



2538 '03 DEC -2 P4:00

VIA COURIER DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

December 1, 2003

RE: Interim Final Rule - Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0276]

Dear Sir or Madam:

On behalf of its members, the International Activated Carbon Manufacturers Association (IACMA) is requesting a clarification that activated carbon (charcoal) is not a "food" within the meaning of the term as used in the Interim Final Rule - Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58893, 58961 (Oct. 10, 2003) (to be codified at 21 C.F.R. § 1.227(b)(4)).

Activated carbon is used by the food and beverage industries for the removal of impurities and decolorization of liquid food ingredients and food. Activated carbon functions by the adsorption of impurities and color bodies from the food onto the porous surface of its substrate. The process entails either passing the food through a column packed with the carbon or adding activated carbon in powder form to the food, always followed by the complete removal of the carbon via filtration during subsequent steps.

We believe activated carbon is properly excluded from the definition of "food" under the Interim Final Rule because it is a "food-contact substance" as defined in section 409(h)(6) of the Food, Drug and Cosmetic Act, 21 U.S.C. 348(h)(6). Section 409(h)(6) of the Act defines a food-contact substance as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." We believe that activated carbon meets this definition in all current food uses and applications; **activated carbon is not intended to become a permanent part of the food, and therefore is never intended to have a technical effect in the food.** In fact, the food product could be considered adulterated if the activated carbon were permitted

2002N-0276

C171

to remain in the food. The function of processing aids such as activated carbon is very different from that of carbonation gases, emulsifiers or defoamers, which become part of the food product, are intended to remain in the food, and exert a continuing technical effect in the food product. Activated carbon, by contrast, is more akin to ion-exchange materials, which are used to extract or remove impurities during manufacturing but do not remain in food and perform no continuing function in food for consumption.

We believe the position that activated carbon is a food-contact substance is consistent with prior FDA-CFSAN communications with industry, including the training seminar given by Dr. Anna P. Shanklin ("FDA's Food Contact Notification Program, Administrative Guidance and Regulations", dated October 15, 2002 (Slide 9); <http://www.cfsan.fda.gov/~dms/fcnwshan.html>.)

IACMA is requesting FDA concurrence that activated carbon is a food-contact substance within the meaning of section 409(h)(6), and consequently that facilities manufacturing, processing or holding this material are not thereby made subject to the Bioterrorism Act facility registration requirements.

In the event that FDA does not agree that activated carbon falls within the definition of "food contact substance" under section 409(h)(6), IACMA requests that the Interim Final Rule be modified to exempt activated carbon from the definition of "food" for purposes of the registration regulations. The rationale for excluding other food contact substances applies with equal force to activated carbon even if it could be thought of as having a technical effect in food. As explained in the preamble, by using the statutory phrase "food for consumption," Congress apparently intended to limit the reach of the Bioterrorism Act and to focus regulatory attention on food in the more conventional sense of the word. *See* 68 Fed. Reg. at 58908-09. Excluding activated carbon, like other food contact substances, is entirely consistent with this understanding. We therefore urge FDA to exempt activated carbon from the definition of "food" under the final rules if the agency concludes it has not already done so.

* * * * *

IACMA is an international organization of the leading manufacturers, regenerators, reactivators, or impregnators of activated carbon worldwide. Its mission is to promote the safe and environmentally sound manufacture, transportation, use, and disposal of activated carbon in all industries, including those affected by this regulation. The member companies of IACMA are Atofina Chemicals, Inc. Calgon Carbon Corporation, Century Chemical Works, Donau Carbon, Envirotrol, Inc., Haycarb Ltd., Jacobi Carbons, MeadWestvaco, NORIT Americas Inc., PICA, US Filter, Westates Carbon, and Waterlink Barenbey Sutcliffe.

IACMA is firmly committed to product stewardship, and is currently in the process of developing security guidelines for its members, independent of regulatory requirements. For further information, please contact the undersigned at 202-721-4154 or by email at helmet@iacma.org.

Sincerely,



C. Tucker Helmes, Ph.D.
Executive Director

Cc:

Ms. Leslye M. Fraser,
Center for Food Safety and Applied Nutrition (HFS-4)
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740
Leslye.Fraser@cfsan.fda.gov