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VIA ELECTRONIC SUBMISSION
AND FEDERAL EXPRESS

July 3, 2003

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

Re: BASF Corporation's Comments on FDA's Proposed Regulation on "Establishment and Maintenance of Records (Docket No. 02N-0277)

Dear Sir:

In response to the Food and Drug Administration's (FDA) notice of proposed rule making entitled "Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," BASF Corporation is respectfully submitting comments. The proposal, which was published in the Federal Register on May 9, 2003, (68 Fed. Reg. 25188) requests comments with regard to the establishment and maintenance of certain records by domestic and foreign facilities that would identify the immediate previous sources and the immediate subsequent recipients of food. Specifically, the proposal applies to domestic facilities that manufacture, process, pack, transport, distribute, receive, hold or import food and to foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States.

Based in Mt. Olive, New Jersey, BASF Corporation (BC) is the North American affiliate of BASF Aktiengesellschaft, Ludwigshafen, Germany. BC's diverse product mix includes chemicals, coatings, plastic, colorants, and health and nutritional products. Many of these products, which are either manufactured here in the U.S. or imported from our foreign affiliates, have applications in food as food additives. Given the proposal's definition of food as the meaning given in section 201(f) of the Federal Food Drug and Cosmetic Act, BC, as a manufacturer and supplier of both direct and indirect food additives, is subject to the proposed rule.

BASF supports Congress and the FDA in efforts to protect the U.S. food supply from threatened or actual terrorist attacks. Indeed, any and all contemplated measures designed to protect our society from an outbreak of food-borne illnesses are commended and taken seriously. BC believes, however, that FDA is not required to promulgate regulation for the establishment and maintenance of records under the Bioterrorism Act. We are concerned that although FDA was not required to do so, expansive requirements were proposed, irrespective of established industry practices, placing an undue burden on business without a corresponding benefit to the security of the food supply. Further, BC believes that Congress intended the Bioterrorism Act to place safeguards on edible foods and their intended ingredients. We are concerned that the definition of food in this proposal and others published by the FDA under the Bioterrorism Act¹, is too broad going beyond Congress's original intent, also imposing a substantial burden on industry without a corresponding benefit to the safety of the food supply.

02N-0277

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¹ Reference is made to comments submitted by BC under docket No.02N-0276 and No. 02N-0278.
3000 Continental Drive-North, Mount Olive, New Jersey 07828-1234 Telephone (973) 426-2600

Comments With regard to FDA's Interpretation of Section 306(d) under the Bioterrorism Act

FDA has requested comment with regard to its interpretation that it is required by section 306(d) of the Bioterrorism Act to exercise authority in section 414 (b) of the Federal Food, Drug and Cosmetic Act (the act). BC disagrees with FDA's interpretation. As enacted by Congress the Bioterrorism Act under Title III, subtitle A, provides in part for (1) the registration of food facilities, (2) the prior notice of imported food shipments, (3) the maintenance and inspection of records for foods and (4) administrative detention. While we agree that FDA is required to promulgate regulation for the registration of food facilities, prior notice of imported food shipments, and administrative detention, we do not believe that FDA is required to promulgate regulation for maintenance and inspection of records.

Our interpretation is based on Congress's use of the word "shall" when providing instruction for promulgating regulation for the registration of food facilities, prior notice of imported food shipments and administrative detention². When providing instruction for promulgating regulation for the maintenance and inspection of records³, however, Congress states first that FDA "may" by regulation establish record-keeping requirements and then later that FDA "shall" issue proposed and final regulation no later than 18 months from the date of enactment⁴. The use of the word "may" appears to have given FDA discretion with regard to the need for regulation. We believe Congress instructed FDA to thoroughly consider the status of current trace back capabilities and to promulgate regulation only if the need was clearly identified. If FDA determined that regulation was needed, proposed and final regulations were to be promulgated within the 18-month time frame. Therefore, FDA was not required to promulgate regulation, rather could exercise discretion with regard to the promulgation of regulation for the maintenance and inspection of records.

BC believes that established industry practice with regard to investigating product defects and conducting product recalls are consistent with the terms of the Bioterrorism Act allowing for the rapid identification of the immediate previous source and immediate subsequent recipient of foods. In addition, industry's response to the events of 9/11 has strengthened these existing practices. For example, as an inevitable result of our commitment to Responsible Care Security Code #7 and increased requests from our customers, emphasis is now shifting from security at fixed plant sites and major distribution centers to security of products throughout the value chain. This shift in emphasis furthers our need to ensure the integrity of our products until it reaches its final destination and ultimately enhances existing trace back capabilities. Thus, we believe the controls needed to effectively trace the source and recipient of foods are already in place.

As noted above BC believes that FDA was not required to promulgate regulation with regard to the establishment and maintenance of records, yet an expansive set of requirements were proposed without regard to established industry practice. Although the information specified by FDA is typically available, the cost associated with redesigning systems, practices and access procedures to meet the requirements of the proposal, aimed at allowing FDA to trace the transportation of food, is substantial. The justification for the cost is questionable when industry itself is well equipped to trace the transportation of the foods they produce without an additional set of governing regulations. Thus, we believe that FDA should consider established industry practice and current trace back capabilities and to partner with private industry when responding to or containing adulterated foods that present a threat of serious adverse health consequences. This

² In section 305(e) of the Bioterrorism Act, in section 307(c) of the Bioterrorism Act and in section 304(h)(2) of the act as added by section 303(a) of the Bioterrorism Act, respectively.

³ In section 414(b) of the act as added by section 306(a) of the Bioterrorism Act.

⁴ Section 306(d) of the Bioterrorism Act.

approach will maximize the effectiveness of responding to such events while minimizing associated cost.

Request for Indirect Food Additive Exclusion from the Definition of Food

BC believes that Congress intended the Bioterrorism Act to place safeguards on edible foods and their ingredients. While the comments contained herein are in response to FDA's proposal for the establishment and maintenance of records under section 306 of the Bioterrorism Act, reference is made to the registration provisions under section 305. As enacted by Congress, section 305 of the Bioterrorism Act requires facilities engaged in the manufacturing, processing, packing, or holding of "food for consumption" in the U.S. to register with the Secretary. Section 306, in part, informs FDA that it may by regulation establish requirements regarding the establishment and maintenance of records as needed to identify the immediate previous source and immediate subsequent recipient of food. Although the term "food for consumption" is not explicitly used in Section 305, FDA is proposing that foreign facilities required to register under section 305 also be required to establish and maintain records under section 306. Thus, it would appear that FDA views the word "food" as used in section 306 synonymous with the term "food for consumption" used in section 305. Within the true meaning of the words, "food for consumption" can only be interpreted as food that can be eaten in its present state, or edible food.

BC supports proposals under the Bioterrorism Act for edible food including direct food additives insofar as they become intended ingredients of food for consumption. However, BC does not support the inclusion of indirect food additives in *any* proposed regulation under the Bioterrorism Act and is requesting that FDA exclude indirect food additives⁵ from the definition of food as found in all proposals. The primary function of an indirect food additive is associated with the manufacture of food contact articles, not as an ingredient of food for consumption. Although it is a "component of immediate food packaging intended for food use", as described in the proposal's definition of food, BC does not believe it was the intent of Congress to extend any requirement under the Bioterrorism Act to that length. The following comments are provided in further support of our position.

At the 1/29/03 satellite public meeting to discuss the proposed registration requirements, an FDA official stated that the definition of a "manufacturer" means "anyone combining one or more food *ingredients*." While the definition of a "manufacturer/processor" as proposed by the registration requirements and other implementing regulations under the Bioterrorism Act⁶ includes additional language, i.e., "... or synthesizing, preparing, treating, modifying or manipulating food, including food crops or *ingredients*" the language reinforces that manufacturing/processing is making food from one or more ingredient and that the food that is made is "edible". Examples of manufacturing/processing that are included under the definition are clearly examples of edible food. Thus, it would appear FDA believed that Congress envisioned manufacturers of food for consumption (anyone combining one or more food ingredient) subject to the requirements under the Bioterrorism Act. In addition, those synthesizing or preparing direct food additives would be subject to requirements as direct food additives are intended *ingredients* of food for consumption. BC believes that manufactures of indirect additives do not meet the proposed definition of a "manufacture/processor" as indirect additives are components of the packaging material that, due

⁵ Within the context of the definition of food additives as given in 21 CFR 170.3 and the definition of food as found in the proposal, an indirect food additive for purposes of these comments are "components of immediate food packaging or food contact articles that migrate into food from the food packaging or the food contact article".

⁶As defined by 21 CFR 1.227(c)(6) under the proposed registration requirements and, 21 CFR 1.328 under the proposed record-keeping requirements.

to migration, may become an unintentional component, not an intended ingredient, of the finished edible food.

As further support that Congress envisioned the requirements under the Bioterrorism Act to extend to the manufacturing, processing, packing and holding of food for consumption, including direct food additives, is the Bioterrorism Act's reference to the food categories as identified under 21 CFR 170.3. In the Bioterrorism Act, Congress instructed FDA that as part of the registration process it may require each facility to submit the general food category of any food manufactured, processed, packed or held by the facility. FDA's proposal includes, as mandatory fields of the registration form, categories from 21 CFR 170.3. The food categories stated in 21 CFR 170.3 are specific for food products and for direct human food ingredients that may be added to food products (direct food additives). 21 CFR 170.3 does not include categories for indirect food additives.

The inclusion of indirect food additives in the definition of food for purposes of FDA proposals under the Bioterrorism Act will impose a tremendous burden on industry that is disproportionate to the risk associated with contaminating the U.S. food supply from that source. Indirect food additives are not likely to be the method of choice for use in a food-borne related terrorist attack. These substances are too far removed from the food chain in that they become unintended components of the finished food as a result of migration from the food-packaging article. If the components were contaminated with terroristic agents, biological or chemical, most would not survive the manufacturing processes employed during the production of the food-packaging article. For those that may survive, migration from the finished package would have to occur in quantities that would have the desired effect. Thus, choosing this method to launch a terroristic attack poses obstacles that are counter productive to the overall success of any attempt.

BC would also like to note that chemical manufacturers are subject to a variety of initiatives designed to protect our country from terrorist attacks. Most notably are those initiatives under the American Chemical Counsel's Responsible Care Security Code #7 as previously mentioned. These initiatives requires BC and other chemical companies to assess the threats and vulnerabilities associated with each product and institute security measures as appropriate. This type of a targeted assessment maximizes product security at reasonable costs. BC does not believe that requiring manufacturers, packers or holders of indirect food additives to comply with the provisions under the Bioterrorism Act will have the same affect and urges FDA to consider these other initiatives prior to issuing a final rule.

Comment Regarding Record Availability Time Frame

Proposed section 1.361 requires, in part, that records must be made available within 4 hours of a request if the request is made by FDA between 8 a.m. and 6 p.m. Monday through Friday or within 8 hours if made at any other time. BC believes that a 24-hour time frame for records from domestic firms and a 36-hour time frame for records from foreign firms is more appropriate as the time frames proposed are too restrictive and in some cases nearly impossible to meet. As noted by FDA in the proposal, records are often stored in a complex database and depending on the nature of the food product, retrieval of the required information within 4 to 8 hours may be difficult if not impossible. These time frames are of particular concern if U.S. Agents will be required to supply FDA with records from the foreign supplier, as time differences will further impede the process. We appreciate the need to respond rapidly when attempting to remove adulterated food that presents a threat of serious adverse health consequence or death to humans or animals. However, we also believe that a 24-hour time frame for domestic firms and a 36-hour time frame for foreign firms, regardless of the time of the request, is realistically attainable for firms responding to such a request and still provides for an efficient and effective trace back process.

Comment Regarding Identification of Responsible Individuals

Proposed sections 1.337 and 1.345 requires, in part, that non-transporters include in records the name of the firm and a responsible individual at the firm identified as the immediate previous source and immediate subsequent recipient of the food. In addition, non-transporters are required to include in records the name of the firm and a responsible individual at the firm who transported the food to or from you. BC believes that the name of a responsible individual at the firm is not necessary to identify the immediate previous source or subsequent recipient of food and will not assist with the effectiveness of responding to credible threats to the U.S. food supply. This type of information is not generally collected when using automated order processing or purchasing systems. Requiring firms to obtain this information is duplicative and therefore especially burdensome when identifying the non-transporter immediate previous source and immediate subsequent recipient of food as these firms will be required to register under section 305 the Bioterrorism Act and, as part of the registration process, an emergency contact must be identified.

Comment Concerning The Use of a Model Form

In the proposal FDA requested comment on whether a final rule should include additional provisions, such as a model form that can be used to record all the required information. BC does not believe that model forms should be used. If final regulations are promulgated for the maintenance and inspection of records, affected businesses should decide the format in which the required records should be kept as dictated by specific business practices. The use of a model form will be burdensome, as it will minimize flexibility with regard to varying compliance systems.

* * * * *

In summary, BC does not believe that FDA was required to promulgate regulation for the establishment and maintenance of records under the Bioterrorism Act. The expansive set of requirements proposed, designed to give FDA the ability to trace the transportation of food, did not consider industries' current trace back capabilities and places an undue burden on businesses without a corresponding benefit to the security of the food supply. We are also requesting that FDA exclude indirect food additives from the definition of food for all final regulations promulgated under the Bioterrorism Act. We believe the inclusion of these substances is contrary to Congress's original intent and will impose a tremendous burden on industry that is disproportionate to the risk associated with contaminating the U.S. food supply from that source. Finally, comment is provided with regard to the record availability requirements, the identification of responsible Individuals and the use of a model form.

We appreciate the opportunity to comment on the proposed rule and respectfully request that FDA consider them before issuing a final rule.

Sincerely,



Claudia Elias
Regulatory Manager
Product & Trade Regulation