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28 August 2002

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

Dear Sir/Madam,

**PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS RESPONSE ACT
2002: DRAFT IMPLEMENTING LEGISLATION**

The letter from Joseph Levitt of 17 July 2002 asked for initial comments on the four provisions in Title III, Subtitle A (Protection of the Food Supply) of the above Act. The FDA also arranged an Embassy briefing on 13 August to discuss the Act and reinforced the requirement for initial comments to be received by 30 August. This letter is therefore being sent by e-mail (to meet the deadline) and by post.

The UK has contributed to initial comments that will be provided by the European Commission on behalf of the European Union. However, I have set out here some of the key points/requests for clarification that colleagues in the UK have made in the time available. There has not been an opportunity to consult with trade bodies in the UK so these comments should be treated very much as initial ones.

Docket No. 02N-0275

- Section 303 covers administrative detention of assignments. The UK's concern is that detention procedures could be misused as a barrier to trade, or could be used maliciously. It would be helpful to clarify whether the overall burden of requirements on companies exporting to the US are more or less onerous than on firms within the US producing for the domestic market.

Docket No. 02N-0276

- Section 305 of the Act covers registration of food facilities and requires a list to be drawn up of premises sampling food and animal feed from overseas to the US. It would be helpful to have clarification that it would be the US authorities that would collect the information, maintain it

02N-0276

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and bear the potentially considerable administrative burden. The UK would like to see this register published, not least so that it can check against the records it and its local authorities hold on food premises requiring registration.

Docket No. 02N-0277

- Section 306 covers maintenance and inspection of records for food. This appears to require considerable information on the traceability of food consignments – “all records relating to the manufacturer, processing, packing, distribution, receipt, holding or importation of the food”. It would be helpful to know how the US plans to check that this requirement is being met.

In addition to these comments, we would find it helpful if the implementing legislation were to be explicit as to its scope. The division of responsibilities between US Departments is not always clear. If this legislation is not to cover the commodities for which USDA is responsible it would be helpful to confirm that.

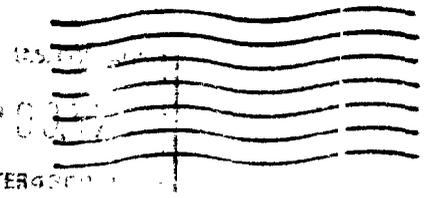
I hope that these very initial comments are helpful in your consideration as you prepare the implementing legislation. The UK would be very happy to participate in any further discussions that you may decide to hold between now and the issuing of the provisional rules in December.

Yours sincerely

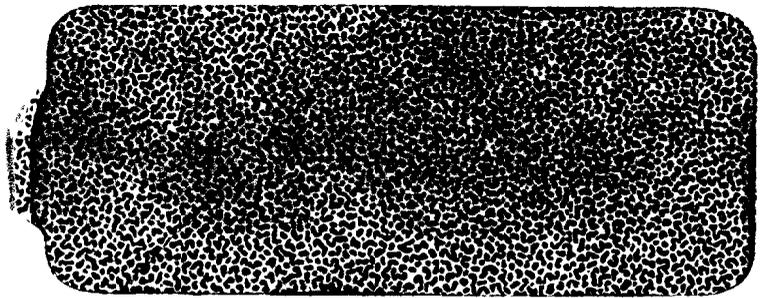


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