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THE FORUM FOR THE FRESH PRODUCE INDUSTRY
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COMMENTS ON FDA PROPOSALS FOR

**THE ADMINISTRATIVE DETENTION OF FOOD - FED REG 9 MAY 2003 (DOCKET N° 02N-0275)
ESTABLISHMENT AND MAINTENANCE OF RECORDS - FED REG 9 MAY 2003 (DOCKET N° 02N-0277)**

Dear Sir or Madam

Freshfel Europe - The European Fresh Produce Association represents the interests of European exporters, importers, wholesalers and retailers in the fresh fruit and vegetables sector.

Freshfel Europe very much welcomes the opportunity to submit comments on the above-mentioned FDA proposals implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act).

Freshfel Europe fully understands the FDA's aim to enhance the security of the US food supply in view of recent potential terrorist threats. We are, however, highly concerned about the potential trade - distorting effects of the implementation of the Bioterrorism Act (cfr our letter of 26 March on the registration of food facilities and the prior notification of food imports). More specifically, we would like to submit our comments on the provisions regarding the administrative detention of food and the requirements regarding the establishment and maintenance of records as published in the Fed Reg of 9 May 2003.

Administrative detention of food

- It is important that exporters are immediately informed in case their goods are detained by FDA. We therefore propose that FDA includes in its proposals a clear timeframe for the notification of any detention of food to the exporter in question. In addition, we suggest that FDA creates an easily accessible contact and information point to ensure an efficient information flow between customs authorities and foreign exporters.
- The proposal as published in the Fed Reg of 9 May does not provide for any compensation in cases where the detention of the products turns out to be based on unjust suspicions, and the quality and value of the goods is negatively affected by the detention. We therefore propose that the FDA includes in its proposals detailed specifications on how exporters can be compensated for any losses resulting from the unjust detention of their products.
- The proposal stipulates that an article of food may be detained if there exists '*credible evidence or information*' indicating that such article presents a threat of serious adverse health consequences or death to humans or animals'. The proposal, however, does not lay down detailed criteria for the determination of the *credibility* of any evidence or information. This situation may lead to arbitrary decisions by FDA officials. For reasons of legal transparency and predictability, we propose that the FDA includes in its proposal clear guidelines on when a certain piece of evidence or information may justify the administrative detention of the products in question.

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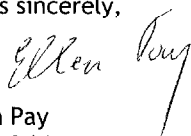
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- The proposal as published in the Fed Reg of 9 May provides for the detention of food products under 'appropriate storage conditions, such as temperature, humidity, and other conditions', to 'protect the safety and wholesomeness of the detained article of food'. We propose that the FDA keeps detailed records of the manner in which the detained goods are handled, and that it sets up a procedure whereby the exporter can verify the storage conditions of his products. In addition, exporters should have the possibility to claim damages in case the quality and value of their goods are affected by inappropriate storage conditions.

Establishment and maintenance of records : the proposal as published in the Fed Reg of 9 May requires 'the establishment and maintenance of records' by 'foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States'. It is unclear how the FDA is planning to enforce ie verify records outside its territorial jurisdiction, the US.

Freshfel Europe is closely monitoring every development regarding the finalising of both regulations and would be pleased to work with the FDA to improve the proposals in view of the above remarks. We are convinced that the FDA shares our concern to avoid any impediments of EU - US trade flows, which would not only affect European traders, but also imperil the provision of the US consumer with fresh fruit and vegetables from the EU.

Yours sincerely,



Ellen Pay
Freshfel Europe