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**Bundesvereinigung  
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**Federation of German Food  
and Drink Industries**

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April, 3rd, 2003

**Re: Notice of Proposed Rulemaking Under the Public Health Security  
and Bioterrorism Preparedness Act of 2002**

- **Docket No. 02N-0276 (Section 305 – Registration)**
- **Docket No. 02N-0278 (Section 307 – Prior notice)**

**Comments of the Federation of German Food and Drink Industries (BVE)**

Dear Sir or Madam,

the Federation of German Food and Drink Industries (BVE) welcomes the opportunity to provide comments on the FDA proposals to implement Sections 305 and 307 of the Bioterrorism Act.

BVE is the leading association of the food and drink industry in the Federal Republic of Germany, for the area of economic and trade policy. It represents the interests of Germany's fourth-largest industrial sector, an industry that comprises an especially large number of small and medium-sized companies and that produces a broad range of wholesome, high-quality products. The food and drink industry exports almost 20% of its produce to foreign countries, mainly within the EU and Europe. The US is its largest single overseas export market, with an export volume of roughly US-\$ 800 bn or 3.2% of total German food and drink exports. Over the last years, trade has developed very favourably—in 2002 alone, the volume of German food and drinks exported to the US rose by 7.4%. At the same time, imports originating in the US rose by 7.7% to almost US-\$ 700 bn.

However, this positive trend risks to be disrupted by the proposed rulemaking of FDA.

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In principle, BVE considers legitimate the US objective to protect consumers against the risk of intentional adulteration or any other sort of risks concerning products that are marketed to US consumers.

However, BVE is concerned about the impact the proposed measures may have on trade, notably where these could add cost, delay and uncertainty for exporters. BVE considers that the proposed measures to be applied to food importers—notably the registration requirement of Section 305 of the Act—and imports into the US—the prior notice requirement of Section 307—will impose heavy and costly burdens upon German and EU exporters and will act as a clear non-tariff 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. In our view, FDA seems to have significantly underestimated both the costs of registering and of giving prior notice to FDA.

The US law also appears to contradict attempts made within the WTO in the context of current negotiations to agree on measures that would facilitate trade through the simplification and streamlining of customs procedures.

Finally, further to the rule-making on the Bioterrorism Act, BVE is concerned about the other new US rules relating to international trade which were also inspired by the aim to increase security and prevent terrorist attacks—namely the Container Security Initiative (CSI) and the Customs-Trade Partnership Against Terrorism (C-TPAT). It is BVE's suggestion, therefore, to create links between the different projects in that compliance with one automatically counts as compliance with others. For example, shipments originating in a CSI harbour could be exempt from the prior notice at the FDA. Or, companies taking part in the C-TPAT could be exempt from the proposed keeping of records and from having to register explicitly with the FDA (this could be done internally between US agencies). To be sure, on top of all this, there are already strict EU regulations that member companies need to comply with before products leave our shores.

BVE—as a member of the Confederation of EU food and drink industries (CIAA)—fully endorses the CIAA's comments on the proposed rulemaking which was sent to FDA recently. In addition to that, the German Food and Drink Industry wishes to spell out its specific concerns with the proposed measures. You will find enclosed further more specific and detailed comments on certain provisions of the proposed laws which should be simplified or amended in order to relieve some of the burden that German exporters will have to bear.

Thank you for taking our concerns into consideration.

Yours sincerely,



Dr. Sabine Eichner Lisboa  
Managing Director

**2 Annexes enclosed**