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8 July 2003

Dockets Management Branch (HFA-305)
Food & Drug Administration
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Dear Sir/Madam

PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS RESPONSE ACT 2002: COMMENTS ON PROPOSED RULE-MAKING

Docket No. 02N-0277 (Section 306 establishment and maintenance of records)

The Notice of Proposed Rule-Making which appeared in the Federal Register on 3 February 2003 invited comments on FDA proposals for Registration of Food Facilities. The UK has contributed to the response being provided by the European Commission on behalf of the European Union. However, this letter is intended to support the responses submitted to the FDA by the Scotch Whisky Association and the UK's Food & Drink Federation. Copies of their responses are attached to this letter and I would be grateful if you could take account of their concerns in revising the provisional rule and also respond in detail to their concerns.

Yours sincerely

James

James Hughes
First Secretary (Agriculture & Trade Policy)

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7 July 2003

Further Proposed Regulations under the US Bioterrorism Act (Section 303 administrative detention; docket no. 02N-0275 and Section 306 establishment and maintenance of records; docket no. 02N-0277)

Thank you for your letter of 23 April, detailing two further regulations proposed under US bioterrorism legislation, Section 303 (administrative detention) and Section 306 (establishment and maintenance of records). The Food and Drink Federation FDF[1] again welcomes the opportunity to comment on these new proposals and trusts our previous comments on Section 305 (registration of food facilities) and Section 307 (prior notice), sent to you on 4 April, were useful.

Our trade with the US is of critical importance, with current trade flows for food and drink approaching £1 billion a year in each direction. Many of our leading member companies have significant links and long-standing trading interests with the US and therefore wish to work closely together with US authorities to ensure a safe and commercially viable trading system for all concerned.

FDF shares the FDA's objective of protecting the safety and security of food supplies, a fundamental requirement for our member companies. However, whilst welcoming recent news that the FDA and US Customs and Border Protection (CBP) will work together to streamline the implementation of prior notice requirements (Section 307 docket number: 02N-0278), we remain deeply concerned at the impact the increasing number of new regulations may have on trade, notably where these are likely to add cost, delay and uncertainty for exporters to the US.

We consider that the proposed measures to be applied to food imports into the US will impose heavy and costly burdens upon UK and other EU exporters and will act as a clear non-tariff trade barrier. Small and medium sized companies in particular risk being prevented from continuing to export to the US, especially where the new regulations and the administrative burdens imposed on them would render their exports too costly to be economically viable.

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[1] FDF represents the UK food and drink manufacturing industry. It purchases some £11 billion worth (about two thirds) of UK agricultural produce but also imports a further £7 billion worth of produce for processing. UK food and drink exports in 2001 were £8.55 billion. Some two fifths, £3.4bn, of these exports went to non-EU countries.

Specifically regarding Sections 303 (administrative detention) and 306 (establishment and maintenance of records), FDF believe these regulations to be overly bureaucratic and in some aspects an unnecessary duplication of existing security measures. We also support the detailed comments sent to you on these proposals by our sister federation, the Grocery Manufacturers of America (GMA).

Section 303 is of particular concern to FDF as any detention of incoming shipments at US borders would directly affect UK companies exporting to America. Moreover, the Container Security Initiative (CSI) already operates in five major UK ports. To facilitate the initiative, US CBP officers are stationed alongside UK Customs personnel to enhance co-operation in sharing of information and pre-screening of 'suspect' containers before departure for the US. To this end we do not understand why shipments traveling from the UK ports named above should be subject to a second possible check and delay at US borders.

As outlined in our previous response of 4 April, FDF believes that companies who participate in the US Customs Trade Partnership Against Terrorism (C-TPAT) initiative (aimed at protecting global commerce from terrorism) should be subject to reduced scrutiny by the FDA. This would lessen the need for the detention of goods and the ensuing disruption of shipments/delays in meeting customer orders. Known traders who, by definition, are not considered a security risk to the supply chain should also be able to benefit from reduced checks and inspections, allowing US Customs to focus on those consignments which do not come from "trusted" or reputable sources. Each of our member companies pride themselves on their reputation as trusted traders.

FDF believes that the FDA has significantly underestimated the costs and strategic requirements of applying this new legislation that is due to come into force in less than 6 months time on 12 December 2003. To this end we urge them to fully consider all industry comments on the proposed regulations under the US Bioterrorism Act to ensure that such new laws enhance rather than inhibit transatlantic trade flow and reduce, as far as possible, the threat of terrorist intervention.

Finally, we are also seeking clarification regarding exemption from US Bioterrorism Act regulations for small amounts of food product (typically 100g-1kg) sent to the US as technical samples i.e. not for human consumption at any stage. I enclose a more detailed account of the situation at Annex 1.

I trust that you will find our comments helpful and we look forward to being kept informed of further developments on this critical issue. We are copying this letter to relevant officials from DGs Enterprise, Agriculture, Trade and Sanco, US Mission to the EU and DEFRA.

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Annex 1 – Exemption of technical samples from US Bioterrorism Act regulations

A number of FDF member companies periodically send technical food samples to their US subsidiaries for evaluation. The samples may comprise raw or semi/processed goods and are typically 100g to 1kg in volume.

As the samples are used for evaluation purposes only, i.e. not further processed into products for retail to general public or consumption by human beings at any stage, **FDF believe participating companies should be exempt from the requirements of regulations proposed under the US Bioterrorism Act.**

FDA guidelines state that manufacturers operating in research and development facilities to carry out product development and testing will be exempt from the incoming legislation. However, it is not clear if this applies to the sending of technical samples.

FDF would be grateful for further clarification on this important issue.