EUROPEAN UNION
DELEGATION OF THE EUROPEAN COMMISSION

Head of Delegation

December 19, 2003

BY UPS

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sirs:

Docket No. 02N-0276

Docket No. 02N-0278

Please find herewith comments from the European Commission on the Interim Final Rules on Registration of Food Facilities and Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Yours faithfully,

Dr. Günter Burghardt
Ambassador

Att.

02N-0278 C 245

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Comments to FDA on the interim final rules on Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Docket Nos. 02N-0276 and 02N-0278

The European Commission welcomes the opportunity to provide additional comments on the implementation process associated with the Public Health Security and Bioterrorism Preparedness and Reponse Act (BTA) of 2002.

The Commission welcomes the improvements made to the draft rules, such as the dead-lines for prior notice and flexible implementation and education efforts during the first months of operation.

However, our main concerns remain the possible distortive effects of the new rules on international trade. Where these concerns cannot be addressed within the existing authority of FDA, we would like to invite you to include these issues among those that need to be amended within the orginal Act itself.

Impact on EC exports

The European Commission has serious concerns about the potential adverse impact on EC exporters of the above measure. Small and medium-sized enterprises are, of course, particularly concerned by the implementation of this measure and their possibility to trade could be seriously compromised.

FDA has identified that a disproportionate cost of compliance with the registration measure falls on foreign suppliers (Table 42, "Total cost of options..."). The costs are in the order of 30 times greater for foreign facilities than for U.S. facilities. Furthermore, FDA acknowledges that as a result of the registration measure, up to 16 % of exporters to the U.S. (those who export fewer than 10 trades a year) will cease trading to the U.S. (Section 9, paragraph b). FDA recognises that for these small exporters the 'trade distorting impact' will be total.

Specific comments on impact of regulation and prior notice filed by the Dutch Government are enclosed in Annex 1. The European Commission endorses these comments.

Legal uncertainty

The current opportunity to comment is provided by the 75 day period connected to the publication of two "interim final rules" related to the Registration of Food Facilities and on the Prior Notice of Imported Food. However, despite the fact that the implementation of the BTA has already begun (i.e. since 12 December), the two remaining final rules have not yet been published. Therefore, traders are still unclear on what legal requirements they must satisfy.

FDA and CBP have indeed published a "Transitional Compliance Policy on Food Imports Under the Bioterrorism Act" but this has only been published *one* day before the new rules became effective and it does not provide the legal certainty that trade should be based on. These guidelines state on page 7 that :

" The phrase "the action FDA and CBP staff typically should consider taking" used in the tables means that FDA and CBP staff, pursuant to their agencies policies and procedures, may take these actions or may take different or additional actions if they believe particular circumstances warrant them."

Therefore, in the view of the EC, there is a serious lack of clarity on how the new rules will be applied during the eight month transition period and traders have not been provided with sufficient information to ensure that they can comply with the new rules.

Requirement for an agent

In particular, the requirement of a U.S. Agent is according to our analysis redundant because it does not contribute to increased security, while it significantly increases fixed costs especially for small food producers. The reasons why a U.S. agent is not likely to enhance security are clear: if FDA is not able to contact the facility direct in a case of urgency, the U.S. agent is not likely to be more successful. The key in addressing these situations is co-operation with the competent authorities in the exporting country.

Co-operation between U.S. agencies

We also remain concerned about the fact that the FDA and CBP may not be able to process the data and that the same information must be submitted twice to US authorities. More detailed comments on this area are enclosed (Annex 2). In addition, it seems that the difference of treatment between meat and other products under the authority of USDA on the one hand and food stuffs under the authority of FDA will lead to unjustifiable differences (such as need for an agent under the FDA rules while there is no such requirement under the USDA rules), and confusion for importers.

The U.S. has already decided that facilities producing food regulated by USDA can be exempt from registration on the basis that the necessary information is supplied to the U.S. authorities. The same principle should be extended to information supplied to the U.S.A. in the framework of the EC-U.S. Veterinary Agreement and to other U.S. agencies, such as U.S. Customs (CBP) and Tax and Trade Bureau (TTB). The duplication of information supply should be addressed in terms of communication between U.S. departments themselves, before passing the burden of double notification to trade. A duplication of information must be regarded as an unnecessarily trade-restrictive measure.

Co-operation between U.S. and the European Community

While the European Commission agrees that ensuring safe food starts from the producers, it is necessary that U.S. authorities co-operate with their European counterparts in ensuring the respect of the existing rules on food safety and security. U.S. authorities cannot enforce their implementation rules in third countries without prior consent and agreement with the relevant authorities in those countries (extraterritoriality). We are not aware of any such arrangements. Moreover, in order to avoid extra work, use should be made of existing instruments, such as the EC-U.S. Veterinary Agreement for registration, collection and exchange of information. In more general terms, ensuring security in food chain requires multilateral co-operation.

The Commission would like to invite the FDA to embark on this road, and the Commission is committed to work with the FDA with a view to contributing to a robust and effective international framework for food security.

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Annex 1

Comments by Government of Netherlands

With specific regard to international mail and mail by express carriers, the Netherlands would like to make the following comments:

1. The FDA-interim final rule "Prior Notice of Imported Food" also applies to international mail and mail by express carriers. In terms of quantities and movements of mail between the US and the Netherlands, this represents a tremendous financial en administrative burden. This would even seem disproportionate, whereas most shipments represent only small values.

2. FDA should be aware of the fact that most required information is not available to private persons, and therefore not available to international mail and mail by express carriers. This is particularly urgent, since FDA does not provide information on registration of facilities. The Netherlands would like to point out that a business relation between the buyer of the goods (for instance a private person), the mail service and the manufacturer will in general not be present.

3. With regard to the estimated disproportionate economic impact of the regulation, the proposed measures for international mail should be reduced to a minimum. The Netherlands would like to suggest the following:
   - Private persons should be excluded from prior notification;
   - The requested information is limited to some key-information, like the submitter and the type of food;
   - All mail services, including express carriers will fall under the definition of "international mail";
   - FDA provides (on their website) dedicated information for companies and consumers about international mail, in different languages.

4. Problems will occur with the shipments travelling longer than 5 days, for instants by ship from Europe. Since Prior Notice has to be submitted no longer than 5 days before arrival it is impossible to accompany the shipments with the prior notification. The Netherlands would like to suggest Prior Notification can be done longer than 5 days before departure.

5. The proposed rule on prior notice stipulates that a prior notification is required for *each article of food* and for *each producer, if known*. Given the production structure in some agribusiness sectors like the fresh produce sector, whereby produce in one lot is often sourced from many different growers, this requirement seems disproportionally burdensome. It is not clear if the information of producers is compulsory if the information is known. The Netherlands suggests exempting the growers and providing the information of growers on a voluntary basis.

Annex 2

EC questions and remarks on the prior notice provisions of the new Bioterrorism Legislation (ref. 21 November 2003 meeting between FDA and EC)

(1) EU exporters are obliged to use FDA's Prior Notice System as they cannot register as users of the bureau of Customs and Border Protection's (CBP) Automated Broker Interface. EU exporters, not being able to combine in one operation the prior notice (PN) and a customs declaration for import, will be in a disadvantaged position compared to U.S. importers. The EU exporter, after having completed his PN, will receive a PN reference number which he has to transmit to his U.S. importer or customs broker. This appears to be a time-consuming process and may lead to unnecessary blockage of EU shipments in US ports. As it concerns mostly perishable products, unnecessary holding of shipments will have a negative influence on the condition of the goods and may consequently lead to refusal of the goods by U.S. companies.

(2) Ship's sailing from EU ports normally need 7 to 9 days to reach a port at the east-coast of the U.S.A. Carriers have to submit information to CBP in respect of the Advanced Cargo Information Rule, 24 hours before loading in the EU port. It is not possible to submit at that same moment the message of advance cargo information together with the prior notice, as the earliest time to submit the PN is 5 days before arrival. Would it be possible to stretch the earliest possible time to submit the PN up to 10 days?

(3) Why is FDA requesting the shipment information, such as the vessel's name and voyage number? These are data which carriers are already providing to other U.S. agencies, such as CBP and US Coastguard, at an even earlier stage then requested for the prior notice.

(4) FDA has recently announced the signing of an MOU with CBP to commission CBP officers in ports and other locations to conduct on behalf of FDA, investigations and examinations of imported foods. Will this have also consequences on the selections for controls by CBP officials stationed in EU ports?

(5) Does FDA consider producing user-guidelines on the procedures to submit a PN either via FDA's Prior Notice System or CBP's ACS/ABI? Such guidelines would be very helpful and could also contain instructions on cancellation or change of a PN, which procedure is not clearly explained in the current proposal. It would also be necessary to describe more clearly what is meant by identifying the goods by the common, usual or market name, e.g. should the description of a shipment of whisky be as an alcoholic beverage or Scotch Whisky or Bell's 8 year old Scotch Whisky?

(6) Provisions are made for the segregation of refused shipments, under possible FDA or CBP supervision. From the provisions it is not clear who would be responsible for the physical segregation of the refused food from the rest of the shipment, will that be the carrier, handling agency, the customs broker or importer? Will FDA or CBP officials always supervise the segregation?