

Annex 2

Specific remarks and demands for amendments to the FDA proposals on prior notification (Section 307 of the Bioterrorism Act 2002)

Docket No. 02N-0278

The importer or the purchaser will have to provide for prior notice due by noon of the calendar day before the article of food arrives at the port of entry but not earlier than five days before arrival. This provision will impose heavy administrative burdens on operators as a prior notification will have to be submitted for each different product in a shipment, and for each different format / packaging of the same product. BVE wishes to make the following specific comments:

- BVE deeply regrets the FDA's failure to coordinate the prior notice requirement with existing customs measures, resulting in duplication and complication of systems. US Customs already receive notice of the arrival of each ship and its manifest well in advance of the ship's arrival. Most of the data required for the prior notice are provided to Customs. There should be no need for the FDA to require duplicate information already obtained by Customs. A close coordination between the FDA and US Customs Service is necessary to avoid redundant regulations.
- On this same point, the prior notice provision is similar to the "24-hour" rule of the Container Security Initiative. Here again BVE would stress that systems must be integrated rather than duplicated. It is conceivable that the notice given to US Customs within the 24-hour-rule of the CSI is passed on to FDA automatically. In some cases this information would be available earlier than five days before the arrival of the shipment in the port of entry to the US. The Act does not preclude the possibility to supply this information earlier than foreseen in the proposed FDA regulation. Thus BVE requires FDA to delete the early boundary of the time-frame for prior notice. If a prior notice is given earlier than five days before importation it should be possible for FDA to store this information in its databases and retrieve it when needed.
- Having said this, we would like to stress, that for control purposes it should be sufficient to receive the same data that US Customs receive from the importer. Any extra information required by FDA does not enhance trade flow security. Indeed the FDA is calling for considerably more information than is actually necessary; for practical reasons, it is impossible to include the FDA registration numbers for all operators that have handled the food to be imported in the prior notice; in addition, it is difficult to see why this information should be necessary for all shipments; in case of a risk related to food imports, the proposed requirement to keep records suppliers / customers ("one up-one down") should be sufficient.

- Also, the classification of food that the FDA requires not only differs in part from Customs classifications but is also more detailed. For practical reasons, the product code to be submitted should be the customs code, not the FDA code.
- FDA proposes a definition of “originating country” that is not the same in all respects as the definition of “country of origin” for Customs Services purposes. Employing a different definition under prior notice will engender confusion and create an apparent inconsistency between prior notice filings and Customs entry documents. Operators will have an almost impossible task of keeping the nuances of the two definitions in mind as they complete the required notices and filings for the Customs Service and for FDA. BVE urges FDA to use the Customs Service definition of “country of origin” in the prior notice final regulation.
- Again, we are concerned about the treatment of samples under the Prior notice regulations. Clarification is requested on whether shipments of small quantities for market-testing or tasting will be permitted without being subject to Prior notice requirements.
- On the sanction regime, although under the proposed rule the purchaser, owner, importer or consignee would be responsible for the correct implementation of the rules, ultimately the exporter will bear the economic consequences of a detention of the products; moreover, exporters will be subjected to sanctions even though the same data will be available in another agency, namely Customs
- As already stated in connection with registration of food facilities, in order to get the system operational without disrupting trade flows, operators who supply inadequate or incomplete information should be exempt from prosecution for a defined period after implementation.