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GELATINE MANUFACTURERS OF EUROPE

25 June 2003
MVE/mcv/465/cor/03-161

Food and Drug Administration
Docket Management Branch
HFA –
5630 Fishers Lane – room 1061
Rockville MD 20582
USA

Attention : Docket N° 02N-0275

**RE BIO TERRORISM ACT
SECTION 303 (ADMINISTRATIVE DETENTION)**

Dear Sirs,

The Gelatin Manufacturers of Europe (GME) represents 9 European companies with a total of 18 production plants and accounts for 45% of worldwide gelatine production and as such we would like to comment on the above proposed Regulation for Registration of Food Facilities.

We thank you in advance for your clarifications and hope you will take our comments into consideration.

Yours sincerely



Marc Vermeulen

Appendix (Comments on Section 303)

02N-0275

249

Bio-terrorism Act - Section 303

Administrative Detention

1. Chapter I. „Background“ (page 4) and III.B.2 „Criteria“ (pages 17, 18):

GME supports the intention of the FDA to require detention only in case of "credible evidence or information indicating" that food presents a threat of serious adverse health consequences. GME also supports the idea that detention will only be ordered on the basis of inspections, examinations, or investigations.

2. Chapter II. Stakeholder Comments (page 12):

It is important that if a detained food is moved to a secure facility, the food will be handled under conditions that will maintain the value and quality of the food. This is important to prevent spoilage of detained food.

3. Chapter III.C.2 „Detention Order“ (page 29):

In this section the FDA is required to issue the detention order to "the owner, operator, or agent in charge of the place where the article of food is located". GME understands that this agent is the US agent who is responsible for registration and prior notice as well. If this interpretation is not correct, there should be a clarification in the text of the proposed regulation.

4. Chapter III.D.1 „Who is Entitled to Appeal“ (page 31):

GME understands from the text that the US agent is also entitled to appeal a detention order ("any person who would be entitled to be a claimant for such article of food"). If this interpretation is wrong, a clarification should be provided in the proposed regulation.