



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 measure, 306 (Record Keeping) Docket N° 02N-0277

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 comments on these proposals are contained in two separate documents, the present one, TCO/19203E (Record Keeping) and TCO/19303E (Administrative Detention).

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 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.

We trust that you will take our concerns into consideration.

Yours sincerely,



Raymond Destin
Director General



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>

Sections 306: Establishment and Maintenance of Records – Docket N°02N-0277

The FDA issued a proposal to implement Section 306 of the Bioterrorism Act which provides food facilities to establish and maintain records. Some aspects of the draft law raise a number of concerns and other items should be clarified:

- From a general point of view, CIAA fears that the implementation of the FDA draft law leads to additional burdens upon EU exporters. It is of particular importance that no new records will be required by the FDA. The proposed rule states that the existing records can be used if they contain the information required.

Records to be maintained must include:

- (1) Firm name, responsible individual and contact information (address, phone number, and, if available, fax number and email address) of the non-transporter immediate previous source or subsequent recipient (whether domestic or foreign);
- (2) Adequate description of the type of food received or released, including brand name and specific variety;
- (3) Quantity and information on how the food is packaged;
- (4) Dates of receipt or shipment;
- (5) Firm name, responsible individual and contact information (address, phone number, and, if available, fax number and email address) of the transporter who delivered the food to the non-transporter or transported the food to another non-transporter;
- (6) Lot or code number or other identifier (to the extent it exists).

It is usual business practice that purchase and / or shipping records, e.g. bills of lading, include all the information listed under points (1) to (3). This also applies to dates of shipment (no. (4) above) and, in most cases, upon receiving a shipment: in the receiving entity, the date of receipt is noted on the recipient's copy of the purchase or shipping record. Thus, in order to comply with the proposed rule insofar as keeping records on the information listed under points (1) to (4) is concerned, maintaining the appropriate records (bills of lading for example) should satisfy the FDA.

However, it is not at all general practice to include all the information listed under point (5) in the different documents mentioned above. Instead, separate order papers are usually established by the ordering party instructing the transporter to transport the food in question. Usually some sort of reference, e.g. an invoice date or a lot number stated on these order papers, can serve as a link between these papers and the corresponding purchase / shipping documents. Hence, it should be sufficient in order to comply with the proposed rule, insofar as the data elements in (5) above are concerned, to maintain these transport ordering papers. In other words, it should not be required to merge the information on the two sets of records into a new form of document which would have to be introduced at great cost.

Furthermore, concerning the information listed under point (5), it should be made explicitly clear that only the party ordering the transport is obliged to maintain the records containing the information in question. In a usual transportation process, it is either the sender or the recipient of the food who orders the transportation. The information required about the transporter is only reasonably available to the ordering party. Where -- as is typically the case -- the sender orders the transportation, it would be an extreme additional burden -- in some cases even impossible -- for the recipient to check the identity of the transporter of every shipment received and create appropriate records. This applies, vice versa, to cases where the recipient orders the transportation, as is becoming more and more commonplace in Europe. The burden would be seriously increased because the transporter used by each sender or recipient may vary from shipment to shipment.

Proposed § 1.337 (6) specifies that the "name of the [...] transporters who transported the food *to you*" should be recorded. Proposed § 1.345 (6) likewise specifies to record the "name [...] of the transporters who transported the food *from you*". Both rules should be altered to read "name [...] of the transporters who transported the food *for you*".

Concerning the recording of a lot or code number or other identifier, if it exists, -- see number (6) -- it should not be an obligation to use lot numbers at all. Concretely, companies using lot numbers, in any document, should not be required to take these lot numbers for any new documentation set up to fulfill the Bioterrorism Act. For those that use lot numbers for tracing raw materials in their finished products, it should not be required to adapt their documentation system to fulfill the Bioterrorism Act.

This is of particular importance as CIAA would object strongly to any demand to implement mandatory procedures to trace the use of all raw materials in all finished products (see next paragraph). Where such an identifier exists it must be sufficient to record it on any one (but not necessarily all) business documents mentioned above or any other separate document.

- **Information to be maintained in records:**

According to the draft rule, records must include *all information reasonably available to the food manufacturer to identify the specific source of each ingredient* that is used to make every lot of finished products. FDA acknowledged that the industry relies on several sources of ingredients to make foodstuffs. For all but the largest producers it would be a tremendous effort to implement systems that enable them to trace the use of each and every ingredient in each and every finished product.

This was acknowledged in the European Union Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (*Official Journal L 031, 01/02/2002 P. 0001 - 0024*). This regulation provides for the establishment of records of the immediate sources or recipients of food (i.e. "one up, one down") without requiring a tracing of ingredients in finished products (Article 18). Such tracing systems may however be implemented on a voluntary basis. CIAA would therefore strongly argue for the adaptation of a similar system in the USA.

Having expressed this, CIAA would like to stress that it does not oppose the disclosure of ingredient tracing information where it is available in a documented form in the producing companies. Thus, CIAA asks the FDA to state more precisely what "reasonably available" means. We would like to reiterate that it should not mean to require the creation of new "tracing records". In fact, CIAA would welcome the FDA's assurance that the identification of the potential sources of all the ingredients which might be present in lot of the processed products -- upon request -- would be sufficient to comply with the proposed rule.

- **Items excluded from the scope of the records access:**

The proposals exclude food recipes from the scope of the records access. However, given the proposed definition for food recipes, FDA would have access to the records containing the list of individual ingredients used in food products but not to the quantities used in the manufacturing of the products. CIAA is concerned by the potential disclosure of confidential ingredient formulation and would like to know how the confidentiality of sensitive business information will be ensured in case of application of the records access authority.

- **Records availability requirements**

As regards the extraterritoriality of the law, the US authorities seem to have stated that the FDA has no jurisdiction to either access records or sanction entities outside the US. Anyhow, the EU should request clarification on the approach the US will use in case of an emergency situation. The FDA plans to work closely with foreign governments. The question that must be addressed is how does the FDA justify the application of its record keeping rules and, hence, the access required to confidential information) in a EU company?

Records must be available for inspection and copying by the FDA in short time limit (4 or 8 hours). It is questionable how this will be managed in practice if non-US companies are involved. First, outside the USA, the FDA has no officials to inspect the records on-site (nor does FDA have or should have the legal right to undertake such inspections). Secondly, there is the question of different time zones that must be taken into consideration. CIAA would therefore ask the FDA to reconsider and explicitly state the time periods and procedures for inspection of maintained records for non-US firms.

- **Small and medium-sized companies**

CIAA welcomes the longer time-scales granted to businesses with up to 500 employees for compliance with the proposed record keeping rules.

Finally, the CIAA would like to have clarifications concerning the languages in which records should be kept. Given the amount of detail required, it may not always be possible to provide information in English, in particular for small companies.