continue to meet unplanned customer needs. For example, a hamburger bun manufacturer could find the need to schedule additional production if weather forecast changes in order to support outdoor activities. Similarly, perishable goods producers could see significant variances in daily crop yields that would trigger the need to bolster planned U.S. shipping activity. Short shelf life perishable foods are often driven by weather/climatic conditions within the trading region and FDA’s proposed rules should consider the unique business requirements of this industry.

Other examples include Ontario cucumber crops harvested in June and July. Due to restricted storage capacity in relation to the excess crop yield, there are occasions whereby last minute exports loads are sold into the US or risk full loss of the load. As the exporter located within one hour of the border, a four-hour window would not be a reasonable expectation since most of the data elements, including U.S. consignee, would not be available until the truck is completely loaded.

Another example is regarding just-in-time deliveries. General business practices typically build in minimum order times however on occasion, a US customer will call in a panic and request product after the noon cut off time resulting in economic loss to the exporter and U.S purchaser.

#### ***How Prior Notice is Submitted***

The FDA proposal states that all Prior Notices must be electronically submitted.

FCPMC recommends that if it is necessary to submit information to the FDA as well as Customs and the systems are not integrated that the information required for both bodies should be the same. The elected format as it stands does not have the capability to receive standard EDI transaction sets of data to populate the form and eliminate the manual typing of data. FCPMC urges the FDA to contact the UCCNet, a multi-industry product registry. The UCCnet will be able to provide invaluable technical assistance.

Also, according to the Trade Act of 2002 Customs expects to develop eight different sets of notice requirements – inbound and outbound rules for each of the four modes of transportation. Synchronization of these notice requirements along with the FDA Prior Notice is imperative in order to minimize additional administrative time and burden.

#### ***Concerns***

FCPMC wishes to address several concerns regarding the potential scope of the proposed Prior Notice System. FCPMC believes that the amount of unnecessary duplication of data already tendered to U.S. Customs Service fails to demonstrate any practical utility of such detailed information. Coordination of required information between Customs and FDA is essential.

Prior Notice will be required for shipments not intended for consumption within the U.S. including those for immediate export or in-bond transport. Statutory language stipulates for “human and animal consumption” and FCPMC believes that FDA has exceeded the intent of the statute. FCPMC recommends FDA provide specific exemptions, allowing for transportation for exportation, personal baggage, Internet and mail, R&D (not intended for consumption). It is reasonable to expect that imposing Prior Notice for items such as mail and Internet food shipments will be difficult to enforce and burdensome to the system.

***Conclusion***

While FCPMC understands the objectives of Prior Notice, the current proposal is too complex and is not likely to meet FDA’s intended objectives in an effective and efficient manner. The requirement of who is to submit the prior notice, the quantity of information, the time at which the information is required, the rigidity of the time periods for the provision of the information, and the inability to change information that has already been provided all suggest that the component parts of the system will not interact in a seamless and efficient manner. The consequences of failure not only affect the food supply but also manufacturers and retailers on both sides of our border. The proposal needs to be streamlined and integrated with the Customs information.

FCPMC appreciates the opportunity to provide our Canadian perspective and we look forward to the FDA’s evaluation of submitted comments. If you have any questions about FCPMC’s submission, please contact Barbara Tordoff, (416) 510-8024 ex. 2243 or [barbt@fcpmc.com](mailto:barbt@fcpmc.com)

Respectfully submitted

A handwritten signature in black ink that reads "Laurie Curry". The signature is written in a cursive, flowing style with a distinct underline for the name "Curry".

Laurie Curry, Vice President  
Public Policy

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