

02N-0275_emc-000028.txt

MessageFrom: Bill Herz [WCHerz@tfi.org]
Sent: Thursday, July 03, 2003 5:04 PM
To: fdadockets@oc.fda.gov
Subject: The Fertilizer Institute Comments on two May 9, 2003 Federal Register Notices

Importance: High
Sensitivity: Confidential

Dear Sir or Madam:

Please find attached The Fertilizer Institute Comments on two May 9, 2003 Federal Register Notices regarding implementation of detention and record - keeping regulations under the Bioterrorism Act. Please note that a hard copy of these comments will follow by regular mail. Thank-you,

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The Fertilizer Institute

Nourish, Replenish, Grow

William C Herz
Director of Scientific Programs

July 3, 2003

VIA FIRST CLASS MAIL

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

Re: Docket 02N-0275

Dear Sir or Madam:

The Fertilizer Institute (TFI), on behalf of its member companies, submits these comments in response to a Food and Drug Administration (FDA) notice of proposed rulemaking (NPRM) published in the *Federal Register* on May 9, 2003 (68 Fed. Reg. 25,242). This notice, entitled "Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002", proposes regulations to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

Statement of Interest

TFI represents the nation's fertilizer industry. Producers, manufacturers, retailers, trading firms and equipment manufacturers which comprise its membership are served by a full-time Washington, D.C., staff in various legislative, educational and technical areas as well as with information and public relations programs.

Some TFI member company facilities produce animal feed and feed additives and, therefore, these facilities are potentially subject to regulation under FDA's NPRM. Further, some TFI member companies hold agricultural commodities for sale and may be eligible for an exclusion from the administrative detention provisions for retail facilities that FDA proposed in another rulemaking as part of its implementation of the Bioterrorism Act (68 Fed. Reg. 5378 (February 3, 2003)). As such, TFI and its members have a substantial interest in this rulemaking.

TFI's Comments

TFI submitted comments on FDA's February 3, 2003 proposal to implement the Bioterrorism Act. The current NPRM adopts the definitions as proposed in the February 3rd proposal. As such, TFI incorporates by reference a copy of its April 4, 2003 comments on the February 3rd proposal (included as an attachment to this letter). TFI recognizes that its members may become subject to the present NPRM, depending on how FDA interprets its statutory authority to regulate "food" under the Bioterrorism Act. Thus, the February 3rd rulemaking wherein the definition of a "food" is provided is the key rulemaking for TFI and its members.

Should you have any questions regarding our comments, please call me at 202-515-2706.

Very truly yours,

William C. Herz
Director, Scientific Programs

Enc.

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