Mr. Michael Hanley
USDA
American Embassy
42 Elgin Road
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IRISH exporters association

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16 June 2003

Dear Michael,

Re: FDA Proposed Regulations to Implement the Bioterrorism Preparedness and Response Act 2002.

Please find enclosed the Irish Exporters Association submission on the subject.

We would be grateful if you would pass this on to the appropriate person within the FDA.

Yours Sincerely,

John Whelan
Chief Executive

cc. Mr Brian Whitney – Assistant Secretary General, Department of Enterprise Trade and Employment

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Chief Executive
John F Whelan
A company limited by guarantee

IRISH exporters association

Dublin, 16 June 2003

Irish Exporters Association Position Paper

US Bioterrorism Act 2002
And Associated Proposed Regulations

The Irish Exporters Association (IEA) is pleased to submit its comments to the Food and Drink Administration (FDA) in relation to the US Bioterrorism Act 2002 insofar as it affects the Irish exporting industry.

The IEA was formed in 1951 and is the representative body of the Irish exporting industry. Our members are responsible for approximately 75% of exports from Ireland which last year were valued at approximately €93billion. The US is at present our second biggest market taking €22billion in 2002 with the food and drink sector accounting for €200million.

The Irish Exporters Association recognises the need and desire in the current international climate for the US government to take proportionate measures to enhance the security and safety of the food supply chain in the US. We have no objection in principle to the imposition of new legislative requirements governing the shipment of food products to the US, whether for consumption in the US, onward shipment through US territory or for re-export from the US provided that the specific requirements are appropriate and proportionate to securing the desired objective. In particular we believe that the measures introduced should be the least trade restrictive possible and should not preclude smaller companies from shipping their products to the US.

There appears to be a real risk of proliferation of separate but connected initiatives within the US designed to meet objectives similar to that of the Bioterrorism Act and which impinge on each other. For example the processing of shipments in regard to the mandatory requirements of the Container Security Initiative (CSI) with its accompanying 24-hour rule varies if the voluntary provisions of the Customs-Trade Partnership Against Terrorism (C-TPAT) are met. The IEA would like to request the US authorities to explore in detail methods for the US agencies to share information to help alleviate the necessity of Irish exporters supplying the same information to separate US agencies in relation to the same shipments.

As you are aware Irish exporters operate under EU legislation. It is noted with concern that the US Customs has not approached the EU as a Customs region regarding the implementation of these requirements. We understand that the EU as well as other international organisations such as the International Maritime Organisation (IMO) and the World Customs Organisation (WCO) are working on their own security initiatives and our concern is to ensure that the implementation of the Act does not lead to the creation of confusing or conflicting requirements.

We note that the Act specifically excludes those foodstuffs under the jurisdiction of the US Department of Agriculture (USDA) ie meat, poultry and egg products. As alcoholic beverages are already regulated under the requirements of the Alcohol and Tobacco Tax and Trade Bureau (TTB) as well as the US Customs Service and each US State's own Alcoholic Beverage Control Authority, we request that a similar exemption for alcoholic beverages be examined, as information now required to be submitted to the FDA under the Act is already being submitted to the agencies mentioned above as part of separate legislation. It is our view that the detailed measures adopted by the FDA are more trade restrictive than is necessary to achieve the stated objectives and that unnecessary obstacles to the international trade of food and drink are being imposed.

In view of the short registration period of 2 months and the amount of information which will be needed to be gathered, the IEA is concerned that the systems designed by the FDA to handle these tasks will be robust enough to take and manipulate the expected volumes of data. We point out that the period chosen for the registration coincides with the run up to Christmas which is a peak time for the majority of our members so any significant delay in the registration process could have very serious implications for the companies concerned. We would also ask for a guarantee that some flexibility will be shown for any problems which arise and are attributable to deficiencies in FDA systems whether electronic or otherwise.

Provision by the FDA of a validation number for each notification submitted is seen as essential. Exporters will need a unique reference number to tie up with each shipment in the event of a problem arising. Similarly in the event of a notification being rejected the exporter will need immediate notification of the rejection and the reason for it.

The IEA would ask for clarification of exactly what details will be required in respect of ingredients labelling. This will be seen as particularly significant in the drinks and speciality food sector.

Conclusions and Recommendations:

While the Irish Exporters Association is supportive of the US government's efforts to protect its citizens and its food supply chain we have reservations that the scope of the Act and its associated regulations has the potential to cause disruption to trade flows and that its impact might turn out to be disproportionate to its stated objective. We would be grateful if the FDA would give consideration and supply a response to the issues which we have raised in this paper and which we summarise as follows:

- To avoid unnecessary and costly duplication of information demands by US government departments, we strongly recommend a centralised system that captures US customs supplied information and feeds this into the FDA or any other US government department associated with homeland security provisions.

- The US customs authorities should immediately enter into discussions with EU customs, the WCO and the IMO to agree international standards for security of international trade. It is not in the long-term interest of the USA to have costly proliferation of non-compatible security standards.

- The IEA strongly urges the USFDA to use the 'known consignor / approved shipper' system of risk analysis which currently exists for all air-freight shipments to ensure a balance between security and trade facilitation of bona fide international exporters.

- The timescale for the introduction of the FDA Bioterrorism regulations are unlikely to be satisfactorily met within the October to December 2003 timeframe with unnecessary resultant costs and delays. The IEA urge the FDA to push back the implementation date of these regulations to12th March 2004. (Regulations 303, 305, 306 and 307).

END

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United States Department of Agriculture

Foreign Agricultural Service

Office of Foreign Agricultural Affairs

American Embassy
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June 18, 2003

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

Dear Sir/Madam:

We have been asked to pass the attached submission on FDA actions on New Bioterrorism Legislation.

It would appear that the submission addresses the whole issue of the Bioterrorism legislation rather than a specific docket number. I have asked the Irish Exporters Association to also forward this submission electronically to you.

Sincerely,

Michael Hanley
Agricultural Specialist

Enclosure

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International Replace leading 0 with +353 -

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