THE GLUTAMATE ASSOCIATION
UNITED STATES

April 4, 2003

*BY ELECTRONIC AND FIRST CLASS MAIL*

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

**Re: Docket No. 02N-0278 (Prior Notice)**

Dear Sir or Madam:

The Glutamate Association (TGA) welcomes this opportunity to submit comments on the aforementioned proposed rule that would implement Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act" or the "Act") which relates to the notice required prior to importing food into the country. TGA is the trade association that represents manufacturers and users of monosodium glutamate (MSG). Our member companies routinely import foods and food ingredients and as such will be impacted by this proposed rule.

TGA supports the Food and Drug Administration (FDA) in its efforts to implement this very important provision of the Act. Although we are supportive of many provisions of the proposed rule, we are concerned that certain provisions have the potential to be unduly restrictive and as such could significantly curtail the ability of the food industry to import products. We believe that relatively minor modifications to the proposed rule would provide the flexibility that is needed to allow for the importation of foods while also satisfying the food security objectives of the Bioterrorism Act.

The Bioterrorism Act requires importers to submit notice to FDA in advance of importing food for consumption into the U.S. FDA's proposal would require importers to submit prior notice to FDA by noon of the calendar day before arrival of most imported food at the border crossing and in the port of entry, but no


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later than five days before the arrival date. The proposal also would allow amendments and updates in very limited circumstances. We offer the following comments on the proposed rule:

**The final regulation must define the arrival time.** FDA's proposal would require prior notice submissions to include, among other things, the anticipated time that the article of food will arrive at the port of entry, which is defined as the port where food first arrives in the U.S. The proposal does not define, however, what is meant by the "arrival time." With regard to border crossings, the arrival time could be the time that the vehicle reaches the border or it could be the time in which the vehicle reaches the traffic that is backed up leading to the border crossing. To the extent that FDA considers the arrival time to be the time that the vehicle arrives at the border crossing, the agency should revise the final rule to provide this specificity.

Specificity on the arrival time is of even greater importance for products arriving in this country's coastal ports. The arrival time could be the time that the boat first enters the waters of the port and calls for the escort to the dock or it could be the time that the vessel actually is docked at the port. The final rule must specify what is meant by the "arrival time" to avoid any confusion and to ensure the consistent application of the notice provisions.

**The final regulation should allow for a shorter prior notification period.** FDA's proposal would require importers to submit prior notice to FDA by noon of the calendar day before arrival of most imported food at the port of entry, but no later than five days before the arrival date. A shorter prior notice period would reduce the need for importers to submit updates, amendments, and cancellations to prior notice submissions, which would save both FDA and industry time and resources. Moreover, a rolling notice period would prevent the delays that would otherwise occur due to the inevitable bombardment of prior notice submissions FDA would receive at noon every day for shipments due to arrive at the border crossing the next day. A reasonable prior notice period would be eight hours for foods imported via ocean carriers and less--perhaps two hours--for foods imported from Mexico and Canada.

**More flexibility is needed to accommodate delays that may occur at the border crossing or getting into the port.** To the extent that FDA

is unwilling to adopt a shorter notice period (as discussed above), more flexibility has to be established for filing the updates. In addition, the regulations must contain more clarity on how and when the updates may be filed.

FDA's proposal would require the notice to identify the anticipated port of entry, the anticipated date and the anticipated time. If a change occurs that would result in the product arriving outside of a four-hour window contained in the original notice (*i.e.,* more than one hour earlier or 3 hours later than anticipated), the importer must submit an update with the correct information more than two hours before the revised arrival time. Only one update will be allowed.

Given the logistics of our importation system, it simply will not be possible to consistently predict the arrival time of a vessel within a four-hour window. There could be delays caused by severe weather or unforeseen circumstances that would prevent an ocean freighter or a truck from arriving at their designated time. We believe that this issue could be addressed in large part by either decreasing the amount of time required for a prior notice, as discussed above, or expanding the allowable window of time for arriving at the port of entry. We would recommend replacing the proposed four-hour window with an 8-hour window. By increasing the window for arriving, the agency will decrease significantly the number of updates that would need to be filed.

To the extent that FDA is unwilling to increase this time, we believe that the agency must provide greater clarity on how the update system will be implemented. For example, the proposal would require the update to be provided at least two hours prior to the anticipated time of entry but it is silent on whether there is any relationship between the filing of the update and the arrival time specified in the original notice. There will undoubtedly be many instances when the arrival time may need to be many hours later than originally predicted, particularly if there are storms or other unforeseen circumstances adding significant delays to the arrival time. In such cases, the proposal apparently would allow the importer to submit an update, provided it is submitted at least two hours before the new arrival time -- even if that arrival time is many hours or days beyond the original arrival date and time. The proposal would not, however, require that the importer provide any notice within the original four-hour window of anticipated arrival.

We are concerned that this ambiguity will lead to potential confusion and inconsistent application of these provisions. Some ports may take the position that the update must be provided within the four-hour window so the agency will be informed that the shipment will not be arriving when originally anticipated. Yet other ports may take the position that the update requirements are satisfied as long as the update is received at least two hours prior to arrival, regardless of how many hours or days it arrives after the originally identified arrival time.

We interpret the proposal as allowing the update to be filed any time after the originally scheduled arrival time provided it is filed greater than two hours before the new anticipated arrival time. We believe that this approach reflects the inherent difficulties in predicting the arrival times and provides the flexibility that is needed for the efficient enforcement of the notification requirements. We encourage FDA to clarify in the final regulation that the update may be filed any time after the originally identified arrival time provided it is filed at least two hours before the new arrival time.

**It is unnecessary to specify the exact quantity of product in a shipment.** FDA's proposal would require the prior notice submission to include the quantity of articles offered for import into the U.S., but would allow importers to revise this information as an amendment, two hours prior to the arrival of the food into the U.S. FDA requested comments on whether changes in quantity are likely to occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes may be. We question the need for the agency to know the exact quantity of the products in the shipment. There will undoubtedly be many instances where manufacturers in Canada and Mexico may not know how many units of a particular food will be loaded onto the truck until hours before the truck is ready to leave the facility. Because the prior notice must be submitted no later than noon the day before the truck is anticipated to arrive, the notice will have been submitted before the final orders for the truck have been fulfilled.

FDA presumably should be most concerned with the nature of the foods in the shipment rather than the exact quantity of each food item. The proposed requirement would undoubtedly lead to the submission of numerous amendments that would create a tremendous burden on the agency, as it will be forced to process these amendments. It also would unduly burden the industry with

no apparent corresponding benefit to food security. We, therefore, ask that the agency delete the requirement that the notice identify the exact quantity of each food in the shipment.

**The prior notice should not identify the countries of intermediate destination.** FDA's proposal would require the prior notice submission to include the country from which the article of food was shipped and defines this term as "the country in which the article of food was loaded onto the conveyance that brings it to the United States." In the preamble to the proposal, FDA requests comment on whether this term should include the countries of intermediate destination. We are concerned that requiring the identification of "intermediate destination" could be overly burdensome. We further believe that the most important issue for FDA is the country from which the article or foods was shipped. We, therefore, ask FDA to clarify in the final rule that it only is necessary to identify the country from which the article of food was shipped.

**It is unnecessary to identify the trade/brand name of the food articles.** FDA's proposal would require the prior notice submission to include the trade/brand name of the article offered for importation. It is common for one manufacturer to produce the same product and sell it under several different brand names. We believe that the important issue for importation purposes is the type of food that is coming into the country rather than the brand/trade name appearing on the food.

**The final regulation should only require the submission of that information specified in the Bioterrorism Act.** FDA's proposal requires the submission of much more information than specified by Congress in the Bioterrorism Act. The chart below identifies the information required by the proposal compared to that specified in the Bioterrorism Act.

| Information | Statutory | Proposed |
|---|---|---|
| Submitter (individual, firm address, email address, phone, fax and registration number); | | X |
| Customs entry type | | X |
| ACS entry number | | X |
| Hold information; | | X |

| Information | Statutory | Proposed |
|---|---|---|
| ***Growers,*** *if known* | X | X |
| ***Originating country*** | X | X |
| ***Shipping Country*** | X | X |
| ***Anticipated Port of Entry*** | X | X |
| Date & Time | | X |
| ***Article identity*** | X | X |
| FDA product code | | X |
| Common name | | X |
| Trade or brand name, | | X |
| Quantity (smallest package size to largest container) | | X |
| Lot | | X |
| Code | | X |
| Identifying Numbers | | X |
| ***Manufacturer*** | X | X |
| Address | | X |
| email address | | X |
| Phone | | X |
| Fax | | X |
| Registration number); | | X |
| ***Shipper*** | X | X |
| Address | | X |
| email address | | X |
| Phone | | X |
| Fax | | X |
| Registration number); | | X |
| Customs port of Entry | | X |
| Customs Date of Entry | | X |

| Information | Statutory | Proposed |
|---|---|---|
| All Carriers | | X |
| Address | | X |
| email address | | X |
| Phone | | X |
| Fax | | X |
| Registration number | | X |
| Standard Carrier Abbreviation Code (SCAC) | | X |
| Importer | | X |
| Address | | X |
| email address | | X |
| Phone | | X |
| Fax | | X |
| Registration number | | X |
| | | X |
| Owner | | X |
| Address | | X |
| email address | | X |
| Phone | | X |
| Fax | | X |
| Registration number | | X |
| | | X |
| Consignee | | X |
| Address | | X |
| email address | | X |
| Phone | | X |
| Fax | | X |
| Registration number | | X |
| | | X |

A review of the chart reveals that FDA has proposed to require the collection of much more information than originally specified in the Bioterrorism Act. We believe that the agency should limit the information collected to that specified in the Bioterrorism Act. We, therefore, ask the agency limit the notice to include only that information specifically identified in the Bioterrorism Act.

**The final regulation should not require duplicate submission to FDA and Customs.** The proposal would require the importer to submit prior registration via a stand-alone FDA website separate and distinct from OASIS and Customs' information systems. This proposed requirement is redundant and overly burdensome since importers already submit much of the same information (e.g., shipper, originating country) to Customs through its Automated Broker Interface. We encourage FDA to work with Customs and use the information currently submitted in OASIS rather than require importers to submit information to both Customs and FDA.

**FDA should clarify in the final regulation that it will provide a "grace period" for implementation of the notice requirements.** FDA has stated that it is considering instituting a "trial period" immediately after the final rule on prior notice goes into effect during which the agency would not take enforcement action against importers who submit inadequate prior notice. FDA should memorialize and clarify this plan in the final rule.

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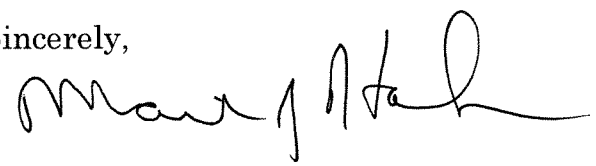
TGA once again commends the agency on its efforts on establishing final regulations that would implement the import provisions of the Bioterrorism Act. We encourage the agency to consider these and the other comments as it finalizes the final regulations.

TGA would be more than happy to provide additional information if it would be of assistance to the agency.

Sincerely,



Martin J. Hahn
Executive Director

HahnMJ/hahnmj