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1572 '03 APR -3 A 9105 ELECTRONIC SUBMISSION
AND FEDERAL EXPRESS

April 2, 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 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket No.02N-0278)

Dear Sir:

BASF Corporation ("BC") respectfully submits comments (to Docket Number 02N-0278) regarding the Food and Drug Administration's (FDA) notice of proposed rule making entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" ("the Act"), which was published in the *Federal Register* on February 3, 2003, (68 *Fed. Reg.* 5428). FDA's notice of proposed rulemaking requested comments with regard to the proposal to require prior notice of imports to be submitted to the FDA.

Based in Mt. Olive, New Jersey, BC is the North American affiliate of BASF AG, 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 imported¹ from our foreign affiliates, have applications in food as food additives. Given the proposal's definition of food is 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.

BC supports Congress and the FDA in efforts to protect the U.S. food supply from threatened or actual terrorist attacks. 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 certain measures set forth in the proposed rules will not assist in protecting the U.S. food supply and will unnecessarily increase the workload for both the FDA and industry. Therefore, BC respectfully asks that FDA consider our comments.

Request for Exclusion for Indirect Food Additives Not in Final Form and in Contact with Food from the Definition of Food

As the definition of "food" used in the proposed rule includes "food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food" the proposed rule potentially applies to the importation of food contact substances on an individual basis prior to them being incorporated into a food package, and to food packaging at its time of import prior to its in contact with food. The Bioterrorism Act is not specific on this point regarding indirect food additives; however, there is legislative history as to Congressional intent. The Act's Committee Report states that the requirements of prior "import notification should not be construed to apply to packaging materials if, at the time of importation,

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¹ The comments submitted to this docket specifically relate to the proposed rule regarding the prior notice of imported food shipments. BC will be submitting under separate cover comments on FDA's notice of proposed rulemaking regarding the registration of food facilities.

such materials will not be used for, or in contact with, food as defined under section 201 of the FFDCFA." This language clearly expresses the intent to exclude from prior notice all food packaging and food packaging materials not in contact with food at the time of import.

Given this legislative history, the comments of Rep. John Shimkus (R-Ill.), one of the sponsors of the Bioterrorism Act, entered on May 24, 2002 into the Congressional Record clearly indicate that the import of food contact substances and food packaging materials of which food contact substances are components, are not required to have prior notice. Congressman Shimkus stated that "Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances, if at the time of importation, they are not used in food" [emphasis added].

BC believes it is Congressional intent to exclude from prior import notification, all food contact substances, as individual components or as packaging itself. There is limited, if any, increase in protection of the U.S. food supply by requiring notice of such imported materials. Furthermore, BC is a manufacturer of food contact substances such as resins and other components used downstream by other manufacturers in the production of food packaging. Should there be a question of safety or contamination of the food contact substances, the processing used to manufacture a food packaging would likely either eliminate or detect such toxic components.

Furthermore, we believe including indirect food additives such as food contact substances and food packaging in the prior notice import process would require additional work on the part of FDA before such additives could be included in the prior notice program. Currently many indirect food additives, such as monomers and polymers for food packaging (or even direct food additives such as hydrochloric acid) do not have FDA product codes, a required field on the prior notice forms. Before requiring prior notice, FDA would need to develop and publish the FDA product codes for all such ingredients.

BC requests clarification from FDA that the proposed requirement for prior notice of import of food does not include food contact substances or food contact packaging imported prior to their contact with food.

Pre-approval Process/Program for "Low Risk" Importers Similar to U.S. Customs' "C-TPAT"

BC asks FDA to consider implementing a program similar to the U.S. Customs "Customs-Trade Partnership Against Terrorism" (C-TPAT). This program allows importers who have been identified as being "low risk" to be subject to less extensive inspections upon submission of proof that they have secured their supply chains.

Harmonized Tariff Numbers

BC would like to mention that some Harmonized Tariff Schedule numbers used for tariff classification purposes for chemicals and chemical products found in Section VI of the Harmonized Tariff Schedule of the United States are of a general nature, i.e. they are general descriptions that can cover various products, which may or may not cover a food or non-food article. BC is concerned that such tariff numbers may trigger a requirement for prior notice for such an article when in fact the article is not a "food." Section B(2)(d) of the preamble to the proposed regulations states that "[with] respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required if the article is being imported for use as food". We assume that the importer is to make this determination, but we are concerned that the FDA may indeed request a prior notice if the imported goods are entered under a generic Harmonized Tariff Schedule number that could refer to a food or non-food article import. We urge FDA to address this ambiguity and establish a mechanism to ensure that a non-food article with a generic tariff number does not trigger a requirement for prior notice.

Growers' Identification, If Known, Is Not Applicable to Food Additives

FDA requires identification of a grower of an article of food, if known. BC is a manufacturer of synthetic food additives. In most cases, an import of a food additive would not have a "grower" associated with such an

import as the additive is manufactured from synthetic chemical or other components. BC has noted that the fields for "Grower" does not have a non-applicable ("N/A") box associated with them. BC requests that FDA include a N/A box in the field along "Name of Firm" for growers to indicate that a grower does not apply to food additives and other synthetic food components or compounds. Without such a N/A box, BC is concerned that the application may be considered incomplete and an import refused, when in fact the application is complete either because there is no grower for the article or because the grower is not "known at time of submission" of the prior notice.

Clarification on Prior Notice Forms

In BC's review of the proposed prior notice forms, it noted a number of fields that may lead to ambiguous results or difficulty in obtaining data within prescribed timeframes. BC asks that the FDA consider clarifying the requirements for these fields, or adding additional explanatory language to address these concerns. In addition, if a prior notice is deficient, will the FDA indicate to the submitter which fields on the form are deficient? Such identification will assist in the rapid resubmission of the corrected prior notice.

As previously mentioned, there are no FDA product codes for many food contact substances such as monomers and polymers for food packaging, or even for some direct food additives such as hydrochloric acid. BC requests, that if FDA intends to require prior notice food contact substances and food packaging, that it develop and publish a list of the FDA product codes in sufficient time before the implementation of the final rule for the regulated entities to comply with the prior notice requirements.

BC has multiple sites for manufacture, warehousing, administration, and other activities. Frequently the BC site as a "submitting firm" will be an administrative site, that is not required to be registered as a food facility under the Bioterrorism Act or the proposed rules for registering domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States (68 *Federal Register* 5377, February 3, 2003). The proposed section 1.288(a) requires that information required on the form includes "...if a firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility." This proposed language implies that if a firm is required to register a facility associated with the article of food being imported, then it must be submitted on the prior notice form under "Submitting firm" information. As BC has multiple facilities, some of which may be associated with the imported article of food and registered facilities, but none with the address listed for the Submitting firm, we ask FDA to clarify what, if any, registration number be placed in this field.

Also, the requirements for including the FDA registration numbers of facilities not known to the Submitting firm, or to the agent, is information not previously required for importation. Furthermore, the port of arrival is not always entered into databases of the Submitting firm, or to the agent, and will require additional investigation. The U.S Customs port of arrival is the information customarily obtained by Submitting firms. Obtaining this additional information regarding registration numbers of other facilities or the port of arrival may require more time on behalf of the Submitting firm or its agent. Consequently, BC would like FDA to consider the timeframes for submitting the prior notices given the amount of time that maybe needed to obtain all the required data for the submission. We also request that FDA issue guidance to address approaches to obtaining the FDA registration numbers of third-party facilities that would facilitate completion of the prior notice forms.

It is not an unusual occurrence to have a product exported by BC returned without having left the foreign port warehouse. BC requests clarification on whether FDA intends to have exported articles of food that are returned be required to have a prior import notification. If FDA should require prior notification in such circumstances, we ask that FDA clarify how the form should be completed for Manufacturer and Originating Country.

Confidential Business Information and the Need for On-line Security of Notices

BC commends FDA for the proposed provisions under 21 CFR 1.243 as some of the sensitive information provided in the registration form should clearly be protected from disclosure. We believe this sensitive information disclosed in the prior notice form should also receive the same protection as the information in

the registration form. We request that FDA expand such coverage to "confidential business information" ("CBI") that will appear in the prior notice forms.

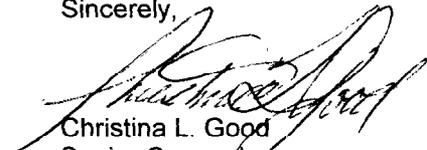
At the public meeting to discuss the proposed regulation, an FDA official stated that it will share the information in the registration with other agencies, provided the other agencies give written assurance of confidentiality. BC is concerned that this written assurance will not ensure that the information obtained by other agencies will receive the same confidential treatment that would be given by FDA where it is specifically protected from public disclosures. We therefore urge FDA to ensure that the same level of CBI protection is required and required for the same data from other agencies if information from the prior notice form is shared. For example, the U.S. Customs Regulations restrict the publication of confidential information contained on inward manifests (Part 103, Subpart C – "Other Information Subject to Restricted Access" noted), but the information in the prior notice forms may not be the same as on an inward manifest.

BASF is also concerned about the security of the registration information submitted electronically. Specifically, we would like the final rule to address the security measures with regard to accuracy and access that will be taken to protect the transmittal of information.

In Conclusion

In summary, BC believes that it was not the intent of Congress to require prior notice of importation for food contact substances or packaging prior to being in direct contact with food. We believe such extension of the requirements of prior notice to indirect food additives places an undue burden on business and FDA without a corresponding benefit in protecting the food supply. We therefore are requesting that FDA exclude these food contact substances and food packaging from the proposed regulation's definition of food. We also are requesting clarification with respect to information required for the prior notice form, the extent of protection for confidential business information, and certain U.S. Customs procedures and classifications. We appreciate the opportunity to comment on the proposed regulations and respectfully request that FDA consider our comments prior to issuing a final rule.

Sincerely,



Christina L. Good
Senior Counsel
Product and Trade Regulation