



The Fertilizer Institute

Nourish, Replenish, Grow

William C. Herz
Director of Scientific Programs

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VIA ELECTRONIC DELIVERY

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

Re: Dockets 02N-0276 & 02N-0278

Dear Sir or Madam:

The Fertilizer Institute (TFI), on behalf of its member companies, submits these comments in response to the Food and Drug Administration's (FDA's) interim final rule (IFR) regarding the registration of food facilities, entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," Docket No. 02N-0276, and the IFR regarding prior notice of imported food, entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," Docket No. 02N-0278. Both IFRs were published in the *Federal Register* on October 10, 2003 (68 Fed. Reg. 58894 and 58974, respectively).

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 companies manufacture fertilizer materials that may be used as either fertilizer or animal feed. As such, TFI and its members have a substantial interest in this rulemaking.

TFI's Comments

The key to whether or not a facility is subject to the reporting requirements under the above-referenced regulations is whether a facility manufactures, processes, packages or holds "food" for consumption in the United States. Both IFRs currently define "food" by incorporating the definition of same given in section 201(f) of the Food, Drug, and Cosmetic Act (21 U.S.C.

§ 321(f)), *except* that the definition excludes “food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. § 348(h)(6))” and “pesticides as defined in 7 U.S.C. § 136(u).” Section 201(f) of the Food, Drug, and Cosmetic Act defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”

The issue TFI addresses here is whether companies that manufacture fertilizer materials are subject to the registration and notice of importation regulations. TFI member companies that produce fertilizer materials fall into one of three general categories: (1) those that know the fertilizer materials they produce are used for fertilizer, (2) those that know the fertilizer materials they produce are used for animal feed, and (3) those that produce fertilizer materials that represent multiple use products and the ultimate end use is not specified. It appears those companies that manufacture fertilizer materials for known use in animal feed are subject to the regulations. However, as discussed below, the member companies that fall into categories 1 and 3 above do not appear to be subject to the regulations.

A. Companies That Know the Fertilizer Material They Produce is Used as a Fertilizer are not Subject to the Regulations

Based on our review, it does not appear that fertilizers meet the FDA’s interpretation of “food” under the registration and notice of importation regulations. TFI previously sought clarification of this issue in a comment filed under the docket for each IFR in April 2003.¹ The IFR on notice of importation does not appear to include any response to the comment that fertilizers do not meet the definition of “food.” Response to Comment 64 on Docket No. 02N-0276 for the IFR on registration of food facilities notes that FDA received several comments requesting “an exemption for facilities dealing with agricultural chemicals (*fertilizer*, pesticides).” *See* 68 Fed. Reg. 58911 (emphasis added). While FDA’s response specifically addresses pesticides and concludes that pesticides are excluded from the definition of “food,” it does not specifically address whether fertilizers are also excluded from the definition of “food.”

In addressing pesticides, FDA concluded that where another regulatory agency such as EPA already specifically and comprehensively regulates a certain substance, such as pesticides, it is appropriate to interpret “food” as not to include those substances. *See* 68 Fed. Reg. 58911. Like pesticides, fertilizers are specifically and comprehensively regulated by a number of regulatory agencies at the state level. The 48 contiguous states, Canada, and Puerto Rico have laws and administrative regulations that govern registration of fertilizer products, licensing of firms, label information, inspections, tonnage reports, quality control, guaranteed analyses, etc.² Generally, the state’s department of agriculture or its equivalent is responsible for enforcing fertilizer control laws and regulations.

State regulation of fertilizers is more comprehensive than the proposed FDA regulations. For example, many states specify minimum nutrient contents for fertilizers and require firms selling fertilizers to specify the source of nutrients on the registration application. Many states require

¹ TFI’s comment was filed under Docket No. 02N-0276 on April 8, 2003 and under Docket No. 02N-0278 on April 4, 2003.

² For convenience, TFI attaches with its comments a comprehensive summary of state regulation of fertilizer, entitled “2003 Summary State Fertilizer Laws.”

companies distributing fertilizer to report the amount of fertilizer distributed on a monthly, quarterly, semi-annual, or annual basis. Under quality control regulations, many states test samples of fertilizer and impose penalties on companies selling fertilizer that fail to meet the quality control requirements. Because states already have comprehensive authority to regulate the safety of fertilizers, fertilizers, like pesticides, should not be considered “food” for the purposes of the Bioterrorism Act and FDA’s implementing regulations.

Our understanding that the definition of “food” does not include fertilizer is further supported by FDA’s “Food Facility Registration Form,” Form 3537. Section 11 of the form asks a registering facility to select the general product categories that apply to it. It is broken down into two subsections: (1) section 11a for “Food for Human Consumption,” and (2) section 11b for “Food for Animal Consumption.” The step-by-step instructions provided on-line for registering a food facility indicate that section 11a is required, while section 11b is optional. Under section 11a, the facility is instructed to select as many of the 36 listed categories as appropriate for that facility. The instructions then indicate that “[i]f your facility does not manufacture, process, pack or hold food for human consumption, select box 37: ‘None of the Above Mandatory Categories.’” The instructions indicate that if the facility produces food for human consumption, it must fit into one of the 36 listed categories; otherwise, the only choice left is box 37, indicating the facility does not in fact produce food for human consumption. Also, fertilizer does not fit within any of the 36 listed categories (e.g., bakery products, cheese, fishery/seafood products, meat, soft drinks and water, etc.). Therefore, it must not be a “food” for human consumption. Fertilizer is not a food for animal consumption under section 11b because fertilizers are typically used to promote the growth of articles used in human consumption. Therefore, fertilizers do not come under any of the listed general product categories on the registration form.

As stated in our prior comment, it does not appear that fertilizer meets the definition of “food” under the regulations, and therefore, fertilizer manufacturers are not subject to the registration and prior notice of importation requirements. However, because FDA failed to respond to TFI’s comment in the IFRs, TFI again seeks confirmation of this conclusion

B. Companies that Produce a Fertilizer Material that has Multiple Uses are Not Subject to the Regulations

FDA provided some guidance on whether articles capable of multiple uses meet the definition of “food” in its response to comments on the rule for notice of importation. *See* 68 Fed. Reg. 58986. The FDA stated that it “will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import . . . reasonably believes that the substance is reasonably expected to be directed to a food use.” 68 Fed. Reg. 58987.

Some TFI member companies manufacture fertilizer materials and do not know whether the material, as produced and distributed to down-stream users, will be used for fertilizer (which does not appear to be regulated) or animal feed (which appears to be regulated). For example, some companies may sell the fertilizer material to a broker who then resells the material, some for use as fertilizer, and some for use as animal feed. The company that manufactured the fertilizer material has no way of knowing to whom the broker will sell the material. These

companies should not be subject to the regulations because they do not know with reasonable certainty what the fertilizer material will be used for.

This problem is further compounded by the information required on the registration form. The company that does not know how its fertilizer material will be used down-stream does not know whether it has to register or not. If ultimately all of its material is sold for use as fertilizer, which does not appear to fall under the regulations, the company is not required to register. But the company does not know this beforehand. If some of the fertilizer material is sold as animal feed, it is likely that the facility is required to register and select all applicable food categories under section 11 of the form. But again, the company does not know this information beforehand. This is compounded by the fact that at the end of the registration form, the company must sign a certification statement certifying that the information in the registration is true and accurate. A facility that does not know how its fertilizer material will be used cannot legitimately sign the certification statement.

The issues raised above are resolved when the third party that ultimately makes use of the fertilizer material as animal feed complies with the regulations. That party will be subject to the registration and notice of importation regulations if it stores or uses the material as animal feed, bringing the material into FDA's registration program.

Therefore, we believe that manufacturers of fertilizer materials who are uncertain of the ultimate use of their products are not subject to regulation. **We seek confirmation of this conclusion.**

Conclusion

TFI is pleased to submit these comments. Should you have any questions regarding our comments, please call me at 202-515-2706.

Very truly yours,

A handwritten signature in cursive script, appearing to read "William C. Herz".

William C. Herz
Director, Scientific Programs