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Food and Drug Administration
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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) supplemental notice in which the agency proposes to amend its 2013 proposed rule for current good manufacturing practice (CGMPs) and hazard analysis and risk-based preventive controls 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 response to the agency’s proposed rule issued Jan. 16, 2013, the NGFA submitted extensive comments in which we recommended many significant changes so that the proposed requirements would conform to 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 recommended FDA make available a second draft of the proposed regulation reflecting the agency’s views after reviewing stakeholders’ initial comments on its proposed rule given the very significant nature of these regulations and the extent of revisions being recommended by the NGFA and other stakeholders. As such, we commend FDA for issuing the supplemental notice and providing this additional opportunity to make comments on key provisions of the proposed rule.

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 hazard analysis and risk-based preventive controls for human food.

**FDA’s Proposed Requirements for Facilities Solely Engaged in the Storage of Raw Agricultural Commodities Other than Fruits and Vegetables**

The NGFA provides the following comments and recommendations on provisions of FDA’s supplemental notice 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 Act (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 intended for further distribution or processing represents a sound risk-based approach, and clearly reflects the view of Congress that both industry and FDA should focus their finite resources on segments of the food production and distribution system where the greatest benefits to product 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 product safety.

**FDA’s Proposed Exemptions for “Holding” Raw Agricultural Commodities**

Within its 2013 proposed rule, FDA recognizes the appropriateness of a risk-based approach and used 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 [hazard analysis and risk-based preventive controls] 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 [CGMPs] 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
The NGFA continues to strongly agree with FDA’s intent to exempt facilities engaged in the storage of raw agricultural commodities other than fruits and vegetables intended for further distribution or processing from requirements that would be established within its proposed regulations for CGMPs and preventive controls. We strongly concur with FDA’s tentative conclusion expressed within the preamble of its 2013 proposed rule for human food 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.”

To clarify the scope of the intended exemptions, FDA within its supplemental notice revised the proposed definition for “holding.” The agency’s proposed definition for “holding” now states, “Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.”

The NGFA strongly supports FDA’s revised definition for “holding.” We agree that “holding” rightfully should encompass activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity). We also concur with statements made by FDA within the preamble of the supplemental notice that, either for the purposes of safe or effective storage or for meeting customer specifications, a variety of activities incidental to “holding” of raw agricultural commodities may be performed, including:

- Drying grain;
- Fumigating grain;
- Cleaning grain;
- Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation;
- Using modified atmosphere treatments to control pests;
- Using biological controls for pests;
- Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds;
- Weighing grain;
- Sampling and grading grain; and
- Aerating grain to control temperature.

The NGFA believes that FDA’s revised “holding” definition and proposed exemptions for facilities holding raw agricultural commodities other than fruits and vegetables appropriately
reflect the limited public health risk pertaining to such facilities and the fact 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. Therefore, we urge FDA to codify the proposed definition for “holding” within its final regulation.

Proposed Requirements for “Packing” Raw Agricultural Commodities

As proposed with FDA’s 2013 rule, the 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” within the 2013 proposed rule stated, “Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities 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).”

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 regulations, FDA within its 2013 proposed rule for preventive controls for human food cited examples of foodborne illness outbreaks and contamination events associated with fresh produce and other raw agricultural commodities, and stated that the agency continues to be concerned about sanitation practices at establishments that pack raw agricultural commodities. In addition, FDA stated 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 regulations 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 regulations 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 (e.g., placing grain in a container for shipment) is involved in this distribution process. Therefore, the 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.

Moreover, FDA within its supplemental notice proposes to revise the definition of “farm” and “packing” to:

- Provide for on-farm packing and holding of raw agricultural commodities to remain within the farm definition regardless of ownership of the raw agricultural commodities;
- Clarify that packing also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food); and
- Provide that activities performed incidental to packing a food would apply to all establishments that pack food, not just to farms and farm mixed-type facilities.

Therefore, under FDA’s revised definitions, the agency proposes to differentiate requirements associated with packing between establishments that are “facilities” and those that are “farms.” A “farm” that packs raw agricultural commodities other than fruits and vegetables, regardless of ownership of such commodities, would not be subject to CGMPs and preventive control regulations because the establishment would still meet the definition of a “farm.” In contrast, a “facility” that packs raw agricultural commodities other than fruits and vegetables, regardless of ownership of such commodities, would be subject to CGMPs and preventive control regulations under FDA’s proposal. 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.

Based upon the minimal level of public health risk and the authority provided to the agency, the NGFA strongly recommends that FDA expressly exempt facilities that pack 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 regulations.

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)(1)(iii): “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.”

### Proposed Requirements for Hazard Analysis and Risk-Based Preventive Controls

As indicated in our previous statement to FDA, the NGFA believes the agency’s 2013 proposed rule would have establish an extremely burdensome regulatory framework that is not necessary to ensure the safety of food. As proposed, we believe the preventive controls provisions would have required excessive and unnecessary management control and oversight of potential product safety hazards that is not commensurate with the risk posed by the vast majority of potential food hazards. Further, the proposed requirements would have diverted finite resources away from industry practices that have and continue to effectively ensure the safety of food products.

Within NGFA’s previous statement, we strongly recommended that FDA not use the term “reasonably likely to occur” within its regulation when defining hazards that are to be addressed within a facility’s written food safety plan. We did so for two reasons. First, FDA uses this term within its mandatory seafood and juice HACCP regulations. However, FSMA clearly does not mandate that facilities implement regulatory HACCP plans. In fact, FSMA does not use the phrase “reasonably likely to occur” to define a threshold for determining preventive controls nor does it provide any other basis for using such a phrase to differentiate among various hazards and associated preventive controls. Second, we believe using the term “reasonably likely to occur” when defining hazards would be interpreted as requiring all such hazards be dealt with in the same manner as a critical control point within a HACCP program. Such an outcome is clearly inconsistent with FSMA, which explicitly provides for the use of a range of preventive controls that is commensurate with the hazard.

Instead, the NGFA recommended that FDA closely follow FSMA’s statutory language that provides for consideration of “known or reasonably foreseeable” hazards to make an appropriate distinction between mandatory HACCP regulations and the preventive controls regulation as required by FSMA. Further, the NGFA recommended that FDA’s regulation provide that both likelihood and severity need to be considered in a scientific hazard analysis, consistent with international standards, when evaluating hazards. Considering both severity and probability is necessary 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.

We also strongly recommended that FDA within its regulation 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.
In response to comments made by the NGFA and other organizations, FDA within its supplemental notice proposes to use the new term “significant hazard” and, in general, use this new term instead of “hazard reasonably likely to occur” throughout the proposed preventive controls regulation. FDA proposes that “significant hazard” would mean “a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.”

As proposed by FDA, determining whether a “significant hazard” exists within a facility would involve a two-part analysis. First, the facility would narrow potential “hazards” to those hazards that are known or reasonably foreseeable – i.e., those biological, chemical (including radiological), or physical hazards that have the potential to be associated with the facility or the food. Second, the facility would narrow the known or reasonably foreseeable hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food, as well as components to manage those controls. The hazard analysis also would require an evaluation of known or reasonably foreseeable hazards to assess two key aspects of risk – i.e., the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

The NGFA generally supports FDA’s use of the term “significant hazard” within its proposed regulation and the process to be used by facilities to determine whether such a hazard exists within their operations. We believe the agency’s proposed approach acknowledges the safety benefits derived from the use of prerequisite programs, such as CGMPs, and provides for a framework whereby appropriate decisions may be reached regarding hazards that require management controls that may include monitoring, corrections or corrective actions, verification, and records. However, as expressed later within this statement, the NGFA does have suggested revisions to the proposed definition for “significant hazard,” which we believe will enhance the meaning and application of the term.

Although FDA’s use of the term “significant hazard” will help to clarify the types of hazards to be subject to rigorous management oversight, i.e., monitoring, corrective actions, verification and recordkeeping, the NGFA believes for compliance purposes a baseline understanding between industry and regulatory officials will need to be established as to what constitutes a “significant hazard” and what preventive controls will be deemed to be adequate to control such a hazard.

Pertaining to the issue of developing a common understanding between industry and FDA about “significant hazards,” the NGFA believes the Food Safety Preventive Controls Alliance provides the best forum to identify what constitute “significant hazards” in food, and to develop timely and appropriate guidance and training for addressing such hazards, as well as other issues for use by both industry and FDA/State investigators. 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
human food and animal feed/pet food safety experts from regulatory bodies, industry and
academia, is uniquely positioned to serve in this essential role 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 made available that will enable both FDA and industry
to implement the preventive controls regulation in a consistent manner that maximizes benefits
to food safety.

Our comments and recommendations pertaining to specific provisions proposed within the
preventive controls regulation further address NGFA’s views pertaining to the scope and
application of the proposed requirements.

**Proposed Requirements for Product Testing, Environmental Monitoring, Supplier Programs and Economically Motivated Adulteration**

FDA requests comment on potential requirements that would be included within its preventive
controls regulation for product testing, environmental monitoring, supplier programs, and
hazards that may be intentionally introduced for purposes of economic gain.

The NGFA offers the following overarching perspectives pertaining to these topics, and provides
further comments and recommendations concerning specific proposed regulatory provisions later
in this statement.

**Product Testing**

The agency’s proposed product testing provisions would require that a facility conduct product
testing as an activity for verification of implementation and effectiveness as appropriate to the
nature of the preventive control used to control a significant hazard, facility, and the food. Under
FDA’s proposal, a facility, as appropriate, would be required to have written procedures for
product testing, corrective action procedures to address the presence of a pathogen that is a
significant hazard, appropriate indicator organism, or other significant hazard in food detected as
a result of product testing, and records of product testing.

Pertaining to such potential requirements, section 418 of the FD&C Act states that a facility shall
verify that “the preventive controls implemented under [section 418(c) of the FD&C Act] 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.” Concerning this language, FDA has acknowledged that “the statute does not indicate the
specific circumstances where product testing would be required or the specific manner in which
such testing should be performed” and “the role and need for these measures varies depending on
the type of products and activities of a facility.”

The NGFA agrees that in some circumstances product testing may be used as an appropriate
verification activity, and that the nature and extent of testing needs to be adapted to the particular
circumstances of each facility and product. In general, each kind of product testing has its own
role and purpose. Testing of incoming raw materials 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 testing is necessary to ensure that any identified significant hazards are being effectively controlled, 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 products.

Environmental Monitoring

The proposed requirements for environmental monitoring would, if included in a final rule, require that a facility conduct environmental monitoring as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control if contamination of a ready-to-eat (RTE) food with an environmental pathogen is a significant hazard. The facility would be required to have, as necessary, written procedures for environmental monitoring, corrective action procedures to address the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring, and records of environmental monitoring.

The NGFA believes the nature and extent of environmental testing appropriately should be adapted to the particular circumstances of each facility and its products. In this regard, FDA’s proposal would specify one situation where environmental monitoring would be required – when a facility’s hazard analysis determines that an environmental pathogen is a significant hazard to a RTE food and the RTE food is exposed to the environment prior to packaging and the packaged RTE food does not receive a treatment that would significantly minimize an environmental pathogen.

The NGFA generally agrees that environmental monitoring under this specific situation would be appropriate. However, to further clarify the scope of the proposed requirement, we recommend that FDA define within its regulation what is meant by “exposed to the environment.” Based on previous statements made by FDA, we understand the phrase “exposed to the environment” to mean the product is in a form that is exposed and/or subject to direct human contact. We believe providing a definition for “exposed to the environment” is necessary to avoid confusion over what is meant by this phrase.

Supplier Programs

FDA’s supplier program would, if included in a final rule, require supplier controls when the receiving facility’s hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient. Further, FDA proposes a receiving facility would not be required to establish supplier controls if it controls the significant hazard, or if its customer controls that hazard.
FDA proposes that with one exception, the receiving facility would have flexibility to
determine the appropriate supplier verification activity (e.g., onsite audit; sampling and testing
of the raw material or ingredient; review of the supplier’s food safety records; or other
appropriate verification activity). The one exception would be when there is a reasonable
probability that exposure to the hazard will result in serious adverse health consequences or
death to humans or animals (SAHCODHA). In this circumstance, FDA proposes the receiving
facility would be required to have documentation of an onsite audit of the supplier before using
the raw material or ingredient from the supplier and at least annually thereafter, unless the
receiving facility determines and documents that other verification activities and/or less
frequent onsite auditing of the supplier provide adequate assurance that the hazards are
controlled. FDA also proposes that instead of an onsite audit, a receiving facility would be able
to rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA
or the food safety authority of a country whose food safety system FDA has officially
recognized as comparable or has determined to be equivalent to that of the United States,
provided that the inspection was conducted within one year of the date that the onsite audit
would have been required to be conducted.

The NGFA offers the following views pertaining to any potential requirements for supplier
programs:

- **The role of audits should not be overemphasized.** The NGFA believes that potentially
  requiring facilities to conduct mandatory audits of suppliers would be much too
  prescriptive and not allow the necessary flexibility for a facility to tailor an effective
  supplier program based upon risk. Although the NGFA believes that audits may be an
  effective verification tool, they only offer a “snapshot” of a supplier’s performance at a
given time. The value of audits within any potential requirements for supplier programs
should not be overemphasized or prescribed in a narrow manner. Rather, effective audits
are risk-based, assess a supplier’s food safety system as a whole, and occur at a frequency
tailored to the risks presented by both the supplier and food.

In addition, for audits to facilitate food safety, the NGFA strongly believes that any
potential regulations must include provisions to ensure the confidentiality of audit
findings. The vast majority of information included in audit reports and that would be
available for review by FDA under its proposed regulations would be process- and
facility-specific. Therefore, the results contain such information as facility and
equipment design, and processing and monitoring parameters based on product formulas.
We believe that these design parameters and process and monitoring plans fall within the
bounds of trade secret or commercial confidential business information and must be
protected from public disclosure.

Moreover, confidentiality protections are necessary to encourage robust scrutiny and an
open dialog during the audit process without creating fears about consequences from
subsequent FDA review of the resulting report. We believe FDA’s potential records
access to audit findings should be limited, and primarily focus on information that
demonstrates appropriate actions were taken in response to the audit as needed to ensure
product safety.
Any potential requirements must conform with international standards and agreements. Section 404 of FSMA expressly states 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 its 2013 proposed Foreign Supplier Verification Program rule, that the agency is obligated to take a parallel approach to domestic supplier verification within its preventive controls regulations to enhance compliance with WTO obligations and ensure trade access.

Therefore, the NGFA believes that FDA should take a cautious and balanced approach when implementing the requirements associated with foreign and domestic supplier programs, recognizing such requirements have potential trade implications and that foreign countries likely will impose similar obligations on domestic suppliers that export products. Such requirements must be flexible in application and commensurate with both the risk associated with the product and the supplier itself so as to avoid unnecessary and burdensome costs.

The complex and comingled nature in which raw agricultural commodities and other bulk ingredients move through the supply chain must be recognized. Within the agency’s proposed regulation, FDA proposes to define “supplier” to mean, “the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.”

Therefore, FDA’s proposed definition of “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 previously has stated that it tentatively concludes Congress intended for the importer (or receiving facility) to verify a single supplier for a particular shipment of a food.

The NGFA agrees with FDA’s tentative conclusion. The agency’s proposed requirements cannot feasibly be applied to all of the potential establishments that may have been involved in the production and distribution of the 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 supplier, as appropriate, that has the greatest impact on the safety of the product.

Further, any potential supplier program requirements should appropriately reflect the complexities associated with the origination and movement through the supply chain of
raw agricultural commodities and many other bulk ingredients used by the food industry. A wide variety of bulk ingredients are handled and distributed in a comingled nature thereby making it unfeasible to determine the specific identity of each ingredient manufacturer whose product may be present in a given lot or shipment of the ingredient. The NGFA strongly believes any potential requirements pertaining to supplier programs must reflect the realities of the bulk ingredient supply chain by not attempting to impose untenable pedigree traceability standards and appropriately considering the risk posed by the raw agricultural commodity or ingredient.

- **Substitution of a regulatory inspection (e.g., by FDA or a comparable state regulatory agency, or food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States) should be allowed:** The NGFA strongly believes that FDA should not prescribe mandatory and rigid requirements for any potential supplier program. However, when a facility determines through an appropriate assessment of risk that verification activities of a supplier are necessary, we believe it would be appropriate for the facility to rely on the results of an inspection of the supplier conducted by FDA, a comparable state regulatory agency, or food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States. We believe this approach would adequately accomplish the required verification activity, and avoid costly and unnecessary redundancy.

**Economically Motivated Adulteration**

In FDA’s 2013 proposed rule for preventive controls, the agency announced its intent to implement the statutory requirements for hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking rather than include them in the requirements for preventive controls. However, when FDA developed its 2013 proposed intentional contamination rule, the agency tentatively concluded that economically motivated adulteration would be best addressed through the approach in the preventive controls rules for human food and animal food, rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as acts of terrorism. Therefore, FDA seeks comment on whether to add provisions to its preventive controls regulation to specifically address the potential for economically motivated adulteration.

FDA states that provisions proposed within its supplemental notice pertaining to economically motivated adulteration would require the hazard analysis to consider hazards that may be intentionally introduced for purposes of economic gain. Further, FDA states the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public health harm. Therefore, FDA notes that it would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their food products, but instead focus on circumstances where there has been a pattern of such adulteration in the past.
The NGFA strongly agrees that FDA should not require facilities to consider hypothetical economically motivated adulteration scenarios. To do so 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 supply.

If FDA establishes within its final regulation that an affected facility’s hazard analysis is to consider economically motivated adulterants, we strongly believe the facility should only be required to consider those adulterants for which there has been an historical pattern of occurrence. In addition, we believe that such an analysis should solely focus on inbound products, since it is obvious that intentional economic adulteration of products by the facility itself will not be prevented via a hazard analysis. Further, we believe that for facilities involved in the food industry, adulterants intentionally added to products that are identified through the hazard analysis likely would not meet the threshold of a “significant hazard” and therefore would be appropriately dealt with through supplier agreements and/or CGMPs.

In addition, the NGFA believes that guidance for both industry and FDA’s investigators would need to be developed and provided to ensure that regulatory obligations associated with any final requirement to consider economically motivated adulterants during required hazard analyses are clearly defined. As expressed previously, the NGFA believes the Food Safety Preventive Controls Alliance is the best forum through which such guidance may be developed.

**Detailed Comments on Proposed Part 117 Provisions**

The NGFA provides the following comments and recommendations on certain requirements proposed within FDA’s hazard analysis and risk-based preventive controls regulation. In several instances, we propose revisions to the draft codified language. In such cases, text that is recommended as being deleted is noted with a strikethrough (strikethrough) and text that is recommended as being added is noted by being boldfaced and underscored (boldfaced and underscored) for emphasis.

**Definitions**

The NGFA provides the following comments on the revised definitions proposed within § 117.3. For proposed definitions in which we are in agreement with FDA, we generally offer no comments.

- **FDA proposed definition:** *Environmental pathogen* means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

  The NGFA believes that FDA’s proposed definition for “environmental pathogen” is too general as it would include any pathogen that is capable of surviving or persisting in the environment. Instead, we believe the definition should be limited to pathogenic bacteria
that are more relevant when protecting human food safety. As such, we recommend the definition be revised as follows:

NGFA recommended definition: *Environmental pathogen* means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

- **FDA proposed definition: Hazard** means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

  The NGFA agrees with FDA’s proposed revision to include radiological hazards as a subset of chemical hazards in the definition of “hazard.”

- **FDA proposed definition: Known or reasonably foreseeable hazard** means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

  The NGFA agrees with FDA’s proposed revision because it provides for the proper consideration of both the food and the facility when making determinations pertaining to a “known or reasonably foreseeable hazard.”

- **FDA proposed definition: Holding** means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), 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. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

  The NGFA strongly supports FDA’s revised definition for “holding.” We agree that “holding” rightfully should encompass activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity).

- **FDA proposed definition: Pathogen** means a microorganism of public health significance.

  The NGFA believes the significance of pathogens to public health is dependent on the organism’s severity and exposure nature and, as such, recommends the definition be modified as follows:
NGFA recommended definition: **Pathogen** means a microorganism of such severity and exposure that it would be deemed of public health significance.

- **FDA proposed definition: Significant hazard** means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

As expressed previously, the NGFA generally supports FDA’s new term “significant hazard” and the process to be used by facilities to determine whether such a hazard exists within their operations. However, because the evaluation of severity and probability are so integral in making a proper determination as to whether a hazard is “significant,” the NGFA recommends that FDA revise its proposed definition to include these concepts. In addition, for the purpose of clarity, we also recommend the definition be modified to state that determinations of significant hazards are to be made by a “qualified individual.” Further, we suggest the definition include the concept of intended use of the food because it is essential to making appropriate determinations about hazards. As such, we recommend the proposed definition be revised as follows:

**NGFA recommended definition:** **Significant hazard** means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of food **qualified individual** would, based on the outcome of a hazard analysis that assesses the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of a preventive control, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the intended use of the food, the facility, and the control.

- **FDA proposed definition: Qualified auditor** means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 117.180(c)(2).

The NGFA strongly supports FDA’s proposal that would allow supplier audits to be conducted by a “qualified auditor” that is a receiving facility’s employee or by a third-party “qualified auditor” that need not be accredited under the requirements to be established under the agency’s forthcoming third-party certification regulation. We believe such an approach would provide for appropriate flexibility for conducting audits when necessary, while still ensuring the audits are performed with the required rigor to verify the safety of raw materials and ingredients.
In addition, the NGFA believes that a “qualified individual” may appropriately acquire the technical expertise to become a “qualified auditor” by training, education or experience. As such, we recommend the definition of “qualified auditor” be revised as follows.

**NGFA recommended definition: Qualified auditor** means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training, **education and or** experience appropriate to perform the auditing function as required by § 117.180(c)(2).

- **FDA proposed definition: Receiving facility** means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

  The NGFA supports FDA’s proposed definition for “receiving facility.”

- **FDA proposed definition: Supplier** means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

  The NGFA supports FDA’s proposed definition for “supplier.”

### § 117.5(j) and § 117.5(k) – Exemptions for Raw Agricultural Commodities Other than Fruits and Vegetables

Although not specifically addressed within FDA’s supplemental notice, the NGFA reiterates its belief that, based upon the minimal level of public health risk and the authority provided to the agency, FDA should modify its proposed rule 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 regulations.

As such, we restate our recommended revisions to § 117.5(j) and § 117.5(k)(1)(iii):

- § 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)(1)(iii): “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.”
§ 117.126 Food Safety Plan

Proposed § 117.126(b)(4) would require that the written food safety plan include a recall plan. In response, the NGFA believes that establishing and maintaining a recall plan is appropriate for facilities subject to FDA’s CGMPs regulation, not just those subject to FDA’s preventive controls regulation. Therefore, we believe the requirement for a recall plan rightfully should be established within FDA’s CGMPs regulation and that the reference to the recall plan within the section should be deleted:

- § 117.126(b)(4): The written recall plan as required by § 117.137(a);

§ 117.130 Hazard Analysis

The NGFA provides the following comments pertaining to proposed § 117.130 that would establish various provisions that require covered facilities to identify and evaluate hazards associated with the types of food manufactured, processed, packed or held at the facility.

- We note that FDA in its 2013 proposed rule used the phrase “experience, illness data, scientific reports, or other information” when defining criteria to be used when determining a “hazard reasonably likely to occur.” [Emphasis added.] We believe § 117.130(a)(1) should be similarly revised as follows to state the hazard analysis is to consider “experience, illness data, scientific reports, and or other information” about hazards, since it is not necessary to evaluate all of the criteria specified in all cases:

  - § 117.130(a)(1): You must identify and evaluate, based on experience, illness data, scientific reports, and or other information, known or reasonably foreseeable hazards for each type of food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards

- As previously expressed, we strongly believe facilities should not be required to consider hypothetical economically motivated adulteration scenarios within their hazard analysis. To do so 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 supply. If FDA establishes within its final regulation that the hazard analysis is to consider economically motivated adulterants, we strongly believe the facility should only be required to consider those adulterants associated with raw materials or ingredients for which there has been an historical pattern of occurrence. As such, we recommend that § 117.130(b)(2)(iii) be revised as follows:

  - § 117.130(b)(2)(iii): The hazard has an historical pattern of occurrence of may be being intentionally introduced for purposes of economic gain.

- Proposed § 117.130(c)(1)(ii) specifically would require that the hazard analysis include an evaluation of environmental pathogens under certain circumstances. In response, the NGFA believes it is unnecessary to establish a specific provision that identifies environmental pathogens as a hazard that is required to be evaluated. During the hazard
analysis, a facility already would be required to consider “known or reasonably foreseeable hazards” that have the potential to be associated with the facility or the food. Therefore, we recommend this provision be deleted:

- § 117.130(c)(1)(ii): The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

If FDA does not delete § 117.130(c)(1)(ii), we strongly recommend that FDA define within its regulation what is meant by the phrase “exposed to the environment.” Based on previous statements made by FDA, we understand “exposed to the environment” to mean the product is in a form that is exposed and/or subject to direct human contact. We believe providing a definition for “exposed to the environment” is necessary to avoid confusion over what is meant by this phrase.

- The NGFA believes that the proposed language in § 117.130(c)(2)(viii) referencing “intended or reasonably foreseeable use” is too open ended and vague to provide clear direction to industry and regulators pertaining to compliance obligations. Accordingly, we recommend that proposed provision be revised as follows:

  - § 117.130(c)(2)(viii): Intended or reasonably foreseeable Expected use;

§ 117.135 Preventive Controls

Pertaining to the proposed requirements in § 117.135 to implement preventive controls, the NGFA believes provisions for recall plans should be included within FDA’s CGMPs regulation. Therefore, we recommend that § 117.135(c)(5) related to recall plans be deleted:

- § 117.135(c)(5): Recall plan. Recall plan as required by § 117.137;

§ 117.136 Supplier Program

The NGFA provides the following comments pertaining to proposed § 117.136, which would require supplier controls when the receiving facility’s hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient.

- We believe § 117.136(a)(5) is confusing and contrary to other provisions that establish the receiving facility is to conduct verification activities as necessary and appropriate. We therefore recommend the provision be deleted:

  - § 117.136(a)(5): For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the
Proposed § 117.136(b)(4) would require the receiving facility to consider the applicable FDA food safety regulations and information regarding the supplier’s compliance with those regulations, including whether the supplier is the subject of an FDA warning letter or import alert relating to the safety of the food.

The NGFA believes that regulatory information such as FDA’s warning letters or import alerts can be a helpful tool to consider when assessing supplier risk, but that review of such information is only one benchmark that should be considered as part of such an assessment. Moreover, we believe receiving facilities should have the flexibility to determine what responsive action is appropriate based upon the significance of such regulatory actions for their intended use of the food, such as the food being supplied, the nature of the regulatory findings and whether the supplier has instituted effective corrective actions.

Further, we believe that a distinct and prescriptive review of regulatory information should not be required unless FDA develops a system that allows receiving facilities to efficiently monitor new regulatory enforcement actions. Currently, there is no way to ensure that warning letters and import alerts are timely when they are made available publicly, as this information is not typically posted in real time. Warning letters often are posted to FDA’s website several months after being mailed to a company. Before imposing any distinct regulatory requirement to review these materials, FDA first would need to develop an improved process to ensure that receiving facilities can obtain this information about their suppliers in an efficient manner and on a timely basis.

Proposed § 117.136(c)(2)(i) and (ii) would establish that for a SAHCODHA hazard controlled by a supplier, the receiving facility must have documentation of an annual onsite audit of the supplier, unless the receiving company documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

As expressed previously, the NGFA believes audits may be an effective verification tool, but they only offer a “snapshot” of a supplier’s performance at a given time. Therefore, the value of audits within any potential requirements for supplier programs should not be overemphasized. As such, the NGFA generally supports FDA’s proposed approach of allowing receiving facilities to document determinations that instead of an annual onsite audit other verification activities and/or less frequent onsite auditing of a supplier provide adequate assurance that a SAHCODHA hazard is being controlled.

Further, as expressed previously, the NGFA strongly supports FDA’s proposal that would allow audits to be conducted when necessary by a third-party “qualified auditor” that need not be accredited under the requirements to be established under the agency’s forthcoming third-party certification regulation.
FDA’s proposed rule specifies that if a supplier is a farm that is not subject to the produce safety regulations, the receiving facility of food from the supplier would not be subject to the “standard” verification requirements, but would instead be required to obtain written assurance biennially that the supplier is producing the food in compliance with the FD&C Act.

As such, under § 117.136(c)(4), if a supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with § 112.4 regarding the food being received, the receiving facility would not be subject to the supplier verification activity requirements in § 117.136(c)(1) and (c)(2) if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

These alternative verification requirements would apply to receiving facilities of raw materials from farms that do not grow and harvest “produce,” as defined in § 112.3(c) of the proposed produce safety regulations. For example, because grains are not “produce,” the alternative verification requirements would apply to receiving facilities that receive grain.

The NGFA believes that such a proposed requirement is contrary to the traceability provisions of the Bioterrorism Act and FSMA. Under the Bioterrorism Act regulations, a facility only is required to be able to trace food “one-step back.” Requiring receiving facilities to engage in supplier verification further back to the source of the food would be contrary to the Bioterrorism Act and the traceability provisions in FSMA. Significantly, FSMA specifically restricts FDA from requiring facilities to maintain records of the full pedigree of a food – even high-risk foods – and also limits trace back requirements for commingled raw agricultural commodities to the immediate previous source of the food. Any regulation that would require a receiving facility to verify a grower of grain, generally violates these traceability restrictions since receiving facilities typically would be required to go more than one-step back.

Further, as previously expressed, for reasons given by FDA in the preamble of its proposed Foreign Supplier Verification Program regulations, Congress intended for the importer (or receiving facility) to verify a single supplier for a particular shipment of a food. Since most grain received by receiving facilities is commingled and produced by multiple growers, FDA’s proposed requirements clearly are contrary to what Congress intended.
Moreover, the NGFA opposes such provisions because FDA has not established safety standards for the growers of grain. Therefore, attempting to receive “written assurances” from growers of grain to indicate that the grain supplied was produced in compliance with applicable FDA food safety regulations is not feasibly possible. As such, we believe the proposed requirement ultimately could result in the exchange of token paperwork that would have no appreciable benefit to food safety.

Therefore, the NGFA strongly urges that proposed § 117.136(c)(4) be deleted:

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§ 117.136(c)(4): If a supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with § 112.4 regarding the food being received, the receiving facility would not be subject to the supplier verification activity requirements in § 117.136(e)(1) and (e)(2) if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

Further, the NGFA urges FDA to appropriately exempt raw agricultural commodities other than fruits and vegetables from domestic and foreign supplier verification program requirements because of the low risk such commodities pose to food safety and because such products undergo further processing that addresses potential hazards.

- The NGFA supports proposed § 117.136(e)(1) that would, instead of an onsite audit, allow a receiving facility to rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within one year of the date that the onsite audit would have been required to be conducted.

- The NGFA believes § 117.136(g) should be revised to clarify that documentation and review of various verification activities is only necessary when such verification activities are used within the supplier program. To do so, we recommend the provision be revised as follows:

  § 117.136(g): The receiving facility, as appropriate to its supplier program, must document the following in records and review such records in accordance with § 117.165(a)(4)

In addition, consistent with our recommendation that raw agricultural commodities that are not fruit and vegetables be exempted from the supplier program requirements, we believe § 117.136(g)(11) should be deleted:
§ 117.136(g)(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

§ 117.137 Recall Plan

Proposed § 117.137 would establish requirements that a facility develop a written recall plan for food and assign responsibility for performing all actions in the plan.

As expressed previously, the NGFA believes that requirements associated with recall plans should be relocated to FDA’s CGMPs regulation. Further, pertaining to proposed § 117.137, the NGFA opposes FDA’s requirement in § 117.137(b)(2) that facilities notify the public about any hazard presented by the food when appropriate to protect public health. We believe such a requirement would be highly subjective and create a nebulous regulatory burden that could subject facilities to unnecessary regulatory oversight and enforcement actions. As such, we recommend that this provision be deleted:

- § 117.137(b)(2): Notify the public about any hazard presented by the food when appropriate to protect public health;

§ 117.140 Preventive Control Management Components

For reasons previously expressed, the NGFA believes that the proposed provision within § 117.140 pertaining to recall plans should be deleted:

- § 117.140 (c): The recall plan established in § 117.137 is not subject to the requirements of paragraph (a) of this section.

§ 117.150 Corrective Actions and Corrections

The NGFA provides the following comments pertaining to proposed § 117.150 that would require facilities to establish and implement written procedures for corrective action that is to be taken if preventive controls are not properly implemented.

- We believe the use of the term “all” with “affected” in § 117.150(a)(2)(iii) and (iv) and § 117.150 (b)(2)(i) is redundant and may contribute to unwarranted and unnecessary regulatory emphasis being placed on the extent of products that potentially may be subject to corrective actions if a preventive control is not properly implemented, if a preventive control is not properly implemented and a corrective action procedure has not
been established, or if a preventive control is found to be ineffective. Therefore, we recommend that these provisions be revised as follows:

- § 117.150(a)(2)(iii): All affected food is evaluated for safety; and

- § 117.150(a)(2)(iv): All affected food is prevented from entering into commerce if you cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

- § 117.150(b)(2)(i): Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section;

- The NGFA believes that FSMA provides that procedures be required for corrective actions, as opposed to a requirement that all individual preventive controls must have a specific corrective action procedure. We believe FDA should clarify within the preamble of its final rule that it is not necessary for all individual preventive controls to each have a specific corrective action procedure. As such, we recommend § 117.150(b)(1)(i) be revised as follows:

- § 117.150(b)(1)(i): A preventive control is not properly implemented and a specific corrective action procedure has not been established;

§ 117.160 Validation

The NGFA provides the following comments pertaining to § 117.160 that proposes to establish requirements for validating that preventive controls are adequate to control significant hazards.

- § 117.160(b)(1)(i) proposes to require that validation of preventive controls occur prior to implementation of the food safety plan or, when necessary, during the first six weeks of production. The NGFA believes that prescribing a specific timeframe for such activity is arbitrary and does not provide sufficient flexibility to facilities to always complete validation of the range of controls and/or control combinations that may be used to effectively control a hazard. We strongly recommend that FDA allow facilities to complete validation within a reasonable time, and that this provision be revised as follows:

- § 117.160(b)(1)(i): Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production within a reasonable time as justified by the qualified individual;

- Rather than requiring validation of preventive controls through collection and evaluation of scientific and technical information or studies as outlined in § 117.160(b)(2), the NGFA strongly recommends that FDA revise this provision 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. Therefore, we recommend that § 117.160(b)(2) be revised as follows:

- § 117.160(b)(2): Must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) evidence to determine whether the preventive controls, when properly implemented, will effectively control significant hazards;

- For reasons previously expressed, the NGFA believes that § 117.160(b)(3)(iv) pertaining to recall plans should be deleted:


§ 117.165 Verification and Implementation of Effectiveness

The NGFA provides the following comments pertaining to proposed § 117.165 that would require facilities to verify that preventive controls are implemented and effectively controlling significant hazards.

- We believe that § 117.165(a)(2) pertaining to product testing should be revised to clarify that such testing would apply to significant hazards. As such, we recommend the provision be revised as follows:

- § 117.165(a)(2): Product testing, for a significant hazard (e.g., a pathogen (or appropriate indicator organism) or other hazard;

- The NGFA believes proposed § 117.165(a)(4)(i) that would require a review of monitoring and corrective action records within one week after the records are created is arbitrary, too rigid and does not provide sufficient flexibility to facilities to perform required reviews under different timeframes that may be equally or more effective in achieving food safety. As such, we recommend the provision be revised as follows:

- § 117.165(a)(4)(i): Records of monitoring and corrective action records within a week after the records are created a timeframe determined to be appropriate to ensure that adulterated product does not enter commerce;

§ 117.170 Reanalysis

The NGFA provides the following comments on proposed § 117.170 that would establish requirements for reanalysis of written food safety plans.
• We believe that § 117.170(a)(3) pertaining to the need for reanalysis when “new”
information becomes available is an ambiguous requirement that would establish vague
compliance obligations. Further, the concept embodied by this provision does not align
with FSMA’s statutory language. As such, we believe the provision should be deleted:

  - § 117.170(a)(3): Whenever you become aware of new information about potential
hazards associated with the food;

• § 117.170(b) proposes that any additional preventive controls identified as necessary
during the reanalysis be implemented before the change in activities at the facility is
operative or, when necessary, during the first six weeks of production. The NGFA
believes that prescribing a specific timeframe for such implementation is arbitrary and
does not provide sufficient flexibility to facilities to always complete implementation of
the range of controls and/or control combinations that may be used to effectively control
a hazard. We strongly recommend that FDA allow facilities to complete implementation
of an additional preventive control within a reasonable time, and that the provision be
revised as follows:

  - § 117.170(b): You must complete the reanalysis required by paragraph (a) of this
section and implement any additional preventive controls needed to address the
hazard identified, if any, before the change in activities at the facility is operative or,
when necessary, during the first 6 weeks of production another timeframe
determined to be appropriate to ensure that adulterated product does not enter
commerce.

§ 117.180 Requirements Applicable to a Qualified Individual and a Qualified Auditor

Proposed § 117.180 would require that one or more qualified individuals prepare the food safety
plan, validate the preventive controls, review records for implementation and effectiveness of
preventive controls, and perform reanalysis of the food safety plan. Further, it would establish
criteria whereby individuals would be qualified to develop and oversee the food safety plan and
conduct audits used for verification purposes within supplier programs.

The NGFA generally agrees with FDA’s proposed definition for “qualified individual,” but
believes that education also is an appropriate criterion by which an individual may be qualified to
develop and apply a food safety system. In addition, we believe that a “qualified individual” may
appropriately acquire the technical expertise to become a “qualified auditor” by training,
education or experience.

As such, the NGFA recommends that the relevant provisions in § 117.180 be revised as follows:

  - § 117.180(c)(1): To be a qualified individual, the individual must have successfully
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 education or job experience to
develop and apply a food safety system. Education or job experience may qualify an
individual to perform these functions if such education or experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

§ 117.180(c)(2): To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training, education and or experience appropriate to perform the auditing function.

§ 117.305 General Requirements Applying to Records

The NGFA provides the following comments pertaining to proposed § 117.305 that would establish general requirements for the form, content and accuracy of required records.

- FDA proposes at § 117.305(a)(1) to require that electronic records be kept in accordance with 21 CFR part 11 (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 regulations may be retained electronically, provided that they comply with Part 11.

FDA stated in the 2013 proposed rule that it tentatively concluded that it is appropriate to apply the requirements of Part 11 to such records. However, FDA also requested comment on whether there are any circumstances that would warrant not applying Part 11 requirements within the regulation. As an example, FDA asked 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 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 ensure compliance with regulatory requirements or food safety.
Instead, the NGFA recommends FDA partner with key stakeholders to develop guidance that describes the kinds of practical principles, protocols and systems that may be used to ensure the integrity of electronic records without imposing specific technical requirements that are unnecessary and inappropriate.

- § 117.305(f)(2) proposes that all required records include the date and time of the activity performed. In response, the NGFA believes such a requirement to include the time of the activity with all required records is unwarranted. While the time of the activity may be of significance to records that document the monitoring of certain preventive controls that have parameters associated with them, recording of a specific time is not relevant or practical in many other instances when records are proposed to be required. For example, corrective actions may consist of multiple steps that occur over a period of time. In such a case, we believe it would be burdensome and unnecessary to require recording of a specific time when each step of the corrective action activity occurred. Further, we believe that requiring the notation of a specific time for records associated with verification activities is unwarranted. The effectiveness of such activities is not dependent upon the hour and minute at which they are performed. Therefore, the NGFA believes that FDA should require that records include time only when necessary to ensure the effectiveness of the activity being recorded.

Therefore, the NGFA recommends that proposed § 117.305 be revised as follows:

§ 117.305 General requirements applying to records

Records must:
(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;
   (i) Electronic records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in 21 CFR 11.3(b)(6) are exempt from the requirements of 21 CFR 11.
(b) Contain the actual values and observations obtained during monitoring;
(c) Be accurate, indelible, and legible;
(d) Be created concurrently with performance of the activity documented; and
(e) Be as detailed as necessary to provide history of work performed.
(f) All records must include:
   (1) The name and location of the plant or facility;
   (2) The date and, where necessary and appropriate, time of the activity documented;
   (3) The signature or initials of the person performing the activity; and
   (4) Where appropriate, the identity of the product and the production code, if any.

§ 117.330 Use of Existing Records

Proposed § 117.330 would establish that facilities may use existing records to satisfy the record requirements associated with the preventive controls regulation. Further, the provisions would establish that required information does not need to be kept in one set of records.
The NGFA strongly supports proposed § 117.330, as it would provide flexibility to facilities to comply with the record requirements in an efficient manner.

**Conclusion**

The NGFA wishes to again thank the FDA for issuing the supplemental notice and providing an additional opportunity to make comments on key provisions of this very significant proposed rule. As FDA is well aware, the agency’s regulations for preventive controls will set the regulatory landscape for the food industry for decades to come. We believe it is essential that requirements in the final rule are practical, achievable and demonstrably serve to ensure food safety.

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,

David Fairfield  
Vice President  
National Grain and Feed Association