

TCO/087/03E-A-Final

Brussels, 3rd April 2003

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

**Re: CIAA comments - US Bioterrorism Act - Section 305
Docket No. 02N-0276 (Registration)**

Dear Sir or Madam,

The Confederation of the EU Food and Drink Industries (CIAA) welcomes the opportunity to provide comments on the FDA proposals to implement Sections 307 and 305 of the Bioterrorism Act.

CIAA represents the largest manufacturing industry in the EU with 600 billion euros production value. CIAA members are also major employers since 2.6 million employees work in the sector in the EU, equivalent to 12% of the total employment in the manufacturing sector.

In principle, CIAA considers legitimate the US objective to protect consumers against the risk of intentional adulteration or any other sort of risks concerning products that are marketed to US consumers.

However, CIAA is very concerned about the disproportionate character of the law. Despite the constraining and detailed provisions that will have to be respected by imported goods, the law will be ineffective in eliminating the risk of contamination or adulteration. CIAA considers that the measures envisaged to be applied to food imports will impose heavy and costly burdens upon EU exporters and will act as a clear non tariff barrier. Small and medium sized companies in particular risk being prevented from continuing to export to the US as the new regulations and the

administrative burdens imposed on them render their exports too costly to be economically viable.

The FDA proposals are also in clear contradiction with attempts made within WTO in the context of current negotiations to agree on measures that would facilitate trade through the simplification and streamlining of customs procedures.

You will find enclosed further more specific and detailed comments on certain provisions of the proposed laws which should be simplified or amended in order to relieve some of the burden that EU exporters and US importers will have to bear. CIAA would therefore be grateful if the FDA would give consideration to how it may effectively resolve the issues which are raised in this submission without undermining the objective of its legislation.

Yours sincerely,

A handwritten signature in black ink, appearing to read "R. Destin", with a horizontal line underneath the name.

R. Destin
Director General

Enclosure

Specific CIAA comments to the FDA proposals on Registration of Food Facilities

US and foreign facilities will have to register between 12 October and 12 December 2003 to help counteract terrorist threats or outbreaks of food-borne illness, by determining the source and cause of a problem. The draft law raises a number of concerns:

- Processing the registration applications of all the facilities subject to the Act is self-evidently a considerable task for the FDA. Businesses may therefore be affected by delays in this process during the relatively short period of 2 months during which registration must be effected, i.e. October to December 2003. The period in question is a peak time for some food industries in the run up to Christmas and the New Year. Thus, any significant delay in the registration process could have an adversely impact on exports of certain EU foodstuffs to the US.

In this regard, CIAA would welcome the FDA's assurance that it has the capacity to handle the overwhelming number of facility registrations that will result from the legislation and, in particular, that hard copy registration applications will not receive second-class treatment.

- As stated in the notification, total cost of registration will be higher for foreign companies than for US ones. Exporting facilities which would often change their range of products sent to the US would have to face further cost increases.
- In many cases, foreign (i.e. non-US) companies send finished or semi-finished goods or even raw materials only to their own subsidiaries in the US, where these products undergo a more than minimal further processing. The US subsidiary is therefore ultimately responsible for bringing these products into the food chain in the US. Hence, their foreign parent company should not have to register with the FDA.
- In some cases, the foreign facility only packs raw materials previously bought (some on international markets) in order to send them to its US subsidiary for final processing. Under the proposed provision, not only this facility, but also all of its suppliers would have to register with the FDA. Again, this should not be necessary as the US subsidiary's registration should suffice. Also, the consequences of a failure to register for one of the suppliers, i.e. a product detention at the port of entry, would possibly be borne by the foreign facility sending the packed products. Thus the sending facility would have to make sure that all of its suppliers are registered with the FDA. This would be an extreme administrative burden as some of these suppliers may be located in another third country, and may not be held responsible for not registering under the respective legal systems of the countries in question.
- The quasi obligation to have an agent in the US is a matter of concern for EU operators. As a matter of fact, as recognized in the notification text, a number of EU exporters do not have an agent yet and the additional cost a company will incur for the hiring of an agent may lead to the decision not to enter registration. In practice, small exporters and/or SMEs will be most affected by the measure. CIAA considers that this part of the text interferes in commercial relations between companies. It should not be compulsory

to hire an agent and hence procedures should be made easier for exporters who would not have an agent.

- Moreover, the requirement to have a single agent in the USA does not acknowledge the commercial reality of some European producers, who often deal with two or more importers in the USA (because of geographical or products differences).
- Consideration and clarification of the requirements for limited quantities of samples (e.g. for market testing or tasting) are requested since any requirement to comply with the registration provision before their importation could create a serious impediment to the introduction of new products or promotion of products already in the market.
- In order to get the system operational step-by-step and not disrupt trade flows a period of exemption from prosecution should be foreseen for operators who do not register correctly (or at all) in time.

Finally, further to the rule-making on the Bioterrorism Act, CIAA is concerned about the other new US rules relating to international trade which were also inspired by the aim to increase security and prevent terrorist attacks - namely the Container Security Initiative (CSI) and the Customs-Trade Partnership Against Terrorism (C-TPAT). It is CIAA's suggestion, therefore, to create links between the different projects in that compliance with one automatically counts as compliance with others. For example, shipments originating in a CSI harbour could be exempt from the prior notice at the FDA. Or, companies taking part in the C-TPAT could be exempt from the proposed keeping of records and from having to register explicitly with the FDA (this could be done internally between US agencies).