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

Re.: CIAA comments - US Bioterrorism Act 2002
FDA Interim Final Rules on Registration
Dockets No. 02N-0276

Dear Sir or Madam,

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 305 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 the registration of food facilities issued on 10 October 2003.

Yours sincerely,

R. Destin
Director General

Enclosure

Avenue des Arts, 43 • B-1040 Bruxelles
Tel.: +32 2 514 11 11 • Fax: +32 2 511 29 05 • E-mail: ciaa@ciaa.be • Web: http://www.ciaa.be

Specific comments on registration on food companies

Companies are busy registering. Most are using the FDA web portal. However, practical problems and uncertainties still remain.

- **The obligation to nominate an agent in the U.S. remains a matter of concern for EU operators**. Smaller or occasional exporters will be the most affected by this measures. The additional cost a company will incur for the hiring of an agent may lead to the decision not to register.

  Moreover, the exact responsibility and possible liability of an agent is not sufficiently clear. This is one of the reasons why the usual U.S. importers are reluctant to offer being an exporter's agent. CIAA requests FDA to spell out the responsibilities of agents in terms of the Bioterrorism Act more precisely, and to define clearly his liability in case of wrong, imprecise, erroneous, late or otherwise incomplete or misleading information given by the agent to FDA.

  Many operators fear they have to disclose confidential information to their agent and are thus reluctant to use one of their importers as agent. These companies would rather be able to nominate more than one agent. We ask you to indicate if and how this can be accomplished.

- For certain companies which do not export directly to the US, it may be difficult to use FDA's web portal for registering: users that are not familiar enough with English cannot understand the registration system on the web sufficiently. **We would like to see the form as well as a help file in different EU languages.**