Confédération des industries agro-alimentaires de l'UE
Confederation of the food and drink industries of the EU

TCO/338/03E-Final

Brussels, 19 December 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room1061
Rockville, MD USA 20852
USA

Re.: CIAA comments - US Bioterrorism Act 2002
FDA Interim Final Rules on Prior Notice
Dockets No. 02N-0278

Dear Madam or Sir,

The Confederation of the EU Food and Drink Industries (CIAA) welcomes the opportunity to provide comments on the FDA interim final proposals to implement Sections 307 of the Bioterrorism Act.

CIAA represents the largest manufacturing industry in the EU with 630 billion euros of production value. CIAA members are also major employers as more than 3 million employees work in the sector in the EU, equivalent to 12% of the total employment in the manufacturing sector. Trade with the US represents an important share of the total EU third country exports of agri-food products totalling about one fourth. Administrative procedures and their costs matter most to the many small and medium sized companies engaged in trade with the U.S.

You will find enclosed specific and detailed comments on certain provisions of the interim final rules on prior notice of imports issued on 10 October 2003.

Yours sincerely,

R. Destin
Director General

Enclosure

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Specific comments on prior notice

The requirement of prior notices will increase the cost of exporting to the U.S. Failure to fulfill this requirement, even if inadvertently, poses serious threats to the ability of exporters to continue to export. If prior notice is to work smoothly, at least the automation of prior notices through customs IT systems needs to be much improved. CIAA would like to reiterate that close coordination between FDA and US Customs is necessary to avoid unnecessary and redundant regulations.

- The submission of the prior notice by the EU exporter is impossible, in most cases, because of the time frame for the prior notice. It would be much easier for EU operators if FDA accepted the submission of the prior notice earlier than foreseen in the interim final rule. For sea travel, the time frame of between 5 days and 8 hours before arrival effectively means that no prior notice for shipments from European ports can be submitted at the time of departure of the vessel. This is not acceptable as U.S. Customs, in major ports around the world, requires a subset of the information included in the prior notice even earlier for purposes of the CSI. Thus **CIAA requests to enable operators to submit CSI information and prior notices at the same time.**

- FDA offers the possibility to submit the prior notice in a variety of ways if other means do not work. However all ways of submitting the prior notice eventually rely on electronic systems (even the fax). **CIAA is therefore concerned that food will not be allowed for importation into the U.S. only because no working method of submission of the prior notice was available**. The usual flow of goods should be allowed to continue unhindered, with the paperwork sorted out afterwards.

- **CIAA remains concerned about the treatment of samples,** in particular samples to be used in trade fairs. Such samples are not intended to enter the food chain and be consumed by the general public. Instead they are examples used when bidding for contracts with importers, wholesalers and retailers. Requiring prior notices for samples thus faces a huge and unnecessary bureaucracy. In addition, it is unclear whether sending samples by express delivery will be considered as “international mail” or “express carrier”, the latter being submitted to the general rules of prior notice, while the former will have to be notified using a slightly different prior notice form.

- CIAA would welcome clarification on the **definition of “shipper” :** the FDA representative who explained the prior notice rule to CIAA in November in Brussels was unable to give concrete guidance on how this is to understood. In particular, when the producer’s shipping platform is involved in the shipment, who is the shipper : the transporter who takes responsibility for the whole shipment or the producer’s own facility (assuming that neither would be classified as “manufacturer”) ?

- Similarly, CIAA would like to hear from FDA whether there is a recommendation on the definition of the “**common / usual / market name**” of the product ? Do operators have only to write down the names mentioned in the list of the "FDA Product Code Builder" ?

- CIAA would also appreciate if the FDA could validate the "**Product codes**" that operators have to build on the FDA website. Indeed, what would be the consequence of a mistake on one of the 7 characters ? That concerns especially the PIC fields, which could be hard to define. Would the goods be subject to detention if the code does not precisely reflect the nature of the products ?