National Grain
and Feed Association
www.ngfa.org

1250 Eye Street, N.W., Suite 1003
Washington, DC 20005-3922
P: (202) 289-0873
F: (202) 289-5388

June 8, 2015

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

RE: Docket No. FDA–2002-N-0323 – Proposed Rulemaking: Amendments to Registration of Food Facilities

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration's (FDA) proposed rule that would amend its regulation for registration of food facilities, which was published in the April 9, 2015 edition of the ***Federal Register***.

Established in 1896, the NGFA comprises more than 1,050 member companies that operate more than 7,000 facilities and handle more than 70 percent of the U.S. grain and oilseed crop. The NGFA's membership encompasses all sectors of the industry, including country, terminal and export grain elevators; commercial feed and feed ingredient manufacturers; biofuels producers; cash grain and feed merchants; end-users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also has strategic alliances with the North American Export Grain Association and Pet Food Institute. In addition, affiliated with the NGFA are 26 state and regional grain and feed trade associations. Canadian and Mexican firms also are NGFA members.

FDA's proposed rule to amend the agency's regulations for food facility registration, 21 CFR Part 1, Subpart H, contains several proposed revisions that are intended to codify facility registration-related provisions of the Food Safety Modernization Act (FSMA). In addition, FDA also is proposing a number of amendments that the agency believes would "improve the utility" of the food facility registration database. The NGFA's comments within this statement are directed at the latter category of FDA's proposed amendments – those that are not mandated by FSMA, but rather are being proposed by the agency for other purposes.

Specific Comments on Proposed Amendments

Use of DUNS Numbers

FDA is proposing that facility registrations must include a Dun and Bradstreet's Data Universal Numbering System (DUNS) number – a unique 9-digit identifier provided by Dun and Bradstreet that can be specific for each facility.

According to FDA's proposal, after a facility completes its registration, the agency would verify the accuracy of the facility's DUNS number and confirm that the facility-specific address associated with the DUNS number is the same address associated with the registration. In addition, FDA would not confirm the registration or provide a registration number until it verifies this information.

FDA in the preamble of the proposed rule states that requiring facilities to submit DUNS numbers would enable the agency to verify the facility-specific address information associated with those numbers, which would increase the accuracy of the registration database. In turn, FDA states that its inspection activities would be more efficient because the agency would be able to more readily identify and locate food facilities for inspection.

Although the NGFA supports FDA's efforts to maintain an accurate list of registered food facilities and more efficiently conduct its inspection activities, the NGFA is strongly opposed to the proposed provision that would require each facility to obtain a DUNS number and provide it to the agency during its food facility registration.

Many NGFA members do not have DUNS numbers for each facility that is required to register with FDA. Further, many of our members have experienced significant difficulties when attempting to obtain a DUNS number for a given facility in the past. Resolving issues that arise when attempting to obtain a DUNS number can be a long and extensive process. Thus, we believe that the additional burden placed upon facilities to submit a DUNS number would be significantly greater than FDA's estimated one minute per registration.

In addition, the NGFA believes that FDA's proposal to require facilities to submit a DUNS number has the potential to cause major disruptions to the registration process. For example, if FDA's method to verify the facility address provided during the registration to the address associated with the DUNS number is similar to that used for the agency's annual drug establishment registration, virtually any discrepancy between the two addresses (e.g., abbreviating the word "street" in one system and spelling out the word "street" in the other) would cause the system to reject the registration. We believe that such minor discrepancies very likely could occur between the two addresses. If FDA's system rejects registrations in such cases, that could cause registration failures and a larger number of inaccuracies within the agency's food facility database than otherwise would be experienced without the requirement for each facility to submit a DUNS number.

As such, the NGFA believes that requiring each facility to obtain and submit a DUNS number would impose a substantial burden on the industry that outweighs any potential benefits that FDA believes may be derived. Further, we believe that the agency already can effectively carry out its food safety activities through existing information obtained in its food facility registration and inspection databases.

Verification via Email Address for Authorizing Party

FDA proposes that an individual authorized to register, update, or renew a facility registration on behalf of the owner, operator, or agent in charge must provide FDA with the email address of the individual who authorized the submission. Under the proposal, after the submission is made, FDA would email the individual identified as the owner, operator, or agent in charge to verify that they, in fact, authorized the submission on behalf of the facility. FDA would not confirm the registration, update, or renewal, or provide a registration number, until that individual confirms they authorized the submission. FDA states this proposal is intended to address unauthorized third-party registration submissions.

Although the NGFA appreciates the agency's desire to prevent unauthorized registrations, we do not support the use of the proposed email verification system to do so. A food company with multiple facilities typically has a person assigned to complete the registration process for each of its facilities. At such companies, the assigned person may designate the same individual as owner, operator or agent in charge for all the company's facilities or the assigned person may designate a different individual as owner, operator or agent in charge for each separate facility. Under either of these scenarios, the designated owner, operator, or agent in charge is not directly involved with FDA registration process and has limited knowledge to readily verify registrations, registration renewals or changes to registrations. As such, the NGFA believes the proposed email verification system could create a significant communication and coordination burden for food companies.

Further, the NGFA believes that use of the proposed email verification procedure would not effectively prevent unauthorized facility registrations by those parties who are determined to make unauthorized submissions. For example, a party who desires to make an unauthorized submission easily can provide an email address for a bogus owner, operator, or agent in charge of a facility that could readily be "verified" by the designated recipient of the email.

As such, the NGFA strongly recommends that FDA delete the proposed email address verification requirement from its final rule. In addition, we encourage FDA to engage in an active dialogue with stakeholders to discuss other potential methods to minimize unauthorized registrations.

Timing for Updates and Cancellations

FDA proposes to shorten the time period for a food facility to update or cancel its registration from 60-calendar days to 30-calendar days. The agency's proposal would not change the exiting requirement that updates are to occur when there are changes to any information previously submitted. FDA states that the shorter time period is necessary so that the agency has food facility information that is accurate and up-to-date.

In response, the NGFA does not support shortening the time period provided to facilities to update or cancel their registrations to 30-calendar days. We note that within the preamble of the proposed rule, FDA does not provide examples of situations when the proposed shortened time period for updates or cancellations would have better facilitated FDA's ability to schedule inspection activities or more effectively address food safety issues. As such, the NGFA is not aware that the proposed 30-calendar day time period would provide demonstrable benefits to the agency. However, we do believe the shortened time period would increase the regulatory burden on food facilities by providing less time to submit required information.

Mandatory Submission of Activity Type for Each Food Product Category

FDA proposes to require registrations to include the type of activity conducted at the facility for each identified food product category. Currently, facilities may provide the type of activity for each product type as optional information. FDA states the proposed requirement is necessary to assist the agency in allocating its limited resources effectively, including with regard to its inspectional oversight. In addition, FDA states that the activity type requirement would provide the agency with important information about a given facility's role in the U.S food supply, allowing it to better access the facility's potential impact in cases of bioterrorist incidents or food-related emergencies.

Regarding FDA's proposal, the NGFA recommends that the selection of activity type for each food product category identified during facility registration remain optional. We believe completing the food category/activity designation would be burdensome, particularly for facilities that hold numerous products and perform a wide variety of activities. In addition, we believe such information provided by warehouses or holding facilities would be of little value to the agency.

Instead, the NGFA believes it would be of more value to FDA if facilities simply identified the types of activities conducted at the facility, rather than type of activity by each food product category. We believe submission of this information would facilitate more efficient allocation of FDA's resources and allow the agency to make appropriate assessments concerning a given facility's potential impact in the event of a food safety incident without imposing a significant burden on facilities.

FDA Initiated Facility Registration Cancellations

FDA proposes that the agency would cancel a registration if: 1) it independently verifies that the facility is not required to register; 2) information about the facility's address was not updated in a timely manner; 3) the registration was submitted by an unauthorized person; or 4) it has expired because the facility failed to renew the registration. FDA believes it would improve the utility of the registration database and efficiently enforce its registration requirements, including registration renewal, by canceling registrations in such circumstances.

The NGFA generally supports FDA's proposal to cancel a registration when the prescribed situations occur. However, we strongly recommend that FDA establish appropriate procedures to notify a facility of the agency's intent to cancel its registration and provide a reasonable time period for such a facility to respond before its registration is cancelled. We believe such a notification process is warranted so that potential gaps in communication or misunderstandings between FDA and the facility may be resolved. Cancellation of a facility's registration is significant, and FDA should not take such action until the affected facility is provided an appropriate opportunity to respond to the basis for the cancellation.

U.S. Agent Access to Foreign Facility Registration Information

FDA is proposing that the U.S. agent of a foreign facility would be able to view information submitted in the foreign facility's registration. Additionally, under the proposal, after a foreign facility completes its registration or updates its U.S. agent information as part of registration renewal, FDA would email the person identified as the U.S. agent for the foreign facility to verify that they have agreed to serve as the facility's U.S. agent. FDA would not confirm the registration or provide a registration number until that person confirms that they agreed to serve as the U.S. agent. FDA is proposing this verification step because sometimes the persons identified as U.S. agents are unaware of this and have not agreed to do so.

The NGFA supports FDA's proposal that would allow the U.S. agent of a foreign facility to view information submitted in the foreign facility's registration. We believe that FDA's proposed verification process would be valuable in cases when U.S. agents are not aware that they had been so identified, and also in ensuring the accuracy of the agency's registration database.

U.S. Agent Voluntary Identification System

FDA is requesting comments on whether it should establish, through guidance, a U.S. Agent Voluntary Identification System. FDA states that such a system would be designed to ensure the accuracy of U.S. agent information and enable U.S. agents to independently identify the facility or facilities for which the agent has agreed to serve. Currently, FDA only receives U.S. agent contact information through foreign food facility registrations, many of which are submitted and updated by the facility rather than the U.S. agent for the facility. The proposed system would allow agents to provide information about themselves to FDA and receive an identification number that could then be used by the foreign facility in its registration.

In response, the NGFA generally supports the concept of FDA developing a U.S. Agent Voluntary Identification System. We believe such a system could be useful to increase the accuracy of U.S. agent contact information and reduce the number of unauthorized and/or fraudulent U.S. agent listings. We encourage FDA to engage with stakeholders to further explore this potential system.

Conclusion

The NGFA appreciates FDA's consideration of the recommendations expressed in this statement, and would be pleased to respond to any questions the agency may have.

Sincerely,

David Fairfield
Vice President of Feed Services
National Grain and Feed Association