



ATOFINA Chemicals, Inc.

VIA ELECTRONIC SUBMISSION AND OVERNIGHT DELIVERY

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

November 20, 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:

ATOFINA Chemicals, Inc. (ATOFINA Chemicals) is a diversified manufacturer of chemicals and polymers headquartered in Philadelphia, PA. ATOFINA Chemicals is part of ATOFINA, the chemical branch of TOTAL, a major international oil and gas company. ATOFINA Chemicals is requesting clarification of certain elements of the Interim Final Rule - Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") [68 FR Page 58893-58974, October 10, 2003] and whether certain of our facilities are subject to the registration requirements under these regulations. Our company is segmented into the following business groups: Intermediate and Fine Chemicals, Performance Polymers, and Performance Chemicals. Additionally, Ceraxagri, Inc., a wholly-owned subsidiary of ATOFINA Chemicals offers products for the aquatic, turf and ornamental, and specialty pre- and post-harvest crop markets. Aside from the business activities of Ceraxagri, the facilities owned or operated by ATOFINA Chemicals do not manufacture, process, pack or hold "traditional" food products for human or animal consumption.

**Issue 1 – Status of Facilities that Manufacture, Process or Hold Certain Food Processing Aids**

ATOFINA Chemicals has facilities that manufacture, process or hold certain processing aids, such as activated carbon and perlite, used by the food and beverage industries for purification via the removal of impurities and decolorization of liquid food ingredients and food. Food applications include use in food acids (e.g., citric acid), food proteins, fruit juices, and sweeteners. Activated carbon and perlite function by the adsorption of impurities and color bodies from the food onto the porous surface of the carbon or perlite substrate. The process entails either passing the food through a column packed with the activated carbon or perlite, or by adding activated carbon in powder form to the food, always followed by the complete removal of the carbon via filtration during subsequent steps.

It is our position that processing aids, such as activated carbon or perlite, are food-contact substances as defined in section 409(h)(6) of the Food, Drug and Cosmetic Act (21 U.S.C. 348(h)(6)), and facilities that manufacture, process or hold activated carbon or perlite are not subject to the facility registration requirements under the Bioterrorism Act. 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 processing aids such as activated carbon or perlite meet this definition in all current food uses and applications; these processing aids are not intended to become a permanent part of the food, and therefore never intended to have a continuing technical effect in the food. In fact, the food product could be considered to be adulterated if the activated carbon or perlite were permitted to remain in the food. The function of processing aids such as activated carbon in food processing is very different from that of carbonation gases, emulsifiers or defoamers that become part of the food product, are intended to remain in the food, and exert a technical effect in the food product.

We believe the position that processing aids, such as activated carbon or perlite, are food-contact substances 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> (Slide attached))

A TOFINA Chemicals is requesting FDA concurrence that processing aids used for food decolorization and purification, such as activated carbon or perlite, are food-contact substances, and facilities that manufacture, process or hold these materials are not subject to the Bioterrorism Act facility registration requirements.

## **Issue 2 – Status of Facilities that Manufacture, Process or Hold Certain Secondary Direct Food Additives**

A TOFINA Chemicals has facilities that manufacture, process or hold certain chemical substances that may be used in applications that are regulated as secondary direct food additives (21 CFR PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION) such as boiler water additives used in the preparation of steam that will contact food. Historically, FDA has informally characterized a food additive as being a “direct additive” if it was intended to have a technical effect in food, a “secondary direct additive” if it was intended to have a technical effect on food during food processing but not in the finished food as consumed, or an “indirect additive” if it was intended to have a technical effect in a food contact material. There may be a carryover of chemical residuals to food resulting from the use of secondary direct food additives.

Chemicals used as boiler water additives inhibit scale and corrosion within the boiler system, and improve the efficiency of steam boiler systems. These chemicals are also important for maintaining safe conditions within the steam system as a whole. It is our position that secondary direct food additives, such as boiler water additives, are food-contact substances as defined in section

409(h)(6) of the Food, Drug and Cosmetic Act (21 U.S.C. 348(h)(6)), and facilities that manufacture, process or hold chemical substances that are used as boiler water additives in food facilities are not subject to the facility registration requirements under the Bioterrorism Act. The steam generated by the boiler system in the food facility is intended to contact food and produce the intended effect in or on the food. Boiler water additives, which may be present as residuals in steam, is not intended to have any technical effect in food when consumed.

ATOFINA Chemicals is requesting FDA concurrence that boiler water chemicals used to ensure proper functioning of the boiler system in food facilities are food-contact substances, and facilities that manufacture, process or hold these chemical substances are not subject to the Bioterrorism Act facility registration requirements.

### **Issue 3 – Status of Facilities that Manufacture, Process or Hold Multi-Use Chemical Substances**

ATOFINA Chemicals has facilities that manufacture, process or hold certain multi-use chemical substances. These chemical substances may be used in a variety of markets such as industrial, consumer, food, or cosmetic product applications. Certain commonly used industrial chemicals may be the subject of a regulation under 21 CFR PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION, for example, as synthetic flavoring substances, anti-caking agents or multipurpose food additives. For ATOFINA Chemicals, the sales of multi-use chemicals substances for food applications is typically a minor portion of total sales for the product. Additionally, the company may decide not to market or pursue any sales of a specific product into the food industry due to product stewardship concerns regarding the impurity profile of the chemical substance, or the additional management and handling practices that must be implemented in the facility to ensure the substance is in compliance with the requirements of 21 CFR PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD and the general safety provisions for direct food additives (21 CFR §172.5). It is a standard practice for companies seeking to purchase multi-use chemical substances for use in food applications to require a certification or assurance letter from the supplier regarding the suitability of his product for food use.

In response to Comment 62 of the interim final rule, the Agency stated, “FDA will consider a (multi-use) product as one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance is reasonably expected to be directed to a food use.” It is our position that unless ATOFINA Chemicals has taken steps to market or sell its multi-use chemical substance as a direct food additive via the distribution of promotional product literature, or the issuance of assurance\certification letters to customers regarding the suitability of the chemical substance for use as a food additive, that neither ATOFINA Chemicals nor a food facility would have any reasonable expectation or belief that the chemical substance may be directed to a food use.

ATOFINA Chemicals is requesting FDA concurrence that facilities that manufacture, process or hold multi-use chemicals substances that are the subject of regulation as a direct food additive are not subject to the facility registration requirements under the Bioterrorism Act unless the owner, operator, or agent in charge of the facility has distributed promotional product literature or assurance statements regarding the safe use of the chemical substance as a direct food additive.

#### **Issue 4 – Status of Facilities that Hold Food Ingredients for Use Only in the Production of Food-Contact Substances**

ATOFINA Chemicals has facilities that hold certain chemical substances commonly used as food ingredients, such as vegetable oils or animal product derivatives, for use solely in the production of food-contact substances as defined in section 409(h)(6) of the Food, Drug and Cosmetic Act (21 U.S.C. 348(h)(6)), or as industrial products. These food ingredients are purchased and held at the facility until they are used as chemical reactants or functional additives in the manufacture of various food-contact substances or industrial products.

It is our position that facilities that hold chemical substances that are commonly used as food ingredients for use solely in the manufacture of food-contact substances or industrial products are not subject to the facility requirements under the Bioterrorism Act since these substances are not held for human or animal consumption in the U.S.

ATOFINA Chemicals is requesting FDA concurrence that facilities that hold chemical substances commonly used as food ingredients, such as vegetable oils or animal product derivatives, for use solely in the manufacture of food-contact substances or industrial products are not subject to the facility requirements under the Bioterrorism Act.

#### **Issue 5 – Status of Registered Pesticide Producing Facilities that Manufacture, Process, Pack or Hold Food Additives**

ATOFINA Chemicals has facilities that manufacture, process, pack or hold two types of products: pesticide products and adjuvants for pre- and post-harvest agricultural use, and non-pesticidal fruit and vegetable coatings and cleaners. Fruit or vegetable cleaners are used to remove light field dirt, calcium deposits or surface bloom from harvested produce prior to coating. Fruit or vegetable coatings are used after the washing processes to protect the produce during handling, transportation and storage, and to enhance the attractiveness of the fruit or vegetable to the consumer. Substances used in fruit/vegetable washes and cleaners are typically substances considered to be Generally Recognized as Safe (GRAS), or otherwise regulated for safe use on fruits/vegetables under the food additive regulations.

Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that no person shall produce any pesticide or any device in any state/territory unless the establishment in which it is produced is registered with the US Environmental Protection Agency (EPA). The ATOFINA Chemicals facilities that manufacture, process, pack, and hold fruit and vegetable cleaner and coating products are registered pesticide producing establishments due to their primary business activity with the manufacture of pesticides.

ATOFINA Chemicals is requesting clarification as to whether these EPA-registered pesticide producing establishments must also register with FDA under the Bioterrorism Act.

**Issue 6 – Designation of an Emergency Contact for a Domestic Facility**

The interim final rule on facility registration requires facilities to provide an emergency contact who is accessible 24 hours/day, 7 days/week. As noted in the Agency's response to Comment 116 and Comment 120 of the interim final rule, the emergency contact does not have to be located at the facility, but does need to be accessible to FDA in case of an emergency. The interim final rule does not require an individual to be designated as the emergency contact. Based on these responses, ATOFINA Chemicals believes that we can provide the phone number of an organization such as CHEMTREC® (Chemical Transportation Emergency Center) as the emergency contact for certain facilities under the Bioterrorism Act. CHEMTREC's 24-hour Emergency Call Center is located in Arlington, Virginia and is an integral part of the American Chemistry Council (ACC). ATOFINA Chemicals, Inc. is a member company of the ACC, is registered with CHEMTREC, and provides emergency and administrative contacts for our company and facilities to CHEMTREC in the event additional information or emergency assistance is required.

ATOFINA Chemicals is requesting FDA concurrence that we may provide the CHEMTREC phone numbers as our emergency contact for certain domestic facilities.

ATOFINA Chemicals Inc. appreciates this opportunity to comment on FDA's interim final rule on facility registration.

Should you require any additional information or clarification regarding our request, please feel free to contact me.

Sincerely,

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/enclosure



## More Examples of FCS

- Substances that are used in the manufacture of food. **For example, boiler water additives, ion exchange resins.**
- Constituents of Food Additives. **For example, monomers of polymeric material.**
- GRAS and Prior-sanctioned substances that meet the statutory definition of a food contact substance. **For example, pulp and sodium sulphate.**