

9967 03 10 29 1137
December 8, 2003

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

re: **Comments Regarding Food-Facility Registration #: 15085136788**

Dear Sir or Madam:

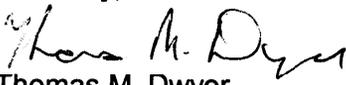
These comments are being submitted in response to the interim final rule of October 12, 2003 (68 FR 58894), which required the registration with FDA of certain food facilities. Concurrent with this letter, International Dioxide Inc. (IDI) is electronically submitting the registration form for its Rhode Island facility. A hard copy of this form is attached.

Although IDI is submitting the facility registration form it is questionable whether the interim final rule actually requires the IDI facility to be registered. By way of background, IDI's Rhode Island facility currently manufactures and distributes chlorine dioxide and sodium chlorite products that are used as antimicrobials on certain processed foods pursuant to 21 CFR ' 173.300 and ' 173.325. The interim final rule under 21 CFR ' 1.227(b)(4) specifically excludes facilities that manufacture or distribute pesticides as defined in 7 U.S.C. 136(u), which is Section 2(u) of the Federal Insecticide, Fungicide and Rodenticide Act or FIFRA. Under this section of FIFRA, a pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pests. In its implementing regulations for FIFRA, EPA specifically exempted from the definition of pest any fungus, bacterium, virus, or other microorganisms on or in living man or other living animals and those in or on processed food (40 CFR ' 152.5).

Accordingly, chlorine dioxide and or sodium chlorite used as an antimicrobial on processed food is not regulated as a pesticide under FIFRA even though its mode of action and function is the same as its use on a raw agricultural commodity. Consequently, the food facility regulations may be interpreted as requiring the registration of facilities that manufacture or distribute chlorine dioxide and or sodium chlorite used on processed foods but exempting facilities that manufacture or distribute chlorine dioxide use on raw agricultural commodities. In our opinion, there is no reasonable basis or public benefit for this discrepancy. Therefore, IDI is requesting that FDA issue an opinion that exempts from the food facility registration requirement any facility that manufactures or distributes antimicrobial products that are not regulated as pesticides because they are exempt under 40 CFR ' 152.5.

If you have any questions about this correspondence, please contact me at 401-295-8800.

Sincerely,


Thomas M. Dwyer
General Manager

2002N-0276

C214