



**North American Millers' Association**

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April 3, 2003

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

**Re: Docket No. 02N-0278, Proposed Rulemaking "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002"**

To Whom It May Concern:

The North American Millers' Association (NAMA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed regulation on prior notice of imported food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (a.k.a. The Bioterrorism Act). After the tragic events of September 11, 2001, protecting the United States public became of even greater importance and several legislative and regulatory actions have led to a significant increase in security. NAMA supports this focus on increased security and the need to better protect the U.S. food supply and food imports against the potential for terrorist attack.

As the national association representing 46 milling companies and over 95% of the U.S. milling capacity for wheat, corn, oats and rye, NAMA and its members have a vested interest in not only maintaining a safe domestic food supply, but also in maintaining secure and open borders to facilitate trade. Many U.S. millers rely on certain grains that U.S. farmers never produce in significant quantities to satisfy commercial demand. In order to meet the consumer demand millers must import grains such as durum wheat for pasta and oats each year. For this reason it is important to the milling industry that international trade not be unduly restricted through the implementation of this new regulation.

FDA's proposed regulations concerning Section 307 of the Bioterrorism Act provides for additional food security, but does not consider the impacts on trade. As currently proposed, the regulation for prior notice of imported foods will likely enhance the safety of food imported into the United States, but will undoubtedly inhibit and perhaps prohibit trade with foreign countries. NAMA believes the proposed regulations for prior notice should be amended in several ways to better facilitate commercial trade

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and that such amendments can be accomplished without sacrificing the safety or security of the imported food supply.

The following are NAMA's main points of concern that should be addressed in FDA's final regulation.

**Allow option for exporter to submit a prior notice**

The Bioterrorism Act does not specify what entity must submit the prior notice, only that it must be submitted prior to arrival at the anticipated port of entry. Under the proposed regulations FDA has limited the group of entities that can submit prior notice. The entities are limited to a purchaser or importer of an article of food 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 U.S. importer. FDA states it will also allow submission by a customs broker/filer if it is the U.S. agent of the U.S. importer or U.S. purchaser.

Despite FDA's stated intent to create "less confusion" and "greater compliance", NAMA believes that by excluding the exporter from the list of those permitted to submit prior notice, the FDA is making it more difficult and time consuming for companies to comply with the prior notice regulation. In most situations the exporter already has direct access to the required information since much of it is currently required for customs notification. The exporter therefore will be able to more quickly and effectively execute the prior notice, in some cases. By requiring the prior notice to be submitted by the importer or purchaser, FDA is creating a "middle-man" where none is necessary and subsequently adding more confusion and possibly delay into the system.

None of the reasons FDA provides to explain why the submitter must have U.S. residency are significant enough to outweigh the advantages of including the exporter as an approved submitter. A variety of options should be available as to who the submitter can be, since FDA will maintain jurisdiction over the article of food and right of refusal at the border if prior notice is not received. Flexibility regarding the submitter will leave both the choice and responsibility in the purview of the commercial sector that can best determine the most efficient and effective entity to submit the prior notice. The need for U.S. residency in order to conduct audits is also unnecessary since U.S. purchasers could simply be required to maintain records of all prior notices for food imports subject to FDA inspection, making it a matter of administrative record keeping and not unnecessary information shuffling.

**Time period for submission of prior notice**

Section 307 of the Bioterrorism Act requires that the notice be provided by a specified period of time in advance of the time of the importation. The Bioterrorism Act goes on to clarify that the required time of submission "may not exceed five days" and sets a minimum default time of eight hours if final regulations are not established by December 12, 2003. Under the Bioterrorism Act FDA was given a clear window in which to establish a specified period of time and the flexibility to consider several different

factors when determining the period of time such as the effect on commerce, the modes of transportation, and locations of ports. However, the proposed regulation does not appear to take into consideration any of these very important factors. Instead, FDA claims that “noon of the calendar day before the day the article arrives at the border crossing” is the time necessary for it to receive, review and appropriately respond to a notice.

### **Need for 24/7 staffing**

NAMA believes that FDA has established a period of time that is both impractical and unnecessary. FDA is within the mandates of the Act to establish this period of time, however such an extended period of time should be unnecessary if the FDA is truly concerned about receipt, review, and response. According to the regulations, submission and receipt will be completely electronic and therefore be instantaneous. A review process will likely take a longer period of time, but FDA already possesses the basic structure of a successful and expedient review process under OASIS. Modifications to the OASIS procedure, if not directly to the system, could greatly reduce the time needed for review. The last and most critical reason that FDA points to as a basis for establishing the calendar day before arrival requirement is the need to “ensure it can plan and that its staff can travel to the arrival point” in response to a notice. To address this concern the FDA should not put additional time into the process, but rather consider better utilizing the resources available to it. In order to have an effective prior notice system FDA will have to allocate resources such that there will be staff available twenty-four hours a day and seven days a week (24/7) throughout the year at every port of entry for receipt, review, and response. How to accomplish 24/7 staffing at every port is a decision for FDA, but NAMA believes that it is possible by working with U.S. Customs or through the hiring of more inspectors as authorized under the Bioterrorism Act. These actions should be taken first before unnecessary and costly regulations are promulgated.

### **Consideration of modes of transport and shorter submission deadline**

An additional concern that the proposed period of time raises is the restriction that is placed on short lead-time shipments. The proposed regulation does not differentiate between various modes of transportation such as air, rail, truck, and sea. By applying a one size fits all time period for all modes of transportation, the FDA has indirectly inhibited cross-border trade that in many cases relies on same-day or immediate shipping. These shipments are not confined to businesses dealing in “catch of the day” transactions, but also involve many food industries that rely on same-day shipments on a weekly or daily basis where customers are mere minutes from the Canadian or Mexican border. Same-day cross-border shipments typically involve transport by truck or rail and thus the unnecessary impediment to trade could effectively be reduced by adjusting the period of time for prior notice based on different modes of transport. Sea carriers will traditionally have more time than rail, truck or even air carriers and therefore should be considered separately. Time periods for these modes of transportation could be significantly reduced without sacrificing security if FDA establishes 24/7 staffing as suggested above.

The time window for arrival at the anticipated port of entry should also be adjusted based on the mode of transport. The proposed four hour time frame for arrival is not practical when shipping via rail. There is currently no mechanism for train shipments to alert FDA or the port of entry as to an adjustment of arrival time within a four hour window. This requirement might be possible for other modes of transport, but an alternative should be considered for rail shipments.

NAMA also contends there is a practical reason to shorten and better specify the time period for prior notice. As a practical matter the current proposal of noon the calendar day before will cause delays in the receipt, review, and response of FDA, delays at the border, and confusion regarding the time of arrival. The reality is that the noon the day before time period will lead to the submission of the majority of prior notices by 11:59 a.m. and will subsequently mean the arrival of trucks at the given port of entry at 12:01 a.m. of the next day. Conversely, if a submission is received at 12:01 p.m. the shipper must wait until 12:01 a.m. the day after next. This provides an unclear and undesired window of approximately 12 to 36 hours and an inevitable “bunching” of submissions at noon, and of vehicles at midnight every day. The solution is for the FDA to follow the default minimum time period established in the Bioterrorism Act of 8 hours. A shorter specified minimum time period will facilitate a more regular flow of submissions, decrease the need for amendments, and reduce restrictions on same-day shipments.

#### **Clarification of requirement for specifying grower “if known”**

The Bioterrorism Act specifies that several items must be provided in any prior notice including the grower of the article, if known, within the specified time period. The FDA is proposing to require the submission of the identity of “all growers of each article and the growing location if different from the grower’s business address, if known at the time of submission of the prior notice.” The regulations go further to require identification of the growers if discovered between the time of first submission and amendment. The proposed regulation also requires the identification of all growers if a product is sourced from more than one grower, if known.

The grower if known requirement needs to be clarified to address bulk grain products that are typically sourced from grain storage facilities that mix grain from many different growers. The practice of mixing and blending grain is common in the grain storage and handling industry and poses a problem in complying with the FDA proposed regulation. These facilities may in some cases possess the names and locations of the growers from which it purchases grain, but it does not maintain records on which farmer’s grain was sold to which customer. Such a system does not exist for the majority of bulk grain in commerce today and in the few cases where the identity is preserved, there is a premium associated with the service.

FDA’s expectation that all bulk grain shipments must identify all possible growers though “known” to some degree puts an undue and useless burden on the submitter. The information is of no practical use since it cannot truly help to determine

the actual growers. A better alternative is for FDA to provide flexibility in the definition of “if known” to require the submitter to identify the grower only when direct connection between the production of the article and grower can be shown and therefore definitively known. If the actual grower of an article needs to be determined, in the case of contamination, the FDA can and should use the information collected under Section 305 of the Bioterrorism Act, Registration of Food Facilities, to locate the grain storage facility and subsequently the growers associated with that facility.

### **FDA inspections at the port of entry**

The implementation of the prior notice regulation significantly increases the likelihood for inspections to occur on food articles at the port of entry. In the process of inspecting trucks or rail cars it is necessary for the inspector to break several tamper resistant seals that are put on by the exporter. From previous experience, it is known that seals are not always replaced by the inspector and can cause the exporter to incur additional costs in the form of rejections once the food reaches the purchaser. Though the procedure for the resealing of rail cars and trucks after inspection is not addressed in the Bioterrorism Act, NAMA believes that FDA should determine a set of standard procedures for the inspection of truck and rail cars that explicitly states the responsibility of the inspector to replace all broken seals, document the resealing, and provide the information to the exporter. A standard procedure described in the final regulations will help to reduce problems with loss and liability after implementation and help to ensure the security of the food once in the U.S.

### **Additional Concerns**

NAMA would also like to express additional concerns regarding the proposed regulations that should be addressed subsequent to the changes outlined above.

- What will be FDA’s role in the new border security bureau under the Department of Homeland Security?
- Is the prior notice requirement in compliance with NAFTA and WTO agreements?
- How will the liability for cargo that is inspected and subsequently held at the port of entry be determined?
- Will FDA truly be capable of handling the number of prior notices that will be submitted under the new system?

### **Conclusion**

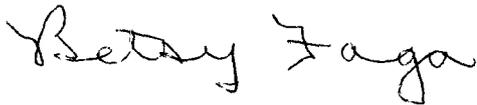
FDA’s proposed regulations implementing Section 307 of the Bioterrorism Act accomplish the intent of the legislation in the most restrictive and commerce restricting manner possible. The flexibility that was intentionally added to the Bioterrorism Act to make it possible to protect the U.S. food supply and at the same time not unduly restrict foreign trade does not appear in these proposed regulations. The FDA must change several provisions in the final regulations if it is to provide both effective food safety at the borders and the continuation of robust international trade.

NAMA again strongly recommends the following changes be made:

- Allow the exporter to submit prior notice
- Provide 24/7 staffing at the ports of entry
- Make the period of time for submission shorter and defined with consideration for mode of transport
- Clarify the grower “if known” requirement
- Determine procedures for the resealing of inspected shipments

NAMA appreciates the opportunity to provide comments to FDA on its proposed regulation, and we look forward to working with the agency in developing a prior notice system that is both effective and will continue to facilitate international trade. If you have any questions about these comments or would like further information please contact T.J. Cantwell at 202/ 484-2200, ext. 109 or [tjcantwell@namamillers.org](mailto:tjcantwell@namamillers.org).

Sincerely,

A handwritten signature in black ink that reads "Betsy Faga". The signature is written in a cursive, flowing style.

Betsy A. Faga  
President