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July 8, 2003

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

Re: Docket No. 02N-0277, Proposed Rulemaking "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002"

To Whom It May Concern:

The North American Millers' Association (NAMA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed regulation on the establishment and maintenance of records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (a.k.a. The Bioterrorism Act). The tragic events of September 11, 2001 demonstrated the need to protect the U.S. public from the threat of terrorist attacks, and the FDA plays an important part by ensuring the security of the U.S. food supply. NAMA supports the increased focus on security and the efforts of Congress and the FDA to improve current food chain practices to help guard against potential attacks.

As the national association representing 46 milling companies and over 95% of the U.S. milling capacity for wheat, corn, oats and rye, NAMA and its members have a vested interest in maintaining a safe food supply. To help maintain a safe food supply NAMA members work diligently to comply with all U.S. regulations governing food safety and plant security. In addition, NAMA members often set higher internal standards in order to ensure the products a mill is processing are of the highest possible quality.

Since NAMA members firmly believe in the need for a safe food, NAMA members support the concept of enhanced record maintenance that FDA has proposed.

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However, as members of the entire food chain and companies in the business of providing food to U.S. and foreign customers, NAMA wants to emphasize several points that the FDA should clarify and address in its final regulations.

Clarification of Reasonably Available

In section 1.337(a), FDA is proposing to require that anyone governed by the regulation "include information reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products." The proposed regulation continues by recognizing that many companies in the food industry rely on multiple sources of ingredients and commonly commingle those ingredients to produce a finished product. While NAMA appreciates FDA's recognition of the commingling of ingredients, NAMA is concerned that the regulations do not properly clarify what will satisfy the requirement of "reasonably available" to effectively avoid failing to comply.

FDA officials have verbally expressed their willingness to be flexible regarding what information is reasonably available to the food industry given their standard practices as long as the basic information requirements are met. NAMA believes that a written definition of what is meant by "reasonably available" and some criteria by which this definition can be objectively determined by an FDA official would give industry a better guideline and avoid possible disputes.

Maintain Flexibility

NAMA wants to commend the FDA for providing flexibility in its regulations on records by allowing for the use of existing records to meet these requirements. Many millers already request and keep much of the information the FDA is proposing to require. However, NAMA cautions against using any "one size fits all" generic form as an example or requirement. Example forms can become informal requirements out in the field though originally only meant as a guide. Providing further example scenarios where records would be in compliance and non-compliance within the final regulations may solve this problem.

NAMA also encourages FDA to maintain its flexibility regarding the exact type of information that is available to the food industry. Not all companies require or need the same type of identification as other members in the food chain, i.e. lot numbers and identity preserved ingredients. Recognizing this fact, the FDA should not define rigid identification requirements. By keeping this flexibility, the FDA can preserve the intent of the Bioterrorism Act and still avoid dramatic changes to what are currently efficient and effective business practices.

Protection of Trade Secrets and Confidential Information

NAMA desires the addition of explicit procedures that the Secretary plans to implement to prevent the unauthorized disclosure of any trade secrets or confidential information. The level of document access granted to FDA officials under the Bioterrorism Act should require an equally high level of protection of sensitive information. Reemphasizing the importance of current protections and legal requirements during FDA instruction will not suffice. Documents deemed confidential or trade secrets by a company should not be subject to the Freedom of Information Act (FOIA) and should only be accessed by appropriate FDA officials if deemed critical to an ongoing investigation. These safeguards need to be specifically addressed in the final regulation.

Compliance Assistance

The FDA should recognize that not all companies in the food chain and, not even all companies in a specific sector of the food chain, have the same capability to understand or comply with the proposed requirements. The additional time FDA provides for small businesses to comply with the regulation is necessary and correct. NAMA encourages FDA to also provide all businesses, upon request, additional assistance in order to ensure proper compliance by the respective deadlines. The assistance will help small or conservatively staffed companies better understand how they might comply with the regulations using existing information and what new information might need to be collected. Compliance assistance will help to assure that the food industry is meeting requirements and that food security is not jeopardized due to an inability to fully comply.

Possible Impact on International Trade

NAMA is concerned that the proposed regulations may lead to unintended consequences to the regulation of U.S. goods in foreign trade. The system that FDA is proposing provides for the establishment and maintenance of records identifying the previous and subsequent source for all food articles. This system, while conceived solely as a mechanism to secure the U.S. food supply, also establishes a precedent for government regulated traceability of food articles. Though this system has substantial flexibility and the process of tracking food back to its source is currently conducted by government agencies, the codification and regulation of such a process is new. FDA should work with other government agencies to demonstrate the differences between this proposed system and a system of traceability and identity preservation proposed by many foreign countries for use with genetically modified crops. Without collaboration and careful planning, this proposed regulation could be used to legitimize foreign trade proposals detrimental to U.S. trade interests.

Thank you for the opportunity to provide comment on this proposed regulation. NAMA looks forward to working with the FDA on these and other regulations to help ensure the security of the U.S. food supply. If you have any questions please contact me at 202/484-2200, ext. 104 or at bfaga@namamillers.org.

Sincerely,

Betsy Faga

Betsy Faga
President