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Food and Drug Administration
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Room 1061
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RE: Proposed Rule - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Docket No. FDA–2011–N–0920

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's (FDA) proposed rule that would amend its regulation for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMPs) and add requirements for domestic and foreign facilities that are required to register as a food facility with FDA to comply with Hazard Analysis and Risk-Based Preventive Controls regulation for human food.

The NGFA, established in 1896, consists of more than 1,050 grain, feed, processing, exporting and other grain-related companies that operate more than 7,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. Its membership includes grain elevators; feed and feed ingredient manufacturers; biofuels companies; grain and oilseed processors and millers; exporters; livestock and poultry integrators; and associated firms that provide goods and services to the nation's grain, feed and processing industry. The NGFA also consists of 26 affiliated State and Regional Grain and Feed Associations, and has strategic alliances with Pet Food Institute and North American Export Grain Association.

In this statement, the NGFA begins by providing comments pertaining to the statutory language within the Food Safety Modernization Act (FSMA) that authorizes FDA to, by regulation, exempt or modify the requirements for compliance under the hazard analysis and preventive controls section (Section 103) with respect to facilities that are solely engaged in the storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing, and the manner in which FDA has chosen to exercise this authority within its proposed rule. Similarly, we also provide comments on how FDA proposes to apply its CGMPs regulation to facilities that store raw agricultural commodities. We then provide comments and recommendations regarding specific aspects of the proposed regulations for CGMPs and hazard analysis and risk-based preventive controls for human food.

In response to the agency's proposal and as detailed within our statement, the NGFA believes that FDA should make many significant changes to its proposed rule so that requirements will conform to the intent of FSMA's statutory language and provide sufficient flexibility to allow facilities to adopt food safety practices that are practical and effective for their specific,

individual operations. In addition, the NGFA is very concerned that FDA suggests establishing additional requirements for several major areas, but does not propose codified language on which to provide comment.

As such, the NGFA believes that FDA's rulemaking should proceed in a manner that makes available a second draft of the proposed regulations for CGMPs and hazard analysis and risk-based preventive controls for human food that reflects the agency's views after reviewing stakeholders' comments on its proposed rule. Making available a second draft through an interim step, such as a re-proposal or an interim final rule, would provide stakeholders with another opportunity to offer informed and meaningful comment on the requirements that FDA foresees within its final rule. Given the very significant nature of this regulation, we believe that a second opportunity for stakeholder comment is essential to ensure that the requirements in the final rule are practical, achievable and enhance food safety. Further, we believe FDA has the ability to re-propose or issue an interim final rule and still comply with the court-ordered deadline to publish a final rule by June 30, 2015.

Raw Agricultural Commodities Other than Fruits and Vegetables

The NGFA provides the following comments and recommendations on provisions of FDA's proposed rule that apply to raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing.

Rulemaking Authority Provided to FDA

As amended by the FSMA, Section 418(m) of the federal Food, Drug and Cosmetic (FD&C) Act provides in relevant part that FDA may by regulation "exempt or modify the requirements for compliance under [Section 418 - hazard analysis and risk-based preventive controls] with respect to facilities that are solely engaged in … the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing."

The NGFA strongly believes this authority that would apply to raw agricultural commodities other than fruits and vegetables represents a sound risk-based approach, and clearly reflects the view of Congress that both the food industry and FDA should focus their limited resources on segments of the food production and distribution system where the greatest benefits to food safety can be achieved. This same risk-based approach is embraced by food safety experts who widely recognize that the use of hazard analysis and critical control point (HACCP) principles (like those that would be required under Section 418) is most appropriately and effectively applied during food processing activities. It is at this step of the food supply chain that effective controls are most readily available to eliminate or minimize significant hazards so as to ensure food safety.

FDA's Proposed Exemptions for "Holding" Raw Agricultural Commodities

Within its proposed rule, FDA recognizes the appropriateness of a risk-based approach and uses the authority provided to the agency when proposing certain provisions that would apply to raw agricultural commodities as follows:

- Proposed § 117.5(j) states, "subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing."

- Proposed § 117.5(k) states, "subpart B of this part does not apply to 'farms' (as defined in § 1.227 of this chapter), activities of 'farm mixed-type facilities' (as defined in § 1.227) that fall within the definition of 'farm,' or the holding or transportation of one or more 'raw agricultural commodities,' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act."

The NGFA strongly agrees with FDA's intent to exempt facilities engaged in the storage of raw agricultural commodities other than fruits and vegetables from requirements that would be established within its proposed CGMPs regulation. As the agency notes, as early as 1969, FDA exempted establishments "engaged solely in the harvesting, storage, or distribution" of raw agricultural commodities from certain regulatory requirements. Accordingly, such facilities currently are exempt from CGMP regulation (21 CFR § 110.19(a)). We believe such an exemption reflects an appropriate risk-based approach and accurately reflects the level of food safety risk associated with the operations at such facilities. Indeed, FDA acknowledges the limited public health risk pertaining to facilities that store raw agricultural commodities, other than fruits and vegetables, when it states within the preamble of its proposed rule that "outbreaks of foodborne illness have not been traced back to storage facilities solely engaged in the storage of non-fruit or vegetable raw agricultural commodities."

The NGFA also strongly agrees with FDA's intent to exempt facilities engaged in the storage of raw agricultural commodities, other than fruits and vegetables, from requirements that would be established within its proposed preventive controls regulation. For reasons expressed previously, we strongly concur with FDA's tentative conclusion that "there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable raw agricultural commodities intended for further distribution or processing [to such] requirements." Further, as FDA rightfully notes within the proposed rule, such facilities would remain subject to the requirements of the FD&C Act that require food to be stored in a manner whereby the food does not become contaminated with filth or rendered injurious to health.

However, as FDA is aware, the intended exemptions for facilities solely engaged in the storage of raw agricultural commodities, other than fruits and vegetables, from requirements that would be established by the CGMPs and preventive control regulation is severely constrained because FDA has proposed to define "holding" in a very narrow – and we believe unrealistic, impractical and counterproductive – manner within its proposed rule.

FDA's proposed definition for "holding" states, "Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the

Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act."

As such, facilities, such as grain elevators, that engage in activities customarily performed for the safe or effective storage of raw agricultural commodities other than fruits and vegetables – such as drying, screening, conditioning, fumigating and blending – would **not** be exempt from the proposed CGMPs and preventive controls requirements because such activities fall outside of FDA's proposed definition for "holding."

From an operational standpoint, essentially all grain elevators engage in activities to safely and effectively store raw agricultural commodities beyond what is provided for within the proposed definition of "holding." Such activities are inherent to safely store such commodities. Therefore, essentially all grain elevators and other facilities that are engaged in the storage of raw agricultural commodities other than fruits and vegetables would be subject to the proposed CGMPs and preventive controls requirements.

The NGFA strongly believes that FDA's proposed definition for "holding" that would apply to facilities storing raw agricultural commodities other than fruits and vegetables does not reflect the regulatory flexibility provided for within the statutory language of FSMA, nor does it appropriately recognize the minimal level of food safety risk associated with the operations at such facilities. Further, the NGFA believes that subjecting such facilities to CGMPs and preventive controls requirements simply because activities are inherently performed to safely and effectively store raw agricultural commodities does not constitute sound food safety policy.

Further, FDA has constructed its proposed definition of "holding" to differentiate between "facilities" and "farms and farm mixed-type facilities." For farms and farm mixed-type facilities, holding would include activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity. In contrast, for facilities, the proposed definition for holding would not include activities traditionally performed by facilities for the safe or effective storage of raw agricultural commodities, but that also does not transform a raw agricultural commodity. The NGFA believes that this proposed regulatory distinction between two types of operations that perform identical activities lacks sound reasoning and is not justified when a risk-based approach to food safety is applied.

Accordingly, the NGFA strongly urges FDA to modify its proposed definition for "holding" to read as follows *[new language boldfaced and underscored]*:

> *"Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.* ***For facilities, holding also includes activities performed for the safe or effective storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.*** *For farms*

and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act."

As FDA is aware, facilities holding raw agricultural commodities other than fruits and vegetables, such as grain elevators, may combine or "blend" different lots of the commodity when preparing the commodity for further distribution so as to meet desired quality specifications contracted for by the customer. The NGFA strongly believes that this "blending" activity does not constitute manufacturing or processing, since such activity in no way transforms the raw agricultural commodity into a processed food. In addition, the resulting lot of raw agricultural commodity still is intended for further distribution or processing. As such, the NGFA believes that such blending activities performed on raw agricultural commodities rightfully should be encompassed within those activities recognized by FDA within its "holding" definition.

FDA's Proposed Requirements for "Packing" Raw Agricultural Commodities

As proposed, FDA's exemptions under § 117.5(j) and § 117.5(k) would **not** apply to facilities engaged in "packing" raw agricultural commodities. FDA's proposed definition of "packing" states, "Packing means placing food into a container other than packaging the food." For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act."

In contrast to FDA's proposal, current 21 CFR § 110.19(a) does provide an exemption from CGMPs regulation for establishments "… engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in Section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public." As a matter of application from a regulatory standpoint, the activity of packing has been encompassed within the term "distribution," and, therefore, has not been subject previously to CGMPs regulation.

In attempting to justify its proposal to exclude from exemption "packing" of raw agricultural commodities from requirements proposed within the CGMPs and preventive controls regulation, FDA cites examples of foodborne illness outbreaks and contamination events associated with fresh produce and other raw agricultural commodities, and states that the agency continues to be concerned about sanitation practices at establishments that pack raw agricultural commodities. In addition, FDA states that packing of raw agricultural commodities has been implicated as a likely source of contamination in multi-state foodborne illness outbreaks associated with such products.

The NGFA respectively submits that FDA's proposal to exclude from exemption "packing" of **all** raw agricultural commodities from requirements proposed within its CGMPs and preventive controls regulation represents a one-size-fits-all approach that is not risk based. The examples and concerns cited by FDA as justification to exclude from exemption packing of raw agricultural commodities from its regulation pertain to produce, such as fruits and vegetables, but **not** other raw agricultural commodities, such as grains and oilseeds. Indeed, as cited previously within this statement, FDA has noted the minimal public health risk associated with those activities that pertain to the storage of raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing.

Further, the NGFA believes that FDA has authority to provide such an exemption from CGMPs regulation for packing of raw agricultural commodities other than fruits and vegetables that are intended for further distribution or processing. As expressed previously in this statement, the current exemption provided in 21 CFR § 110.19(a) includes distribution activities that inherently encompass packing. In addition, Section 418(m) of the FD&C Act authorizes FDA to exempt or modify its preventive controls requirements with respect to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing. Clearly, facilities solely engaged in the storage of raw agricultural commodities other than fruits and vegetables also distribute such commodities. In many situations, packing is involved in this distribution process. Therefore, NGFA believes it is reasonable to conclude that the authority granted to FDA to exempt such facilities from regulation justifiably may be applied to all activities that are inherent to storing raw agricultural commodities, other than fruits and vegetables, that are intended for further distribution or processing.

Based upon the minimal level of public health risk and the authority provided to the agency, the NGFA strongly recommends that FDA modify its proposed regulation and exclude "packing" activities associated with raw agricultural commodities other than fruits and vegetables intended for further distribution or processing from the CGMPs and preventive controls requirements to be established under its proposed rule.

To do so, the NGFA recommends that FDA modify proposed § 117.5(j) and § 117.5(k) to read as follows *[new language boldfaced and underscored]*:

- § 117.5(j): *"Subpart C of this part does not apply to facilities that are solely engaged in the storage* ***or packing*** *of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing."*

- § 117.5(k): *"Subpart B of this part does not apply to 'farms' (as defined in § 1.227 of this chapter), activities of 'farm mixed-type facilities' (as defined in § 1.227) that fall within the definition of 'farm,' or the holding or transportation of one or more 'raw agricultural commodities,'* ***or the packing of 'raw agricultural commodities' (other than fruits and vegetables,*** *as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act."*

Potential Economic Impact of Regulations on Grain Elevators

As expressed previously, FDA's CGMPs and preventive controls regulations, as proposed, would apply to virtually all FDA-registered grain elevator facilities. This is because such facilities are engaged in storage-related activities that are inherent to the safe and effective storage of raw agricultural commodities other than fruits or vegetables intended for further distribution and processing that fall outside FDA's current proposed definition for "holding." In addition, many grain elevators also are engaged in packing activities as part of their activities associated with distributing raw agricultural commodities for further processing. As such, under the FDA proposal, grain elevator facilities performing packing also would be subject to the CGMPs and preventive controls regulations.

Based upon NGFA's review of the agency's analysis of economic impacts of the proposed rule, FDA apparently failed to estimate the cost for grain elevators to comply with the rule's proposed requirements – even though such facilities would be covered under the definition of "holding" as currently proposed by FDA. Therefore, NGFA believes that FDA's estimated economic impact for the proposed rule is significantly too low.

If NGFA's recommendation to revise the proposed rule to exempt grain elevators from the preventive controls regulations is not implemented within the final rule, we conservatively estimate that the cost for compliance for domestic facilities to be at least $130 million per year. This dollar amount is the product of the NGFA's current estimate that there are approximately 10,000 commercial domestic grain storage facilities multiplied by FDA's estimated annualized cost to comply with the proposed regulation of $13,000 per facility. Further, we do not believe any of the grain storage facilities would be classified as a very small business or a qualified facility under FDA's regulation, and, therefore, none would be subject to modified requirements. In addition, we believe the actual cost of compliance for grain storage facilities would be significantly higher because only a very small fraction of these facilities currently employ food safety programs that incorporate the use of hazard analysis and preventive control principles. As such, grain storage facilities essentially would be starting with a "blank page" when developing and implementing a written food safety plan to comply with FDA's requirements.

Regarding the cost of compliance for FDA's proposed CGMPs regulation, the agency's analysis of economic impacts states that "because this provision only clarifies the meaning of the existing rule, we assume that facilities would not incur a cost." However, this clearly would not be the case if FDA's regulation applies to grain storage facilities that previously have not been subject to the regulation's requirements. Therefore, if grain storage facilities are not exempted from the CGMPs regulation, these facilities will incur additional and extensive compliance costs.

The NGFA is not in a position to estimate the additional economic cost for foreign facilities that also likely would be affected adversely by the lack of an appropriate exemption. However, we note that such costs likely would be at least equivalent to those that would be incurred by domestic facilities.

Proposed Requirements for Current Good Manufacturing Practices

The NGFA provides the following comments on specific selected requirements proposed within FDA's CGMPs regulation:

Reconditioning of Food

Current 21 CFR § 110.80(b)(9) requires that food, raw materials and other ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food. It further requires that if the adulterated food is capable of being reconditioned, it be reconditioned using a method that has been proven to be effective or it be reexamined and found not to be adulterated within the meaning of the Act before being incorporated into other food.

Within its proposed CGMPs regulation, FDA proposes to delete the option for reexamination so that adulterated food only can be disposed of or reconditioned if the food is capable of being reconditioned. FDA states that it is proposing this deletion because a food may test positive for a contaminant in one test and negative in one or more additional tests although the food continues to be contaminated. Therefore, under FDA's proposal, a food found to be adulterated must be reconditioned before it is reexamined.

The NGFA notes that FDA's proposal is in conflict with provisions of the U.S. Grain Standards Act (USGSA) found at 7 CFR § 800.125 and § 800.135. These provisions currently permit a review inspection of grains by the USDA for either official grade/factors or official criteria. Specifically, these provisions provide for review inspection services for the presence of aflatoxin in grains on either a new sample or the file sample in accordance with regulations without reconditioning.

The USDA promulgated these provisions for a review process in 1985 as a result of inherent sampling and inspection variability associated with determining official grade/factors or official criteria of grains. As such, users of USDA's official grain inspection system have an opportunity to obtain another inspection service when certificated results are questionable.

The NGFA believes the current review inspection process serves an important function for both USDA and industry in ensuring that official grade/factors and/or official criteria are determined accurately. Therefore, we request that, if FDA proceeds to promulgate within its final CGMPs regulation a requirement that a food found to be adulterated must be reconditioned before it is reexamined, the agency clarify such a requirement does not apply to grains subject to the review inspection provisions provided for by 7 CFR § 800.125 and § 800.135.

Employee Training

FDA's CGMP regulation currently contains guidance and recommendations on employee training and education pertaining to the production of clean and safe food. However, within its proposed rule, FDA requests comments on whether to establish specific requirements for employee education and training in its CGMPs and preventive controls regulation. In doing so, FDA asks for comment concerning the appropriateness of:

- Specifying that each person engaged in food manufacturing, processing, packing or holding (including temporary and seasonal personnel and supervisors) receive training as appropriate to the person's duties;

- Specifying the frequency of training (e.g., upon hiring and periodically thereafter);

- Specifying that training include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility; and

- Specifying that records document required training of personnel and, if so, specifying minimum requirements for the documentation (e.g., the date of the training, the type of training, and the person(s) trained).

The NGFA agrees that appropriate employee training and education is necessary for the production and distribution of safe food. However, we believe that the scope and format of appropriate employee training may vary dramatically according to the type and size of a given food facility, and the scope of food products that it manufactures, packs or holds. For example, in some facilities, employee training that is highly structured and conducted at preset intervals may be appropriate, while at other facilities on-the-job employee training that is provided under supervision may be sufficient to achieve the goal of safe food. Therefore, the NGFA strongly recommends that FDA's regulations continue to allow facilities to conduct employee training in a flexible manner, with the facility determining the training content and training frequency that is appropriate for the duties of a given employee as they relate to ensuring the safe production and distribution of food.

Proposed Requirements for Hazard Analysis and Risk-Based Preventive Controls

The NGFA provides the following comments and recommendations on certain requirements proposed within FDA's Hazard Analysis and Risk-Based Preventive Controls regulation.

Scope of Requirements for Preventive Controls

Within its proposed preventive controls regulation, FDA defines a "hazard" to mean "any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control." Further, FDA defines a "hazard reasonably likely to occur" as "a hazard for which a prudent person who manufactures, processes, packs, or holds food would establish controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being manufactured, processed, packed, or held in the absence of those controls."

Among other things, FDA's proposed regulation would require that – for hazards identified in the hazard analysis as "reasonably likely to occur" – the owner, operator or agent in charge of a facility identify and implement preventive controls, including at critical control points, if any, to provide assurances such hazards will be significantly minimized or prevented, and the food

manufactured, processed, packed or held by such facility will not be adulterated under Section 402 of the FD&C Act or misbranded under Section 403(w) of the FD&C Act.

FDA proposes to define "preventive control" as "those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."

Further, FDA's proposed regulation would require that all preventive controls implemented for identified hazards that are "reasonably likely to occur" be subject to detailed requirements associated with monitoring, corrective actions, validation and verification, and recordkeeping.

The NGFA believes these core aspects of FDA's proposed regulation essentially would require that all preventive controls implemented for hazards identified as being "reasonably likely to occur" be managed in a manner similar to a "critical control point" that has been established within a formal hazard analysis and critical control point (HACCP) plan.

The NGFA strongly believes that such an outcome is not consistent with the intent of Congress when FDA was provided authority under FSMA to promulgate a hazard analysis and preventive controls regulation. Clearly, the statutory language within FSMA does not mandate that covered food facilities implement regulatory HACCP plans. Had Congress intended to provide FDA the authority to promulgate formal HACCP regulation through FSMA, it plainly could have done so within the statutory language it crafted. Further, the statute does not mandate that food facilities address all hazards that are "reasonably likely to occur" in the same demanding and burdensome manner that would be required of a critical control point within a formal HACCP plan.

In contrast, the NGFA believes that FDA's preventive controls regulation should follow the FSMA statutory language to provide for: 1) consideration of known or reasonably foreseeable hazards (as opposed to the "reasonably likely to occur" hazards language in the proposed rule); and 2) implementation of a range of preventive controls (not just at critical control points) as needed to control those hazards. The level of rigor used to manage the range of necessary preventive controls should be commensurate with the nature of the risk and the type of controls being used, with only critical control points receiving the most rigorous management oversight.

The NGFA strongly recommends that FDA not use the term "reasonably likely to occur" within its regulations when defining "hazard." FDA uses this term within its mandatory seafood and juice HACCP regulations. However, FSMA clearly does not mandate that facilities implement regulatory HACCP plans. Instead, the NGFA recommends that FDA follow FSMA's statutory language that provides for consideration of "known or reasonably foreseeable" hazards to make an appropriate distinction between mandatory HACCP regulation and the preventive controls regulation as required by FSMA.

Further, the NGFA believes it is extremely important that FDA's regulation provide that both likelihood and severity need to be considered in a scientific hazard analysis, consistent with

international standards. Significantly, as outlined in the Codex Alimentarius Commission's HACCP guidelines, the selection and management of controls requires consideration of two important elements: severity and probability. By considering both severity and probability, facilities are able to evaluate successfully the significance of potential hazards on a case-by-case basis, determine the appropriate control measures, and decide how such measures need to be managed.

Importantly, it is very common during the hazard analysis to consider the contributions of prerequisite programs in deciding a hazard is not reasonably likely to occur, and therefore one that does not need to be addressed through a critical control point framework. The NGFA strongly believes that FDA within its regulation needs to acknowledge the safety benefits derived from the use of prerequisite programs, such as CGMPs, so as to avoid the unnecessary and untenable outcome of every hazard and control being subject to the burdensome requirements of monitoring, corrective actions, validation and verification, and recordkeeping.

The NGFA strongly urges FDA within its regulation to provide flexibility for management oversight of hazards and preventive controls that is tailored to each facility's operation and commensurate with the nature of food safety risk that may be present. Indeed, FSMA instructs FDA, when developing such regulations, to provide "sufficient flexibility to be practical for all types and sizes of facilities," acknowledge the differences in risk that exist between different types of foods and facilities, and not prescribe specific practices, technologies or critical controls for individual facilities. FSMA itself is non-prescriptive, stating that preventive controls "may include," but certainly are not limited to, such measures as supplier verification, CGMPs, training, sanitation, hygiene practices and environmental monitoring, among others. This statutory language cites illustrative examples. As such, the NGFA believes that any regulations addressing hazard analysis and preventive controls need to be science- and risk-based, non-prescriptive, and provide sufficient flexibility to allow facilities to adopt practices that are practical and effective for their specific, individual operations.

It also is important to stress that <u>both</u> CGMP prerequisite programs and HACCP-based principles expressly are recognized in FSMA as acceptable means for achieving the performance-based goal of minimizing or preventing hazards that could cause food to be adulterated or misbranded. FSMA clearly does <u>not</u> mandate that food facilities adopt regulatory HACCP plans.

As such, the NGFA believes that FDA's codified regulation should mirror the non-prescriptive, flexible and risk-based language used in FSMA. However, we also believe that it is important for the agency to provide some frame of reference concerning the type(s) of hazards that various industry sectors should consider addressing, as well as illustrative examples of effective preventive controls and appropriate points in the supply chain where those controls can be implemented to have the greatest positive impact on significantly minimizing or preventing targeted hazards.

In previous statements to FDA concerning its development of preventive controls regulation, the NGFA recommended that such benchmarks be provided by FDA through non-binding guidance, rather than regulation. Further, we encouraged FDA in such guidance, as well as through other

means, to provide access to background resources, such as scientific studies, risk analyses and risk-based modeling.

We continue to hold the same view, and fully support the activities that FDA has initiated within the Food Safety Preventive Control Alliance to provide meaningful guidance to both regulators and industry on how to implement FDA's preventive controls regulation in an appropriate and effective manner. The NGFA was very pleased to be invited to serve on the organizing committee and steering committee of the Alliance, and has been an active participant in its on-going activities. We believe the Alliance, which appropriately consists of food safety experts from regulatory bodies, industry and academia, should serve as the vehicle through which industry-specific guidance is developed and conveyed to the regulated industry to further explain what its obligations are under the preventive controls regulation. We strongly believe it is through the cross-cutting interaction provided for within the Alliance that effective guidance may be developed that will enable both FDA and industry to implement the preventive controls regulation in a manner that maximizes benefits to food safety.

Supplier Approval and Verification Requirements

Section 418(c) of the FD&C Act requires the owner, operator, or agent in charge of a facility to identify and implement preventive controls. Section 418(o)(3) defines "preventive controls" to mean "those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent [identified hazards] and that are consistent with current scientific understanding of safe food manufacturing, processing, packing, or holding…" Section 418(o)(3) indicates that those procedures, practices and processes ***may*** include environmental monitoring, supplier verification activities, certain sanitation controls and allergen controls. *[Emphasis added.]*

As allowed by statute, FDA's proposed regulation does not include requirements for supplier approval and verification activities. However the agency states that such activities, when implemented appropriately in particular facilities, can play important roles in effective food safety programs. In addition, FDA has made available for review the supplier approval and verification language initially included within the proposed regulation as submitted to the White House Office of Management and Budget (OMB) – the OMB Redline document. Accordingly, FDA requests comment on when and how supplier approval and verification would be an appropriate means of implementing its statutory directives for their potential inclusion in the agency's final rule.

Related to such potential requirements, FDA on July 29 published its proposed rule for Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP). Within the proposed rule, FDA proposes requirements that would apply to importers to help ensure that food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the FD&C Act.

In addition, FDA requests comment within the proposed FSVP rule on how to coordinate the FSVP and preventive controls regulation to avoid imposing duplicative requirements on importers whose customers could be subject to any supplier verification requirements that ultimately are included in the preventive controls regulation. As such, FDA again has signaled that it is considering including some or all of the proposed FSVP requirements as supplier verification requirements within the agency's final preventive controls regulation.

The NGFA wishes to express concern about the procedural process by which FDA may choose to establish supplier approval and verification requirements within its preventive controls regulation. We believe FDA is obligated to give stakeholders ample opportunity to review and provide comment on proposed codified language related to supplier approval and verification requirements before FDA incorporates such requirements into its final preventive controls rule for human food. We do not believe that the questions and concepts posed by the agency within the proposed preventive control rule concerning potential supplier approval and verification requirements or the release of the OMB Redline document constitute the appropriate process by which final requirements may be codified. Nor do we believe that the proposed requirements within the FSVP rule establish an adequate basis to promulgate supplier approval and verification requirements within the final preventive controls regulation.

Therefore, we urge FDA to publish proposed codified language pertaining to supplier approval and verification, and expressly provide for appropriate stakeholder review and comment if it seeks to add such requirements into its final preventive controls regulation.

The NGFA will address specific aspects of FDA's proposed FSVP rule in a separate statement to the agency. However, at this time we wish to provide the following comments on the application of FSVP requirements and potential supplier approval and verification requirements as it relates to trade issues and raw agricultural commodities other than fruits and vegetables.

- **International Standards and Agreements:** Section 404 of FSMA states that the provisions of FSMA are not to be construed in a manner inconsistent with U.S. international obligations. As a World Trade Organization (WTO) member, the United States is to act consistently with its WTO obligations, including those contained in the Agreement on the Application of Sanitary and Phytosanitary Measures.

  As such, the NGFA generally agrees with FDA's position, as explained in the preamble of the proposed FSVP rule, that the agency is obligated to take a parallel approach to domestic supplier verification within the preventive controls regulation to enhance compliance with WTO obligations and ensure trade access. Importantly, the United States is the world's largest economy and the largest exporter and importer of goods and services. Trade is critical to our country's prosperity – U.S. food and agricultural exports reached an all-time high in 2012 at over $145 billion, and supported an estimated 923 thousand jobs on and off the farm.

  Therefore, the NGFA believes that FDA should take a cautious and balanced approach when implementing the requirements associated with foreign supplier verification, recognizing such requirements have potential trade implications and that obligations

placed on foreign suppliers also will be imposed in a parallel manner on domestic suppliers. Such requirements must be flexible in application and commensurate with the both the risk associated with the food product and the supplier itself so as to avoid unnecessary and burdensome costs.

- **Raw Agricultural Commodities Other than Fruits and Vegetables:** For each imported food except for those expressly exempted, FDA's proposed FSVP regulation would require that the importer develop, maintain and follow an FSVP that provides adequate assurances the importer's foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under Section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and is producing the food in compliance with Sections 402 (regarding adulteration) and 403(w) (regarding misbranding with respect to labeling for the presence of major food allergens). FDA's proposed regulation further prescribes the FSVP include specified activities that would apply to both the food and the foreign supplier of the food.

  Pertaining to the term "foreign supplier," FDA proposed to define "foreign supplier" to mean, for an article of food, "the establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/ processing that consists solely of the addition of labeling or any similar activity of a de minimis nature."

  Therefore, FDA's proposed definition of foreign supplier does not include firms that only hold or pack the food, regardless of whether such a facility is required to register with FDA under Section 415 of the FD&C Act. As justification, FDA states that it tentatively concludes that Congress intended for the importer to verify a single supplier for a particular shipment of a food.

  The NGFA agrees with FDA's tentative conclusion. The agency's proposed FSVP requirements cannot feasibly be applied to all of the potential foreign facilities that may have been involved in the production and distribution of the imported food. Attempting to do so would result in a situation that would be extremely complex, burdensome, costly and counterproductive to enhancing food safety. Rather, the requirements should reflect a risk-based approach and rightfully focus on the foreign supplier, as appropriate, that has the greatest impact on the safety of the food.

  Specifically pertaining to raw agricultural commodities other than fruits and vegetables, the NGFA strongly urges FDA to construct its FSVP requirements in such a manner as to recognize the low risk to food safety posed by facilities that hold and pack such products that are intended for further manufacture or distribution, and the complex and comingled nature in which such commodities move through the food supply chain.

  Related to risk – and as previously referenced within this statement – FDA already recognizes the limited public health risk pertaining to facilities that store raw agricultural

commodities other than fruits and vegetables when it states within the preamble of the proposed preventive controls rule that "outbreaks of foodborne illness have not been traced back to storage facilities solely engaged in the storage of non-fruit or vegetable raw agricultural commodities."

In addition, for reasons expressed previously, the NGFA strongly believes that FDA rightfully should exempt from its CGMPs and preventive controls regulation facilities that store and pack raw agricultural commodities other than fruits and vegetables that are intended for further manufacture or distribution.

Accordingly, the NGFA supports FDA's proposal to exclude from its definition of "foreign supplier" those establishments that only hold or pack food, including such facilities engaged with raw agricultural commodities.

However, the NGFA believes that appropriate FSVP (and any potential supplier approval and verification) requirements necessarily must further be structured to function differently for suppliers of comingled raw agricultural commodities that will be subject to further processing or distribution. From a practical standpoint, there are thousands of suppliers located worldwide involved in producing and harvesting raw agricultural commodities, and it often is not possible or feasible to verify the individual suppliers that produced and harvested such commodities. Within the supply chain, these commodities typically are handled as fungible products, and are readily commingled at local receiving facilities and held for further distribution. When a lot of a commodity is distributed from a local receiving facility, the individual lot distributed potentially may consist of commodities received from hundreds of suppliers.

Given the nature of how raw agricultural commodities are produced and distributed, the NGFA strongly believes that it is not feasible to attempt to identify each supplier associated with a raw agricultural commodity shipment, let alone perform supplier verification activities for every supplier. Moreover, the NGFA believes there would be no value or improvement to public health by conducting in-depth verification activities of such suppliers, such as grain and oilseeds farms. These suppliers do not have a significant impact in controlling, reducing or eliminating food safety hazards.

Further, in accordance with statutory authority, farms in the United States that produce raw agricultural commodities other than fruits and vegetables will not be subject to FDA's CGMPs or preventive controls regulation. Since FDA's mandate when promulgating FSVP requirements is to ensure the importer's foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those processes and procedures required of domestic suppliers, it would be incongruent for FDA to establish detailed requirements to verify that processes and procedures are adhered to by foreign farms when domestic farms are not mandated by regulation to adhere to specific processes or practices within their operations.

Therefore, the NGFA urges FDA to exempt raw agricultural commodities other than fruits and vegetables intended for further processing or distribution from its proposed supplier-verification requirements. We believe that potential hazards associated with such products are controlled adequately by the facility that receives such products and performs further manufacturing/processing activities.

Potential for Intentional Adulteration

The NGFA strongly agrees with FDA's proposed decision to implement food defense separately from preventive controls. In addition, we believe hazards that may be introduced intentionally for economic reasons should not be required to be addressed in the food safety plan.

The methods used by various industry sectors to identify, assess and control risks as part of a food defense plan is separate and fundamentally different and distinct from the type of process used to analyze other kinds of naturally occurring or unintentionally introduced hazards as part of the development of food safety plans. In addition, addressing food defense separately would help facilitate consistency of any regulations and guidance issued pursuant to intentional adulteration.

We also urge the agency, when proposing its regulation for food defense, to apply to intentionally introduced hazards the same "known or reasonably foreseeable" hazard "associated with the facility" criteria specified in Section 103 of FSMA for unintentional contamination. Doing otherwise would subject the industry to a costly, unreasonable and unproductive exercise of trying to identify and assess any hazard – foreseeable or not – that conceivably could be introduced into the food or feed supply.

Submission of Facility Profile Information

FDA seeks comment within the proposed rule on whether to require facilities to submit "facility profiles" that summarize hazards and controls to the agency. FDA states that data elements that could be required as part of the facility profile information include: 1) contact information; 2) facility type; 3) products; 4) hazards identified for each product; 5) preventive controls established for each of the identified hazards; 6) third-party audit information, if any; 7) preventive controls employee training conducted; 8) facility size (square footage); 9) full time operation or seasonal; and 10) operations schedule.

FDA states that having such information available will help the agency better allocate inspection resources – for example, by helping inspectors prepare for inspections (potentially reducing inspection time), and possibly guiding decisions about a facility's risk status. FDA further states this information could be submitted at the same time as facility registration and updated biennially simultaneously with the required biennial update of the food facility registration.

While the NGFA supports the agency's goal of making inspections more efficient and effective, we strongly oppose requiring submission of facility profiles and do not believe they will assist in accomplishing FDA's stated objective.

The NGFA particularly is concerned about FDA's proposal to request that facilities identify the hazards associated with product types and the controls in place for each. We believe this kind of information is critical to review during an inspection, but offers little, if any, value outside of the context of the facility's operation. If FDA were to review a simple listing of hazards and controls prior to an inspection, the agency would be looking at those controls in isolation, not how they interact with each other as part of an overall system of food safety. Further, the listing would not provide any indications as to the rigor of the hazard analysis or effectiveness of the preventive control. Only by reviewing the food safety plan and simultaneously observing actual operations can FDA gain an accurate perspective from which to evaluate a facility, and to potentially determine how it should be classified in terms of risk.

The NGFA also is concerned about other information FDA proposes to potentially collect, such as third-party audits and employee training. Again, we strongly believe the value of obtaining basic information about third-party audits and employee training is extremely limited without the facility's operation in view. As would be the case with a listing of hazards and preventive controls, we believe this basic information on third-party audits and employee training does not provide FDA the means to evaluate the potential risk associated with a facility, or facilitate the inspection process.

In addition, the facility profile information would be difficult and time consuming to collect, and would represent only a snapshot in time. Facilities often change their products, processes and procedures. It would be overly burdensome to expect companies to continually update the information submitted to FDA. As such, FDA potentially could have information that is not up-to-date and perhaps make flawed decisions based upon a facility's profile.

The process of submitting facility profile information to the agency also would be complex and time consuming, as FDA saw firsthand during its facility profile pilot session on June 26, 2013 conducted in conjunction with industry stakeholders, in which the NGFA participated. The NGFA believes that FDA's Analysis Note of the session released on Aug. 5, 2013 accurately summarizes industry's concerns about the pilot facility profile module and the industry's views concerning the potential value of submitting such information.

Therefore, for all these reasons, the NGFA strongly recommends that FDA not require the submission of facility profile information to the agency, either through written or electronic forms.

Qualified Individual

FDA proposes under §117.155 that a "qualified individual" who successfully has completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience perform or oversee a facility's food safety plan. Further, FDA proposes that the qualified individual may be, but is not required to be, an employee of the facility.

Pertaining to "qualified individual," the NGFA requests that FDA clarify whether individuals who have successfully completed training in the development and application of risk-based preventive controls though programs delivered and recognized under the International HACCP Alliance would be considered to have completed training "equivalent" to that recognized by FDA. As FDA likely is aware, many individuals in the food industry already have completed such training successfully.

Concerning the employment status of a "qualified individual," the NGFA agrees with FDA's proposal that such an individual may be, but is not required to be, and employee of the facility. We believe this proposed flexibility is necessary since it is not feasible for all facilities to employ a qualified individual to perform or oversee the facility's food safety plan.

Parameters Associated with Preventive Controls

FDA proposes under § 117.135(c)(1) and (2) that preventive controls must include, as appropriate to the facility and the food, parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating and refrigerating foods, and the maximum or minimum value, or combination of values, to which any biological, chemical, physical or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur.

Pertaining to this proposed requirement, the NGFA believes that parameters should not be required for all preventive controls. As FDA rightfully notes in the preamble of the proposed regulation, some preventive controls, such as those associated with CGMPs, are not conducive to specific parameters and therefore should not be required. We believe FDA's regulation should provide flexibility for the appropriate oversight of preventive controls to be tailored to each facility's specific program. In addition, we believe that FDA can best provide industry further direction on the use of parameters through non-binding guidance, rather than regulation.

Validation of Preventive Controls

Proposed § 117.150(a) would require "validation" by facilities that preventive controls are adequate to control the identified hazard. FDA proposes to define the term "validation" to mean that element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards. The proposed definition is consistent with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP guidelines, the Codex HACCP Annex, and FDA's HACCP regulation for juice.

For the purpose of validation, FDA proposes that facilities be required to collect and evaluate scientific and technical information (or conduct studies) to demonstrate the preventive controls are effective in controlling the hazards prior to control implementation or within six weeks of initiating production, if necessary. The proposed validation time-period also would apply when facilities perform required reanalysis of their plans.

Regarding the proposed requirement, the NGFA notes that "validation" is not specifically required by FSMA. Rather, FSMA states that "the owner, operator, or agent in charge of a facility shall verify that: 1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b); 2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d); 3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (e); 4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and 5) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility and new and emerging threats."

The NGFA believes that FDA's proposal for validation of preventive controls constitutes a requirement that exceeds the mandate of FSMA and represents, as FDA references, a provision that more appropriately would be found within a formal HACCP regulation. Instead, FSMA instructs FDA, when developing regulations, to provide "sufficient flexibility to be practical for all types and sizes of facilities" and not "prescribe specific practices, technologies or critical controls for individual facilities." We believe the proposed requirement to validate all preventive controls by collecting and evaluating scientific and technical information or studies does not reflect "sufficient flexibility" as mandated by FSMA.

Further, the NGFA believes it is not possible to validate all preventive controls in such a manner. For example, facilities rightfully may rely on CGMPs to control a given hazard. In many cases, it is not feasible to scientifically validate the effectiveness the good manufacturing practice. Nor do we believe that such an exercise should be necessary.

Rather than requiring validation of preventive controls through collection and evaluation of scientific and technical information or studies, the NGFA strongly recommends that FDA amend its proposed rules to allow facilities the flexibility to verify that preventive controls are effective in the manner prescribed by FSMA. That is, such controls should be deemed to be effective by an appropriate means, as determined and supported by the facility within its food safety plan. In addition, we believe FDA should allow facilities the flexibility to verify combinations or systems of controls, and not require specific verification of every control.

Product-Testing Requirements

While not included in its proposed rule, FDA seeks comments on whether to add finished product testing requirements to its preventive controls regulation. Regarding testing, FDA asks whether a product-testing program should be limited to finished products or include raw material testing. Likewise, the agency asks whether it should specify: 1) the organism to be tested for in an environmental monitoring program; 2) corrective actions; 3) testing locations; and 4) testing frequency.

Although the NGFA agrees that testing may be used as an appropriate "verification" activity (not a "control" step), the nature and extent of testing needs to be adapted to the particular

circumstances of each facility and product. In general, each kind of testing has its own role and purpose. Environmental testing is usually most beneficial to verify if sanitation and other preventive controls are working effectively. Testing of incoming raw materials also has may have an appropriate role in certain manufacturing situations. But finished product testing is a beneficial verification activity only in limited circumstances. Because of the statistical limitations of finished-product testing, lot-by-lot testing generally does not help improve food safety.

Accordingly, the NGFA believes that FDA's regulation should provide facilities the flexibility to determine if there are circumstances in which product and/or environmental testing is necessary to ensure food safety, to explain the basis for making such determinations, and to incorporate such testing, if any, within its written food safety plan. Such regulatory flexibility would allow facilities to use product testing in a manner that is commensurate with the particular circumstances associated with the facility and its food products.

The NGFA also notes that FDA did not propose specific codified language pertaining to product testing. As such, we believe that if FDA does wish to add product-testing requirements to its regulation that the agency should provide an additional opportunity for public comment, either as a re-proposal or as an interim final rule that would not be enforced until after an opportunity for public review and comment and publication of a final rule.

Verification Activities

FDA's proposed requirements at § 117.150(b) and (c) do not specify the verification activities that are to be conducted for corrective actions and monitoring. Instead, the agency seeks comment on whether it should and, if so, what activities would be appropriate.

Pertaining to this issue, the NGFA believes that FDA should not mandate specific activities that facilities must complete to verify that monitoring is being conducted or that appropriate decisions about corrective actions are being made. Instead, FDA rightfully should provide facilities the ability to establish and implement appropriate verification activities for these areas that reflect the nature of their operations.

In addition, as with other aspects of FDA's proposed rule in which the agency seeks comment, the NGFA believes that if FDA wishes to establish additional requirements for verification activities that the agency should provide an additional opportunity, either as a re-proposal or as an interim final rule, for public review and comment.

Written Recall Plans

FDA proposes under § 117.137 to require each facility that identifies a hazard reasonably likely to occur to establish a written recall plan. FDA requests comment on whether the agency should require a recall plan to include procedures for notifying FDA of a recall, and whether it should include a requirement for mock recalls as a verification activity for the recall plan.

The NGFA agrees that it is reasonable for FDA to require a facility that identifies known or reasonably foreseeable hazards within its operation to establish a written recall plan. However, we do not believe that FDA should establish further requirements to mandate that such facilities conduct mock recalls or notify FDA in the event of every recall.

Pertaining to the potential requirement to notify the agency of all recalls, the NGFA reminds FDA that facilities already are obligated to inform FDA of "reportable food" in accordance with the Reportable Food Registry requirements prescribed under the Food and Drug Administration Amendments Act of 2007. FDA often has likened the reportable food reporting threshold to that of a Class I recall situation. Therefore, facilities currently are mandated to report such situations to FDA. The NGFA believes the requirements associated with the Reportable Food Registry represents a risk-based approach, and draw an appropriate distinction between situations that have the potential to cause serious adverse health consequences or death to humans or animals, and those where food products likely are not to cause serious adverse health consequences. Therefore, we believe that establishing a requirement to report all recalls to FDA would needlessly consume the limited resources of industry and FDA by causing both parties to engage in reporting and response activities that would not significantly benefit public health.

Concerning mock recalls, the NGFA opposes establishing such a requirement as a verification activity for the recall plan. As FDA knows, food facilities vary greatly in scope and type of operation. Accordingly, we believe that a requirement to conduct a mock recall may not be feasible or beneficial for all types of facilities. The NGFA strongly believes that facilities should have the flexibility to determine whether conducting a mock recall is a meaningful way to evaluate the effectiveness of the written recall program designed for their specific operation.

Consumer Complaints

FDA did not include within the proposed rule a provision requiring that verification activities include a review of consumer complaints to determine whether the complaints relate to the performance of the food safety plan. Instead, FDA is requesting comment on whether and how a facility's review of complaints should be required.

The NGFA strongly opposes adding a provision within the rule that would require a review of consumer complaints to determine whether the complaints relate to the performance of the food safety plan. Although the review of consumer complaints may be an appropriate verification procedure in certain circumstances, we believe it should not be required by regulation.

As FDA rightfully states within the proposed rule, most consumer complaints are related to quality issues, not product safety issues. After receiving a customer complaint that is related to a food product, facilities typically conduct an investigation to evaluate the complaint and its potential consequences. The extent of a facility's investigation is commensurate with the nature and scope of the complaint, with some investigations being very simple and others being highly complex. Complex investigations may have a multitude of variables that facilities need to consider before a conclusion may be reached regarding the quality or safety of a product. Given the highly competitive business environment, food facilities have a very strong incentive to

address consumer complaints in an appropriate manner, and to make sound decisions as to whether a given complaint relates to the performance of its food safety system.

FDA's potential provision would make complaint review a required verification activity, and therefore the review and its associated records would become subject to FDA oversight. The NGFA believes that such an outcome potentially could pit food companies and FDA in time-consuming and unproductive debates over the complexities associated with complaints.

Instead, the NGFA points out that FSMA already has provided FDA with expanded records access authority to investigate records when the agency: 1) has a reasonable belief that a suspect article of food, and any other article of food that it reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals; or 2) believes there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Therefore, FDA already has access to records, including complaint files, associated with foods for which it has a reasonable belief to be adulterated and present a threat of serious adverse health consequence.

Therefore, the NGFA urges FDA to not include within its final rule a provision that would require a review of consumer complaints to determine whether the complaints relate to the performance of the food safety plan. We believe such a provision is not necessary to enhance food safety.

Record Retention and Location

FDA proposes under § 117.315 that required records be retained for two years, and that this two-year time period run either from the date the record was prepared, for day-to-day operational records; or from the date at which use of the record is discontinued, for records relating to the general adequacy or equipment or processes (e.g., the written food safety plan and records that document validation of the written food safety plan). FDA proposes to permit use of offsite storage for records after 6 months following the date that the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review. FDA also proposes that the food safety plan would be required to remain onsite.

The NGFA believes that FDA's record retention and location requirements should specify the expectations for record availability and allow companies flexibility to use appropriate systems for meeting those expectations. At many companies, important records, such as food safety plans, are kept at corporate headquarters or other central locations; not at individual facilities. Requiring all records to be kept at individual facilities would be duplicative and unnecessary so long as they can be produced promptly for official review. Further, the NGFA believes that the six-month onsite record retention requirement is an arbitrary time frame. Instead, we believe FDA should establish a workable requirement that provides for the efficient storage and retrieval of records in a manner whereby facilities may make required records available promptly upon request.

Electronic Records

FDA proposes at § 117.305(a) to require that electronic records be kept in accordance with part 11 (21 CFR part 11). Part 11 provides criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. The proposed requirement clarifies and acknowledges that records required by the proposed CGMPs and preventive controls regulation may be retained electronically, provided that they comply with part 11.

FDA states that it tentatively concludes that it is appropriate to apply the requirements of part 11 to such records. However, FDA also requests comment on whether there are any circumstances that would warrant not applying part 11 within the regulation. As an example, FDA asks whether the requirement that electronic records be kept according to part 11 would mean that current electronic records and recordkeeping systems would have to be recreated and redesigned, which the agency determined to be the case in its Bioterrorism Act recordkeeping regulation, and in other cases. In such cases, FDA has not required resulting predicate records to comply with part 11.

The NGFA strongly urges FDA not to apply Part 11 to a facility's electronic records that would be required under the proposed regulation because, as with the Bioterrorism Act and other cases, such a requirement is disproportionate to the regulatory need and would create a tremendous burden on industry. Electronic recordkeeping systems are widely used throughout all sectors of the food industry to document and store business-related information. The requirements that FDA proposes within its regulation would require that numerous and extensive documents and records to be established and maintained. The most efficient and cost-effective manner in which to establish and maintain such documents and records is with existing electronic systems. The vast majority of such systems do not meet the very stringent provisions detailed in Part 11. As such, facilities would be required to recreate and redesign their current electronic systems at an enormous cost or scrap the use of existing systems and create and maintain records in a paper format. Both of these options represent an overwhelming expense and burden that is not necessary to assure compliance with regulatory requirements or assure food safety.

Facility Review of Required Records

FDA seeks comment on its proposed record review requirements that would be established under § 117.150(d)(2)(i). Such provisions would require review of the: 1) monitoring and corrective action records within one week after the records are made; and 2) records related to calibration of monitoring instruments within a "reasonable" time after the records are made.

The NGFA believes that the proposed requirement of reviewing monitoring and corrective action records within one week after the records made is arbitrary and that a specific frequency for the review of such records is not warranted. Instead, we believe that FDA should allow facilities to establish a review frequency that is appropriate for their operation and provide FDA supporting justification for their determinations.

FDA Review of Required Records

FDA's proposed records access requirements under § 117.320 do not require a facility to send records to the agency. Instead, facilities would be obligated to make required records available to FDA for review at a facility's place of business upon oral or written request. However, the agency requests comment on whether the proposed requirement should be modified to explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically. FDA states that obtaining a facility's food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by effected facilities.

As expressed previously, the NGFA stresses that such records most appropriately are reviewed by the agency during on-site facility inspections in the context of the operations at the facility's site. Only by seeing how a written food safety plan is applied in practice at a facility's operation can FDA obtain a meaningful and accurate view of the facility's compliance status. As such, we urge FDA not to require paper or electronic submission of written food safety plans and its associated records. Further, we reiterate our previously stated position that FDA should not require submission of facility profile information to the agency.

The NGFA also wishes to emphasize the importance of FDA developing adequate procedures to preserve the confidentiality of facility records to which it now will have access under FSMA, including hazard analyses, preventive controls and monitoring of such controls, and food/feed defense plans. As the agency is aware, food and feed safety or quality-assurance plans contain sensitive, often-proprietary information about a facility's products or manufacturing processes or methods, and product formulas and recipes. Of equal importance is the need to preserve the confidentiality of facilities' vulnerability assessments and food/feed defense plans, which if inappropriately disclosed could compromise the facility's security. This is not a hypothetical concern, as there have been instances in the past in which FDA inspectors have disclosed highly proprietary commercial facility business information to which they had access through records. The NGFA urges FDA in regulations to articulate how it plans to protect the sanctity and confidentiality of such records.

Public Disclosure of Records

FDA under § 117.325 proposes that all records required by the CGMPs and preventive controls regulation would be subject to the disclosure requirements under 21 CFR part 20, the Freedom of Information Act.

Pertaining to this issue, the NGFA believes that the written food safety plans and associated records to be required by regulation fall within the bounds of trade secret or commercial confidential information and should, therefore, be protected from public disclosure. Such plans and records will be process- and facility-specific. Therefore, they will contain such information as facility and equipment design, and processing and monitoring parameters based on product formulas. Moreover, each facility will have expended considerable time and money to develop its written food safety plan. We believe that equity should not readily be given away to

competitors through freedom of information requests. Therefore, the NGFA believes that written food safety plans and associated records rightfully will meet the definition of trade secret or In addition, the NGFA believes it is in the best interest of public health to protect written food safety plans and associated records so as to promote the most effective implementation of its regulation. We believe that FDA reasonably can expect facilities to tailor written food safety plans in a more comprehensive manner if there is not a concern of public disclosure.

Therefore, the NGFA urges FDA within its final rule to clarify that written food safety plans and associated records are not subject to public disclosure because they represent trade secret or confidential commercial information.

Conclusion

The NGFA believes that FDA should make many significant changes to its proposed rule so that requirements will conform to the intent of FSMA's statutory language and provide sufficient flexibility to allow facilities to adopt food safety practices that are practical and effective for their specific, individual operations. In addition, the NGFA is very concerned that FDA suggests establishing additional requirements for several major areas, but does not propose codified language on which to provide comment.

As such, the NGFA believes that FDA should make available a second draft of the proposed rule through an interim step, such as a re-proposal or an interim final rule, to provide stakeholders with another opportunity to offer informed and meaningful comment on the requirements that FDA foresees within its final rule. Given the very significant nature of this regulation, we believe that a second opportunity for stakeholder comment is essential to ensure that the requirements in the final rule are practical, achievable and enhance food safety. Further, we believe FDA has the ability to re-propose or issue an interim final rule and still comply with the court-ordered deadline to publish a final rule by June 30, 2015.

The NGFA appreciates FDA's consideration of the recommendations expressed in this statement, and looks forward to being a fully engaged and constructive participant in future discussions and rulemakings with the agency.

Sincerely yours,

David Fairfield
Vice President
National Grain and Feed Association