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

Brussels, 7 July 2003

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

CIAA comments on the FDA proposed measures, Section 303 (Administrative detention), Docket N° 02N-0275

Dear Sir, Dear Madam,

The Confederation of the Food and Drink Industries (CIAA) has already commented on the two draft regulations prepared by the FDA concerning Registration of food facilities and Prior notice. On May 9, the FDA issued two proposals which provide for the Establishment and Maintenance of Records and for Administrative Detention. CIAA has examined these FDA proposed rules and welcomes the opportunity to express its concerns as to their potential trade impact. CIAA's views on these proposals are contained in two separate documents, the present one TCO/19303E and TCO/19203E.

As already mentioned in our previous comments, CIAA considers the US objective legitimate to protect consumers against the risk of intentional adulteration by terrorist or any other criminal actors of food and drink products that are marketed to US consumers. However, the CIAA is concerned by the disproportionate character of the proposed rules. Despite the constraining provisions that will have to be respected by food companies, the proposed regulations will be ineffective in eliminating the risk of contamination or adulteration. CIAA considers that the measures envisaged to be applied to food facilities and to food imports will impose heavy and costly burdens on EU exporters. 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 burdens are twofold: The proposed regulation on maintenance of records imposes high *direct* costs for establishing and maintaining the required records. The rules on detention involve a *potentially* very high cost to operators in cases of detention of their products.

Please find enclosed further 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.

We trust that you will take our concerns into consideration.
Yours sincerely,

Raymond 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

Section 303: Administrative Detention – Docket N°02N-0275

The FDA issued a proposal to implement Section 303 of the Bioterrorism Act according to which an officer of the FDA may order detention of food if credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.

- **CIAA criticism on the definitions used**
  The FDA does not give any clarification concerning the meaning of "*serious adverse health consequences"* (or death to humans or animals)". Indications should be given in order to limit the scope of implementation of the law. Specifically, in CIAA's view, some sort of reference to a risk to a large part of the population -- as opposed to merely a few individuals -- should be included. If a risk associated with a food product only affected a very limited group of people, detention would not be the appropriate action to take. Furthermore, health consequences must be really severe to the average person in order to justify a detention. It cannot be the case that, for example, only a risk of a limited effect on the well being of people triggers a detention.

  The FDA also explicitly rejects to define "*credible evidence or information*" indicating such article presents a threat. Rather it points out such a vague definition is common practice in US law making. Nevertheless CIAA is concerned that this vague definition offers the FDA too much discretion when deciding to order a detention. This is aggravated by the fact that the FDA may order a detention on the basis of confidential / classified information. Given that the potential damage to a company of a wrongly ordered detention will usually be considerable, it is CIAA's opinion that the FDA's ability to detain food shipments should be more strictly limited by a more precise definition.

- **Appeal process**
  Even though the FDA has elaborated at length the process of ordering a detention, giving notice to the holder / owner of the food, inviting and conducting an appellate hearing and relieving the detention, some "question marks" still remain.

  First, the detention rules proposed are modelled after the existing detention rules for medical devices. It could be questioned whether these rules are a model for food, given the usually short "best before" dates of foods.

  Second, the proposed rule states that the owner, operator or agent in charge of the place where the article of food is located shall be issued a copy of the detention order. Also, as will be typical for food imports to the US, the owner of the food shall receive a copy if he can be determined "readily". CIAA would wish that the FDA stated more clearly what "readily" meant in these circumstances. Clearly, in any case of detention it is absolutely vital that the European sending company is informed about the detention immediately. We would like to remind the FDA that it has required operators to register themselves with the FDA. Therefore there can be no excuse not to "readily", i.e. "at once", find out the identity of the sending company, the buying company and all intermediaries of the food detained. At least one of them will typically be the owner, so there would be no harm in informing all of them of a detention order. In fact, this is the only way to give the owner a realistic chance to file an appeal.

Third, the reasons for a detention should be stated more clearly than foreseen in the draft regulation. Otherwise the filing of an appeal will be made unduly difficult.

Fourth, the proposed rulemaking only foresees a requirement to give notice of the opportunity for a hearing. In other words, the agency believes that it has the discretion to grant or deny requests for hearings. CIAA would strongly oppose such a provision. It believes that a right for a hearing as well as a written appeal must be given to the owner of the food.

- **Detention period**
  The FDA foresees a *reasonable detention period* of 20 calendar days which may be extended to 30 days. CIAA would like to call into question if 20 days are reasonable for perishable foods that the FDA itself defines as being marketable only for 7 days. It is CIAA's strong belief that the FDA should be required to limit -- in each and every case -- the detention period to that period that is absolutely minimally necessary to undertake the investigations into the possible threat that underlies the detention order. Therefore, it must be made clear that a detention will typically vary in length from case to case, up to a maximum of -- regularly -- 20 days. For perishable food it should be considered to limit the maximum detention period to 7 days. Considering the possible extension to 30 days it must be made clear that this is not an extension by a "block" of 10 days but rather a possible extension of up to 10 extra days.

- **Erroneous detention orders**
  For food companies, erroneous orders of administrative detention will constitute a very costly and unnecessary economic burden to EU exporters. The cost of administrative detention may include transportation, storage, marking and labelling, loss of product, loss of product value and appeal. According to its impact analysis, the FDA estimates that up to 48% of the food that is administratively detained may be held up erroneously. The FDA calculates the costs of a detention to at least $20,000, up to $330,000 for SMEs, and even larger sums for bigger companies. So the potential economic impact of the law may be substantial, in particular for small companies, as underlined by FDA. With these considerations in mind, CIAA requests that the US foresee a reimbursement of companies falsely accused with erroneously detained food shipments.

- **Detention of partial shipments**
  If a lot is detained because it is considered as potentially dangerous, the whole container may be detained. The FDA should further develop this possibility and propose rules that would regulate that only "risky" food is detained while the rest can proceed into commerce as usual.