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

Re: Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food (Docket No. FDA–2011–N–0920; RIN 0910–AG36)—GMA Comments on Food Safety Plan Requirements

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments on the food safety plan requirements as outlined in the Food and Drug Administration’s (FDA’s) proposed rule regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (78 Fed. Reg. 3646 (Jan. 16, 2013)).

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation’s economy.

GMA strongly supported the FDA Food Safety Modernization Act (FSMA) and looks forward to working with FDA for successful implementation of this groundbreaking law. GMA applauds FDA for the considerable efforts to reach out to stakeholders during the pre-rulemaking stage of the proceedings and for the agency’s willingness to continue that dialogue during the public comment period. We appreciate the Agency’s desire to develop a regulatory framework that is
protective of public health, risk-based, and practical. We all share a common goal of providing safe food to American consumers.

GMA is filing seven separate comments in response to the proposed rule, which address (1) the food safety plan; (2) testing; (3) supplier verification; (4) recordkeeping; and (5) current Good Manufacturing Practices (cGMPs), as well as (6) the economic analysis and (7) information collection burdens. The attached comments address aspects of the proposed rule involving the food safety plan requirements.

**Executive Summary of Comments**

We share FDA’s goal of implementing a regulation that mandates industry employ effective food safety systems that improve public health. We are concerned, however, that the proposed rule will not achieve this important goal and is not consistent with the statutory framework. FSMA did not introduce new food safety concepts – quite the opposite. FSMA embraced modern, well-recognized international standards for food safety already employed through much of the food industry. The concepts of hazard analysis, based on probability and severity, and the implementation of preventive controls to address such hazards, are deeply engrained in Codex Alimentarius and other international standards, and therefore already are employed by leading food companies around the globe. The result of this work is consistent production of safer food. The goal of FSMA was to take those recognized food safety principles and apply them in a structured way to all food producing companies – thereby raising the floor for broader, more consistent application.

Accordingly, we urge FDA to follow more closely the legal framework provided by FSMA. We believe the Agency can and should take a less prescriptive approach to identifying and managing preventive controls that would still result in providing a strong food safety regime and improving the performance of food companies who use inadequate food safety management systems. We are particularly concerned that the proposed rule is not consistent with leading food safety practices employed by many of our members and could result in significant added requirements and associated costs without commensurate food safety benefit. Senior FDA officials have stated many times that the Agency has no desire to add unnecessary requirements for food companies that already employ effective food safety programs. We believe our comments provide a constructive approach that would make the regulations more consistent with FSMA’s statutory framework, leading industry food safety practices, and, most importantly, help achieve FSMA’s goal of improving food safety. If the FDA adopts our proposals, then we agree the final regulations would have net food safety benefit as intended.

FDA’s proposed approach would require all preventive controls to be subject to management elements usually reserved for critical control points (CCPs) in Hazard Analysis and Critical Control Point (HACCP) systems, unless FDA has noted a specific exemption. This is because the proposed rule focuses on hazards “reasonably likely to occur,” which require CCPs in HACCP programs. We are concerned by this approach because CCPs are only one component of an effective food safety system. The term “preventive controls,” as defined under FSMA, is much broader than CCPs under HACCP programs. Food safety plans under FSMA must focus more broadly on food safety systems, including a foundation of horizontal “prerequisite” programs. GMA is proposing that “preventive controls” include the spectrum of controls that
food safety experts consider necessary to achieve the FSMA food safety goals, consistent with the statute.

Because there is such a wide range of preventive controls under FSMA, the regulations should not require all preventive controls to be managed in the same way. Each facility should determine, in the first instance, what level of management oversight is needed to accomplish the food safety goal of significantly minimizing and preventing hazards. For CCPs, the appropriate level of oversight would be consistent with that in the proposal (i.e., all CCPs should be subject to monitoring, corrective actions, and verification). But for the much broader range of preventive controls that are not CCPs, the level of management oversight applied should be commensurate with the nature of the risk and the type of control being used. Full management oversight is only needed for CCPs. FDA suggests this type of flexibility in different places in the preamble. We therefore urge the Agency to modify the codified language to more directly reflect this principle in the content of the final rule.

In short, as our comments explain in much more detail, we urge FDA to revise the regulations to:

(1) apply the statutory framework by using hazards “known or reasonably foreseeable” as the basis for hazard analysis with an evaluation of probability and severity to determine how hazards are controlled within the food safety system, taking a broader view of the definition of “preventive controls” as directed by the statute; and

(2) allow flexibility for the application of management elements for preventive controls so that such controls are managed with a level of rigor commensurate to the nature of the risk and the type of control employed.

We also want to emphasize that because FSMA provides FDA with on-site records access to oversee the implementation of all preventive controls for food safety, not just those at CCPs, FDA would have substantial records access if it follows GMA’s recommended approach. This access to records regarding the range of preventive controls would assist FDA with oversight and enforcement of the law. We also encourage FDA to use guidance documents to add greater clarity about ways FDA would find it acceptable to achieve compliance. Together, risk-based regulations, records access, and thoughtful guidance will ensure the law is enforceable.

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1 This approach, where the management oversight applied for a preventive control depends on what is appropriate and necessary for food safety, is sometimes referred to as the “sliding scale.” This expression illustrates that there are a wide range of preventive controls that are each managed with a different level of oversight intensity.

2 GMA supports giving FDA access to many food safety related records on a routine basis as part of an on-site facility inspection, but our comments note some limitations. For example, our comments on supplier verification urge limits on FDA’s access to supplier audit reports in order to encourage thorough and robust scrutiny of suppliers. Our comments on records access also discuss legal limitations on FDA’s access to consumer complaints. Additionally, our comments on records-related issues express our concerns about remote records access by FDA and requirements for electronic records to comply with 21 CFR Part 11.
Our attached comments first provide a thorough discussion of GMA’s suggested changes to the proposed framework for the hazard analysis and preventive controls. This is followed by detailed comments on subparts A, C, and D of the proposed rule. Throughout our comments, we suggest revisions to the regulations that have the following three characteristics to accomplish the objectives envisioned by FSMA:

- **System-based:** The regulation should address all controls within the context of a food safety system necessary to produce safe food and meet the food safety standards set out in FSMA, as judged by qualified food safety experts – not just those at critical control points.

- **Risk-based and tailored:** The regulation should make clear that facilities must select controls and determine how the controls need to be managed based on a hazard analysis that is fact-based and risk-based, taking into account food safety needs driven by specific products, processes, the nature of the controls involved, and other relevant factors.

- **Implemented appropriately:** The regulation should provide for effective enforcement, which requires an approach to regulatory verification that assesses the evaluation and management of risk within a food safety system and does not rely on a prescriptive list of regulatory requirements. Strategies to assist with implementation include providing examples in the preamble to the final rule and in Agency guidance documents, ensuring that all examples are treated as instructional and not applied as binding requirements.

**Implementation**

In addition, we want to emphasize the following essential points that should inform the Agency’s efforts for FSMA implementation:

- **The Final Rule Should Be Cost Neutral for Food Companies with Advanced Food Safety Programs:** GMA understands that the task of quantifying the economic impact of a sweeping food safety regulation such as the preventive controls proposal is difficult, and we appreciate FDA’s efforts to clearly define both the costs and benefits associated with the proposal. We agree with FDA’s stated goal of issuing regulations on preventive controls that would be essentially cost neutral for food companies that already have advanced food safety systems. As part of our comments on the preventive controls proposal, we are submitting proposed alternate regulatory language that will ensure the final rule is consistent with this goal – as well as consistent with both the letter and purpose of FSMA and the corresponding Preliminary Regulatory Impact Analysis (PRIA). The implementation cost estimates should accurately reflect the true costs the food industry will incur. GMA encourages the FDA to adopt the approach to preventive controls outlined in the comments based on our analysis that they are more cost effective and are aimed at preventing the diversion of resources from important food safety activities.
• **Effective Implementation Will Require Comprehensive Inspector Training:** Even after the Agency issues final regulations and publishes guidance, FSMA can only be successful if it is enforced effectively, uniformly, and fairly by the Agency’s inspectorate on both the federal and state levels. FDA should start now—with stakeholder input—to develop and implement a comprehensive program to train investigators about a wide range of issues, including what the regulations require, how inspections should be conducted, and what types of observations are appropriate to include on FDA Form 483s. Investigator calibration also will be essential so that the law is enforced consistently from one region to another, and by both federal and state officials.

FSMA inspections should take a “systems approach” and focus on whether the facility has designed and implemented effective systems to ensure food safety. Inspections should also reinforce incentives for behavior that promotes food safety, such as implementing robust environmental testing programs. Given the wide diversity of approaches that can be followed to make safe food, FDA also should establish a mechanism for investigators to consult with experts from the Agency’s Center for Food Safety and Applied Nutrition (CFSAN) if they have questions about technical issues regarding a facility’s operations. We also strongly support development of a timely appeals mechanism so companies that disagree with an investigator’s conclusion can readily bring the issue to the attention of CFSAN experts. We believe it is in everyone’s interest that the inspection process be transparent in both its planning and decision-making.

• **Guidance Cannot Be Treated as Binding:** GMA strongly supports the use of guidance to assist facilities with implementing the FSMA regulations, provided that guidance is appropriately treated as illustrative but non-binding. Guidance can be a helpful way to provide more “meat” on the “bones” of the regulation itself by explaining in some detail the various approaches a facility can use to comply with the regulations. Guidance also is an important tool to explain the Agency’s expectations and help companies with limited resources understand specific steps they can follow to develop compliant programs. GMA welcomes the opportunity to assist the Agency with guidance development.

We ask FDA to take steps to ensure that FSMA guidance is not implemented as legally binding responsibilities. The Agency’s Good Guidance Practices regulation, 21 CFR § 10.115, very clearly explains that guidance does “not legally bind the public or FDA” and companies “may choose to use an approach other than one set forth in a guidance document.” FDA’s inspectors need to understand this limit so that they do not seek to enforce guidance as imposing regulatory requirements, as has occurred at times in the past. Rather, inspectors should treat guidance as a “safe harbor” that represents an acceptable compliance approach but not the only approach to compliance. The Agency should ensure inspectors have this limitation during inspections.
Support for Other Industry Comments

GMA is proud to lead a coalition of industry trade associations that are working together to ensure FSMA is a success. Together, members of the GMA FSMA Coalition hope our comments will assist the Agency in revising the proposed rule so that it will be both practical for industry and implementable for FDA. As some members of the Coalition focus more specifically on certain commodities within the food industry (e.g., frozen foods, dairy foods), their comments will focus on issues that are not discussed or emphasized in our broader, industry-wide comments. GMA wants to highlight our agreement with the following points made by coalition members:

- We endorse comments on the current good manufacturing practices portion of FDA’s proposed rule, as submitted by the American Frozen Food Institute (AFFI), and joined by other members of the CGMP Modernization Coalition.
- We support the comments submitted by the International Dairy Foods Association (IDFA) that FDA should determine that facilities regulated by the Pasteurized Milk Ordinance (PMO) are deemed to be in compliance with the preventive controls regulation so that these companies are not subject to two differing sets of rules.
- We endorse the comments filed by Coalition members regarding the produce safety proposed rule, though we are not submitting comments to that docket.

* * *

We appreciate the opportunity to submit these comments and look forward to continuing to work with the Agency to ensure FSMA implementation is a success. Keeping food safe for consumers is our top priority.

Sincerely,

Leon Bruner, DVM, Ph.D.
Senior Vice President for Scientific and Regulatory Affairs &
Chief Science Officer
GMA Feedback and Recommendations on Proposed Rule:
Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food 21 CFR Part 117

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Comments on Proposed Regulatory Framework

GMA strongly supported the Food Safety Modernization Act (FSMA) and looks forward to working with FDA for successful implementation of this groundbreaking law. GMA applauds FDA for the considerable work put into the proposed rule, and appreciates the Agency’s efforts to develop a regulatory framework that is protective of public health, risk-based, and practical. GMA is concerned, however, that the proposed rule as drafted will not achieve these important goals.

FSMA is a transformative law that mandates effective food safety systems, requiring facilities to rigorously analyze potential hazards (which can be present in a myriad of ways, depending on the circumstances), select the right preventive controls, and manage those controls in a risk-based way to meet specific food safety goals relevant to the product, process and consumer. The proposed rule appears to take a prescriptive approach to identifying and managing preventive controls, and does not account for the role of many horizontal “prerequisite” controls in ensuring product safety. More specifically, FDA has defined preventive controls in the proposed rule as if FSMA mandated Hazard Analysis and Critical Control Point (HACCP) systems instead of food safety plans. This is a concern because HACCP is designed to focus on only the most critical controls in a process (i.e., critical control points, or CCPs), is only one component of an effective food safety system, and is built on a foundation of horizontal “prerequisite” programs; in contrast, food safety plans focus more broadly on food safety systems. GMA appreciates that FDA has identified some horizontal prerequisite programs as preventive controls, but the proposed rule does not adequately account for the role of many other prerequisite controls for ensuring product safety.

A HACCP focus means that many preventive controls will be subject to a management approach typically reserved for CCPs, and this is reflected in the requirements of the proposed rule. Applying a CCP-like approach to the full range of preventive controls raises several concerns:

- It does not align with and is not authorized by FSMA, which mandates a risk-based regulatory framework that extends beyond HACCP systems.

- It does not accommodate existing systems that are used effectively today, creating the potential for confusion, unnecessary debates, needless duplication of records and procedures and likely enforcement difficulties for FDA. As a result, the proposed rule contradicts FDA’s economic analysis, which assumes few changes to existing food safety programs.

- It would create requirements that are not needed for food safety and divert focus away from measures that are proven effective for ensuring food safety.
To satisfy the intent of FSMA, the implementing regulatory scheme must enhance food safety, anticipate future developments in technology, and include enhanced authority for FDA to regulate not only facilities with a history of successful food safety programs, but also facilities that may be less capable of implementing appropriate food safety systems. GMA contends that a preventive controls regulation with the following three characteristics will accomplish the objectives envisioned by FSMA:

- **System-based**: The regulation should address all controls within the food safety system necessary to produce safe food and meet the food safety standards set out in FSMA, as judged by qualified food safety experts.

- **Risk-based and tailored**: The regulation should make clear that facilities must select controls and determine how the controls need to be managed based on a hazard analysis that is fact-specific and risk-based, taking into account food safety needs driven by specific products, processes, the nature of the controls involved, and other relevant factors.

- **Implemented appropriately**: The regulation should provide for effective enforcement, which requires an approach to regulatory verification that assesses the evaluation and management of risk within a food safety system and does not rely on a prescriptive list of regulatory requirements. Strategies to assist with implementation include providing examples in the preamble to the final rule and in Agency guidance documents, ensuring that all examples are treated as instructional and not applied as binding requirements.

To set out the basis for GMA’s proposal, these comments offer perspectives on the food safety plan and related portions of the FDA preventive controls proposed rule and are divided into two parts:

- **Changes to the proposed regulatory framework** that GMA believes will best promote food safety and be consistent with FSMA, as presented in the following sections:
  - Challenges presented by the proposed rule
  - GMA’s recommended modifications to the proposed regulatory framework
  - Advantages of GMA’s recommended changes

- **Detailed comments about particular provisions and recommendations for codified language.**
  - Food safety plan (proposed § 117.126)
  - Hazard analysis (proposed § 117.130)
  - Preventive controls (proposed § 117.135)
Recall plans (proposed § 117.137)

Monitoring (proposed § 117.140)

Verification (proposed § 117.150)

Qualified individuals (proposed § 117.155)

Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 117.206)

GMA comments on related but separate FSMA topics, such as records, supplier verification, verification testing and good manufacturing practice requirements, are being submitted separately.

I. Challenges Presented by the Proposed Rule

Perhaps the most important principle underlying FSMA is the need for the regulatory framework to be risk-based, meaning that a “one size fits all” approach will not work for the design and management of all preventive controls. GMA appreciates that FDA has frequently emphasized this important objective in the preamble and at public meetings and other forums. After carefully reviewing the proposed regulatory language, however, GMA is concerned that the proposed rule itself will not accomplish FDA’s intended result. FSMA was designed to provide for broad oversight of food safety systems, but as drafted, the proposed rule appears to view all preventive controls as if FSMA were HACCP, which is only one component of an effective food safety system. As a result, the proposed rule is likely to be interpreted to require most preventive controls to be managed in an unnecessarily prescriptive way—more specifically, like CCPs, which are the focus of HACCP systems.

To lay the groundwork for GMA’s specific recommendations (discussed in Section II, below and in detailed comments), this section reviews FDA’s intent to provide flexibility and explains why changes are needed to align the proposal with this intent.

A. The Preamble to the Proposed Rule Recognizes that Risk-Based, Flexible Systems Are Needed

In discussing several examples of food safety measures in the preamble to the proposed rule, FDA recognizes that not every control measure needs to be subject to the same kind and amount of oversight. For example, FDA explains that the specific parameters required for a preventive control, and how the parameters would be controlled, “would depend on the facility and the food, also stating that “the types of preventive controls implemented would depend on the facility and the food it produces,” 78 Fed.Reg.3739-40. The Agency further explains that parameters may not be necessary in all cases:

Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal
contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters. Similarly, label controls for food allergens do not involve identification of specific parameters. 78 Fed.Reg. 3740.

As another example, FDA has decided to not require controls to be monitored at a specific frequency in recognition that the “frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process.” 78 Fed.Reg. 3748. FDA explains that if the temperature needed to ensure safety of roasted nuts is 290 °F, non-continuous monitoring would need to be more frequent when an oil roaster for nuts is operated at 300 °F than when the oil roaster is operated at 350 °F. Similarly, if temperatures vary by 10-15 degrees during processing, monitoring would need to be more frequent than if variation is only 1-2 degrees. 78 Fed.Reg. 3748-49. GMA appreciates these examples and agrees that they show the need for facilities to manage controls in a manner consistent with the underlying circumstances, which include the relevant hazard analysis, the food, the facility, and the nature of the preventive control, among other factors.

B. The Actual Regulatory Language Needs to Ensure that Controls Can Be Adapted to Meet Diverse Food Safety Needs

GMA has carefully compared the proposed rule to FDA’s important goal, as reflected in FSMA, of a risk-based framework that allows controls to be managed according to specific food safety needs. GMA concludes that two kinds of changes are needed for the regulation to achieve the result FDA and FSMA intended. First, changes are needed to make clear that facilities must manage individual preventive controls in a way that accommodates specific circumstances and a range of identified hazards. Indeed, in many situations, managing controls to meet specific food safety needs is essential to protect public health. Second, for clarity and to accommodate current effective food safety programs, the scope of the proposed rule should be changed to reflect a broader range of controls that successful facilities manage as part of overall effective food safety systems. Together, these changes will make it clear that facilities must choose preventive controls based on a scientific hazard analysis and determine how these controls must be managed to meet specific and very diverse food safety needs.

1. The Proposed Language Appears to Prescribe Specific Management Elements, But Facilities Need to Manage Controls to Meet Diverse Food Safety Needs

GMA’s first concern stems from several places where the proposed regulations appear to prescribe exactly how preventive controls are to be managed. For example, the proposed regulations explain that, “except as otherwise provided, preventive controls are subject to monitoring, corrective actions, and verification.” (Proposed § 117.135(e) (emphasis added)). This appears to require all of these management elements for all preventive controls, unless FDA has provided a specific exception. Also of concern, the regulations do not expressly state that where a particular management activity is required, the design and implementation of the activity may vary based upon the nature of the control measure and the hazard being controlled (e.g.,
where a control must be monitored for food safety, the way the control is monitored may vary based on the particular food safety need).

The proposed regulation also states that, unless a specific exemption applies, all preventive controls must be validated: “[e]xcept as provided by paragraph (a)(3) of this section . . . a facility must validate that the preventive controls . . . are adequate.” Proposed § 117.150(a) (emphasis added). Paragraph (a)(3) provides exemptions only for allergen controls, sanitation controls, and recall plans. This prescriptive language is both too broad and too narrow: it is too broad because it could be cited as supporting a requirement to validate any non-exempt control, even where validation of such a control isn’t practical or necessary; at the same time, it is too narrow because it would prevent FDA from requiring validation of specific allergen or sanitation controls where it may be prudent to do so, either now or in the future as a result of a newly identified hazard, establishment of regulatory allergen threshold(s), or the development of a tool, such as a test method, which would enable validation of the control of the specific identified hazard.

Where the proposed rule does include language to indicate flexibility, FDA’s intent to allow for differing circumstances is not as evident as it is in the preamble. For example, the proposed regulations state that preventive controls “must include . . . parameters . . . and [t]he maximum or minimum value, or combination of values, to which any . . . parameter must be controlled.” Proposed § 117.135(c) (emphasis added). The proposed regulations also state “as appropriate to the facility and the food,” but this is overshadowed by the emphasis created by the term “must,” and the fact that “as appropriate” could be understood to mean “if possible” or “if suitable,” as opposed to “if necessary for food safety.” As a result, an inspector may interpret this provision to mean if it is possible in any way to define maximum or minimum parameter values, the facility must have them, regardless of the nature of the particular control or the specific food safety need.

For example, maximum or minimum values are not relevant for controls in the storage of ingredients that are food allergens. The ingredients are either segregated appropriately or not. Attempting to assign “parameters” (i.e., appropriate storage conditions) and minimum/maximum values (i.e., where the “minimum” value is proper storage, and the “maximum” value is improper storage) would not be useful or necessary for assessing the implementation of this control.

The regulatory language is a concern because it does not accommodate the approach taken by facilities with successful food safety histories. Such facilities carefully assess hazards and identify the management elements necessary to ensure the effectiveness of each specific control measure. For some preventive controls (e.g., CCPs and certain prerequisite programs) all of the management elements will be necessary. In other cases, however, the facility will identify and implement management elements that make the most sense in light of the hazard analysis, the nature of the control, and other factors.

For example, a facility may determine through its hazard analysis that a specific food safety hazard would be probable if there is variation in the cooling or storage of a specific product and that the process needs to be closely managed to ensure that cooling conditions are controlled. In this case, the process of cooling may be identified as a CCP and management of the control would involve all of the relevant criteria, applied with appropriate intensity:
• The CCP must be validated as effective for control of the identified hazard(s).

• Based on cooling studies, time and temperature must be identified as parameters, with minimum and maximum values that must be met.

• The facility must monitor the parameters and associated values, document the monitoring, and confirm their appropriate use through verification.

• If the parameters are not met, the facility must follow a specific corrective action procedure to address the situation because failure to satisfy the CCP requirements is presumed to potentially create a food safety issue.

In contrast, a facility may determine, based upon product characteristics and/or the process applied, that cooling is a general control instead of a CCP. The criteria used to manage this control would be commensurate with the likelihood and consequences of a loss of control:

• In the case of many refrigerated processed cheeses, the magnitude of the temperature abuse needed to create a food safety issue is quite significant and unlikely due to the nature of the product. The product is cooled and refrigerated primarily to maintain product quality, so that residual heat from the manufacturing process in the center of the cheese block does not change the color of the product. The manner and frequency of monitoring chosen will be sufficient to ensure that the hazard is controlled, and the quality of the product is maintained, so are far less stringent than that applied for cooling as a CCP. A loss of control of the cooling process in this example is highly unlikely to result in a hazardous product and corrective actions in most cases would address quality, and not food safety, concerns.

• A study by a manufacturer of a product placed into frozen storage indicates sufficiently rapid cooling that will prevent microbial growth to hazardous levels. Variations in freezing conditions will not delay adequate cooling of the product to a degree that would result in an identified hazard increasing to unacceptable levels. The performance of the control measure is ensured through a verification that all products are frozen but it is not necessary to monitor the conditions of the freezing process to ensure adequate cooling for safety.

• A facility may have continuous monitoring of cooling through an automated control system that sounds an alarm if temperature specifications are exceeded, but records of monitoring are generated only if the temperature exceeds a pre-set maximum value (an alarm is sounded). The performance of the system is validated, calibrated and verified at a regular frequency. Records are kept only for exceptions. When an alarm occurs, the facility would follow a specific corrective action procedure, which requires the alarm to be documented in a corrective actions log. The log is reviewed once yearly as part of the general review of the applicable food safety plan.

As these examples show, even for the same kind of control, the specific circumstances determine the combination and intensity of management elements that are necessary for food safety. Additional examples showing the way individual management elements may apply across a
range of preventive controls are provided in GMA’s detailed comments on Proposed Subparts A, C, and D.

2. The Use of the “Reasonably Likely to Occur” Standard to Define Preventive Controls is Not Aligned with the Scope of FSMA that Covers the Entire Food Safety System

GMA’s second concern is FDA’s decision for the FSMA requirements to apply only to “hazards reasonably likely to occur” (RLTO), meaning that preventive controls and other FSMA-dictated provisions are required only for hazards that meet this standard. This approach reflects the HACCP focus of the proposed rule: RLTO is the standard used to identify hazards that must be managed by CCPs under FDA’s juice and seafood HACCP regulations as well as FSIS-regulated meat and poultry facilities. By using this HACCP standard, the proposed rule appears to treat all preventive controls as substantially similar to CCPs (i.e., either equal or very similar to CCPs). This approach is well-intended but problematic due to the way the statute is written (with a broad definition of preventive controls) and the inherent difficulty in interpreting what RLTO means.

FSMA was intentionally drafted to be broader in scope than HACCP, defining “preventive controls to include such diverse controls as good manufacturing practices, sanitation, hygiene training and supply chain management. Environmental monitoring programs are also listed as preventive controls, although GMA is in agreement with the FDA that such programs are verification activities and are not effective as control measures. FSMA does not use the term “reasonably likely to occur” to define a threshold for determining preventive controls, nor does it provide any other basis for using such a term to differentiate among various hazards and associated preventive controls. Thus, from a purely legal perspective, GMA does not see a basis for including an RLTO standard in the FSMA framework.

The proposed RLTO standard is also problematic from a practical standpoint because it will be very difficult to apply in the FSMA context. Several issues are particularly concerning: (1) facilities with successful programs routinely consider the contributions of prerequisite programs in assessing whether a hazard is probable, but the continued acceptability of this practice under the proposed regulations is unclear; (2) the regulatory history of the term as used in HACCP regulations reveals significant differences in interpretation; and (3) use of RLTO in the FSMA context has the potential to conflict with existing HACCP regulations and cause confusion.

Prerequisite Programs. Significantly, it is very common to consider the contributions of prerequisite programs—many of which FDA will likely want to regulate as preventive controls, and some of which are expressly identified as preventive controls in FSMA—in determining that a hazard is not reasonably likely to occur. Consideration of prerequisite programs as part of a hazard analysis aligns with authoritative food safety standards, such as those established by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and Codex Alimentarius Food Hygiene Committee. NACMCF emphasized the importance of general prerequisite programs that “provide the basic environmental and operating conditions that are necessary for the production of safe and wholesome foods.” NACMCF 1997. NACMCF concluded that an assessment of the existence and effectiveness of these programs should be made during the design and implementation of HACCP plans. Facilities conducting HACCP studies have historically considered the effectiveness of prerequisite programs in controlling
identified hazards when determining whether there remain hazards of such probability and severity that the identification and management of controls applied at CCPs during the process is necessary to ensure their control. Microbiological hazards at some facilities, such as confectionery or dry mix operations, may be exclusively controlled through prerequisite programs without a need for CCPs.

It is unclear how decisions about prerequisite programs will be treated under the proposed rule. For example, FDA has suggested refrigerated storage for food safety is likely to be a preventive control, but many facilities could consider the reliability of robust refrigeration systems as a factor in deciding that a biological hazard is not reasonably likely to occur. A facility that stores pasteurized milk for further processing may conclude that the milk as stored is not exposed to a significant risk of a biological hazard due to refrigeration systems that make such hazards not probable and thus do not need to be managed at a CCP in the process. GMA is concerned that this common scenario will lead to confusion and uneven results under the proposed rule. Such a facility may be asked (or required) to change its hazard analysis to designate the potential hazard as RLTO, solely for the purpose of making the control a “preventive control” subject to FDA oversight under FSMA. As a result, similar or even identical controls will be “preventive controls” or not depending on the way individual facilities analyze hazards or respond to regulatory inspections. In contrast, the changes GMA is proposing would make clear that all food safety programs are “preventive controls” that must be managed appropriately to meet the FSMA food safety goals.

**Regulatory History**, GMA is concerned that, even though RLTO is a probability term, the RLTO standard itself has been applied in many contexts without a realistic evaluation of probability, and without consideration of prerequisite programs. Several examples that have been discussed in connection with seafood HACCP show the nature of the issues:

- In facilities that handle only one kind of allergen (e.g., a facility that makes only tuna products with no added ingredients), GMA understands the risk of an undeclared allergen to be considered by FDA to be “reasonably likely to occur” even though the relevant allergen (i.e., “tuna”) is declared in multiple places on all labels used in that facility. It has been suggested that these facilities would need to make label application a CCP.

- Potential hazards such as *Staphylococcus aureus* in a particular fish species have been deemed by FDA to be “reasonably likely to occur” in the absence of evidence to suggest it has ever occurred in that species in the past 100 years.

- In a situation involving salmon cream cheese, the risk of growth and toxin formation by spore forming microbes was deemed by FDA as “reasonably likely to occur” despite challenge study data showing that in the unlikely event spores were present, it would take several days at significantly abusive conditions for the organism to grow and produce toxin. Abusive conditions at even a fraction of that time are extremely unlikely under modern conditions of storage and transport.

In these examples, the assessment of whether a hazard was RLTO was indicated by FDA to require an assessment of probability in the absence of any control measures, including general or prerequisite controls. Facilities were to assume that basic systems like refrigeration, sanitation, or
other programs with a long history of consistent performance did not exist or were not operating at all. An RLTO determination that does not allow for a realistic assessment of probability, and that does not allow consideration of the impact prerequisite programs have upon hazard likelihood, directly conflicts with approaches taken in numerous highly effective food safety programs.

Conflict with HACCP Regulations. GMA is also concerned that the proposed RLTO standard has the potential to conflict with existing HACCP regulations, which differ from FSMA. Under these regulations, the term “reasonably likely to occur” is used to identify those hazards of such probability and severity that their control is managed by control measures at CCPs. In the proposed rule, FDA has broadened RLTO to identify not only hazards that are controlled at CCPs but also those that are managed by other process controls and general controls such as food allergen controls and sanitation controls. Because it is used in a narrower context in other rules, the use of the term RLTO in the proposed preventive controls rule could create confusion during inspections, particularly where an investigator is involved in the verification of regulatory HACCP frameworks for seafood and juice. For example, an inspector might expect a facility that has identified a hazard as RLTO to have CCP equivalent records and management elements for all associated preventive controls. This confusion is reinforced by the language of the draft rule that implies that all management elements apply to all preventive controls, regardless of whether they are CCPs (i.e., validation, verification, monitoring, corrective actions). The broader application of RLTO to preventive controls other than CCPs could also cause confusion in facilities that operate under multiple regulatory frameworks (e.g., seafood HACCP and the proposed preventive controls regulations in Part 117) that must accommodate food safety plans with different outcomes resulting from an RLTO determination.

II. GMA’s Recommended Modifications to the Proposed Regulatory Framework

GMA has carefully considered the changes necessary to align the proposed rule with FDA’s goals for a risk-based regulation that advances public health and is consistent with current effective food safety practices, international standards, the statute, and the Agency’s economic analysis. GMA sees the ideal regulatory scheme as one that enhances food safety, accommodates future developments in technology, and includes enhanced authority for FDA to regulate not only facilities with successful programs, but also facilities that may be less capable to implement appropriate systems. GMA respectfully suggests that a regulation with the following three characteristics will accomplish all of these important objectives:

- **System-based:** The regulation should include all controls within the food safety system necessary to meet the ultimate objectives outlined in FSMA—to significantly minimize or prevent known or reasonably foreseeable hazards and/or to prevent food from being adulterated or misbranded due to undeclared allergens (for ease of reference, these comments will highlight these standards as the “FSMA food safety goals”), as judged by qualified food safety experts. In other words, the regulation should ensure that facilities choose appropriate preventive controls for food safety.

- **Risk-based and tailored:** The regulation should make clear that facilities must select controls and determine how they must be managed based on a hazard
analysis that is fact-specific and risk-based, taking into account food safety needs driven by specific products, processes, the nature of the hazards and necessary controls, and other relevant factors. In this respect, the regulation should ensure facilities will manage preventive controls in the right way, with the right kinds of management elements (i.e., monitoring, verification, corrective actions, validation, parameters, and related documentation as appropriate and necessary).

- Implemented appropriately: The regulation should allow for effective enforcement and FDA should illustrate how to effectively manage hazards and related control measures consistent with the regulation by providing examples in the preamble to the final rule and Agency guidance, while ensuring that these examples are not interpreted as binding requirements.

A. System-Based

As drafted, the proposed rule applies only to controls for “hazards reasonably likely to occur.” For example, the regulations say the purpose of a hazard analysis is to “determine whether there are hazards that are reasonably likely to occur.” The primary preventive controls section (proposed § 117.135) is titled “Preventive controls for hazards that are reasonably likely to occur.” The section goes on to limit its requirements to controls for “hazards identified in the hazard analysis as reasonably likely to occur.” As described in Section I, above, GMA is concerned that the proposed use of “reasonably likely to occur” is inconsistent with the statute, will be difficult to interpret, and will not advance food safety. GMA is proposing several modifications to replace the RLTO standard.

First, GMA recommends that FDA determine the scope of the rule based on the statutory definition of “preventive controls”: “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.” FFDCA section 418(o)(3) (emphasis added). In other words, a control should be a “preventive control” if food safety experts (qualified individuals) would use it to achieve the FSMA food safety goals – to significantly minimize or prevent known or reasonably foreseeable hazards identified and evaluated in the hazard analysis and/or to prevent food from being adulterated or misbranded due to undeclared allergens.

Second, GMA recommends that FDA incorporate the statutory standard into proposed section 117.130(a)(1) as follows (showing proposed additions in underlined text and proposed deletions in strikethrough text): “The owner, operator, or agent in charge of a facility is responsible for ensuring that must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility are identified and evaluated by a qualified individual to determine, based on their probability and severity, whether there are hazards that are reasonably likely to occur the hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.”

Third, GMA recommends that FDA consider identifying, in guidance, the types of food safety programs that may generally be regarded as meeting the standards for “preventive controls” set
out in the FSMA definition and food safety goals. In GMA’s experience, food safety experts commonly rely on three categories of controls to address known or reasonably foreseeable hazards across food safety systems:

1. For known or reasonably foreseeable hazards that are identified and evaluated as significant (i.e., they are determined to have a severity and probability of such a nature that they require specific management), facilities use controls that directly address the hazard, such as CCPs or, in some cases, prerequisite programs that target specific hazards.

2. To prevent known or reasonably foreseeable hazards from becoming significant, facilities may expressly rely on one or more prerequisite programs that make a hazard either not probable and/or not severe. For example, a hazard analysis may note that a biological hazard is not probable due to specific good manufacturing practices in place in a facility. In such a case, the prerequisite program is not directly addressing the hazard, but it is expressly relied upon to make the hazard not significant.

3. Facilities implicitly rely on a number of other programs that food safety experts generally recognize as affecting the significance of known or reasonably foreseeable hazards in some meaningful way. In some cases, these programs may be recognized as affecting a specific significant hazard. For example, in a nut facility, hygienic zoning is an essential program to have in place for preventing cross contamination by Salmonella, even though that hazard is directly managed as a significant hazard through controls such as roasting. Hygienic zoning may not be expressly linked to a specific hazard in the food safety plan, but it is nonetheless known to be important. In other cases, a program may help prevent a hazard from becoming significant in the first place, even though it may not be expressly identified as such – e.g., preventive maintenance- may affect the probability of some foreign material hazards, whether or not a facility explicitly highlights it as having that role in the hazard analysis.

Because facilities use controls in these three categories to meet the FSMA food safety goals, GMA recommends that controls in these categories should be “preventive controls.” Under this approach, the FSMA-required “food safety plan” would address all important controls a qualified individual has determined to be necessary for the management of food safety hazards throughout the food safety system.3

Fourth, GMA recommends that FDA takes the following additional steps (among others recommended in the attached detailed comments) to ensure the food safety plan includes all important elements of the food safety system:

- In the hazard evaluation section (117.130(c)), delete the reference to “reasonably likely to occur,” and simply explain the key elements of the evaluation: “The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section,

3 Significantly, a “food safety plan” is usually not a single document but rather will include a network of documents and materials in use across a food safety program, including HACCP plans, prerequisite programs, related procedures, and other relevant materials.
including an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur.” This revision clearly sets out the two key components of a hazard evaluation—severity and probability.

- Also in the hazard evaluation section (117.130(c)), make clear that facilities may consider the impact of prerequisite programs, among other factors, on the probability of a hazard, including:
  - The effectiveness of existing programs, such as GMPs or other general controls;
  - The frequency with which a potential hazard is associated with a food, ingredient, process, or other component of a food safety system;
  - The method of preparation within a processing facility or by the consumer;
  - Storage and transportation conditions;
  - Historical experience within the facility or with the product category;
  - Design of the processing system.

- In the preventive controls section (117.135(a)), and other places where a reference to scope would be helpful, replace terms such as “hazards identified . . . as reasonably likely to occur” with “hazards identified and evaluated as . . . needing to be addressed in the food safety plan.”

A complete list of the changes GMA recommends is provided in the detailed comments that follow.

B. Risk-Based and Tailored

In addition to requiring the use of appropriate preventive controls throughout the food safety system, the preventive controls regulation (including the regulation itself and associated guidance documents) must ensure that controls are managed appropriately. Under FSMA, controls must be risk-based and therefore must be managed differently depending on the specific circumstances; to make this possible, the regulation must expressly provide for such tailored management. FDA has recognized the need for the regulation to be risk-based and able to accommodate a range of food safety needs, so it is imperative to make sure this intent is carried out in the final regulatory language.

To allow facilities to accommodate a wide range of food safety needs, GMA has determined that the regulations for management elements should convey not only that the application of a particular element be appropriate (i.e., suitable for a particular purpose, or capable of being applied), but also necessary for food safety (i.e., to meet the overall FSMA food safety goals, or
to ensure a particular control is effective, taking into account key factors such as the probability of a hazard, its severity, and the nature of the control). For example:

- Assigning a parameter and associated minimum and maximum values may be *appropriate* for controls like refrigeration, acidification, or water activity because these controls may lend themselves to quantification. Such assignments, however, may not be *necessary* for food safety in some instances. For example, a food safety limit for water activity could be set at $<0.85$ based on the control of *Staphylococcus aureus* outgrowth, but a product such as a cheese powder or a dry spice blend has a water activity of 0.2-0.3. Assigning water activity as a parameter with a limit of $<0.85$ is not necessary to assure food safety for such products. As another example, the conditions of many baking processes are significantly higher than that necessary to ensure that microbiological hazards in flour and other raw materials are significantly minimized. In this scenario, all products which have been baked have been subjected to this time/temperature. It is not necessary to set parameter limits of time and temperature.

- In contrast, assigning a parameter and minimum/maximum values is *not appropriate* for controls that are effective based solely on whether the control is performed or not (presence/absence). For example, allergenic ingredients are either appropriately segregated or they are not; glass jars either remain intact or break. By their very nature, these controls do not lend themselves to quantification.

- “Monitoring” of manual equipment cleaning operations, such as scrubbing activities—i.e., confirming they are done to plan as they are ongoing—is neither *appropriate* nor *necessary* for food safety. Such activities, however, may need to be verified during a pre-operation inspection by a supervisor.

The specific language GMA is proposing to incorporate the “appropriate” and “necessary” concepts differs depending on the structure and format of the individual sections for which these concepts are relevant.

Proposed § 117.135(d) identifies the general types of preventive controls that may be required for a facility. To make this section risk-based and not prescriptive, GMA recommends that this general requirement be expressly linked with the FSMA food safety goals—in other words, preventive controls “must include the following types of controls where appropriate and necessary to satisfy the requirements of paragraph (a) of this section.” If a particular kind of control is not appropriate or is unnecessary to achieve the FSMA food safety goals, then it would not be required.

In other cases, the issue of how a specific control should be managed raises the question of what kinds of criteria are needed for that control to be effective. For example, in §117.135(e), the proposed rule specifies when monitoring, corrective actions, and verification will be required and suggests they will all be required unless a specific exemption applies. To ensure these

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4This approach, where the management oversight applied for a preventive control depends on what is appropriate and necessary for food safety, is sometimes referred to as the “sliding scale.” This expression illustrates that there are a wide range of preventive controls that are each managed with a different level of oversight intensity.
management elements are instead applied in a risk-based way, GMA suggests that they be required “where appropriate and necessary to ensure the effectiveness of the controls under paragraph (a) of this section, taking into account the probability and severity of the hazards and the nature of the controls.” As a result, the hazard analysis would guide facilities in deciding whether, and how, to use monitoring, corrective actions, and verification steps in best managing individual preventive controls. As part of this assessment, facilities would consider what is necessary to manage individual controls, taking into account the severity of the hazard, the probability it will occur, and the nature of the control.

Similarly, other criteria for managing preventive controls would be required where appropriate and necessary to ensure the controls are effective. In proposed § 117.135(c), facilities would be required to include parameters “where appropriate and necessary to ensure the effectiveness of the controls under paragraph (a) of this section.” In proposed § 117.150(a) (which GMA is proposing be put in a standalone regulation), facilities would be required to validate that preventive controls are adequate “where required under § 117.135(e).” GMA is proposing similar cross references in the proposed sections addressing monitoring and verification.

GMA is recommending these changes not only to align closely with the statute, but also to align with the practices of facilities with effective food safety systems. These facilities use management elements (i.e., monitoring, verification, validation, corrective actions, parameters) differently across the food safety system, and depending on the food safety need. Examples showing the way individual management elements may apply across a range of preventive controls are provided in GMA’s detailed comments on Proposed Subparts A, C, and D. Additionally, the legal, factual, and policy justifications for GMA’s proposed modifications to the rule are discussed in greater detail in Section III, below.

C. Appropriate Implementation

It is critical for the final rule to be worded in manner that permits a system-wide, risk based approach to preventive controls, but the regulatory language is only a first step in establishing a comprehensive regulatory framework for FSMA. To allow for effective implementation, FDA must reinforce key requirements and principles through the effective use of guidance (both in the preamble to the final rule and in formal Agency guidance), provide for adequate training of inspectors, and develop a plan for facility education and gradual enforcement. GMA will continue work to support the Agency’s efforts in all these areas.

III. Advantages of GMA’s Recommended Changes

GMA’s proposed modifications would allow FDA to assess system-wide compliance of all preventive controls in a facility’s food safety plan. Under GMA’s proposal, “preventive controls” would include all programs qualified experts consider necessary to achieve the FSMA food safety goals. When operating under an RLTO standard, there can be ambiguity surrounding the assumptions made to arrive at a determination of whether a hazard is RLTO or not, raising questions about which controls are “preventive controls” and whether FDA would have access to a range of prerequisite program records. In contrast, the modifications GMA is proposing would bring significant clarity because the Agency would have access to data and records supporting both the hazard analysis and the management of prerequisite programs and general controls.
GMA believes that our proposed modifications offer several advantages:

- Promote food safety and enhance public health
- Comply with FSMA
- Are enforceable, particularly since “preventive controls” and FDA records access includes all control measures essential to the management of relevant hazards
- More effectively provide for new technologies, public health advances, and future development and modification of approaches to food safety management
- Align with FDA’s economic assessment

A. Food Safety and Public Health Protection

To best promote food safety and public health, GMA has proposed modifications to the preventive controls rule to align with successful food safety programs and practices, provide for seamless FDA oversight of food safety systems (putting FDA in the best possible position to address some of the critical gaps that have been identified in recent outbreaks), and promote a culture of food safety in regulated facilities.

1. Alignment with Effective Programs and Practices

A significant and important challenge in implementing FSMA is to strengthen successful food safety programs while addressing critical gaps in problematic or at-risk facilities. For facilities that already have successful programs, the task is threefold: keep what works (because it has been demonstrated to keep food safe), require or encourage changes only if they truly enhance already strong programs and avoid changes that do not advance food safety. A regulation that significantly changes the way facilities with effective food safety programs manage food safety would be concerning if those changes are made solely for the sake of change, with an unnecessary focus on form over substance, and without any improvement to public health.

For example, asking a facility to revisit its food safety plans to reconsider and/or reclassify what it considers to be hazards reasonably likely to occur solely to provide FDA with records access or respond to FDA’s interpretation of RLTO would be an inefficient use of resources, especially if the relevant hazards are being addressed appropriately. Extensive debates about how to classify particular controls (e.g., line by line assessments of existing HACCP plans to assess which controls are “preventive controls”) or how to satisfy standards that may not fit particular circumstances (e.g., how to satisfy a validation requirement that does not make sense) similarly does not add value or enhance food safety. Such results also would directly conflict with the statute and FDA’s economic analysis, which concludes that facilities with effective HACCP plans would need to make minimal changes to their existing food safety systems.

2. Addressing Critical Food Safety Gaps

GMA appreciates that the FSMA framework must address not only facilities with successful programs but also provide for the regulation of facilities with potential or confirmed food safety
gaps. Here too, aligning closely with the statute will put FDA and industry in the best position to ensure food safety.

The first consideration is pragmatic. GMA is proposing that “preventive controls” include the spectrum of controls that food safety experts consider necessary to achieve the FSMA food safety goals. This seamless approach follows the statute’s “preventive controls” definition and thus gives FDA broader records access than the Agency would have with a “reasonably likely to occur” standard, especially if that standard is applied in the way it is commonly used in many facilities. As a result, FDA will be in a better position to routinely review food safety records in facilities of all types, including those at risk.

Second, a review of recent food safety gaps underscores the significance of managing food safety systems effectively, especially with respect to general controls. For example, in multistate outbreaks tied to *Salmonella breedeney*in peanut butter and *Listeria monocytogenes* in Mexican-style cheese, the root cause was determined to be insanitary conditions leading to post-process contamination of product. In the case of peanut butter, the relevant facility was found to have gaps such as inadequate separation between raw and roasted peanuts, inadequate protection of raw materials from contamination, poor cleaning documentation, and inadequate testing programs. In the case of Mexican-style cheese, the facility was found to have cleaning deficiencies and poor equipment maintenance.

Gaps such as these must be addressed by managing general controls more effectively—for example, keeping raw and roasted materials separate, protecting raw materials, validating cleaning procedures, or enhancing verification programs (e.g., for environmental monitoring, taking clear actions in response to positive findings) as necessary for food safety. General controls of this type are amenable to some, but not all, of the criteria for managing CCPs, so the solution is not to make these controls CCPs (or more like CCPs), but rather to choose the right management strategies based on the specific circumstances.

3. **Promoting A Food Safety Culture**

The changes GMA is proposing underscore the need for facilities to use expert judgment to identify controls and make fact- and risk-specific decisions about how to manage them. As a result, the message is not that facilities must manage each control using a pre-determined checklist of management elements, but rather that they must proactively assess food safety needs and make risk-based decisions that protect the public health and can be justified to FDA. In this respect, the changes GMA is recommending will ensure the regulatory scheme is ideally positioned to encourage facilities to adopt a culture of food safety, not one of simply complying with regulations. A food safety culture is present when a concern for food safety permeates all day-to-day work in a facility. In other words, when assessing hazards, identifying controls, and implementing the food safety system, a facility does not simply check boxes but thinks critically about food safety needs.
B. Compliance with FSMA

In addition to promoting food safety, the regulatory framework that implements FSMA must comply with the statute. GMA is proposing important changes to ensure the proposed regulation and any related implementing documents (e.g., Agency guidance) will align with (1) the plain language of the statute that provides for preventive controls to be managed in a risk-based way; (2) the fact that FSMA is based on HACCP principles, but the requirements are broader than (and different from) HACCP standards; and (3) FSMA’s requirements for FDA’s implementing regulations.

1. FSMA Plain Language

GMA is proposing that FDA modify the proposed rule to broaden the scope of “preventive controls” to cover the entire food safety system and to expressly allow facilities to manage preventive controls in a risk-based, tailored way, using the management elements that qualified experts consider necessary to meet FSMA’s food safety goals. These proposals are firmly rooted in the plain language of FSMA.

To ensure the food safety system is covered, GMA is proposing that a control should be a “preventive control” if food safety experts would use the control to achieve the ultimate goals of FSMA – to significantly minimize or prevent hazards identified and evaluated in the hazard analysis and/or to prevent food from being adulterated or misbranded due to undeclared allergens. A requirement to rely on expert judgment to meet the FSMA food safety goals is taken directly from the FSMA definition of “preventive controls”:

“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”

FFDCA section 418(o)(3) (emphasis added). In contrast, there is no basis in the statute for using “reasonably likely to occur” as a threshold for regulating “preventive controls.”

To ensure facilities will manage controls in a risk-based way, GMA is proposing language to make clear that the various management elements set out in the statute (e.g., monitoring, corrective actions, verification) are required where appropriate and necessary for food safety, taking into account the probability and severity of the hazards and the nature of the controls GMA proposed § 117.135(e). The statute provides for this flexibility because it requires food safety systems to include monitoring, corrective action, verification, and related activities (i.e., it does not establish requirements that apply uniformly to individual preventive controls); it requires preventive controls to be risk-based; and it requires facilities to take steps necessary to achieve the FSMA food safety goals.

Food safety systems. The emphasis on food safety systems is evident in the statute’s repeated references to preventive controls in the plural form (i.e., as a collection of food safety measures, rather than individual controls for which specified standards must be uniformly met). Facilities must implement preventive controls (plural) to provide assurances that the food safety standards are met; they must monitor the effectiveness of preventive controls (plural); they must have
corrective action procedures to address preventive controls (plural) that are improperly implemented or are ineffective; they must verify that preventive controls (plural) are adequate. None of these provisions refer to individual controls. The statute easily could have instructed facilities to monitor, verify, or otherwise manage “each preventive control,” but it did not. As a result, “preventive controls” for FSMA purposes are a seamless, holistic, synergistic system—a view that, not coincidentally, aligns with the way facilities with successful programs view food safety.

FSMA’s focus on food safety systems versus individual controls is also illustrated by the statute’s explicit coverage of a range of controls, well beyond CCPs. Indeed, the “preventive controls” definition primarily includes programs that are general controls, and even some programs that are usually not viewed as “controls” at all, such as recall plans, environmental monitoring, and supplier verification. With such a broad range of programs covered, the statutory framework agreed to by Congress could not possibly have intended for all of these programs to use all of the FSMA-listed management elements for individual preventive controls. For example, the statute could not have possibly envisioned recall plans or environmental monitoring activities to be monitored, verified, or subject to corrective action procedures in the HACCP sense. These criteria simply do not fit the nature of these activities, consistent with FDA’s decision to exempt recall plans from these requirements.

Risk-based. The tone for the preventive control requirements is set out in the title to FSMA’s preventive control requirements, section 418 of the Federal Food, Drug, and Cosmetic Act: Hazard Analysis and Risk-Based Preventive Controls (emphasis added). In the food safety context, a program is risk-based only if it prioritizes, and dedicates the greatest resources to, hazards that present the greatest risk. The use of “risk-based” in the title to section 418 necessarily means that a “one size fits all” approach to preventive controls cannot satisfy the statute (e.g., the statute does not support a requirement to validate all controls regardless of the circumstances). Consistent with the statute, GMA’s proposed approach is risk-based because it ensures that facilities will select management elements to meet diverse food safety needs, taking into account factors such as the probability of a hazard, its severity, and the nature of the control.

Necessary for Food Safety. GMA’s proposal to require management elements necessary for food safety carries out the FSMA intent for facilities to take steps needed to achieve the food safety goals outlined in the statute. This is made clear in the “General” requirement of section 418(a), which instructs facilities to implement preventive controls to “significantly minimize or prevent the occurrence of [identified and evaluated] hazards and provide assurances that . . . food is not adulterated . . . or misbranded due to undeclared allergens.” These food safety goals are repeated in whole or in part in section 418(c) (“Preventive Controls”), section 418(d) (Monitoring), section 418(e)(3) (Corrective Actions), and section 418(f)(4) (use of testing as verification).

These important statutory factors—the emphasis on food safety systems, the mandate for preventive controls to be risk-based, and the statute’s emphasis on controls necessary to achieve the FSMA food safety goals—all point to a need for flexibility in selecting management elements for preventive controls. Importantly, although the preamble to the proposed rule does not describe the statute in the same way, FDA has already determined that FSMA expressly permits such an approach. For example, the Agency has proposed to exempt recall plans from
monitoring, corrective action, and verification requirements. Similarly, the Agency has proposed to exempt allergen and sanitation controls from validation requirements. The exemptions FDA has already proposed as permissible would not be lawful if the statute truly required all the management elements to be used for “each” individual preventive control.

GMA concludes that the proposed modifications are not merely allowed by FSMA; such modifications are required. It is the only way to manage preventive controls in a truly risk-based, holistic, and effective fashion. The GMA proposal ensures this approach is reflected in the final regulations.

2. FSMA Requires an Approach Consistent with, but Broader than, HACCP

GMA’s proposed changes are intended to ensure the final regulations will appropriately and effectively address overall food safety systems. As noted previously, the FSMA regulatory framework must be one that can accommodate a broad range of food safety controls, from general controls that are more GMP-like (e.g., refrigeration, hygienic zoning, preventive maintenance) to specific controls that are CCPs or CCP-like (e.g., pasteurization). This differs from a regulatory framework based on HACCP, which focuses on only part of a food safety system.

The statutory language to base FSMA on HACCP principles, but to make it broader than HACCP, is evident in several respects:

- HACCP is globally recognized and is the leading approach to food safety management. In the United States, HACCP is the subject of several sets of regulations for meat, poultry, seafood and juice. Had Congress intended FSMA to be HACCP, or even to be HACCP-like, it could have easily made it so. FSMA, however, does not even use the term HACCP or “Hazard Analysis Critical Control Points.” Instead, it refers to Hazard Analysis and Risk-Based Preventive Controls.
- FSMA also does not use key terminology common to HACCP systems, such as “critical limits” or “reasonably likely to occur.”
- FSMA uses the HACCP term “CCPs,” but makes clear that FSMA is to include a broader focus than CCPs, including general controls such as hygiene training and recall plans, which are not included in HACCP plans.
- Examples of “preventive controls” cited in the statute include general controls, such as sanitation procedures, hygiene training, and current good manufacturing practices. The statute includes two activities—environmental monitoring and supplier verification—that are not “controls” at all under traditional HACCP but rather are “verification” activities. Similarly, food safety experts do not think of recall plans as “controls.” Indeed, of the seven examples given in the statute of “preventive controls,” FFDCA § 418(o)(3), elements of only one example—food allergen control programs—are likely to be CCP-type controls managed within a HACCP plan.
Accordingly, from a legal perspective, FSMA does not permit, much less mandate, the preventive controls rules to be implemented as a kind of HACCP system.

3. FSMA Standards for Implementing Regulations

In addition to aligning with the requirements at the center of FSMA—the “preventive controls” definition, the food safety goals, and other substantive elements of the statute—the proposed GMA modifications to the proposed regulation are also consistent with requirements FSMA established for implementing regulations in section 418(n). This section requires implementing regulations to be flexible, minimize potential paperwork burdens, be risk-based, not require the use of outside consultants or third parties, and be consistent, to the extent practicable, with applicable domestic and international standards. More specifically:

- Section 418(n)(3)(A) requires the regulations to “provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm.” The GMA proposed modifications allow for controls to be identified and managed based on food safety needs, which allows significant flexibility for diverse situations in facilities of all sizes.

- Section 418(n)(3)(B) requires FDA to pay special attention to minimizing the paperwork burden presented by the implementing regulations. The proposed GMA modifications require documentation when appropriate and necessary for food safety, a standard that directly avoids any unnecessary paperwork.

- Section 418(n)(4)(C) requires the regulations to “acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.” The proposed GMA modifications acknowledge differences in risk that may be posed across individual products and food safety systems.

- Section 418(n)(4)(D) prohibits any requirement that a facility hire a consultant or other third party to identify, implement, certify, or audit preventive controls, except in the case of negotiated enforcement. Nothing in GMA’s proposal would require a facility to hire an outside party to identify and implement preventive controls, though, as FDA has proposed, food safety plans must be prepared (or the preparation overseen by) a qualified individual.5

Additionally, section 418(n)(5) requires the regulations to be “consistent, to the extent practicable, with applicable domestic and internationally recognized standards” relevant to hazard analysis and preventive control-type programs. GMA members broadly rely on and

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5GMA appreciates that FDA is concerned that facilities of all types must be able to follow and implement the FSMA rules. A concern is sometimes expressed that leading facilities have the expertise to make scientific decisions, but smaller facilities with fewer resources may not. What GMA is proposing is foundational food safety management that any business in the food industry can achieve, though there may be a learning curve. To facilitate compliance, GMA encourages FDA to use examples in guidance, including in the preamble to the final rule, to illustrate how the framework is applied in a variety of circumstances. Consistent with Good Guidance Practices this guidance should be applied as a “safe harbor” for companies that wish to follow it strictly, but should not be treated as establishing binding requirements.
implement authoritative food safety standards such as those provided by Codex and NACMCF, and have taken the same approach to managing preventive controls that GMA is now proposing. These standards help facilities to (1) prioritize resources to ensure food safety by evaluating the probability and severity of potential hazards to determine their relevance to the product and process, and (2) determine the nature of the measures needed for their control, if any, and the way that these measures need to be managed.

For example, Codex principles for food safety programs emphasize prioritizing resources by focusing on whether a hazard presents a “significant” risk. Under Codex guidelines, HACCP is defined as a “system which identifies, evaluates, and controls hazards which are significant for food safety”6 (emphasis added). Assessing significance requires an evaluation process that includes the concepts of probability and severity. Of note, as applied in many effective food safety systems today, “significant hazards” must be likely (i.e., there must be a realistic probability of them occurring) and are assessed by considering whether general controls affect probability.

The modifications GMA is proposing align well with both domestic and international food safety standards and other food safety standards such as ISO 22000 and GFSI. GMA sees no basis in these standards to conclude that the number of CCP-like controls in a food safety system should be unnecessarily expanded or that general controls must be managed in a fundamentally different way than they are today in successful food safety programs, which may result under FDA’s proposed rule as currently written.

C. Enforceability

GMA understands FDA is concerned that the FSMA regulations must enhance food safety and be enforceable. GMA shares these concerns and is proposing modifications to address both of these important goals. If the proposed GMA modifications are accepted, the resulting regulations will be fundamentally more amenable to enforcement than those set out in the proposed rule because it grants FDA broader authority over food safety systems, consistent with the language and purpose of FSMA.

A key issue in any enforceability assessment is records access. The scope of records access that the proposed rule would afford is uncertain due to the lack of clarity around the “reasonably likely to occur” standard that FDA has proposed to use as a threshold for defining “preventive controls.” By its very terminology, this standard will limit the controls that are “preventive controls,” and with it, FDA’s access to records kept for such controls. For example, if a facility decides a hazard is not reasonably likely to occur due to a prerequisite program, that program would not be a preventive control and thus not subject to FDA’s oversight under FSMA. If FDA did not agree with the facility’s decision—a realistic scenario, given the regulatory history of the term and the inherent ambiguity that can accompany probability assessments—debates about the scope of FDA’s records access could occur. As described above in Section I(B)(2), GMA

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6“Significant” hazards are most often addressed through CCPs, but some facilities use the concept of “significant hazards” to help identify controls considered essential to address specific hazards. These controls have been described by different terms, such as Control Points (CPs), Operational Prerequisite Programs (oPRP), specific prerequisite programs (sPP), or enhanced prerequisite programs.
expects such a standard would lead to considerable confusion and debates about records because historically FDA and industry have interpreted this term differently.

GMA is proposing that the FSMA food safety plan include all preventive controls in the food safety system necessary for the control of identified hazards. This would put FDA in a much better position to assess full food safety system compliance. A system-based approach is also consistent with the regulatory direction USDA-FSIS is taking as indicated by their recent compliance guideline on HACCP validation where the Agency states, “It is important for establishments to realize that those prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system.” FSIS Compliance Guideline HACCP Systems Validation, May 2013. Notably, of the seven major foodborne illness outbreaks cited by FDA in the preamble, 78 Fed. Reg. 3665, that collectively yielded 1,948 confirmed foodborne illnesses, none of these events were due to a breakdown in CCP implementation or management. They were all due to breakdowns in what have traditionally been known as prerequisite programs, underscoring the importance of FDA access to records for these programs.

A second aspect of enforceability is the ability to articulate what is expected, especially for at-risk facilities. Here too, the framework GMA is proposing is straightforward, both in terms of identifying preventive controls and deciding how to manage them in a manner that protects the public health. Under GMA’s proposal, “preventive controls” would include all programs qualified experts consider necessary to achieve the FSMA food safety goals. There is broad agreement around what these programs are, and to make it even clearer, FDA could publish a likely list of such programs in guidance. Similarly, in terms of management, FDA can help make the proper application of FSMA management elements clear through discussion of specific scenarios in Agency guidance, including in the preamble to the preventive controls final rule. With sufficient examples and guidance, GMA is confident that the thought processes necessary to make good decisions and safe food will be ingrained and as readily enforceable as other areas of Agency regulation.

A third aspect of enforceability is inspections. The framework GMA is proposing is as amenable to inspections as current systems that afford FDA broad oversight, such as juice HACCP or low acid canned foods. In GMA’s experience, HACCP inspections often focus on CCPs. In a FSMA inspection, FDA may wish instead to focus on specific controls a facility has implemented to address identified hazards. Those controls may be CCPs or prerequisite programs that target specific hazards.

Once FDA has identified the preventive controls it will emphasize in an inspection, the Agency may wish to examine how those controls are managed. Relevant questions include whether the controls need to be validated, are subject to monitoring and/or verification, or require a specific corrective action procedure for food safety. Facilities must be able to justify the management strategies they have chosen and answer questions FDA may have.

General controls, though included in FSMA, often will address multiple hazards simultaneously. Food safety plans may not expressly link them to specific hazards, nor should it be necessary to do so. It is well understood, for example, that employee hygiene helps to manage many types of biological and physical hazards, and hygienic zoning is important to protect finished product in certain operations. Inspections of such programs can be carried out as they are today, but with
records access and with authority to inquire about management elements that may be necessary for food safety.

**D. Accommodation of Modernization**

A major objective of the Food Safety Modernization Act (emphasis added) is to ensure a truly modern framework for food safety regulation. The FSMA regulations will set the standard for decades to come, so it is crucial that they be able to accommodate not only the thought processes, technologies, and public health standards that prevail today, but also future developments.

The modifications GMA is proposing to the proposed rule will accommodate a modern regulatory framework. Like the statute, GMA’s suggested modifications would require preventive controls to be identified and managed based on expert evaluation of the steps needed to meet FSMA’s food safety goals. The approach is easily adaptable to new ways of thinking, technological advances, and developments in public health.

For example, FDA recognizes that the science today may not support certain measures. For this reason, FDA proposed to exempt allergen and sanitation controls from validation requirements because appropriate allergen test methods are not uniformly available to demonstrate if particular residual allergenic protein remains after a sanitation procedure. 78 Fed. Reg. 3755-56. GMA does not dispute that this is true today, but it may not be true in 10 years. If FDA finalizes the validation standard as proposed, the express exemption would preclude the Agency from requiring facilities to validate allergen and sanitation controls in appropriate situations, to the potential detriment of public health. In contrast, GMA is proposing that controls be validated when appropriate and necessary to meet FSMA’s food safety goals, as assessed by qualified experts. Designing the regulations in this way grants wide latitude for facilities to manage controls to meet diverse food safety needs and for the Agency to assess and enforce the preventive control requirements.

**E. Alignment with FDA’s Economic Assessment**

GMA appreciates that the proposed rule reflects confidence in successful food safety systems operating today. For example, FDA assumes that large facilities will have no to minimal additional costs to comply with the requirement to conduct a hazard analysis and implement process controls. If the Agency believed these company practices were not sufficient to protect public health, the economic analysis would have identified costs that large facilities will incur to comply with the proposed rule.

At the same time, however, there are noticeable differences between the proposed rule as GMA understands it and what successful facilities are actually doing to evaluate hazards and determine how to manage preventive controls. GMA believes a likely outcome of the framework FDA has proposed will be to significantly expand the number of controls that must be managed like CCPs, which currently are not managed in this manner. This would greatly expand the resources needed, including time, employee involvement, capital investments, and documentation burdens without any corresponding public health benefit. Such a result would dramatically conflict with FDA’s assessment of the economic impact of the preventive controls rule.
In contrast to these expectations, GMA’s proposed modifications align closely not only with the statute, but also with the successful practices in place in successful facilities today. As a result, GMA’s proposed framework would better align with FDA’s economic assessment.

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In summary, GMA is concerned that the proposed rule will be interpreted to require individual preventive controls to uniformly require (unless expressly exempt) monitoring, parameters, validation, verification, and control-specific corrective actions at a level generally expected for CCPs. Uniformity in these requirements without recognition of individual circumstances leads to a “check the box” approach where facilities and inspectors simply look to see if the various elements are somehow accounted for, without analyzing more deeply what is really needed to make safe food. Such an approach adds complexity without enhancing food safety, is inconsistent with the statute, differs from the way successful facilities manage food safety today (affecting FDA’s economic analysis), and blurs the lines between CCPs and other food safety controls.

To satisfy the intent of FSMA, the regulatory framework must enhance food safety, anticipate future developments in technology, and include enhanced authority for FDA to regulate not only successful facilities, but also facilities that may be less capable (or even unwilling) to implement appropriate systems. With these comments, GMA respectfully proposes modifications to the framework to meet these critical objectives.
GMA Feedback and Recommendations on Proposed Rule:
Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food 21 CFR Part 117

Detailed Comments on Proposed Subparts A, C and D

The following are GMA’s detailed comments on the proposed 21 CFR § 117, Subparts A, C, and D. As a part of the comments there are several instances where GMA recommends that definitions either be modified in or added to § 117.3-Definitions (Subpart A) in order to improve the clarity of the proposed rules. These definition recommendations are also included in this section of our comments. Comments on Subparts B, E and F, testing and supplier verification are provided in separate docket submissions.

GMA strongly supported the Food Safety Modernization Act (FSMA) and looks forward to working with FDA for successful implementation of this groundbreaking law. GMA applauds FDA for the considerable work put into the proposed rule, and appreciates the Agency’s efforts to develop a regulatory framework that is protective of public health, risk-based, and practical.

The comments below provide feedback on each element of the proposed rule and on related issues. Many of the comments focus on two main aspects of the proposed rules; clarifying the hazard analysis process and providing flexibility through regulatory language in the management elements for preventive controls, which GMA members feel is integral for the effectiveness of modern, successful food safety programs.

In the preamble to the proposed rules, the Agency has indicated that it has intended to align the preventive controls rule with existing HACCP standards. While HACCP remains a very important part of successful food safety systems, the FSMA statute included food safety programs that go beyond specific controls like CCPs or CCP-like controls. Indeed, the foodborne illness outbreaks referenced in the preamble (78 FR 3665) by the Agency do not represent failures of CCP or CCP-like controls, but are due, in large part, to the failure of managing general programs that are components of GMPs or prerequisite programs.

In order to include these more general programs as part of the overall food safety system, GMA is recommending modifications to the proposed hazard analysis process. The Agency’s approach can be viewed as very much aligned with identification of critical control points (CCPs) in HACCP systems. Since the FSMA statute intended to include many programs outside of HACCP, GMA is proposing modifications that would ensure a more inclusive food safety plan that includes CCPs and CCP-like preventive controls along with more general preventive control programs that are important to the manufacture of safe products.

The management of the more general preventive controls programs differ from the management of CCP or CCP-like preventive controls. Some preventive controls will be CCPs and require all the proposed management activities while others may require a different combination of the management elements (validation, monitoring, corrective actions, records, and verification) due to the nature of the control measure. GMA is proposing modifications to the proposed regulatory language that allows flexibility in the application of the management elements to ensure that
those that are necessary and appropriate are applied to specific preventive controls. Consistent with the proposed rule, the hazard analysis, the identification of appropriate preventive controls and determination of how they are effectively managed is the responsibility of the qualified individual. In this way, the food safety plan rules will closely reflect the practices employed today by companies with strong, effective, and successful food safety systems. This approach will also allow food safety plans to adapt in a continuous improvement manner to any of the criteria cited by the Agency in the Reanalysis section of the proposed rules, § 117.150(f).

GMA has provided a structured approach to the comments below; the format of which is described here. First, the section of the proposed rule to be discussed is quoted. This is followed by a section entitled “GMA Feedback” where general comments and suggestions on the particular proposed rule section are presented. This is subsequently followed by a section entitled “GMA Recommends” where specific recommendations are made for changes to the proposed rule language and other items. The proposed changes in the language are presented as follows; 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 underlined (underlined). Italics (italics) are used for emphasis. For further clarity, GMA provides Appendix I, which is a summary of all the suggested regulatory language changes in proposed § 117.3 Subpart A Definitions, § 117 Subpart C, and § 117 Subpart D.

Proposed Rule
§ 117.126 Requirement for a Food Safety Plan.
§ 117.126(a) Food safety plan. The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

GMA Feedback
• GMA agrees with FDA’s intentions to require the development of written food safety plans as described in the preamble to the proposed rule and § 117.126(a).
• We note that throughout the preamble to the proposed rule and the proposed regulation there are considerable references to “facility” based preventive controls. FDA should be aware that for companies containing more than one manufacturing facility, many food safety activities are administered corporately, not at individual facilities. For example, supplier approval, recalls, consumer complaints, and some validation documentation and activities are typically handled corporately, not at an individual facility. Training or instructing FDA personnel to address such activities at the facility level will not be a good use of Agency resources. Further, requiring every facility to maintain entire programs on the above examples would create an unnecessary burden on food manufacturers without any augmentation of the public health.
• GMA agrees that if an outside qualified individual(s) writes the food safety plan, the owner, operator, or agent in charge is still responsible for ensuring that the food safety plan is implemented.
• GMA notes the owner, operator, or agent in charge may not be the same party listed on the facility’s registration. For example, the owner’s name could be on the facility registrations and the facility operator could sign and date the food safety plan.
• GMA agrees with the Agency’s position as indicated in proposed § 117.305(a) that written food safety plans can be a paper or electronic document or both. In other words, some parts of the plan can be a paper copy and other parts located in an electronic file.
• As technology progresses over the life of the final rule, greater opportunities for efficiency will be available to food processors, including electronic formats for food safety plans.

GMA Recommends
• The Agency clarify that the qualified individual preparing the food safety plan need not be the same person listed on the facility’s registration.
• The Agency confirm in the final rule a “written” plan does not need to be printed on paper and that the word “written” be interpreted as “any type of recordable and reproducible format.”

Proposed Rule
§ 117.126(b) Contents of a Food Safety Plan. The food safety plan must include:
§ 117.126(b)(1) The written hazard analysis as required by § 117.130(a)(2)
§ 117.126(b)(2) The written preventive controls as required by § 117.135(b)
§ 117.126(b)(3) The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by § 117.140(a)
§ 117.126 (b)(4)The written corrective action procedures as required by § 117.145(a)(1)
§ 117.126 (b)(5) The written verification procedures as required by § 117.150(e); and
§ 117.126 (b)(6) The written recall plan as required by § 117.137(a).

GMA Feedback
Required contents of food safety plans
• GMA agrees with FDA’s intentions for a food safety plan as stated in the preamble to the proposed rule, 78 Fed. Reg. 3672, “We propose to require that the owner, operator, or agent in charge of a facility have and implement a written food safety plan that includes as applicable:
  o A hazard analysis;
  o Preventive controls;
  o Monitoring procedures;
  o Corrective action procedures; and
  o Verification procedures.”
• GMA notes that unlike preamble language, the proposed regulation § 117.126(b) removed the words “as applicable” and replaced them with the words “must include.” This change in proposed text found in the preamble could be interpreted as creating requirements that may not be applicable, appropriate, or pertinent to all individual preventive controls.
• The list of management elements listed in § 117.126(b)(2) through (b)(5) are those traditionally associated with CCPs. These CCP activities do not apply to all preventive controls. Thus the terminology “as appropriate” is more germane and a better description of both the Agency’s stated intentions and the development of effective food safety plans that will fully protect public health. Statements in the Agency’s preamble support this position:
o “We do not expect that all possible preventive measures and verification procedures would be applied to all foods at all facilities.” 78 Fed. Reg. 3648.

o “Although the approach in section 418 and this proposed rule aligns well with HACCP, it differs in part in that preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls.” 78 Fed. Reg. 3660.

• The risk-based nature of the FSMA statute allows companies to manage controls with the management activities needed to achieve FSMA’s food safety goals. As a result, following the statute preserves the key elements of successful food safety systems. These include the analytical frameworks and thought processes necessary – how science is evaluated and applied to specific products and circumstances; the way management activities are customized to fit diverse food safety needs; the use of CCPs, enhanced and general controls, only where a qualified individual has determined that general controls are not adequate to manage a hazard.

Written food safety plans

• A food safety plan may be an interrelated set of documents, which may exist in different formats and locations. For example, some preventive control programs and procedures may be outlined in specific program documents apart from the written hazard analysis. Some validation documents may be stored outside of the manufacturing site as such records are not needed for the ongoing management of the preventive control programs. Supplier verification programs are often centrally managed and individual facilities may not maintain copies of related records.

Grouping of food safety plans

• GMA agrees with Agency statements in the preamble to the proposed rule that facilities shall be able to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical. Accordingly we concur with:
  o The statement from 78 Fed. Reg. 3730 that says, “Proposed § 117.126 would provide flexibility for facilities in the development of their food safety plans by allowing facilities to group food types or production method types if the hazards, control measures, parameters, and required procedures such as monitoring are essentially identical;” and
  o The statement from 78 Fed. Reg. 3732 that states, “Federal HACCP regulations... allow the HACCP plan to group food types or production method types if the hazards, critical control points, critical limits and required procedures such as monitoring are essentially identical, provided that any required features of the plan that are unique to a specific product or production method are clearly delineated in the plan and are observed in practice.... This type of grouping would be allowed under proposed § 117.126 and, thus, would provide flexibility for facilities in the development of their HACCP plans.” (Emphasis added).

• It is important to emphasize that while HACCP plans may be part of food safety plans, food safety plans are broader, covering control measures that are not managed with CCPs alone.
Inclusion of the recall plan in food safety plans

- GMA strongly believes that the requirement for a recall plan should be moved to Subpart B, GMPs. Requirements for firms to maintain recall plans should be facility-wide, not product and process specific and therefore moved to Subpart B, GMPs.
  - Recall plans are often tailored to a given facility or company, not to a given product, process or production line.
  - For companies with more than one production facility, recall plans are often written at the corporate office and recall activities administered corporately as well.
  - Recall plans are a crisis management tool and are used after an adulterated product is released into the marketplace. In contrast, the food safety plan’s goal is to prevent a potentially-adulterated product from being produced and/or entering commerce.
  - A facility may process several categories of food in one building and have several food safety plans to do so. However, such a facility typically has one recall protocol.

- FSMA requires all food processors to be responsible for recalling their goods when the public health might be threatened. However, because the requirement for a recall plan is part of subpart C and certain firms are exempt from these provisions, these firms would not be required to maintain recall plans. If the requirement for a recall plan is part of the GMPs, these exempt firms will be required to have a recall plan. Ensuring that all facilities can conduct effective recalls is a better outcome for the public health.

- FDA should make appropriate confirming changes to the remainder of the regulations (such as § 117.126) to reflect this modification.

GMA Recommends

- FDA modify the language in proposed § 117.126(b) as follows:

  § 117.126(b) Contents of a Food Safety Plan. The food safety plan must include, as appropriate:
  (1) The written hazard analysis as required by § 117.130(a)(2);
  (2) The written preventive controls as required by § 117.135(b);
  (3) The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by § 117.140(a);
  (4) The written corrective action procedures as required by § 117.145(a)(1); and
  (5) The written verification procedures as required by § 117.150(e),

- FDA include the following definition in § 117.3: “Written means any type of recordable and reproducible format.”

Proposed Rule

§ 117.126(c) Qualified individual - The food safety plan must be prepared by (or its preparation overseen by) a qualified individual.

GMA Feedback

- GMA agrees with the requirement.
GMA recommends

- No changes.

Proposed Rule
§ 117.130 Hazard analysis.
§ 117.130(a) Requirement for a hazard analysis.
§ 117.130(a)(1) The owner, operator, or agent in charge of a facility must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur.

GMA Feedback
- GMA supports the concept that an effective food safety plan includes a thorough hazard analysis to identify and evaluate facility specific hazards that need to be addressed in the food safety plan.
- GMA agrees that the owner, operator, or agent in charge is responsible for the food safety plan and the hazard analysis; however, FDA’s proposed regulations § 117.126(c) call for a qualified Individual to prepare or oversee preparation of the food safety plan, which would include the hazard analysis. While we agree that the owner, operator, or agent in charge is responsible for ensuring that this task is completed, the qualified individual conducting these activities may be a different person(s) from the owner, operator, or agent in charge.
- GMA recommends this language demarcate responsibilities for managing and administering a food safety plan from the task of preparing and overseeing components of the plan.

GMA Recommends
- FDA modify the language in proposed § 117.130(a)(1) as follows:
  § 117.130(a)(1) The owner, operator, or agent in charge of a facility is responsible for ensuring that must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility are identified and evaluated by a qualified individual to determine, based on their probability and severity, whether there are hazards that are reasonably likely to occur, the hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.

Proposed Rule
§ 117.130(a)(2) The hazard analysis must be written.

GMA Feedback
- We agree with the requirement that the hazard analysis must be written and have addressed the definition of “written” in comments regarding § 117.126(a) and in Appendix I.
GMA Recommends
• No changes.

Proposed Rule
§ 117.130(b) Hazard identification. The hazard identification must consider hazards that may occur naturally or may be unintentionally introduced, including:

GMA Feedback
• GMA agrees with FDA’s statements in the preamble that hazard identification should include hazards “known to be associated with a type of food or process and those known to have occurred in a particular facility.” 78 Fed. Reg. 3732.
• GMA advises the Agency to confirm that inspection personnel must not expect to see an exhaustive list of theoretically possible hazards in a facility’s hazard analysis.
  o In many cases specific hazards are not relevant to a product, process or raw material. Documented hazard analyses are limited to those hazards that represent a risk for the end user due to the raw material, the production process, the finished product, or storage and distribution conditions.
• Because they are not known, it is not possible or practical to include an assessment of hazards arising from unforeseen natural disasters in a facility’s hazard analysis. A facility’s response to natural disasters should be part of its crisis management procedure which would include an analysis of potential new hazards and a reassessment of the facility’s food safety plan.
• It is acceptable to document in formal procedures that certain types of hazards are considered in the facility’s hazard analysis. However, detailed documentation of hazard analysis and related justification(s) is only necessary if the hazard has been associated with the product, process, or its raw materials/ingredients, and if the hazard is of such a nature that its control is necessary to ensure safe food.
• GMA agrees with FDA that intentionally introduced hazards are considered in a separate food defense plan and not in the food safety plan. 78 Fed. Reg. 3659.

GMA Recommends
• No changes.

Proposed Rule
§ 117.130(b)(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance.
§ 117.130(b)(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens;
§ 117.130(b)(3) Physical hazards; and
GMA feedback

- As discussed under 117.130(b)(4), radiological hazards should be included as a subset of chemical hazards.

GMA Recommends

- FDA modify the language in proposed 117.130(b), (1) through (3) as follows:
  § 117.130(b)(1) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance.
  § 117.130(b)(2) Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, radiological hazards, and food allergens; and
  § 117.130(b)(3) Physical hazards.

Proposed Rule

§ 117.130(b)(4) Radiological hazards.

GMA Feedback

- GMA agrees with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry that radiological hazards do not need to be examined as a separate and distinct hazard subset. FSMA requires FDA to develop regulations consistent with existing domestic and international programs.
- Radiological contamination occurs very infrequently as concluded in FDA’s own assessments
  - “Radiological contamination of foods is a rare event.” 78 Fed. Reg. 3667.
  - In FDA’s Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities Conducted in a Facility Co-Located on a Farm it states, “…the Hazard Identification section of this document does not include radiological hazards because they are too rare in food to be considered associated with any food category other than water.”
  - In the same document, FDA states, “The presence of radiological hazards in foods is a rare event and consumer exposure to harmful levels of radionuclide hazards is very low (United Nations Scientific Committee on the Effects of Atomic Radiation, 2008). Use of water that contains a radionuclide to manufacture a food is not reasonably likely when using water from a domestic municipal source subject to regulation by EPA (40 CFR 141.66; see 65 FR 76708, Federal Register of December 7, 2000).”
- In the Preliminary Regulatory Impact Analyses for the proposed rule, FDA states that the proposed preventive controls rule would not impose additional costs on large food companies. We expect, however, that all large food companies would incur expenses from revising their food safety plans to address radiological hazards in their hazard analyses. Consideration of radiological hazards as a separate hazard will result in developing new templates for ingredient and process step assessments and the re-documentation of all existing plans. This is an undue burden that will lack a food safety gain; these issues are already considered as part of chemical hazard analysis.
• Event based hazards are handled separately from the food safety plan in programs such as crisis management.
• Changing every hazard analysis currently employed in the industry would require a major dedication of resources, both financial and otherwise.
• We recognize that FSMA requires consideration of radiological hazards; however, consideration of these risks as part of chemical hazards is not inconsistent with the statute.

GMA Recommends
• FDA modify the language in proposed § 117.130(b)(4) as follows:
  § 117.130(b)(4) Radiological hazards.

Proposed Rule
§ 117.130(c) Hazard evaluation.
§ 117.130(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to determine whether the hazards are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur.

GMA Feedback
• GMA agrees that the severity of the illness or injury, if the hazard were to occur, is one component of successful hazard analysis, but not the only or overriding principal component. Consistent with hazard analysis protocols employed throughout the world, GMA contends that probability (likelihood) of the hazard occurring is equally important in a successful, thorough, comprehensive, and robust hazard analysis. GMA believes that analysis of potential hazards must include probability (likelihood) of occurrence as well as severity of potential illness or injury.
  – We note the Agency comments in the preamble to this effect: “we agreed with the NACMCF approach to conducting the hazard analysis—i.e., that the process of evaluating food hazards to determine which potential hazards need to be addressed in the HACCP plan ... takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact.” 78 Fed. Reg. 3735.
• Probability of occurrence is affected by facility specific characteristics such as facility and equipment design, training level of employees, and other facets often referred to as prerequisite programs or general controls.
• GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate for this proposed regulation.
  – The proposed RLTO standard is problematic from a practical standpoint because historically it is the standard used to identify hazards that must be managed by CCPs in HACCP systems including FDA’s juice and seafood HACCP regulations. Under these regulations, RLTO is used to identify those hazards of such probability and severity that their risk is managed by control measures at CCPs. By using this HACCP standard, the proposed rule appears to treat all preventive controls as substantially similar to CCPs (i.e., either equal or very similar to CCPs). This approach is not the manner in which successful food safety programs manage an
overall food safety system. HACCP is but one component of such successful systems. Additionally, adapting existing, modern, successful food safety systems to such an approach would require dedication of large amounts of resources for no augmentation of the public health.

- GMA is concerned that the proposed RLTO standard has the potential to conflict with existing HACCP regulations, which differ from FSMA. In the proposed rule, the regulatory language indicates that FDA has broadened RLTO to identify not only hazards controlled at CCPs but also those managed by other process controls and general controls such as food allergen controls and sanitation controls. Because RLTO is used in a narrower context in other rules (FDA seafood and juice HACCP, FSIS meat and poultry HACCP) the use of the term RLTO in the proposed preventive controls rule could create confusion during inspections, particularly where an investigator is involved in the verification of regulatory HACCP frameworks for seafood and/or juice as well as foods amenable to § 117. For example, for a food amenable to § 117, an inspector might expect a facility that has identified a hazard as RLTO to have CCP-equivalent records and management elements for all associated preventive controls. This would not be the case for juice or seafood items produced in the same facility.

- To increase food safety GMA contends that changes are needed in the proposed rule to make clear that facilities must manage individual preventive controls in a way that accommodates specific circumstances and a range of identified hazards. Accordingly, we have offered comments and proposed changes in the regulatory language for § 117.130(c)(1) as well as many other sections of the proposed rule in order to achieve this goal.

- FSMA was intentionally drafted to be broader in scope than HACCP, defining “preventive controls” to include such diverse controls as good manufacturing practices, sanitation, hygiene training and supply chain management.

- The FSMA statute does not use the term “reasonably likely to occur” to define a threshold for determining preventive controls, nor does it provide any other basis for using such a term to differentiate among various hazards and associated preventive controls.

**GMA Recommends**

- FDA should modify the language in proposed § 117.130(c)(1) as follows:

  §117.130(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section, to determine whether the hazards need to be addressed in the facility food safety plan are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur.

  (2) Assessments of the probability of a hazard may take into account the following factors, among others, that may be relevant:

  (i) The effectiveness of existing programs, such as GMPs or other general controls;

  (ii) The frequency with which a potential hazard is associated with a food, ingredient, process, or other component of a food safety system;
(iii) Method of preparation within a processing facility or by the consumer before consumption of the food;
(iv) Storage and transportation conditions;
(v) Historical experience within the processing facility or with the product category; and
(vi) Design of processing system.  

Proposed Rule
§ 117.130(c)(2) The hazard analysis must include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging.

GMA Feedback
• GMA is concerned that the proposed definition language in § 117.3 for “ready to eat” (RTE) foods that uses the term “reasonably foreseeable” is too open ended and vague to serve as direction to regulatory and industry practitioners.
• FDA states in their preamble to the proposed rule.  78 Fed. Reg. 3736. that under proposed § 117.130(c)(2), a facility that produces an RTE food that is exposed to the environment prior to packaging would be required to identify environmental pathogens as a known or reasonably foreseeable hazard under proposed § 117.130(b) and evaluate whether contamination of RTE food with the environmental pathogen is reasonably likely to occur in the facility.  GMA advises, however, that such an evaluation should not be required for foods exposed to the environment that then receive a pathogen lethality step after final packaging.

GMA Recommends
• § 117.3 be reworded as follows:
  Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable expected that the food would be eaten without further processing that will significantly minimize biological hazards.
• FDA should modify the language in proposed § 117.130(c)(2) as follows:
  § 117.130(c)(2)(3) The hazard analysis must include an evaluation of whether environmental pathogens that must be addressed in the food safety plan are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging and does not receive a pathogen lethality step while in their final package.

7 The source of our proposed codified language on this point is GMA’s Industry Handbook for Safe Processing of Nuts (2010) at 17. This industry guidance document has been cited by FDA in its Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio–Derived Product as an Ingredient (September 2011).
Proposed Rule

§ 117.130(c)(3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;
(ii) The condition, function, and design of the facility and equipment;
(iii) Raw materials and ingredients;
(iv) Transportation practices;
(v) Manufacturing/processing procedures;
(vi) Packaging activities and labeling activities;
(vii) Storage, and distribution;
(viii) Intended or reasonably foreseeable use;
(ix) Sanitation, including employee hygiene; and
(x) Any other relevant factors.

GMA Feedback

• GMA agrees the evaluation of items stated in proposed § 117.130(c)(3)(i through x) can affect the outcome of the hazard analysis.

• Preamble discussion suggests that only *risks* posed by these factors should be considered. However, GMA strongly contends that processors should also consider the benefits, advantages, augmentations or contributions to food safety from these items.

• GMA is concerned that proposed language in § 117.130(c)(3)(viii) referencing “intended or reasonably foreseeable use” is too open ended and vague to serve as direction to regulatory and industry practitioners.

• FDA should change the proposed language in § 117.130(c)(3)(viii) to make it clear that the hazard evaluation must consider intended or reasonably expected use.

GMA Recommends

• FDA clarify in the preamble to the final rule that the items stated in proposed § 117.130(c)(3)(i through x) be evaluated for potential benefits as well as risks.

• FDA modify the language in proposed §117.130(c)(3) as follows:

  §117.130(c)(3) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

    (i) The formulation of the food;
    (ii) The condition, function, and design of the facility and equipment;
    (iii) Raw materials and ingredients;
    (iv) Transportation practices;
    (v) Manufacturing/processing procedures;
    (vi) Packaging activities and labeling activities;
    (vii) Storage, and distribution;
    (viii) Intended or reasonably foreseeable use;
    (ix) Sanitation, including employee hygiene; and
    (x) Any other relevant factors.
Proposed Rule

§ 117.135 Preventive controls for hazards that are reasonably likely to occur.

For hazards identified in the hazard analysis as reasonably likely to occur:

§ 117.135(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur 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 Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

GMA Feedback

- GMA recommends revising the proposed preventive controls regulations to align closer with the FSMA statute, which requires that a facility shall identify and implement preventive controls to provide assurances that
  - known or reasonably foreseeable hazards will be significantly minimized or prevented;
  - the food manufactured, processed, packed, or held by such facility will not be adulterated or misbranded.
- GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate. Please see our comments above regarding § 117.130(c)(1).
- It is GMA’s position that preventive controls must exist to address reasonably foreseeable hazards. However, the rigor and components of management oversight activities for each control must be commensurate with the severity and probability (likelihood) of occurrence of the hazards being controlled.
- Some of the examples of preventive controls in the preamble are not consistent with the RLTO philosophy. For example, FDA states that preventive controls may include “an environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.” 78 Fed.Reg.3738, 3764(Emphasis added). Here, preventive controls are being suggested for a potential hazard rather than one determined to be RLTO by a hazard analysis. However, this would be consistent with applying preventive controls to reasonably foreseeable hazards.
- GMA agrees with FDA that “significantly minimized or prevented” is synonymous with “reduce to an acceptable level.” 78 Fed. Reg. 3700.
- GMA suggests that wording similar to the following should be used in the preamble to the final rule or in future guidance to assist with defining different types of preventive controls:
  - Preventive controls that significantly minimize or prevent hazards include risk-based, reasonably appropriate procedures, practices, or processes that:
    1. Are used to directly control significant hazards;
    2. Are identified in the hazard analysis as making a hazard not significant;
    3. Are food safety programs a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would recognize as affecting the significance of biological, chemical, or physical hazards.
GMA Recommends

- Eliminating the term RLTO as it does not appear in the statute and the proposed RLTO standard is also problematic from a practical standpoint because its meaning is unclear in the FSMA context. Please see our comments above regarding § 117.130(c)(1).
- FDA modify the language in proposed § 117.135 as follows:

§ 117.135 Preventive controls for hazards that are reasonably likely to occur.
For hazards identified in the hazard analysis as reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified and evaluated in the hazard analysis as reasonably likely to occur needing to be addressed in the food safety plan 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 Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

Proposed Rule
§ 117.135(b) Preventive controls must be written.

GMA Feedback

- We agree with the requirements that the preventive controls must be written (see comments regarding § 117.126(a)).

GMA Recommends

- FDA should modify the language in proposed § 117.135(b) as follows:

§ 117.135(b) Preventive controls must be written and maintained in appropriate documents or combination of documents readily available for inspection.

Proposed Rule
§ 117.135(c) Preventive controls must include, as appropriate to the facility and the food:

GMA Feedback

- **Comment on Structure:** GMA notes that as the proposed regulation is currently written, components of preventive controls (§117.135(c)) are introduced before the requirement of preventive controls in general (§117.135(d)). For greater clarity we suggest that the requirements for preventive controls should be introduced before preventive control components. In other words, switch § 117.135(c) with § 117.135(d).
- This portion of the proposed rule addresses the application of management elements to assure that the preventive controls are effective in significantly minimizing or preventing the hazards identified in the hazard analysis. While GMA agrees that management elements are important to ensure that preventive controls are properly applied, the types of management
elements that are relevant and the level of rigor associated with their application must be commensurate with the severity and probability of the hazard and the nature of the control.

- We agree with FDA comments in 78 Fed. Reg. 3739 that “preventive controls may be required at points other than at critical control points and critical limits would not be required for all preventive controls” and “adequate assurances could be achieved via preventive controls implemented through other procedures and practices of a facility, such as its food allergen control program, which may not have specific CCPs.” We appreciate that FDA has proposed flexibility in the types of controls that may be considered preventive. However, we are concerned that the language of the proposed rule appears to require equivalent management elements such as monitoring, verification, corrective action, etc. for all preventive controls, which would impose unnecessary activities that would not contribute to food safety.

GMA Recommends
- FDA modify the language in proposed § 117.135(c) as follows:

  § 117.135(c) Preventive controls must include, as appropriate and necessary to ensure the effectiveness of the controls under paragraph (a) of this section:

Proposed Rule
§ 117.135(c)(1) Parameters associated with the control of the hazard, such as parameters associated with heat processing, acidifying, irradiating, and refrigerating foods, and
§ 117.135(c)(2) 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.

GMA Feedback
- The term parameter should be defined in § 117.3 as a measurable attribute.
- The term value should be defined in § 117.3 as a specific measurement associated with a parameter.
- GMA agrees with the use of parameters “as appropriate to the facility and the food.” However, this language is ambiguous and could be interpreted to mean that all preventive controls must have a parameter. It is also important to include “where necessary” to cover cases where parameters are not necessary to assure food safety.
- We strongly agree with the Agency’s position that parameters would not be required for all preventive controls: “Some preventive controls may not have specific parameters associated with them. For example, preventive controls for metal may include an equipment preventive maintenance program and a metal detector on the packaging line. These programs may not have specific factors that must be controlled to prevent metal contamination. Sanitation procedures may include scrubbing certain pieces of equipment by hand; this may not require the identification of specific parameters. Similarly, label controls for food allergens do not involve identification of specific parameters.” 78 Fed. Reg. 3740
- Additional examples include:
A preventive control specifying that employees wear specific protective clothing such as aprons or gloves to protect an exposed food from pathogens does not have an associated parameter or maximum or minimum values. The control either is or is not being implemented.

A preventive control specifying preventive maintenance on specific equipment to protect exposed food from foreign material contamination does not have an associated parameter or maximum or minimum values. The control either is or is not being implemented.

GMA Recommends
- FDA modify the language in proposed § 117.135(c)(1) and § 117.135(c)(2) as follows:
  1. Parameters associated with the control of the hazard, such as those associated with heat processing, acidifying, irradiating, and refrigerating foods, and
  2. The maximum or minimum value, or combination of values, to which any biological, chemical, or physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard addressed in the food safety plan that is reasonably likely to occur.

Proposed Rule
§ 117.135(d) Preventive controls must include as appropriate:

GMA Feedback
- For the same reasons as stated in our feedback under §117.135(c), we recommend that FDA make clear that the requirements under §117.135(d) only apply where necessary.

GMA Recommends
- FDA modify the language in proposed § 117.135(d) as follows:
  § 117.135(d) Preventive controls must include the following types of controls as appropriate and necessary to ensure the effectiveness of the controls under paragraph (a) of this section:

Proposed Rule
§ 117.135(d)(1) Process controls. Process controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur.

GMA Feedback
- GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate as it does not appear in the statute. Please see our comments above regarding § 117.130(c)(1).
GMA Recommends

- FDA modify the language in proposed § 117.135(d)(1) as follows:
  § 117.135(d)(1) Process controls. Process controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are addressed in the food safety plan reasonably likely to occur.

Proposed Rule

§ 117.135(d)(2) Food allergen controls. Food allergen controls must include those procedures, practices, and processes employed for:
§ 117.135(d)(2)(i) Ensuring protection of food from allergen cross-contact, including during storage and use; and
§ 117.135(d)(2)(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

GMA Feedback

- GMA notes that allergen controls are not always necessary or only specific allergen controls may be appropriate. For example, GMA points out that food allergen controls are unnecessary for facilities that have one or more allergens common to all products manufactured in the facility, other than assuring that the allergens are properly declared on the label.
- We assume that the point of § 117.135(d) is to ensure processors have in place allergen management and sanitation controls; however, some of the controls identified for allergen management are applied during the process and could be considered to be process controls (e.g., labeling, bar-code scanners).
- Consistent with our comments on GMPs we request that the word “allergen” be placed in front of the word “cross-contact” when it is used.

GMA Recommends

- FDA modify the language of proposed § 117.135(d)(2) as follows:
  § 117.135(d)(2) Food allergen controls. Food allergen controls must include those procedures, practices, and processes employed for:
  § 117.135(d)(2)(i) Ensuring protection of food from allergen cross-contact, including during storage, handling and use; and
  § 117.135(d)(2)(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
occurs in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

(A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
(B) Prevention of cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

GMA Feedback

- GMA is concerned that including the parenthetical verbiage “including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard” may appear to be unintentionally prescriptive by limiting the hazards to only those identified here in § 117.135(d)(3)(i). These examples were previously discussed in § 117.130(c)(2) and § 117.130(b)(2) and would be expected to be evaluated in the hazard analysis.
- As discussed in the GMA comments to Subpart B, GMPs, the term “food packaging material” should be changed to “primary packaging” to clarify that “food packaging material” is food contact packaging.

GMA Recommends

- FDA modify the language in § 117.135(d)(3) as follows:

§ 117.135(d)(3) Sanitation controls

§ 117.135(d)(3)(i) Where necessary to significantly minimize or prevent hazards that are addressed in the food safety plan reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

(A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;
(B) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, primary food packaging material, and other food-contact surfaces and from raw product to processed product.
Proposed Rule
§ 117.135(d)(3)(ii) The owner, operator or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

GMA Feedback
• See comments below on § 117.135(d)(3)(iii).

GMA Recommends
• No changes.

Proposed Rule
§ 117.135(d)(3)(iii) The owner, operator, or agent in charge of a facility is not required to follow the corrective actions established in § 117.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(3)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

GMA Feedback
• As noted in our comments on corrective actions (§ 117.145), GMA advises that just as all preventive controls are not managed with the same level of rigor, equally all corrective actions are not the same.
• Components of corrective actions should be commensurate with the nature of the deviation and the potential impact on food safety. GMA concurs with the Agency’s statements in the preamble to the proposed rule that, “In many instances the procedural deviations are not reasonably likely to impact product (e.g., . . . deviations in cleaning solution strength rarely result in the production of unsafe product, . . .).” 78 Fed. Reg. 3744. Corrective actions established for these types of examples would not be as intensive as those applied due to a CCP failure, as they would not create a food safety issue.
• GMA agrees with the FDA approach to not require pre-determined, written corrective actions for all potential issues with implementing sanitation controls as stated in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B).

GMA Recommends
• No changes.
Proposed Rule
§ 117.135(d)(3)(iv) All corrective actions taken in accordance with paragraph (d)(3)(ii) of this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

GMA Feedback
• Reference to § 117.135 (d)(3)(ii) is not clear as that section refers to “actions to correct” which, according to § 117.135(d)(3)(iii) is distinct from corrective actions. Documentation of corrective actions is addressed in § 117.145 and § 117.150 and this section is redundant and should be eliminated for clarity.
• GMA concurs with the preamble language indicating that “…the taking of corrective actions is to restore control and to ensure that hazardous food does not reach the consumer.” 78 Fed. Reg. 3751.
• GMA concurs that as stated in proposed § 117.145(a)(2)(i), corrective action procedures must describe the steps to be taken to ensure that appropriate action is taken to identify and correct a situation when a preventive control is not properly implemented and the Agency’s position when it says “We do expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 117.135(d)(3)(ii).” 78 Fed. Reg. 3744 (emphasis added).

GMA Recommends
• FDA delete proposed § 117.135(d)(3)(iv) as follows:

§ 117.135(d)(3)(iv) All corrective actions taken in accordance with paragraph (d)(3)(ii) of this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

Proposed Rule
§ 117.135(d)(4) Recall plan. Recall plan as required by § 117.137.

GMA Feedback
• See GMA feedback for § 117.126(b). GMA recommends removing the requirement for recall plans from this section (Subpart C) and adding it to the GMP section (Subpart B).
• FSMA requires all food processors to be responsible for recalling their goods when the public health might be threatened. GMA wholeheartedly agrees with this premise. However, because the requirement for a recall plan is part of proposed Subpart C and certain firms are exempt from these provisions, these exempt firms would not be required to maintain recall plans. If the requirement for a recall plan is part of the GMPs (Subpart B), these exempt firms will be required to have a recall plan, which is a better outcome for the public health to ensure all facilities can effectively retrieve problem goods should the need arise.
GMA Recommends

• Requirements for firms to maintain recall plans should be facility-wide, not product and process specific and therefore moved to Subpart B, GMPs.
• FDA modify the language in proposed §117.135(d)(4) as follows:
  §117.135(d)(4) Recall plan. Recall plan as required by §117.137.

Proposed Rule

§117.135(d)(4) Recall plan as required by §117.137.

GMA Comments

• GMA agrees with the Agency that those controls identified by the owner, operator or agent in charge of the facility that are necessary and that are not addressed in elsewhere in §117.135(d) be included.

GMA Recommends

• FDA should modify the language in §117.135(d)(5) as follows:
  §117.135(d)(5) Other controls – Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

Proposed Rule

§117.135(d)(5) Other controls. Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

GMA Comments

• GMA agrees with the Agency that those controls identified by the owner, operator or agent in charge of the facility that are necessary and that are not addressed in elsewhere in §117.135(d) be included.

GMA Recommends

• FDA should modify the language in §117.135(d)(5) as follows:
  §117.135(d)(5) Other controls. Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

Proposed Rule

§117.135(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:
  (i) Monitoring as required by §117.140;
  (ii) Corrective actions as required by §117.145; and
  (iii) Verification as required by §117.150.

GMA Feedback

• GMA is concerned that this portion of the proposed regulation appears to require all of these management elements for all preventive controls, unless FDA has provided a specific exception.
• Also of concern, the regulations do not expressly say that even where a particular management activity is required (e.g., a control must be monitored for food safety), the way the control is monitored may vary based on the particular food safety need.
• The risk-based nature of the FSMA statute allows companies to manage controls with the management criteria needed to achieve FSMA’s food safety goals. As a result, following the statute preserves the key elements of today’s successful food safety systems: how science is evaluated and applied to specific products and circumstances and the way management elements are customized to fit diverse food safety needs. Accordingly, the regulatory language proposed by FDA is a concern because it differs significantly from the approach leading facilities with successful food safety histories take today. For food safety, such facilities carefully assess hazards and choose the management elements that will best fit the
individual circumstances. In some cases (e.g., CCPs and certain prerequisite programs that target specific hazards), all of the management elements are required. In other cases, however, a qualified individual has determined the appropriate management tools that make the most sense as a result of the hazard analysis, the nature of the control, and other factors. Table 1 provides examples of the application of management elements for various control measures when applied to manage food safety hazards.
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<td>Pasteurization</td>
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<td>Addition of acid</td>
<td>Yes</td>
<td>Situational</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Drying</td>
<td>Yes</td>
<td>Situational</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Addition of humectant</td>
<td>Yes</td>
<td>Situational</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
**GMA Recommends**

- FDA should modify the language in §117.135(e)(1) as follows:
  
  §117.135(e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to the following requirements as appropriate and necessary to ensure the effectiveness of the controls under paragraph (a) of this section, taking into account the probability and severity of the hazards and the nature of the controls.
  
  (i) Monitoring as required by § 117.140;
  
  (ii) Corrective actions as required by § 117.145;
  
  (3) Validation as required by § 117.147; and
  
  (iii) Verification as required by § 117.150.

**Proposed Rule**

§ 117.135(e)(2) The recall plan established in § 117.137 is not subject to the requirements of paragraph (e)(1) of this section.

**GMA Feedback**

- As discussed elsewhere in these comments, GMA recommends removing recall plans from this section (Subpart C) and adding it to the GMP section (Subpart B).

**GMA Recommends**

- FDA should remove the requirement for recall plans from the preventive controls section (Subpart C), specifically proposed § 117.135(d)(4), § 117.126(b)(6), and § 117.137. The requirements of § 117.137(a) should be relocated to Subpart B, Good Manufacturing Practices, with a modification as follows:
  
  “The owner, operator, or agent in charge of a facility must establish a written recall plan for the food consistent with 21 CFR Part 7.”

- FDA should modify the language in proposed § 117.135(e)(2) as follows:
§ 117.135(e)(2) The recall plan established in § 117.137 is not subject to the requirements of paragraph (e)(1) of this section.

Proposed Rule

§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur.

For food with a hazard that is reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.

(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

GMA Feedback

- GMA acknowledges recall plans are useful in limiting the amount of potentially adversely affected food in the marketplace, but GMA recommends a recall plan be part of the overall food safety plan (i.e., located in Subpart B), not a preventive control as proposed in § 117.137.
  - Recall plans are often firm specific or facility-specific, but rarely explicit to particular foods and/or hazards as are other preventive controls.
  - For firms having more than one manufacturing facility, a recall may be administered and managed at the corporate office, not at the manufacturing facility.
  - A given facility could manufacture several different product categories, and have several sets of preventive controls specific to the product and possibly even the production line. But this same facility is likely to have only one recall plan for all products produced.

- Recall activities should be in compliance with existing regulations, 21 CFR § 7. There should not be separate requirements for recall activities in § 117 including a requirement that FDA be notified in the event of a recall. Industry is already required by FDA’s Reportable Food Registry (RFR, 415(a) of the FD&C Act (21 U.S.C. 350d)) to report any article of food or feed for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals, which has left a facility’s control. To add a separate requirement in § 117 would create a duplication of effort, with no improvement to the public health. In any event, such a notification requirement is not authorized by FSMA.

- To have repetitive requirements for recall activities, one in proposed § 117, another in § 7, and yet another for the RFR is needlessly redundant and potentially confusing, specifically:
Recall plans can be maintained at a corporate level, so individual corporate warehouses may not need a separate recall plan; third-party warehouses may have a recall plan that indicates that they are operating under customer recall plans. FDA should acknowledge that it is appropriate to have a recall plan handled at corporate offices vs. in each individual facility.

Those facilities that are exempt from Subpart C should still be required to have a recall plan. Moving requirements for a recall plan to Subpart B would also accomplish this goal.

GMA Recommends

- FDA remove the requirement for recall plans from the preventive controls section (Subpart C) specifically proposed § 117.135(d)(4), § 117.126(b)(6), and § 117.137. The requirements of §117.137(a) should be relocated to Subpart B, Good Manufacturing Practices with a modification as follows:
  “The owner, operator, or agent in charge of a facility must establish a written recall plan for the food consistent with 21 CFR Part 7.”
- FDA not require reporting of recalls in § 117 as such activity is already mandated by the FD&C through FDA’s Reportable Food Registry (415(a) of the FD&C Act) and is not authorized by FSMA.
- FDA remove the language in proposed § 117.137 as follows:

**§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur.**

For food with a hazard that is reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.

(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

1. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
2. Notify the public about any hazard presented by the food when appropriate to protect public health;
3. Conduct effectiveness checks to verify that the recall is carried out; and
4. Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.
Proposed Rule

§ 117.140 Monitoring.

§ 117.140(a) The owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.

GMA Feedback

- GMA agrees with the Agency that monitoring is a necessary component of successful food safety plans.
- GMA understands that for preventive controls that are essential for food safety, these controls need to be evaluated to be sure they are effectively implemented. However, for some preventive controls monitoring for performance during the operation is not feasible and in this case verification of performance or effectiveness is used to assure success of the control. For example, performing a preoperative hygiene inspection is verifying the cleaning procedures took place. Other examples include cleaning, labeling and segregation of allergens, and preventive maintenance.
- We agree with the Agency’s position that “some preventive controls may not have specific parameters associated with them.” 78 Fed. Reg. 3740. In these cases, monitoring for performance as in § 117.140(a) would not be appropriate. The performance of these controls is confirmed through verification activities. Verification can be used to evaluate the performance of controls where the parameters do not have maximum or minimum values.
- GMA agrees with FDA comments in the preamble that state, “Monitoring the effectiveness of preventive controls would evaluate whether the preventive controls were working. Requiring monitoring of the effectiveness of the preventive controls would be redundant with required verification activities. … In contrast, monitoring the performance of preventive controls would provide evidence that the preventive controls established to control the identified hazards are implemented appropriately.” 78 Fed. Reg. 3747. However, GMA notes that verification activities in successful food safety programs include not only activities to evaluate the effectiveness of control but also include the activities conducted to evaluate whether a control measure was implemented as planned.
  - The FDA definition in § 117.3 and the discussion in the preamble appear to indicate that activities to confirm performance that are not conducted during the operation of a control would be classified as “monitoring for performance.” This could be confused with activities that verify ongoing implementation of control measures.
- In its definitions of monitoring in § 117.3, the Agency is using a definition of monitoring consistent to that applied to CCPs in NACMCF and Codex HACCP guidances. The Codex definition of monitoring is: “the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.” Codex Alimentarius Commission CAC/RCP 1-1969 Rev.4-2003 Annex. The NACMCF definition is “to conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.” J. Food Prot. 61: 1247. Using these definitions, monitoring would not apply to control measures for which parameters cannot be established and that are not amenable to documentation. Historically, the definitions of monitoring (NACMCF, Codex Alimentarius) are observations conducted...
during the operation of a control measure to ensure that it is under control. To clarify the difference between monitoring activities and verification activities to evaluate performance of a control measure, and to clarify that monitoring may be conducted where appropriate for preventive controls that are not CCPs, FDA should use a definition of monitoring consistent with that provided in ISO 22000:2005: “conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.”

GMA Recommends

- FDA modify the language in proposed § 117.140(a) as follows:
  § 117.140(a) Where required under § 117.135(e), the owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.
- FDA modify the definition of monitor in proposed section § 117.3 as follows:
  Monitor means conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended a process, point, or procedure is under control and to produce an accurate record for use in verification.

Proposed Rule

§ 117.140(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed.

GMA Feedback

- GMA agrees with the requirement in § 117.140(b) that processors “monitor the preventive controls with sufficient frequency to provide assurance that they are consistently performed (our emphasis).”
- GMA also concurs with NACMCF guidelines that acknowledge continuous monitoring is not possible or necessary in all cases.
- Technically, digital recording systems are discrete sampling systems and not by definition “continuous” in an engineering context. However, GMA contends that the sampling rate may be at a high enough frequency as to be equivalent to “continuous” monitoring.
- GMA agrees with the Agency when they state, “frequency of non-continuous monitoring would depend on factors such as the proximity of operating conditions to the conditions needed to ensure safety and the variability of the process.” 78 Fed. Reg. 3748, and as such, the determination of monitoring frequency should be sufficient to demonstrate control before the product is released from the manufacturer’s control.
- Non-continuous monitoring examples may include: formulation, package fill, container closure integrity. Frequency could apply to an event basis or time basis. Event based monitoring may be appropriate for batch systems, e.g., that ingredients were delivered according to the prescribed recipe.
- For those preventive controls where monitoring of maximum or minimum values is not feasible, as described above, verification activities should be sufficient to show that the system maintains adequate control for food safety.
GMA Recommends

FDA modifies the language in proposed § 117.140(b) as follows:

§ 117.140(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls, where required under § 117.135(e), with sufficient frequency to provide assurance that they are consistently performed.

GMA Feedback

• Consistent with the statute, GMA understands this section to indicate that where monitoring is applicable, records of monitoring must be maintained.
• As per our discussion on § 117.140(a), not all preventive controls have monitoring records (e.g. some controls are confirmed through verification activities).
• Exception reporting: In order to be consistent with modern monitoring systems in use today, and even more sophisticated systems that will be available in years to come, GMA highly recommends that the Agency recognize the acceptability of monitoring systems that exclusively provide exception reports. Exception reporting is a structure where automated systems are designed to alert operators and management on an exception basis; i.e., only when a deviation from food safety parameter limits are observed by the system. In many cases, monitoring of preventive controls can be done by automated systems that provide exception reporting in a much more efficient manner than if performed by operators. Automated monitoring allows for increased sampling frequency (often continuous) and reduction of human error.
  o Example: refrigeration temperature control that notifies on exception (e.g., high temperature alarm) may not record temperatures that meet control requirements, only those that exceed them.
  o GMA recognizes that such systems must be validated and periodically verified to ensure they are working properly.
  o GMA requests that the Agency clarify in the preamble to the final rule that monitoring systems can work affirmatively or by exception and that both types of systems and their related documentation are acceptable.

GMA Recommends

• FDA modify the language in proposed § 117.140(c) as follows:
  § 117.140(c) All monitoring of preventive controls in accordance with this section must be documented as appropriate in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with § 117.150(d)(5)(i).
Proposed Rule

§ 117.145 Corrective Actions.

§ 117.145(a) Corrective action procedures

§ 117.145(a)(1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

GMA Feedback

- GMA concurs with the preamble language indicating that “...the taking of corrective actions is to restore control and to ensure that hazardous food does not reach the consumer.” 78 Fed. Reg. 3751.

- GMA further concurs that as stated in proposed § 117.145(a)(2)(i), corrective action procedures must describe the steps to be taken to ensure that appropriate action is taken to identify and correct a situation when a preventive control is not properly implemented and the Agency’s position when it says “We do expect the facility to take action to correct conditions and practices as appropriate to the situation as would be required by proposed § 117.135(d)(3)(ii).” 78 Fed. Reg. 3744 (emphasis added).

- As noted in the emphasis above, GMA advises that just as all preventive controls are not managed with the same level of rigor, equally all corrective actions are not the same.

- Components of corrective actions should be commensurate with the nature of the deviation and the potential impact on food safety.  GMA concurs with the Agency’s statements in the preamble to the proposed rule that, “In many instances the procedural deviations are not reasonably likely to impact product (e.g., . . . deviations in cleaning solution strength rarely result in the production of unsafe product...).” 78 Fed. Reg. 3744. Corrective actions established for these types of examples would not be as intensive as those applied due to a CCP failure, as they would not create a food safety issue.

  - For example, assuming that all sanitation verification steps and a visually clean standard were satisfied, the after-the-fact discovery that a cleaning chemical concentration did not reach its desired level would not require placing affected product on hold.  In contrast, where a pasteurizer is a CCP, the discovery that a thermal process was not adequately delivered could require both placement of substantial product on hold and return of affected goods that had left the manufacturing facility.  The tables below provide further examples for chemical and biological hazards.

- GMA requests the Agency to acknowledge that successfully finding and eliminating a hazard through a preventive control, such as when a metal detector rejects a package containing metal, indicates the preventive control is effective.  Since the preventive control is working as planned, there is no need for a corrective action.  In some circumstances, the root cause investigation of the metal detector rejection may result in a corrective action.  Some preventive controls may work in concert with other preventive controls.  The incorrect functioning of one control may not result in unsafe food if another preventive control(s) has effectively managed the hazard.  For example, a process may employ redundant controls for metal hazards such as magnets and metal detectors.  Metal hazards not addressed by a deficient magnet would be identified and eliminated by a metal detector later in the process
flow. This could also apply to systems that use redundant metal detectors or metal detectors coupled with vision systems. Another example is the use of a vision system to verify cap seating and alignment post filling and a dud detector to verify vacuum on the exit side of the cooling tunnel on the same hot fill and hold processing line.

- GMA requests that the Agency clarify that while corrective actions should restore normal operating conditions that maximize food safety and keep hazardous foods from reaching the consumer, final disposition of affected goods could take a large amount of time. For example, food put on hold for a deviation from a thermal process is often sequestered for an extended period, i.e., 30 – 90 days, before final disposition is completed.

- We urge the Agency to clarify that not all corrections are corrective actions. A well run, hygienic operation may have several corrections during production that are not related to food safety (e.g., cleaning up spills, process adjustments, modifying GMP practices). These types of activities are not corrective actions as referred to in proposed § 117.145.

| Table 2. Different Levels of Corrective Actions for Chemical Hazards | Allergen Management | (Examples only, may not be appropriate to all manufacturing facilities) |
|---|---|---|---|---|---|
| **Example No** | **Preventive Control** | **Preventive Control Failure** | **Likelihood of Food Safety Issue** | **Potential Corrective Action** | **Documentation for 117.145(a)(2)(i-iii)** |
| 1 | Label check | Incorrect label resulting in undeclared allergen | High | - Place product on hold  
- Investigate root cause | Yes - extensive |
| 2 | Allergen specific SSOP | Allergen cleaning found to be ineffective after line start-up | High | - Place product on hold  
- Investigate root cause | Yes - extensive |
| 3 | Allergen specific SSOP | Allergen cleaning found to be ineffective prior to line start-up (e.g., visually clean, ATP etc.) | Low – if issue is corrected | - No action involving product is needed  
- Re-clean line until acceptable result obtained | Yes - moderate |
Example 1: An error during production causes product to be packed with the incorrect label resulting in an undeclared allergen. In this situation, the preventive control of a final product label check identified the problem but the affected product could cause a food safety issue. Corrective actions may include placing product on hold, re-evaluation of the product and conducting a root cause investigation. All corrective actions and subsequent procedures should be well documented and verified.

Example 2: A facility has a preventive control to perform an allergen specific SSOP when changing from a product with allergens to products without that same allergen. The firm verifies that the SSOP was performed properly (e.g., visually clean, ATP, testing CIP rinse water). After production begins, allergenic ingredients from the previous run are found on the production line. These allergens are not declared on the label of the currently running product. In this situation, in spite of monitoring and verification results that met parameter values, the preventive control failed and the affected product could cause a food safety issue. Corrective actions may include placing product on hold and conducting a root cause investigation. All corrective actions and subsequent procedures should be well documented and verified.

Example 3: A facility has a preventive control to perform an allergen specific SSOP when changing from a product with allergens to products without that same allergen. Prior to the start of a production run, allergen-cleaning verification activities found allergenic ingredients from a previous run on the production line. The line is re-cleaned, inspected and parameter values are found to be acceptable. In this situation, the preventive control worked as intended and the error was corrected before any production ensued. Documentation of these activities is recorded. However, a CCP-like corrective action is not needed, there is no food safety issue and there may be no additional activity such as a root cause analysis or putting product on hold.

Example 4: As a general practice, in their warehouse a facility segregates packaged allergenic ingredients from non-allergenic ingredients to minimize the potential for allergen cross-contact. During a walk-through of the warehouse, it was discovered that packaged ingredients containing allergens were not properly segregated. The ingredients were moved to comply with company policy. In this situation, the preventive control was corrected as a result of the verification activity. Corrective actions are not needed since it is highly unlikely there is any affected product and there may be no additional documentation. This is an example of a correction versus a corrective action.
Table 3. Different Levels of Corrective Actions for Biological Hazards
(Examples only, may not be appropriate to all manufacturing facilities)

<table>
<thead>
<tr>
<th>Example No</th>
<th>Preventive Control</th>
<th>Preventive Control Failure</th>
<th>Likelihood of Food Safety Issue</th>
<th>Potential Corrective Action</th>
<th>Documentation for 117.145(a)(2)(i-iii)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pasteurizer divert valve check</td>
<td>Divert valve fails</td>
<td>High</td>
<td>Place product on hold - Investigate root cause</td>
<td>Yes - extensive</td>
</tr>
<tr>
<td>2</td>
<td>Sanitizer concentration measurement</td>
<td>Concentration of sanitizer found to be lower than SSOP minimum</td>
<td>Medium</td>
<td>Situational - Investigate root cause</td>
<td>Situational</td>
</tr>
<tr>
<td>3</td>
<td>High hygiene application area</td>
<td>Hygienic zone violation by employee</td>
<td>Low</td>
<td>No action involving product is needed - Training</td>
<td>No</td>
</tr>
</tbody>
</table>

**Example 1:** During a check of a pasteurizer divert valve, it is determined that it is not functioning properly and it was determined that there was possibility of under-processed product getting downstream. In this situation, the preventive control failed and the affected product could cause a food safety issue. Corrective actions may include placing product on hold and conducting a root cause investigation. All corrective actions and subsequent procedures should be well documented and verified.

**Example 2:** During the review of cleaning and sanitizing records the sanitizer concentration was found to be slightly below the SSOP recommended minimum level but all other procedures of the SSOP were performed correctly. In this situation, the risk of a food safety issue could depend on analysis of the specific situation and results of other verification activities. For example, if ATP and visually clean standards were met and/or the product has inherent properties that limit its ability for microbial growth, simply adjusting the concentration of the sanitizer for future applications and recording the event(s) could be adequate. In other situations more rigorous corrective actions might be in order. All corrective actions and subsequent procedures should be documented and verified.

**Example 3:** Hygienic zoning is used to reduce the risk of microbial cross contamination. Only employees in the high hygiene zone wear white smocks. During production, an employee that should not be in the high hygiene zone mistakenly enters it. The employee is asked to leave immediately and he/she does. In this situation, deviation from the preventive control was corrected immediately. There is no risk to food safety, and there may be no additional documentation. This is an example of a correction versus a corrective action.
GMA Recommends

FDA modify the language in proposed § 117.145(a)(1) as follows:

§ 117.145(a)(1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if the preventive controls are not properly implemented or are found to be ineffective.

Proposed Rule

§ 117.145(a)(2) The corrective action procedures must describe the steps taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur;
(ii) All affected food is evaluated for safety; and
(iii) All affected food is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that 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.

GMA Feedback

• Consistent with the FSMA statute, GMA understands this section to require procedures for corrective actions, as opposed to a requirement that all individual preventive controls must have a specific corrective action procedure. As discussed above, the nature of certain preventive controls will not require specific, pre-determined corrective actions. For example, pre-determined corrective actions would not be appropriate for hygienic zoning/enhanced GMPs.

• § 117.145(a)(2)(i) states that, “Appropriate action is taken to identify and correct a problem with implementation of a preventive control to reduce the likelihood that the problem will recur...” This language could be misunderstood to require establishing a new preventive control as a result of implementing a corrective action procedure. It would be inappropriate to assume that corrective action procedures always correct a problem with the implementation of a new or additional preventive control.

• In addition, specific steps to reduce the recurrence of a preventive control failure are not taken after every corresponding corrective action is implemented. For example if a corrective action is necessary due to an electrical power failure, companies should not be expected to install alternate power sources in order to comply with § 117.145(a)(2)(i). Conversely, repeated failures of a standard formula to achieve the necessary level of acidification would warrant re-evaluation by a qualified individual. Accordingly, we urge FDA to add a section § 117.145(a)(2)(iv) to the proposed regulation in order to further address instances when preventive controls are not properly implemented or when the preventive control is not effective. Our recommended language is below.

• We urge FDA to provide flexibility for general corrective action procedure requirements that can be adapted as needed to fit the wide range of preventive controls. The regulation should recognize that there may be no affected food resulting from the event that triggered the corrective action.
• Corrective action requirements from the Agency should be principle based (e.g., affected product containment, control restored to operation before commencing production) rather than prescriptive.

GMA Recommends
• FDA modify the language in proposed § 117.145(a)(2) as follows:

§ 117.145(a)(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control, when necessary, to reduce the likelihood that the problem will recur;
(ii) All affected food, if any, is evaluated for safety; and
(iii) All affected food, if any, is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that 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; and
(iv) When appropriate, potential actions to reduce the likelihood of recurrence are evaluated and implemented as necessary.

Proposed Rule
§ 117.145(b), Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

§ 117.145(b)(1) Take corrective action to identify and correct the problem to 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 (a)(2)(iii) of this section; and

§ 117.145(b)(2) Reanalyze the food safety plan in accordance with § 117.150(f) to determine whether modification of the food safety plan is required.

GMA Feedback
• This is not in the FSMA statute.
• GMA suggests deleting this section. An unanticipated food safety issue should trigger requirement for reanalysis, which is already addressed in § 117.150(f). Thus this proposed section, § 117.145(b) is repetitive and does not add value for food safety.
• The term “problem” is ambiguous in its meaning. If this section remains, the language “Corrective action in the event of an unanticipated problem” is not clear. “Problem” should be replaced with “food safety issue.”
GMA Recommends

- § 117.145(b) be deleted.
- If this section remains, GMA recommends that the word “problem” be replaced with “food safety issue.”
- FDA should modify the language in proposed § 117.145(b) as follows:
  (b) Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:
    (1) Take corrective action to identify and correct the problem to 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 (a)(2)(iii) of this section; and
    (2) Reanalyze the food safety plan in accordance with § 117.150(f) to determine whether modification of the food safety plan is required.

GMA Feedback

- GMA agrees that corrective actions should be documented and verified.
- There appears to be a typographical error. The proper reference should be § 117.150(d)(2)(i).

GMA Recommends

- For reasons explained in our comments to §117.145(b), FDA modify the language in proposed § 117.145(c) as follows:
  § 117.145(c) Documentation. All corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

Proposed Rule

§ 117.150 Verification.

and

§ 117.3 Definitions.
GMA Feedback

- FDA is proposing to define verification to mean “those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to plan.” (Emphasis added.) While this definition is consistent with the definition in the NACMCF 1997 HACCP guidelines, it is not consistent with the Codex Alimentarius definitions (CAG GL 69 2008 Validation of Food Safety Control Measures). A definition of verification in FSMA that includes validation will continue the common confusion between procedures and activities to validate that control measures are capable of significantly minimizing or preventing an identified food safety hazard, and the ongoing activities to verify the food safety plan and component control measures are operating as planned. GMA requests that the Agency consider using clearly separate definitions of validation and verification, consistent with Codex Alimentarius definitions, to help to avoid confusion about activities related to these important processes. Validation activities should also be included in a separate section of the final rule from verification activities.

- As noted in the preamble to the proposed rule, the Agency considers the term “re-analyze” to refer to “the reassessment of the validity of a preventive control or the food safety plan to control a hazard.” 78 Fed. Reg. 3751. GMA agrees with FDA that such reanalysis is an important activity to ensure the ongoing effectiveness of programs to manage relevant hazards. In practice, reanalysis will have a component of system review and, where necessary, activities to re-validate a control measure or combination of control measures. However, FDA does not define reanalysis in the proposed rule, which could lead to confusion as to the nature and scope of reanalysis activities. GMA requests that FDA provide a definition of reanalysis consistent with that proposed in the preamble.

GMA Recommends

- Changing or adding the following to proposed § 117.3 Definitions …
  - Validation means 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 obtaining evidence that a control measure or combination of control measures, when properly implemented, is capable of effectively controlling the hazard to a level necessary for product safety.
  - Verification means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to plan. The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
  - Reanalysis means a reassessment of the validity of a preventive control or food safety plan to control a hazard. Reanalysis may include a system review and, where necessary, activities to revalidate a control measure or combination of control measures.

- The heading for proposed section § 117.150 remain as is: § 117.150 Verification.
Proposed Rule

§ 117.150(a) Validation. Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

GMA Feedback

- GMA agrees with FDA that scientific validation is an important activity in ensuring that food safety systems and specific control measures are effective and has much precedence for factories that have incorporated HACCP-based food safety management systems. Validation activities are focused on the collection of information to ensure that specific control measures, or control measure combinations, can effectively control identified hazards. Validation may also include a justification of decisions on the probability and severity of identified hazards.

- GMA believes that some specific cleaning and sanitation activities may be appropriate for validation. GMA contends that visual observations, such as “visually clean,” can be an acceptable test (criteria) to be used in the validation of some cleaning and sanitation activities in the absence of a suitable analytical test.

  For example, when conducting allergen changeover cleaning (the removal of soils from equipment surfaces), validation is often determined by visual observation where a specific allergen analytical test is not appropriate or available.

- GMA believes that validation of allergen changeover cleaning is limited not only by an absence of specific allergen tests, but by an absence of established allergen thresholds.

GMA Recommends

- That validation activities (§ 117.150(a)) be included in a separate section of the rule from verification activities (i.e. create section § 117.147 “Validation”) and renumber remainder of § 117.150 is renumbered accordingly.

- That the Agency modify the language in proposed § 117.150(a) as follows:

  § 117.147 Validation

  (a) Validation. Except as provided by paragraph (a)(3) of this section, Where required under § 117.135(e), the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

Proposed Rule

§ 117.150(a)(1) Must be performed by (or overseen by) a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;
GMA Feedback

- FDA should consider including this requirement in a new validation section in order to help separate these two important concepts in a manner more consistent with current international practices.
- In most cases it will be necessary and possible to complete validation prior to implementation of preventive controls; however, GMA agrees with FDA that there are some circumstances where validation activities, such as operational qualification, are completed during initial production of a new product or process. As some new processes are conducted when processing schedules allow, GMA proposes that a period of 90 days be provided to validate a food safety system, which is consistent with the USDA-FSIS (FSIS Compliance Guideline on HACCP Systems Validation, April 2013). In some cases, an even longer period may be required where products are manufactured at a lower frequency.
- In the preamble, FDA indicates that the term “reanalysis” is consistent with “re-validation.” GMA believes that reanalysis includes a system review component and revalidation where necessary for specific control measures or control measure combinations.

GMA Recommends:

- The Agency modify the language in proposed § 117.150(a)(1) to include a section solely for validation as explained in comments under §117.50(a), as follows:
  § 117.150(a)(1) Must be performed by (or overseen by) a qualified individual:
  (1) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks 90 days of production (a longer period requires written justification); and
  (ii)Whenever a reanalysis of the food safety plan reveals the need to do so;

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Proposed Rule

§ 117.150(a)(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

GMA Feedback

- FDA should consider including this section in a new validation section in order to help separate the two important concepts of validation and verification in a manner more consistent with current international practices.
- GMA agrees with FDA that validation must include the collection of scientific and technical information or the execution of studies, consistent with what is outlined in the Codex Alimentarius Commission Guidance CAG/GL 69 2008 Validation of Food Safety Control Measures. Experience with the historical absence of an issue is not a substitution for such information; however, historical data from past or existing operations may be used as technical information for validation of control measures or control measure combinations.
GMA Recommends

- The Agency modify the language in proposed § 117.150(a)(2) to fit in a section solely for validation as explained in comments under §117.50(a), as follows:
  § 117.150(a)(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards identified and implemented in accordance with § 117.135 that are reasonably likely to occur; and

Proposed Rule

§ 117.150(a)(3) Need not address:
(i) The food allergen controls in § 117.135(d)(2);
(ii) The sanitation controls in § 117.135(d)(3); and
(iii) The recall plan in § 117.137.

GMA Feedback

- GMA agrees with FDA that there are some specific control measures and procedures for which scientific validation is not applicable. The specific examples cited by FDA are those for which the nature of the activity is not conducive to formal validation activities, for which formal validation is not necessary, or for which specific methods are not available that enable formal validation. In some cases, such measures are validated through a validation of the effectiveness of a system of controls rather than the individual controls. In some cases, the ongoing effectiveness of such activities is ensured through other verification activities.
  o FDA has listed specific examples in the exemptions provided in the draft rule (e.g., allergen controls, labeling controls, some sanitation controls). Additional examples are provided above in Table 1. See comments to §117.135(e)(1).

- Inclusion in the rule of a specific list of exempted preventive controls implies that no control measures in these categories are suitable for validation and that all other preventive controls are suitable for validation. Flexibility is needed to accommodate the variable nature of current or future control measures.

GMA Recommends

- Specific criteria used to determine which preventive controls are suitable or not suitable for validation as well as examples of validation appropriate for control measures be provided in a guidance document, developed with input from industry.
- FDA eliminate the specific list of excluded controls and instead provide language flexibility for determining when validation is appropriate.
- FDA remove the language to in proposed § 117.150(a)(3) as follows:
  § 117.150(a)(3) Need not address:
  (i) The food allergen controls in § 117.135(d)(2);
  (ii) The sanitation controls in § 117.135(d)(3); and
  (iii) The recall plan in § 117.137.
Proposed Rule
§ 117.150(b) Monitoring. The owner, operator, or agent in charge of a facility must verify that monitoring is being conducted, as required by § 117.140.

GMA Feedback
- GMA agrees with this requirement.

GMA Recommends
- The Agency modify the language in proposed section § 117.150(b) as follows:
  § 117.150 (a) Where required under § 117.135(e), the owner, operator, or agent in charge of a facility must: (1) Verify that monitoring is being conducted, as required by § 117.140;

Proposed Rule
§ 117.150(c) Corrective actions. The owner, operator, or agent in charge of a facility must verify that appropriate decisions about corrective actions are being made, as required by § 117.145 and § 117.135(d)(3)(ii).

GMA Feedback
- While the phrase “appropriate decisions about corrective actions” in this section of the proposed regulations directly reflects the language in the statute, it is somewhat ambiguous and may be misinterpreted. FDA’s language in the preamble, Fed. Reg. 3756, cites an example of verifying appropriate decisions through observation, by a supervisor, that the corrective action is being made and references the use of records review to verify corrective actions. GMA believes that the explanatory text of the preamble indicates that the intent of “appropriate decisions” in this section is to verify that the corrective actions are implemented as devised.
- GMA agrees with this interpretation and would recommend modifying the language as discussed below adding the language “to demonstrate the corrective actions are taken and are effective” within the regulation for clarity.
- GMA agrees with FDA’s position that the verification activities that must be conducted for corrective actions do not need to be further specified in the regulation. 78Fed. Reg. 3756.

GMA Recommends
- The following modifications be made to § 117.150(c):
  (2) Corrective actions. The owner, operator, or agent in charge of a facility must verify that appropriate decisions about corrective actions are made to demonstrate that the corrective actions taken are effective, as required by § 117.145 and § 117.135(d)(3)(ii).
Proposed Rule

§ 117.150(d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the following activities, as appropriate to the facility and the food:

GMA Feedback

- The phrase “effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur” is not consistent with our recommendations in previous sections regarding the modification of the use of RLTO and could be simplified to “effective.” Please see our comments on § 117.130(c)(1).
- For consistency in the application of preventive controls and control measures to be commensurate with the nature of the hazards and controls, GMA recommends the addition of the phrase “where necessary and appropriate” to replace the phrase “as appropriate” in the regulation text for added clarity.
- While specific verification activities are outlined by FDA in this section, GMA notes that there are other activities that could also be suitable for verification (see Table 4 below).

<table>
<thead>
<tr>
<th>Control</th>
<th>Calibration or Accuracy Checks</th>
<th>Records Review</th>
<th>Audit</th>
<th>Testing of environment</th>
<th>Testing of product&lt;sup&gt;a&lt;/sup&gt;</th>
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</thead>
<tbody>
<tr>
<td>GMP</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Shoe change</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Distinctive clothing</td>
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<td>Yes</td>
<td>Situational</td>
<td>No</td>
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<tr>
<td>Zoning controls</td>
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<td>No</td>
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<td>Situational</td>
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<tr>
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<td>Yes</td>
<td>Yes</td>
<td>Situational</td>
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<tr>
<td>Training</td>
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<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
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<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Storage (refrigerated)</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
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<td>Allergen control</td>
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<tr>
<td>Segregation</td>
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<td>No</td>
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<td>Yes (labels)</td>
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<td>No</td>
<td>No&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>Sanitation</td>
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<tr>
<td>CIP</td>
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<tr>
<td>COP</td>
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<tr>
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<tr>
<td>Foreign materials</td>
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<td></td>
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<td></td>
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<tr>
<td>Glass management</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Situational</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Preventative maintenance  |  No  |  Yes  |  Yes  |  No  |  Yes  \\
Detection systems      |  Yes |  Yes  |  Yes  |  No  |  Yes  \\
**Process controls**   |      |        |        |      |        \\
Pasteurization        |  Yes |  Yes  |  Yes  |  No  |  Yes  \\
Addition of acid      |  No  |  Yes  |  Yes  |  No  |  Yes  \\
Drying               |  Yes |  Yes  |  Yes  |  No  |  Yes  \\
Addition of humectant |  No  |  Yes  |  Yes  |  No  |  Yes  \\

*a* Where there is evidence / concern about loss of control  
*b* An examination of product labels may be conducted, but evaluation of finished products for allergens is generally not relevant or useful in the event of labeling concerns.

**GMA Recommends**
- FDA modify the language in proposed § 117.150(d) as follows:
  § 117.150(d)(c) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the following activities, as where necessary and appropriate to the facility and the food:
  - Calibration of process monitoring instruments and verification instruments; and
  - Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities

**Proposed Rule**
§ 117.150(d)(1) Calibration of process monitoring instruments and verification instruments; and

**GMA Feedback**
- GMA agrees with FDA’s position on the importance of calibration for monitoring and verification instruments used with preventive controls for food safety.
- GMA agrees with FDA’s position that the type of instruments used, and the manner of their use, will determine the need for, and frequency of calibration and that the methods and frequency for calibration need not be specified in the regulation.
- GMA advises FDA that calibration is different from an accuracy or performance check, which is a test to confirm that certain equipment or measurement device is accurate but for which calibration may not be possible and for which replacement or application of corrective values may be the corrective action. Accuracy checks are also verification activities.

**GMA Recommends**
The Agency modify the language in proposed § 117.150(d)(1) as follows:
§ 117.150(d)(1) Calibration and/or accuracy checks of process monitoring instruments and verification instruments; and

**Proposed Rule**
§ 117.150(d)(2) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities
reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within a week after the records are made.
(ii) Records of calibration within a reasonable time after the records are made.

GMA Feedback

- § 117.150(d)(2) [Verification] calls for “Review of the following records within the specified timeframes, ... to ensure that ... appropriate decisions were made about corrective actions: (i) Records of monitoring and corrective action records within a week after the records are made.” GMA reminds the Agency that in certain examples, while affected product will be “on hold” corrective actions may not be fully implemented within seven days. For example
  - Certain deviations, such as in thermal processing, may require incubation for greater than seven days before final disposition can be enacted.
  - Potentially affected product “on hold” may be awaiting microbial evaluation where the analytical procedure can take more than seven days.
  - An adverse event (e.g., roof leak) will result in immediate corrective action to mitigate the hazard and prevent re-occurrence, however, the root cause solution (e.g., roof repair) may take much longer than seven days.

- GMA interprets verification of corrective action records to be the review by a responsible individual after the completion of a corrective action to ensure its completion and that a subsequent review of corrective actions is not necessary.

- This section is targeted to verification of preventive controls and the phrase “and appropriate decisions were made about corrective actions” is redundant with section § 117.150(c). Therefore, GMA recommends eliminating this phrase in § 117.150(d)(2).

- GMA notes that the phrase “a week” in subsection (i) should be modified to “seven working days” for consistency in comments and language with § 117.145 (Corrective Actions).

- Specific timeframe language such as in subsection (i) may not always be achievable and does not focus on the intent of the rule. Flexibility language should be included in order that other timeframes can be accommodated and the intent of the rule is emphasized. In section (i) wording such as “or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce” should be added.

- As noted previously, GMA agrees with FDA’s position regarding § 117.150(c) that the verification activities for corrective actions do not need to be further specified in the regulation. 78 Fed. Reg. 3756. Therefore the reference to records review as a verification activity in § 117.150(d)(2)(i) should be eliminated.

- Records of calibration activities are reviewed at the time the calibration is performed. In most cases a formal scheduled review of calibration records is not required to ensure the effectiveness of the control. The requirement for records review of calibration should be based upon the nature of the control being calibrated.
GMA Recommends

- FDA should modify the proposed language in § 117.150(d)(2) as follows:
  § 117.150(d)(2) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, and the preventive controls are effective, and appropriate decisions were made about corrective actions:
  (i) Records of monitoring and corrective action records within seven working days after the records are made or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce.
  (ii) Records of calibration within a reasonable time after the records are made where necessary, based on the nature of the control.

Proposed Rule

§ 117.150(e) Written procedures for verification activities. As appropriate to the facility and the food, the owner, operator, or agent in charge of a facility must establish and implement written procedures for the frequency of calibrating process monitoring instruments and verification instruments.

GMA Feedback

- GMA agrees with FDA’s position to not propose requirements for written procedures for all verification activities, 78 Fed. Reg. 3758, as these are sufficiently covered by section 418(f) of the FD&C Act.
- For consistency in the application of preventive controls and control measures to be commensurate with the nature of the hazards and controls, GMA contends the addition of the phrase “when appropriate for the nature of the hazard and necessary to assure the effectiveness of the control” to replace the phrase “as appropriate to the facility and food” in the regulation text for added clarity.

GMA Recommends

- FDA should modify the proposed language in proposed section § 117.150(e) as follows:
  § 117.150(e) Written procedures for verification activities. As appropriate to the facility and the food, when appropriate for the nature of the hazard and necessary to assure the effectiveness of the control, the owner, operator, or agent in charge of a facility must establish and implement written procedures for the frequency of calibrating and/or accuracy checks of process monitoring instruments and verification instruments.
Proposed Rule
§ 117.150(f) Reanalysis.

GMA Feedback
• GMA agrees with the concept of periodic reanalysis of the food safety plan. 78 Fed. Reg. 3751. GMA contends that providing a definition of reanalysis will help clarify this important concept.

GMA Recommends
• FDA should provide a definition of reanalysis in proposed § 117.3 as follows:
  Reanalysis means a reassessment of the validity of a preventive control or food safety plan to control a hazard. Reanalysis may include a system review and, where necessary, activities to revalidate a control measure or combination of control measures.

Proposed Rule
§ 117.150(f)(1) The owner, operator, or agent in charge of a facility must:
(i) Conduct a reanalysis of the food safety plan;
   (A) At least once every 3 years;
   (B) Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;
   (C) Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;
   (D) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and
   (E) Whenever a preventive control is found to be ineffective.
(ii) Complete such reanalysis 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; and
(iii) Revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

GMA Feedback
• GMA agrees with FDA that periodic reanalysis of the food safety plan is an important element to assure continued effectiveness for food safety and that such reanalysis should be conducted at least once every three years.
• GMA agrees with FDA’s comments in the preamble that indicates the term “reanalysis” is consistent with “revalidation.” 78 Fed. Reg. 3759.
• GMA interprets that reanalysis of the plan to be the reanalysis of the appropriate component of the plan depending on the situation.
• GMA interprets § 117.150(f)(1)(i)(B) to mean that a reanalysis is required only when a change in activities creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard and recommends slight modification to the text for simplicity and clarity.

• GMA agrees with FDA’s position in proposed § 117.150(f)(1)(i)(D) that the absence of a corrective action procedure when a deviation occurs in a preventive control is an appropriate trigger for reanalysis to assure that a corrective action procedure is in place, and followed, for the control. GMA believes that emphasis should be included in the language to recognize that both events (preventive control deviation and the absence of corrective action procedure) are needed to trigger the reanalysis.

• GMA contends that the use of the term “specific” as used in § 117.150(f)(1)(i)(D), to describe the corrective action procedure is not appropriate as many preventive controls will have corrective action procedures that allow flexibility based upon the nature of the hazard and control. The term “specific” in this context is more appropriate for a CCP control and should not be applied to all controls.

• GMA agrees with FDA’s position that any additional preventive controls, as a result of reanalysis, be implemented as soon as possible to the relevant operation/process. The phrase “before the change in activities at the facility is operative” used in § 117.150(f)(1)(ii) is ambiguous as it is unclear if it is referencing the initial change in activities that triggered the reanalysis or a change in activities subsequent to the reanalysis. GMA recommends clarifying the language by substituting the phrase “before the relevant process is operative” in this section.

• GMA agrees with FDA that there are some circumstances where reanalysis activities and implementation of additional preventive controls require operational qualification that is completed during initial production of the process. As some new processes are conducted when processing schedules allow, GMA proposes that, in these cases, a period of “90 days or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce” be provided in § 117.150(f)(1)(ii), which is consistent with the USDA-FSIS requirements.

GMA Recommends

• FDA should modify the language in proposed section § 117.150(f)(1) as follows:

  § 117.150(f)(1) Reanalysis. The owner, operator, or agent in charge of a facility must:
  (i) Conduct a reanalysis of the food safety plan;
     (A) At least once every 3 years;
     (B) Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;
     (C) Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;
     (D) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and
     (E) Whenever a preventive control is found to be ineffective.
(ii) Complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility relevant process is operative or, when necessary, during the first 6 weeks, 90 days of production or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce; and
(iii) Revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

Proposed Rule
§ 117.150(f)(2) The reanalysis must be performed (or overseen) by a qualified individual.

GMA Feedback
- None

GMA Recommends
- FDA should modify the language in proposed section § 117.150(f)(2) as follows:
  § 117.150(f)(2) The reanalysis must be performed (or overseen) by a qualified individual.

Proposed Rule
§ 117.150(f)(3) FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

GMA Feedback
- GMA agrees with FDA that a reanalysis of the food safety plan is required to respond to new hazards and developments in scientific understanding as determined by the Commissioner of Food and Drugs. GMA believes that communication of this nature should be in a formal written manner from the Agency to the appropriate product category. There is a concern that if this comes from the investigator level, it will be inconsistent and may not be scientific.

GMA Recommends
- FDA should modify the language in proposed section § 117.150(f)(3) as follows:
  § 117.150(f)(3) FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

Proposed Rule
§ 117.150 (g) Documentation. All verification activities taken in accordance with this section must be documented in records.
GMA Recommends

- FDA should modify the language in proposed section § 117.150(g) as follows:
  § 117.150(g) Documentation. All verification activities taken in accordance with this section must be documented in records.

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Proposed Rule

§ 117.155 Requirements applicable to a qualified individual.

(a) One or more qualified individuals must do or oversee the following:
  (1) Preparation of the food safety plan (§ 117.126(c));
  (2) Validation of the preventive controls (§ 117.150(a)(1));
  (3) Review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 117.150(d)(2)); and
  (4) Reanalysis of the food safety plan (§ 117.150(f)(2)).

GMA Feedback

- GMA agrees that individuals with the appropriate background and/or training should oversee the important food safety plan requirements defined in the proposed regulation.
- GMA advises that the proposed regulations should indicate that qualified individual(s) may not and need not be present at the facility during operation.
- Examples of qualified individuals and teams can include:
  - A single qualified individual at the facility
  - A team of qualified individuals
  - Remotely located qualified individuals
  - A consultant(s) developing a plan for onsite management by a team or lead person

GMA Recommends

- No changes.

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Proposed Rule

§ 117.155(b) To be qualified, an 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 job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such 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.

GMA Feedback

- GMA agrees with the statement in § 117.155(b) that a qualified individual may be qualified through job experience to develop and apply a food safety system.
- GMA agrees that qualified individuals do not have to be employees of the company. Such individual(s) can include:
  - University professors
  - Consultants
  - Experts from trade associations
- GMA notes also that a given facility may have more than one qualified individual.
- A qualified individual may prepare and oversee multiple food safety plans for different facilities.
- GMA agrees that job experience is an acceptable criterion for qualification and that a demonstrated history of developing and administering successful food safety programs would satisfy this requirement.

**GMA Recommends**
- No changes.

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**Proposed Rule**
§ 117.155 (c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

**GMA Feedback**
- GMA notes that since this subsection is contained under §117.155(c), that it pertains to training for the qualified individual, not food safety training for all employees.

**GMA Recommends**
- No changes.

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**Proposed Rule**
§ 117.175 Records required for subpart C.
(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

1. The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, and recall plan.
2. Records that document the monitoring of preventive controls;
3. Records that document corrective actions;
4. Records that document verification, including, as applicable, those related to:
   (i) Validation,
   (ii) Monitoring,
   (iii) Corrective actions,
   (iv) Calibration of process monitoring and verification instruments,
   (v) Records review, and
(vi) Reanalysis; and

(5) Records that document applicable training for the qualified individual.

(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

GMA Feedback

- GMA has made comments to records requirements in other sections of this document located above.
- GMA notes that proposed § 117 does not contain proposed regulatory language regarding the role of testing and supplier management in food safety plans. If the final rule includes provisions for these two items, then §117.175 should include requirements relevant to appropriate records for these elements as well.
- As noted in many places, it is GMA’s opinion that a comprehensive food safety system contains many types of preventive controls, not all of which will be documented (see Table 1 in comments to §117.135(e)). Where documentation (i.e., records) are generated, it is GMA’s opinion that the Agency should have on-site access to appropriate records to demonstrate the food safety plan is meeting the FSMA food safety goals. These would include on-site records access for the following:
  - Records for preventive controls used to directly control significant hazards (CCPs or some operational prerequisite programs);
  - Preventive controls identified in the hazard analysis as making a hazard not significant;
  - Food safety programs a person knowledgeable about the safe manufacturing, processing, packing, or holding of food (a qualified individual) would recognize as affecting the significance of biological, chemical, or physical hazards.

GMA Recommends

- FDA should modify the language in proposed section § 117.175 as follows:
  § 117.175 Records required for subpart C.
  (a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:
     (1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, and verification procedures, and recall plan.
     (2) Records that document the monitoring of preventive controls;
     (3) Records that document corrective actions;
     (4) Records that document verification, including, as applicable, those related to:
        (i) Validation,
        (ii) Monitoring,
        (iii) Corrective actions,
        (iv) Calibration or accuracy checks of process monitoring and verification instruments,
        (v) Records review, and
        (vi) Reanalysis; and
(5) Records that document applicable training for the qualified individual.
(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

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**Proposed Rule**

§117.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

§ 117.206(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:

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**GMA Feedback**

- GMA was one of the participants in the citizen petition (Docket No. FDA-2011-P-0561) that requested an exemption to allow facilities solely engaged in the storage of unexposed packaged food to be exempt from the requirements that would be established in proposed Subpart C. FDA has indicated that it disagrees with this exemption as it relates to facilities solely engaged in the storage of unexposed packaged food that requires time/temperature control for safety (TCS). 78 Fed. Reg. 3712. GMA is in agreement with the concept of TCS foods in the context for which that concept was developed; that is for a “model code for adoption by states or counties overseeing operations providing food directly to the consumer.” IFT 2001, FDA Ref 140. Further, the FDA Food Code is based on evaluating the safety of a food when it is not being held at refrigerated temperatures. Refrigerated warehouses do not fit the criteria for which the evaluation of whether or not a food is TCS applies.

- Distinguishing between products that require time/temperature control to significantly minimize or prevent the growth of, and subsequent toxin production by microorganisms of public health significance and those that do not could lead to significant semantic arguments between the Agency and the owners, operators or agents in charge of these facilities. Many of the products in these facilities would end up in the PA (Product Assessment required) category according to the FDA Food Code. We contend that the assessment would result in the conclusion that these products are not TCS due to the robustness of the systems, the extensive failure that would be required to produce a food safety issue, and the inappropriate application of the TCS analysis to these facilities. The Agency might argue otherwise resulting in a disagreement that would take time and resources to resolve while not advancing the public health.

- Given the lack of benefit to food safety and the public by implementing these proposed modified requirements, it seems prudent to avoid tying up resources on the discussions of which facilities fall under the modified requirements and which do not. GMA suggests that the Agency consider developing guidance, utilizing industry, professional organizations and industrial consortiums, to help determine which facilities may fall under the modified rules. Consideration should be given not only to the nature of the food being stored, but also to the nature of the facility to assess both the probability and severity of a potential hazard. We
note the Agency comments in the preamble to this effect; “we agreed with the NACMCF approach to conducting the hazard analysis—i.e., that the process of evaluating food hazards to determine which potential hazards need to be addressed in the HACCP plan ... takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact.” 78 Fed. Reg. 3735.

- While GMA agrees that the FSMA rules are meant to be preventive and that temperature control in these facilities is a preventive control, we are not aware of foodborne illness outbreaks due to the failure of commercial refrigerated/frozen food storage facilities to maintain safe storage temperatures.
- The probability of a failure that causes a food safety issue is extremely low in most of these facilities. A failure in the temperature control would need to be severe, extensive, and for an extended period of time in order to impact the food to a degree that would potentially allow a food safety issue to arise. Given the very low probability of an incident that would lead to a food safety issue, GMA requests the Agency to allow for a high degree of flexibility in applying preventive controls management elements to these facilities.
- For the vast majority of refrigerated warehouses, extremely little, if any, improvement in the public health will be gained by applying strict and prescriptive management elements for warehouse temperature control. Rather, facilities have put into practice a variety of monitoring, recording and records reviewing practices that provide assurances to themselves and their customers that the storage temperatures are appropriate and adequately controlled.
- GMA reminds the Agency that warehouses must meet the requirements of current § 110.93 (proposed § 117.93) that requires the warehouse operators to store the food “under conditions that will protect against … deterioration of the food.” Given that refrigerated warehouses have been operating under this requirement for quite some time without any foodborne illness outbreaks, it makes sense that extensive new and/or extensively prescriptive rules are not needed.
- GMA suggests that flexibility in the management criteria for temperature control will allow facilities to operate much as they do today and thereby preventing expending resources for compliance with no increase in public safety benefit. This will also benefit the Agency in that valuable investigator time will not be required to enforce prescriptive requirements that do not enhance food safety.
- GMA concurs with the Agency’s statement in the preamble to the proposed rule, “The temperature and time required for a frozen food to become unsafe would result in significant quality issues for such food. Although there have been occasional problems with frozen food being subject to temperatures that allow some thawing in storage and distribution, we are not aware of situations in which frozen foods have been associated with the food becoming unsafe. Thus, we tentatively conclude that it would be rare for an unexposed frozen packaged food to be a TCS food.” 78 Fed. Reg. 3774.
- Accordingly, we encourage FDA to use the discretion provided by section 418(m) of the FD&C Act to specifically exempt frozen food storage facilities, where the food is not exposed to the environment, from the requirements of proposed § 117.206.

GMA Recommends
- Since the TCS analysis was not intended for refrigerated warehouses, guidance should be developed with the aid of industry, industrial consortia and professional organizations to better define which facilities may be subject to the modified requirements of § 117.206.
FDA modify the language in proposed § 117.206(a) as follows:

§ 117.206(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food (excluding frozen packaged food) that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:

<table>
<thead>
<tr>
<th>Proposed Rule</th>
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<tbody>
<tr>
<td>§ 117.206(a)(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance;</td>
</tr>
</tbody>
</table>

GMA Feedback

- The owner, operator or agent in charge of a refrigerated food storage facility normally does not define the storage criteria. Rather, it is the manufacturer of the product that understands the requirements for maintaining food safety and preventing spoilage and therefore is the one defining the criteria for storage.

<table>
<thead>
<tr>
<th>GMA Recommends</th>
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<tbody>
<tr>
<td>FDA modify the language in proposed § 117.206(a) as follows:</td>
</tr>
<tr>
<td>§ 117.206 (a)(1)Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance as prescribed by the packaged food manufacturer or other designated qualified individual;</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Proposed Rule</th>
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<tbody>
<tr>
<td>§ 117.206(a)(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;</td>
</tr>
</tbody>
</table>

GMA Feedback

- These facilities often have sophisticated systems that monitor temperatures and other critical elements of the system at a high frequency. The systems generally will activate alarms upon equipment failures and upon environmental temperatures (i.e., room temperatures) that are above the prescribed maximums. Given the large thermal inertia in these systems, there is extensive time to correct the problem before a maximum product temperature limit is exceeded.

- As per our discussion on § 117.140(a) not all preventive controls have monitoring records (some are confirmed through verification activities). For example, a refrigeration temperature control that notifies on exception (i.e., high temperature alarm) may not record temperatures that meet control requirements, only those that exceed them.
Exception reporting: In order to be consistent with modernized systems in use today, and even more sophisticated systems that will be available in years to come, GMA highly recommends that the Agency recognize the acceptability of monitoring systems that provide exception reports. Exception reporting is a structure where automated systems are designed to alert operators and management on an exception basis; i.e., only when a deviation from food safety parameter limits are observed by the system.

- GMA recognizes that such systems must be validated and periodically verified and monitored that they are working properly.
- In many cases, by eliminating human error, monitoring of preventive controls can be done by automated systems in a more efficient manner than if performed by operators.

GMA Recommends

- The Agency clarify in the preamble to the final rule that monitoring systems can work affirmatively or by exception and that both types of systems and their related documentation are acceptable.

Proposed Rule

§ 117.206(a)(3) If there is a problem with the temperature controls for such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;
(ii) Evaluate all affected food for safety; and
(iii) Prevent the food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected food is not adulterated (due to the temperature control issue) under section 402 of the Federal Food, Drug, and Cosmetic Act;

GMA Feedback

- The wording in § 117.206(a)(3) is misleading in that it points to “a problem with the temperature controls” and does not focus on the most important variable: the actual product temperature that will be influenced by the environmental temperature. There could be problems with the controls that do not impact the environmental temperature and therefore do not impact the product temperature. The wording should relate to an issue with the maintenance of the environmental temperature within the limits prescribed to preserve the quality and/or safety of the food. When the environmental temperatures do not meet the required limits, then an analysis of the impact on the product temperature may be warranted depending on the extent and duration of the excursion from the limits and depending on the product potentially impacted. The potential food safety impact would then be based on the analysis of the product temperature effect. This impact analysis is generally done by the manufacturer of the product or a designated qualified individual and not by the warehouse owner, operator or agent in charge.
- Paragraph § 117.206(a)(3)(i) implies that every time a corrective action is employed, the likelihood of recurrence needs to be reduced. When a problem is corrected it is not necessarily the case that the likelihood of recurrence can be reduced. Failures in refrigerated warehouse facilities are extremely rare and would be due to highly unusual situations (e.g.
extended power failure) such that there are likely limited options to reduce the likelihood of recurrence.

**GMA Recommends**

- FDA modify the language in proposed § 117.206(a)(3) as follows:
  
  § 117.206 (a)(3) If there is a problem with such that the environmental temperature controls for such is found to exceed the prescribed maximum limits and subsequently the refrigerated packaged food is found to exceed the prescribed food safety temperature limits, then take appropriate corrective actions to:
  
  (i) Correct the problem and investigate the possibility to reduce the likelihood that the problem will recur;
  (ii) Have the packaged food manufacturer or other designated qualified individual evaluate the impact on all affected food for safety; and
  (iii) Prevent the food from entering commerce, if the owner, operator, or agent in charge of the facility or qualified individual cannot ensure the affected food is not adulterated (due to the temperature control issue) under section 402 of the Federal Food, Drug, and Cosmetic Act.

**Proposed Rule**

§ 117.206(a)(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;
(ii) Reviewing records of calibration within a reasonable time after the records are made; and
(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made.

**GMA Feedback**

- The revised 21 CFR § 113 does not use the word calibration. The preventive controls rules should use terminology that is consistent with § 113 which uses the term “tested for accuracy.” This is a more appropriate term since many instruments have very low drift values and may seldom require calibration.
- Reviewing records of calibration or accuracy checks is only needed if a designated tolerance is exceeded. The procedure for conducting the accuracy check should include the notification of appropriate personnel if an out-of-tolerance situation is noted. The proposed rule does not state what the reviewer is looking for. Is the reviewer looking to see that the accuracy check was done or if there was an out-of-tolerance situation? If the latter is implied, then this can also be implied for the accuracy check itself and the review becomes a redundant check-the-checker activity and can be eliminated.
- The frequency of checking monitoring records should be done with a frequency to demonstrate control.
- These verification and review activities are both too prescriptive and too vague at the same time. They are too prescriptive in that they require reviews that are not necessary and they are too vague in that the reasons for the reviews are not defined. More meaningful review activities should be suggested in guidance while the rules should provide the overall
objective (assuring the adequacy of the control) and let the owner, operator or agent in charge
decide on the appropriate measures to accomplish this goal.

GMA Recommends

- FDA modify the language in proposed § 117.206(a)(4) as follows:
  § 117.206(a)(4) Verify that temperature controls are consistently implemented by:
  (i) Performing accuracy checks of calibrating temperature monitoring and recording
devices with sufficient frequency to ensure measurement accuracy;
  (ii) Reviewing records of calibration within a reasonable time after the records are made; and
  (iii) Reviewing records of monitoring and corrective actions taken to correct a problem
      with the control of temperature within a week after the records are made or in a
      timeframe that ensures the effectiveness of the control.

Proposed Rule

§ 117.206(a)(5) Establish and maintain the following records:
(i) Records documenting the monitoring of temperature controls for any such refrigerated
packaged food;
(ii) Records of corrective actions taken when there is a problem with the control of temperature
for any such refrigerated packaged food; and
(iii) Records documenting verification activities.

GMA Feedback

- Temperature controls in refrigerated warehouses are extremely reliable and therefore
  extensive record keeping and record review as prescribed in Subpart F are not value-added.
  Rather, the only substantive record that should be required should be a record of whether or
  not a deviation in the environmental temperature from the prescribed limits was noted. The
  addition of this record would be far less of a burden than making the extensive records of
  every zone in a facility conform to Subpart F of the proposed rules.
- As per our discussion on § 117.206(a)(2) and §117.140(a) not all preventive
  controls have monitoring records. For example, a refrigeration temperature control that notifies on
  exception (i.e., high temperature alarm) may not record temperatures that meet control
  requirements, only those that exceed them.
- Exception reporting: In order to be consistent with modernized systems in use today, and
  even more sophisticated systems that will be available in years to come, GMA highly
  recommends that the Agency recognize acceptability of monitoring systems that provide
  exception reports. Exception reporting is a structure where automated systems are designed
to alert operators and management on an exception basis; i.e., only when a deviation from
food safety parameter limits are observed by the system.
  o GMA recognizes that such systems must be validated and periodically verified and
    monitored that they are working properly.
In many cases, by eliminating human error, monitoring of preventive controls can be done by automated systems in a more efficient manner than if performed by operators. If a deviation from the prescribed maximum temperature is noted then it is appropriate to document the corrective actions taken, the analysis of the impact to the product and the disposition recommendation. Again, FDA’s proposed wording of “problem with the control of the temperature” is too vague and should be made more specific to dealing with an issue that could potentially lead to a food safety issue.

GMA Recommends

- The Agency clarify in the preamble to the final rule that monitoring systems can work affirmatively or by exception and that both types of systems and their related documentation are acceptable.
- FDA modify the language in proposed § 117.206(a)(5) as follows:
  § 117.206(a)(5) Establish and maintain the following records:
  (i) Records documenting the monitoring of the effectiveness of temperature controls for any such refrigerated packaged food;
  (ii) Records of corrective actions taken when there is a problem with the control of the environmental temperature that exceeds a limit that may impact the safety for any such refrigerated packaged food; and
  (iii) Records documenting verification activities.

Proposed Rule

§ 117.206(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

GMA Recommends

- No changes
GMA Feedback and Recommendations on Proposed 21 CFR Part 117
Other Topics Related to the Food Safety Plan

Proposed Rule or Issue
On farm “low risk” activities not subject to the preventive controls rule

GMA Feedback:

- In the proposed rule, FDA proposes to exempt certain packing, holding and manufacturing activities performed on a farm or farm-like facility from the requirements of sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act.

- GMA disagrees with FDA’s conclusions in its Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities Conducted in a Facility Co-Located on a Farm.
  - The Agency describes certain food processing activities as “low risk” when performed on a farm or farm-like facility. The Agency claims that the results of the risk assessment support FDA’s decision that these facilities do not need a food safety plan.

- FDA should not conclude that products known to contain hazards that have resulted in foodborne illness outbreaks and/or Class I recalls, (i.e., grinding and packaging tree nuts – risk of *Salmonella*) are low risk, regardless of facility size.

- GMA contends that the processes listed below present some level of public health risk regardless of the size of facility where they are processed. However, we understand the Agency’s risk assessment especially as it pertains to the low quantities of product produced by farm and farm-like facility. Therefore, we would propose that FDA not fully exempt these facilities but apply modified requirements to them as the Agency’s authority allows.

  - Class I recalls and foodborne illness outbreaks have been associated with the following food groups, which FDA has indicated will be exempt from § 117 Subpart C requirements when produced on a farm or farm-like facility:
    - Grinding and packaging of tree nuts
    - Making items from roasted cocoa beans
    - Coating peanuts and tree nuts or adding seasonings
    - Chopping peanuts and tree nuts
    - Grinding/milling/cracking/crushing peanuts, tree nuts, and cocoa beans
    - Shelling/hulling tree nuts and peanuts
    - Making hard candy, toffee, fudge and similar confectionary items

- GMA does, however, agree that there are certain activities identified in this risk assessment where science and solid food processing principles indicate lower risk. Accordingly, we recommend that these activities should not receive the scrutiny afforded higher risk foods regardless of where they are manufactured, including in the factories of major processors. Class I recalls and foodborne illness outbreaks are rarely, if ever, associated with the following food categories also noted in the FDA proposed list for Subpart C exemption for farm and farm-like facilities:
  - Making jams, jellies and preserves from acid foods
  - Carbonating soft drinks
  - Extracting oils from grains
  - Making sugar from sugar cane or sugar beets
Proposed Rule or Issue: Consumer complaints

GMA Feedback:

- FDA requests comment on whether and how a facility’s review of complaints, including complaints from consumers, customers, or other parties, should be required as a component of its activities to verify that its preventive controls are effectively minimizing the occurrence of hazards.
- GMA advises that review of complaints may be an appropriate verification procedure in certain circumstances.
- GMA notes that not all comments from consumers are “complaints;” some are highly complementary. Thus, we suggest a better terminology is “consumer comments.” Positive comments can also serve as verification that an existing plan is functioning well. GMA urges the Agency to be aware that there is a large variability in the nature and significance of consumer comments as they relate or do not relate to food safety. Frequent comments that don’t influence food safety may include:
  - Can’t find the product in my local store
  - Price points
  - Flavor (non-spoilage related)

- Some consumer complaints have very low scientific validity. For example, GMA members report receiving consumer comments where the consumer has claimed they became ill within minutes of consuming the product (an unlikely association, particularly where symptoms are inconsistent with foodborne intoxication) or finding live insects inside retorted canned goods.
- Therefore, utilizing consumer complaints as a food safety plan verification tool requires considerable knowledge about the nature of the food, its ingredients and processing specifics, and skill in extracting useful information from that provided by the consumer.
- Accordingly, GMA recommends that FDA not enact prescriptive requirements and allow facilities to have procedures/practices/programs in place to review complaints and use that information as a signal to further investigate possible opportunities for improving their food safety plans. The appropriateness of how complaints are investigated and/or reviewed should be determined by those most familiar with the necessary details: the processor.
- GMA also reminds FDA that for firms with more than one manufacturing facility, consumer comment reviews are often a corporate activity, not a facility related function.

Proposed Rule or Issue: Economically motivated adulteration (food defense) (78 Fed. Reg. 3659)

GMA Feedback:

- GMA agrees with FDA’s intention to implement section 103 of FSMA regarding intentionally introduced hazards in a separate future rulemaking.
- GMA also concurs with FDA that intentionally introduced hazards, which are not addressed in traditional HACCP or other food safety systems, will require different kinds of preventive measures than those traditionally employed in HACCP type systems. 78 Fed. Reg. 3659.
• FDA requests comment on whether to include potential hazards that may be intentionally introduced for economic reasons. GMA is concerned that FDA may establish requirements in the final preventive controls rule that certain potential economic adulterants “must” be addressed.

• GMA contends that FDA publishing a list of potential hazards the Agency considers to be reasonably likely to occur through economically motivated adulteration (EMA) is counterproductive to the overall food safety effort.
  o Since nearly all foods are potentially the target of EMA, publishing a selected list is not helpful.
  o Such a designation would require industry and the Agency to focus resources on addressing the specific published examples and away from efforts to identify novel avenues of adulteration or other food safety management activities.
  o A specific list would also be the equivalent of sending a message to would-be perpetrators saying “Do not try and adulterate these foods.”
  o Such a designation would be far too prescriptive and require constant updating to maintain relevance.
  o The Agency and industry would be expending resources towards protecting foods in which EMA would not be attempted because the perpetrators know FDA is watching those items.
  o Fewer resources would be available to address situations where EMA could truly occur.
  o The overall effort would reduce overall food safety and not aid protection of the public health.

• FDA has requested comments on the circumstances in which an economically motivated adulterant can be considered reasonably likely to occur. In general,
  o GMA advises that EMA is a form of intentional adulteration.
  o As FDA has stated, protection against intentional adulteration, also known as food defense, will require different types of controls than traditionally employed in food safety systems.
  o Accordingly, GMA recommends that these issues be addressed in separate rulemaking as FDA has indicated will occur.

• GMA contends that the term "reasonably likely to occur" is based on the probability of an unintentional hazard being introduced into the facility or food where there is some probability of the hazard occurring. Since EMA is a deliberate, opportunistic event, there is no determination of probability but instead a consideration of likelihood of success if EMA is attempted with a particular food item.

• Events which could increase the risk of economically motivated adulterants entering the food supply may include:
  o There is a shortage of the product due to increased demand or import restrictions.
    ▪ Early sell of beef and pork shortages to decrease size of herds when drought raised the cost of grain and access to water.
    ▪ A marketing focus leads to increased consumer interest in the antioxidant properties of pomegranate juice and a broader range of products containing the juice. A higher price for the juice and limited supply increase the potential for adulteration with sugar syrups or less expensive juices.
  o There is a shortage of complimentary ingredient or component of food production.
- Reduction of poultry farms due to feed shortage, making liquid eggs (fake eggs) a better buy.
  - Access to the supplier is limited due to natural disasters.
    - Computer chip shortage due to the Fukushima earthquake was caused by evacuation and shut down of chip manufacturers.
    - Supply of a raw material is restricted from certain regions of Japan due to radiation concerns from Fukushima nuclear reactors following an earthquake.
    - Damage to Port of New Orleans and transport routes during Hurricane Katrina limits the ability to source sugar from this region or through this port.
  - Weather related events impact the availability of materials.
    - Beef and pork shortages in drought situations as herd size decreases due to an increase cost of grain and reduced access to water.
    - Tsunami damage of pineapple fields reduced juice crop.
    - Orange crop freezes in Florida or Brazil.
    - Difficulty in getting sugar through New Orleans after Hurricane Katrina.
  - Poor quality material leads to adulteration to increase material value.
    - Low protein wheat gluten due to drought resulting in a higher risk of melamine adulteration.
  - When transportation costs are high (i.e., high cost of fuel).
    - If an ingredient cannot be sourced closer to a manufacture, adulterated products may suddenly become an option.
  - An increase in the number of times the product is handled increases the opportunity there is for tampering.
    - Transfer of products between containers (i.e., from bulk to smaller bags presents an opportunity for an adulterant to be introduced). The transfer of possession of the product during transport, storage or manufacture, increases the number of individuals and entities with access to the product. Preventive measures against EMA could likely have been performed in the bulk stage, not smaller bags.
  - GMA advises that EMA is a form of intentional adulteration.
  - As FDA has stated, protection against intentional adulteration, also known as food defense, will require different types of controls than traditionally employed in food safety systems.
  - Accordingly, GMA recommends that these issues be addressed in separate rulemaking as FDA has indicated will occur.
**Proposed Rule or Issue:** Pilot plants/test kitchens

**GMA Feedback:**

- For the purpose of these comments, a "pilot plant/test kitchen" would also include "research kitchens" or similar type of facilities that not distribute food into interstate commerce, but could be making products for internal evaluation or "business to business" reviews.
- Many pilot product development facilities are used daily, yet the same product is rarely produced exactly the same way on each pilot run.
- Foreseeable hazards are identified for the range of products developed in the pilot plant/test kitchen and general and specific controls to mitigate those hazards are identified and employed (e.g., thermal processes).
- We are unaware of any foodborne illness outbreaks due to products produced in pilot facilities/test kitchens.
- Developing a formal food safety plan for every product produced in a pilot plant/test kitchen would be unnecessarily cumbersome and restrictive. Due to the variety of combinations of ingredients, formulas and processes being developed at any one time, such facilities often rely on pre-determined process controls and product parameters, cGMPs, sanitation and other necessary prerequisite programs.
  - For example, during a single day on a single run of a development project, the developer may decide to substitute ingredients multiple times, vary cooking temperatures and make multiple process changes;
  - The developed food may never be consumed;
  - If the developer in this example were required to complete a formal hazard analysis, implement preventive controls, recordkeeping, verification procedures and established corrective actions, he/she would be required to spend a significant portion of a day or multiple days writing and re-writing multiple food safety plans for foods that may only be produced in small quantities in a single or limited production run or food that may never be consumed;
  - Relevant product and process design parameters are determined where necessary for novel products and processes.
- The need for a full scale food safety plan in a pilot plant/test kitchen should be determined on a case by case basis. The scope and level of detail in the food safety plan will be influenced by many factors, which may include:
  - The number and sensitivity of consumers, if any, that will be exposed to the pilot plant/test kitchen product;
  - Whether the product leaves the control of the developing company.
- Limited Agency resources should not be diluted by focusing on pilot facilities/test kitchens that are by their very nature relatively low-risk and low-impact.
GMA Recommends:

- As explained in the GMA comments on inspections and record-related issues, GMA urges FDA to reconsider the current interpretation that pilot plants and similar operations must register and therefore would be subject to the food safety plan requirements of Subpart C.
- Should FDA come to the conclusion that full exemption is not the optimum approach, the Agency should exercise enforcement discretion with respect to these facilities, recognizing their uniqueness.
- If the FSMA framework is applied to these facilities, FDA should make clear that FSMA obligations are determined by the specific characteristics of each operation and commensurate with the relevant food safety needs. Any “food safety plan” for such operations, therefore, will be risk-based and tailored to meet the specific food safety needs, and will be very different from plans for facilities that make or hold food for commercial purposes.

Proposed Rule or Issue: Proposed § 117.7—Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

GMA Feedback:

- GMA agrees with the Agency when they state in the preamble to the proposed rule, “There are limited routes of contamination for unexposed packaged food in a facility that solely stores unexposed packaged food (e.g., packaged food in containers in a warehouse). .... the CGMP requirements in proposed part 117, subpart B (e.g., proposed §§ 117.20, 117.35, 117.37, and 117.93) would apply to the storage of unexposed packaged food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator, or agent in charge of a facility to address these routes of contamination by applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C.”
- GMA notes that comments in this subsection refer to food where refrigeration is not necessary for food safety.
- GMA notes that it is typical for food warehouses to do more than simply store pallets of finished product and then re-ship those same pallets. For example, warehouses often breakdown pallets of packaged food for distribution to the retail level in less-than-pallet quantities. They also may use packaged food to build store displays. Such activities, for unexposed foods, where temperature control is not needed for food safety, do not carry enhanced risks for food safety hazards. The food itself remains packaged and is not exposed to the environment. As noted by the Agency in the comment above, cGMP requirements provide adequate protection for the packaged food involved in such activities.

GMA Recommends:

- FDA expand their discussion under §117.7 to clarify that warehouses storing and handling packaged finished food not exposed to the environment and not requiring refrigeration for food safety, do not present additional hazards and therefore do not require a food safety plan under Subpart C.
- An alternative approach GMA would support is recognition by FDA that conducting the above-mentioned activities at a warehouse (e.g., breaking down pallets, building store
displays) fall within the scope of “storing” food such that they are permissible within the warehouse exemption as proposed.

Proposed Rule or Issue: Regulatory duplicity: 21 CFR Part 114 and proposed Part 117

GMA Feedback:

- GMA agrees with proposed § 117.5(d) granting an exemption for microbiological hazards to foods subject to 21 CFR § 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers).
- Since Part 117 is meant to take a scientific approach to food safety; both acid and acidified products would be covered and therefore 21 CFR Part 114 will no longer necessary.
- Accordingly, GMA recommends the Agency rescind 21 CFR Part 114 and its companion regulations in § 108.25.
- Requiring processors currently operating under Part 114 to address microbiological hazards in both regulations Part 114 and Part 117 is confusing, redundant and not an effective use of industry or Agency resources. This duplicitous activity would do nothing to advance protection of the public health.
- FSMA provides for exemptions from the preventive controls rules for products regulated by HACCP based regulations: the FDA Seafood Hazard Analysis Critical Control Points (21 CFR Part 123) and the FDA Juice Hazard Analysis Critical Control Points Rule (21 CFR Part 120), and for microbiological hazards for those foods regulated by the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulations. These exclusions make sense in that the regulations that are exempted are risk based. While FSMA is meant to develop food safety plans that extend beyond HACCP, it encourages the use of concepts of risk analysis such as those used in HACCP-based food safety systems in the development of these plans.
- The regulation 21 CFR Part 114, Acidified Foods is not exempted from the proposed preventive controls rules (§ 117 Subpart C). Part 114 is not well rooted in HACCP principles and therefore the lack of exemption is reasonable. This regulation also tries to differentiate classes of products defined as “acid” and “acidified” where the acidified products are subject to the rule and the acid products are not. A clear, scientific means to distinguish between these classes of products was not provided in the rule. Furthermore, Part 114 provides for many exemptions without providing a scientific basis for the distinction between exempted and non-exempted products. The lack of scientific basis and specificity in Part 114 has led to the development of ad hoc rules for enforcement. While there has been some consistency over the years in the enforcement, not having a true scientific basis for the rules has led to many semantic discussions on whether a food is considered acid or acidified.
- The lack of an exemption means that all products that are considered acid or acidified will have to conform to the preventive controls rules (proposed Part 117). This will require a scientific hazard analysis and require preventive controls to address those hazards, thus putting all these low pH products on a common footing.
- Given that the preventive controls rules (proposed Part 117) would provide the food safety programs for these products, then it makes sense, and GMA recommends, to rescind Part 114 and the associated section of Part 108 (21 CFR § 108.25).
• GMA recognizes that this submission does not serve as a citizen petition for a request to rescind Part 114, but informs the Agency of the current thinking of a significant portion of industry. Industry is very much opposed to having regulation duplicity and is very interested in managing the food safety of these products in a manner consistent with the scientific risk-based programs that will be required for other products under FSMA.

• Since all food facilities are required to be registered and all products will have food safety plans amenable to FDA inspection, then it follows that the need for a separate filing process no longer exists. This will be a benefit both the Agency and industry by eliminating the effort and resources required to provide these separate filing submissions.

• FSMA offers an excellent opportunity to have all high acid products governed by scientific risk-based food safety programs and eliminate the confusion created by the way Part 114 is written and by inconsistent enforcement practices.

Proposed Rule or Issue: Definition of small and very small businesses

GMA Feedback:
GMA contends that food safety practices should be optimized in all food processing operations regardless of size as allowed by law. Food safety issues have occurred in manufacturing operations of all sizes. While business size may impact the internal technical and capital resources available to the manufacturing operation, relevant hazards and necessary preventive controls are specific to the food product, process and facility design and in most cases are independent of business size.
Appendix I: GMA Recommended Regulatory Language

§ 117.3 Definitions (Only those recommended for additions, modifications or deletion by GMA)

- **Allergen cross-contact** means the unintentional incorporation of a food allergen into a food.
- **Correction** means action to eliminate a non-conformity.
- **Corrective action** means action taken when the results of monitoring a preventive control indicate loss of control.
- **Cross-contact** means the unintentional incorporation of a food allergen into a food.
- **Equilibrated pH** is the condition achieved when the solid and liquid parts of the product have the same pH.
- **Environmental pathogen** means a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. a foodborne pathogen of public health significance for which its presence or harborage in the food processing environment may result in product contamination at levels that may result in food-borne illness when the product is consumed.
- **General controls** mean procedures and processes that address operational conditions providing for the foundation of a Food Safety Plan. Examples could be GMPs and other prerequisite programs.
- **Hazard** means any biological, chemical, or physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control.
- **Hazard reasonably likely to occur** means 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.
- **Monitor** means to conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended a process, point, or procedure is under control and to produce an accurate record for use in verification.
- **Parameter** means a measurable attribute.
- **Primary packaging** (a noun) means packaging that is in direct contact with the food.
- **Ready-to-eat food** (RTE food) means any food that is normally eaten in its raw state or any other food, including processed food, for which it is reasonably foreseeable expected that the food would be eaten without further processing that will significantly minimize biological hazards.
- **Reanalysis** means a reassessment of the validity of a preventive control or food safety plan to control a hazard. Reanalysis may include a system review and, where necessary, activities to revalidate a control measure or combination of control measures.
- **Reasonably foreseeable hazard** means a potential biological, chemical, or physical, or radiological hazard that may be associated with the facility or the food.
• **Receiving facility** means for an article of food, a facility or corporate parent of 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.

• **Sanitize** means the application of any effective method or substance to properly cleaned surfaces for the significant reduction of pathogens, and other relevant microorganisms, as far as is practicable to adequately treat cleaned food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. [Note: See GMA comments on the proposed revisions to subpart B, GMPs.]

• **Supplier** means, for an article of food, 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.

• Validation means 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 obtaining evidence that a control measure or combination of control measures, when properly implemented, is capable of effectively controlling the hazard to a level necessary for product safety.

• **Value** means a specific measurement associated with a parameter.

• **Verification** means those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to plan the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

• **Written** means any type of recordable and reproducible format.
Subpart C – Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 Requirement for a Food Safety Plan.

(a) Food safety plan. The owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food safety plan.

(b) Contents of a Food Safety Plan. The food safety plan must include, as appropriate:

1. The written hazard analysis as required by § 117.130(a)(2);
2. The written preventive controls as required by § 117.135(b);
3. The written procedures, and the frequency with which they are to be performed, for monitoring the implementation of the preventive controls as required by § 117.140(a);
4. The written corrective action procedures as required by § 117.145(a)(1);
5. The written verification procedures as required by § 117.150(e); and
6. The written recall plan as required by § 117.137(a).

(c) Qualified individual. The food safety plan must be prepared by (or its preparation overseen by) a qualified individual.

§ 117.130 Hazard analysis

(a) Requirement for a hazard analysis.

1. The owner, operator, or agent in charge of a facility is responsible to ensure that must identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility are identified and evaluated by a qualified individual to determine, based on their probability and severity, whether there are hazards that are reasonably likely to occur the hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.

2. The hazard analysis must be written.

(b) Hazard identification. The hazard identification must consider hazards that may occur naturally or may be unintentionally introduced, including:

1. Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other microorganisms of public health significance.
2. Chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, radiological hazards, and food allergens; and
3. Physical hazards;
4. Radiological hazards.

(c) Hazard evaluation.

1. The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section, to determine whether the hazards need to be addressed in the facility food safety plan are reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur.
(2) Assessments of the probability of a hazard may take into account the following factors, among others that may be relevant:
   (i) The effectiveness of existing programs, such as GMPs or other general controls;
   (ii) The frequency with which a potential hazard is associated with a food, ingredient, process, or other component of a food safety system;
   (iii) Method of preparation within a processing facility or by the consumer before consumption of the food;
   (iv) Storage and transportation conditions;
   (v) Historical experience within the processing facility or with the product category; and
   (vi) Design of processing system.

(3) The hazard analysis must include an evaluation of whether environmental pathogens that must be addressed in the food safety plan are reasonably likely to occur whenever a ready-to-eat food is exposed to the environment prior to packaging and does not receive a pathogen lethality step while in their final package.

(4) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:
   (i) The formulation of the food;
   (ii) The condition, function, and design of the facility and equipment;
   (iii) Raw materials and ingredients;
   (iv) Transportation practices;
   (v) Manufacturing/processing procedures;
   (vi) Packaging activities and labeling activities;
   (vii) Storage, and distribution;
   (viii) Intended or reasonably foreseeable expected use;
   (ix) Sanitation, including employee hygiene; and
   (x) Any other relevant factors.

§ 117.135 Preventive controls for hazards that are reasonably likely to occur.

For hazards identified in the hazard analysis as reasonably likely to occur:
(a) The owner, operator, or agent in charge of a facility must identify and implement preventive controls, including at critical control points, if any, to provide assurances that hazards identified and evaluated in the hazard analysis as reasonably likely to occur needing to be addressed in the food safety plan 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 Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.
(b) Preventive controls must be written and maintained in appropriate documents or combination of documents readily available for inspection.
(d) Preventive controls must include, the following types of controls as appropriate and necessary to ensure the effectiveness of the controls under paragraph (a) of this section:

(1) Process controls. Process controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are addressed in the food safety plan reasonably likely to occur.

(2) Food allergen controls. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) Sanitation controls

(i) Where necessary to significantly minimize or prevent hazards that are addressed in the food safety plan reasonably likely to occur (including any environmental pathogen that is reasonably likely to occur in a ready-to-eat food that is exposed to the environment prior to packaging, any microorganism of public health significance that is reasonably likely to occur in a ready-to-eat food due to employee handling, and any food allergen hazard) sanitation controls must include procedures for the:

(A) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(B) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, primary food packaging material, and other food-contact surfaces and from raw product to processed product.

(ii) The owner, operator or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

(iii) The owner, operator, or agent in charge of a facility is not required to follow the corrective actions established in §§ 117.145(a) and (b) when the owner, operator, or agent in charge of a facility takes action, in accordance with paragraph (d)(3)(ii) of this section, to correct conditions and practices that are not consistent with the procedures in paragraphs (d)(3)(i)(A) or (d)(3)(i)(B) of this section.

(iv) All corrective actions taken in accordance with paragraph (d)(3)(ii) of this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(d)(5)(i).

(4) Recall plan. Recall plan as required by § 117.137.
Other controls. Preventive controls must include any other controls necessary to satisfy the requirements of paragraph (a) of this section.

Preventive controls must include, as appropriate to the facility and food, and necessary to ensure the effectiveness of the controls under paragraph (a) of this section:

1. Parameters associated with the control of the hazard, such as those associated with heat processing, acidifying, irradiating, and refrigerating foods, and
2. The maximum or minimum value, or combination of values, to which any biological, chemical, or physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard addressed in the food safety plan that is reasonably likely to occur.

Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:

1. Monitoring as required by § 117.140;
2. Corrective actions as required by § 117.145;
3. Validation as required by § 117.147; and
4. Verification as required by § 117.150.

The recall plan established in § 117.137 is not subject to the requirements of paragraph (e)(1) of this section.

§ 117.137 Recall plan for food with a hazard that is reasonably likely to occur.
For food with a hazard that is reasonably likely to occur:

(a) The owner, operator, or agent in charge of a facility must establish a written recall plan for the food.

(b) The recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:

1. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
2. Notify the public about any hazard presented by the food when appropriate to protect public health;
3. Conduct effectiveness checks to verify that the recall is carried out; and
4. Appropriately dispose of recalled food — e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

§ 117.140 Monitoring.

(a) Where required under § 117.135(e), the owner, operator, or agent in charge of a facility must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls.
(b) The owner, operator, or agent in charge of a facility must monitor the preventive controls, where required under § 117.135(e), with sufficient frequency to provide assurance that they are consistently performed.

(c) Where required under § 117.135(e), All monitoring of preventive controls in accordance with this section must be documented as appropriate in records that are subject to verification in accordance with § 117.150(b) and records review in accordance with § 117.150(db)(§2)(i).

§ 117.145 Corrective Actions.

(a) Corrective action procedures

(1) The owner, operator, or agent in charge of a facility must establish and implement written corrective action procedures that must be taken if the preventive controls are not properly implemented or are found to be ineffective.

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem with implementation of a preventive control, when necessary, to reduce the likelihood that the problem will recur;

(ii) All affected food, if any, is evaluated for safety; and

(iii) All affected food, if any, is prevented from entering into commerce, if the owner, operator or agent in charge of such facility cannot ensure that 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; and

(iv) When appropriate, potential actions to reduce the likelihood of recurrence are evaluated and implemented as necessary.

(b) Corrective action in the event of an unanticipated problem. If a preventive control is not properly implemented and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective, the owner, operator, or agent in charge of a facility must:

(1) Take corrective action to identify and correct the problem to 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 (a)(2)(iii) of this section; and

(2) Reanalyze the food safety plan in accordance with § 117.150(f) to determine whether modification of the food safety plan is required.

(eb) Documentation. All corrective actions taken in accordance with this section must be documented in records that are subject to verification in accordance with § 117.150(c) and records review in accordance with § 117.150(db)(§2)(i).
§ 117.147 Validation
(a) Validation. Except as provided by paragraph (a)(3) of this section, where required under § 117.135(e), the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(4a) Must be performed by (or overseen by) a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production (a longer period requires written justification); and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2b) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards identified in the hazard analysis as reasonably likely to occur; and

(3) Need not address:

(i) The food allergen controls in § 117.135(d)(2);

(ii) The sanitation controls in § 117.135(d)(3); and

(iii) The recall plan in § 117.137.

§ 117.150 Verification
(a) Validation. Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

(1) Must be performed by (or overseen by) a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is insufficient, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur; and

(3) Need not address:

(i) The food allergen controls in § 117.135(d)(2);

(ii) The sanitation controls in § 117.135(d)(3); and

(iii) The recall plan in § 117.137.
(b) **Monitoring.** Where required under § 117.135(e), the owner, operator, or agent in charge of a facility must: (1) Verify that monitoring is being conducted, as required by § 117.140; and

(2) *Corrective actions.* The owner, operator, or agent in charge of a facility must: Verify that appropriate decisions about corrective actions are made to demonstrate that the corrective actions taken are effective, as required by § 117.145 and § 117.135(d)(3)(ii).

(db) **Implementation and effectiveness.** The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. This must include the following activities, as where necessary and appropriate to the facility and the food:

1. Calibration and/or accuracy checks of process monitoring instruments and verification instruments; and
2. Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, and the preventive controls are effective, and appropriate decisions were made about corrective actions:
   1. Records of monitoring and corrective action records within seven working days a week after the records are made or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce.
   2. Records of calibration within a reasonable time after the records are made where necessary, based on the nature of the control.

(ec) **Written procedures for verification activities.** As appropriate to the facility and the food—When appropriate for the nature of the hazard and necessary to assure the effectiveness of the control, the owner, operator, or agent in charge of a facility must establish and implement written procedures for the frequency of calibrating and/or accuracy checks of process monitoring instruments and verification instruments.

(fd) **Reanalysis.**

1. The owner, operator, or agent in charge of a facility must:
   1. Conduct a reanalysis of the food safety plan:
      1. At least once every 3 years;
      2. Whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent in charge if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard;
      3. Whenever such owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food;
(D) Whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and

(E) Whenever a preventive control is found to be ineffective.

(ii) Complete such reanalysis and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility relevant process is operative or, when necessary, during the first 6 weeks of production or other timeframe determined to be appropriate to ensure that potentially hazardous goods do not enter commerce; and

(iii) Revise the written plan if a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed.

(2) The reanalysis must be performed (or overseen) by a qualified individual.

(3) FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.

Documentation. All verification activities taken in accordance with this section must be documented in records.

§ 117.155 Requirements applicable to a qualified individual.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(c));

(2) Validation of the preventive controls (§ 117.147(a)(1));

(3) Review of records for implementation and effectiveness of preventive controls and appropriateness of corrective actions (§ 117.150(d)(2)); and

(4) Reanalysis of the food safety plan (§ 117.150(d)(2)).

(b) To be qualified, an 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 job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such 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.

(c) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.175 Records required for subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, and verification procedures, and recall plan.

(2) Records that document the monitoring of preventive controls;
(3) Records that document corrective actions;
(4) Records that document verification, including, as applicable, those related to:
   (i) Validation,
   (ii) Monitoring,
   (iii) Corrective actions,
   (iv) Calibration or accuracy checks of process monitoring and verification instruments,
   (v) Records review, and
   (vi) Reanalysis; and
(5) Records that document applicable training for the qualified individual.
(b) The records that the owner, operator, or agent in charge of a facility must establish and maintain are subject to the requirements of subpart F of this part.

§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.
(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food (excluding frozen packaged food) that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:
   (1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance as prescribed by the packaged food manufacturer or other designated qualified individual;
   (2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;
   (3) If there is a problem with such that the environmental temperature controls for such is found to exceed the prescribed maximum limits and subsequently the refrigerated packaged food is found to exceed the prescribed food safety temperature limits, then take appropriate corrective actions to:
      (i) Correct the problem and investigate the possibility to reduce the likelihood that the problem will recur;
      (ii) Have the packaged food manufacturer or other designated qualified individual evaluate the impact on all affected food for safety; and
      (iii) Prevent the food from entering commerce, if the owner, operator, or agent in charge of the facility or qualified individual cannot ensure the affected food is not adulterated (due to the temperature control issue) under section 402 of the Federal Food, Drug, and Cosmetic Act.
   (4) Verify that temperature controls are consistently implemented by:
      (i) Performing accuracy checks of calibrating temperature monitoring and recording devices with sufficient frequency to ensure measurement accuracy;
      (ii) Reviewing records of calibration within a reasonable time after the records are made; and
(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made or in a timeframe that ensures the effectiveness of the control.

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of the effectiveness of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a problem with the control of the environmental temperature that exceeds a limit that may impact the safety for any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.
Appendix II: GMA Comments on the Preliminary Regulatory Impact Analysis

November 22, 2013

Submitted Electronically via email: oira_submission@omb.eop.gov and Faxed

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

Re: Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food (Docket No. FDA–2011–N–0920)—GMA Comments on the Preliminary Regulatory Impact Analysis (PRIA)

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments on the Preliminary Regulatory Impact Analysis (PRIA or the “economic analysis”) in the Food and Drug Administration’s (FDA’s) proposed rule regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (78 Fed. Reg. 3646 (Jan. 16, 2013)).

Founded in 1908, GMA and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with our founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing, and evaluation. We ensure that our members have the very best and latest scientific knowledge available so they can provide consumers with the products, tools, and information they need to achieve a healthy diet and an active lifestyle. The $2.1 trillion food, beverage, and consumer packaged goods industry employs 14 million U.S. workers, and contributes over $1 trillion in added value to the nation’s economy.

GMA strongly supported the FDA Food Safety Modernization Act (FSMA) and looks forward to working with FDA for successful implementation of this groundbreaking law. GMA applauds FDA for the considerable efforts to reach out to stakeholders during the pre-rulemaking stage of the proceedings and for the Agency’s willingness to continue that dialogue during the public comment period. We appreciate the Agency’s desire to develop a regulatory framework that is
protective of public health, risk-based, and practical. We all share a common goal of providing safe food to American consumers.

GMA is filing seven separate comments in response to the proposed rule, which address (1) the food safety plan; (2) testing; (3) supplier verification; (4) recordkeeping; and (5) current Good Manufacturing Practices (cGMPS), as well as (6) the economic analysis and (7) information collection burdens. The attached comments address aspects of the proposed rule involving the economic analysis.

Executive Summary of Comments

GMA strongly urges FDA to ensure the final rule is cost effective for food companies with advanced food safety programs. GMA understands that the task of quantifying the economic impact of a sweeping food safety regulation such as the preventive controls proposal is difficult and we appreciate FDA’s efforts to clearly define both the costs and benefits associated with the proposal. The regulations on preventive controls should be essentially cost effective for food companies that already have advanced food safety systems.

As part of our comments on the preventive controls proposal, we are submitting proposed modifications to the draft rule that will ensure the final rule is consistent with this goal – as well as consistent with the letter and purpose of FSMA and the corresponding PRIA. The implementation cost estimates should accurately reflect the true costs the food industry will incur. GMA encourages FDA to adopt the approach to preventive controls outlined in the GMA comments based on our analysis that they are more cost effective and are aimed at preventing the diversion of resources from the most important food safety activities. If the Agency adopts the proposed rule as currently written, the costs could far exceed the estimates presented in the PRIA. Accordingly, GMA did not attempt to prepare its own economic analysis but instead sought to highlight the actual cost associated with compliance to the draft rule as it is currently written. As discussed in greater detail in our comments below, the preventive controls proposal, as currently written, would cost the industry as much as $18.8 billion to implement in the first year alone, which is more than 20 times greater than FDA’s first year implementation cost estimate of $775 million. Accordingly, we devoted intensive effort to commenting on the proposed preventive controls rule to develop modifications to the draft rule that will deliver improved management to food safety systems at a cost that is in line with the PRIA. We strongly encourage FDA to adopt GMA’s modifications to the draft rule included in all GMA comments.

GMA has worked closely with our member companies to carefully identify and analyze the added costs associated with the provisions included in the preventive controls proposal that are not needed to accomplish FSMA’s food safety goals. Details of GMA’s analysis are provided in the comments below.

Implementation

We also want to emphasize the following essential points that should inform the Agency’s efforts for FSMA implementation:

- **Effective Implementation Will Require Comprehensive Inspector Training:** FSMA can only be successful if it is enforced effectively, uniformly, and fairly by the Agency’s
inspectorate on both the federal and state levels. FDA should start now—with stakeholder input—to develop and implement a comprehensive program to train investigators about a wide range of issues, including what the regulations require, how inspections should be conducted, and what types of observations are appropriate to include on FDA Form 483s. Investigator calibration also will be essential so that the law is enforced consistently from one region to another, and by both federal and state officials. FDA also should establish a mechanism for investigators to consult with experts from the Agency’s Center for Food Safety and Applied Nutrition (CFSAN) if they have questions about technical issues regarding a facility’s operations. We also strongly support development of a timely appeals mechanism so companies that disagree with an investigator’s conclusion can readily bring the issue to the attention of CFSAN experts. We believe it is in everyone’s interest that the inspection process be transparent in both its planning and decision-making.

- **Guidance Cannot Be Treated as Binding:** GMA strongly supports the use of guidance to assist facilities with implementing the FSMA regulations, provided that guidance is appropriately treated as illustrative but non-binding. The Agency’s “good guidance practices” regulation, 21 CFR § 10.115, very clearly explains that guidance does “not legally bind the public or FDA” and companies “may choose to use an approach other than one set forth in a guidance document.” FDA’s inspectors need to understand this limit so that they do not seek to enforce guidance as imposing regulatory requirements, as has occurred at times in the past. Rather, inspectors should treat guidance as a “safe harbor” that represents an acceptable compliance approach but not the only compliant approach. The Agency should take particular precautions to educate its inspectors about this limitation.

* * *

We appreciate the opportunity to submit these comments and look forward to continuing to work with the Agency to ensure FSMA implementation is a success. Keeping food safe for consumers is our top priority.

Sincerely,

Leon H. Bruner, D.V.M., Ph.D.
Senior Vice President for Scientific and Regulatory Affairs &
Chief Science Officer

Cc: Office of Management and Budget, Office of Information and Regulatory Affairs
GMA Feedback and Recommendations on Proposed Rule:  
Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food 21 CFR Part 117

Comments on Preliminary Regulatory Impact Analysis

GMA analysis indicates the PRIA does not accurately reflect the industry’s costs to implement the preventive controls proposed rule as it is currently written. As part of our comments on the preventive controls proposal, we have submitted modifications to the draft rule that will ensure the final rule is consistent with the scope of both the Food Safety Modernization Act (FSMA) and the PRIA. If the Food and Drug Administration, FDA, were to adopt GMA’s proposed language, GMA members believe the costs outlined in the PRIA would more accurately approximate the costs the food industry will incur to implement the final rule. As a result, we strongly encourage FDA to adopt GMA’s proposed modifications to the preventive controls regulatory language.

GMA understands that the task of quantifying the economic impact of a sweeping food safety regulation such as the preventive controls proposal is a difficult one, and we appreciate FDA’s efforts to clearly define both the costs and benefits associated with the proposal. As noted in the seafood industry’s comments on the economic analysis for FDA’s 1994 Hazard Analysis and Critical Control Points (HACCP) proposed rule, quantifying the costs of a major food safety regulation is challenging for many reasons. First, estimating the food safety benefit likely to result from sweeping food safety reforms is difficult because the current system of relying on cases reported to FDA, combined with Centers for Disease Control (CDC) outbreak data for tracking foodborne illnesses, may not adequately allow for a determination of the extent and causes of foodborne illnesses in the United States. Second, estimating the costs associated with implementing comprehensive food safety regulations can be problematic because the food industry is so varied and many costs cannot be easily measured.

While the U.S. food supply is amongst the safest in the world, GMA recognizes the need for continuous improvement in the area of food safety and therefore strongly supported passage of FSMA. GMA understood and accepted that the food industry would necessarily incur some

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8 The seafood industry’s experience with implementing seafood HACCP is particularly helpful to demonstrate the potential economic implications of the preventive controls proposal for the food industry. For example, prior to the enactment of seafood HACCP, the tuna industry managed histamine control mostly through standard operating procedures. Following HACCP implementation, one manufacturer’s annual costs for a single critical control point to manage histamine was approximately $95,000 per year. (The annual costs included the cost of conducting an initial hazard analysis, training for the HACCP team and employees, performing HACCP monitoring and verification, and finished product testing, among other activities.) By contrast, FDA estimated the cost of the final seafood HACCP rule would be $23,000 for domestic facilities in the first year of implementation and $13,000 for subsequent years. See Food and Drug Administration, Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, Final Rule, 60 Fed. Reg. 65096, 65180 (Dec. 18, 1995).

Significantly, in the most recent seafood HACCP guidance, FDA required histamine control and several other standard operating controls to be managed through six additional CCPs (much like the current preventive controls proposal would elevate standard operating controls to preventive control status), resulting in increased costs of approximately $120,000 per year per affected facility. Of note, the costs incurred by this particular manufacturer are for a foreign facility with wage rates for hourly employees and supervisory employees at about $2.00/hour and $4.00/hour respectively.
costs to implement FSMA and realize the more rigorous food safety system established by this important new law. We are, however, concerned the proposed rule considerably exceeds the statutory scope outlined in FSMA and will require measures that do not enhance food safety, resulting in increased costs to the food industry and ultimately to consumers with minimal corresponding public health benefit. In particular, GMA disagrees with the PRIA’s primary assumption that the preventive controls proposal will not require significant implementation costs for larger processing facilities that already operate food safety systems based on HACCP models. Indeed, as currently written, our analysis indicates that the proposed rule would result in significant implementation costs for the entire food industry, including those facilities that already employ HACCP-based systems.

GMA has worked closely with members to carefully identify and analyze the costs associated with the preventive controls proposal. As discussed in greater detail below, we believe the preventive controls proposal, as currently written, could cost the industry as much as **$18.8 billion** to implement in the first year—more than 20 times greater than FDA’s first year implementation cost estimate of $775 million. GMA has separately provided detailed comments to the proposed rule docket, including proposed regulatory language. GMA contends that if FDA were to adopt the proposed regulatory language recommended in GMA’s comments, the food industry’s actual implementation costs would be more consistent with the cost estimate outlined in the PRIA. Accordingly, GMA strongly encourages FDA to adopt the proposed language presented in GMA comments on the preventive controls proposal. Adopting GMAs proposed changes will also ensure that the final rule is more aligned with the scope defined in FSMA.

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9 GMA’s $18.8 billion estimate for implementing the preventive controls proposal is derived by multiplying FDA’s estimated number of affected facilities – 51,549 under Option 1 – by the lowest per facility cost estimate of $364,040 which is broken down in greater detail on pages 117-123 and footnote 11. This number is rounded from $18,765,900,000.

10 FDA’s cost estimates for the food industry to implement the preventive controls proposal vary significantly depending on which definition of “very small businesses” is used. The Agency offers three estimates of the costs to implement the proposal depending on which definition is used. Under Option 1, FDA proposes to define “very small business” to mean a business with less than $250,000 in annual food sales. Option 2 defines “very small business” to mean a business with less than $500,000 in total annual sales of foods. Option 3 defines “very small business” to mean a business with less than $1,000,000 in total annual food sales. GMA believes that small facilities with less than 20 employees will incur a large portion of the costs associated with implementing the preventive controls proposal because they lack experience with HACCP-based models. For example, the Food GMP survey indicated that less than half of facilities with fewer than 20 employees (42%) operate using HACCP. Accordingly, we encourage FDA to use definition for “very small business” in Option 1 so that costs will be captured for the largest number of facilities (51,549 affected facilities) and therefore more accurately reflect the true costs of implementing the preventive controls proposal. FDA estimates that, under Option 1, the total costs to domestic facilities in the first year—the year when the industry incurs the largest cost—will be approximately $775 million, with total annualized costs discounted at 7% of $475 million. We use these estimates as the point of reference for cost estimates identified in these comments.
A summary of GMA comments is as follows:

- GMA’s estimate of the costs industry will incur to implement the preventive controls proposal as it is currently written far exceed the $13,000 average annualized costs per facility identified in the PRIA. In fact, we estimate the costs will range between $364,040 and $524,960 per affected facility to implement only a portion of the requirements.11

- The preventive controls proposal, as it is currently written, takes a prescriptive approach to managing preventive controls, and does not adequately account for the role of horizontal “prerequisite programs” in ensuring food safety. As explained in the GMA preventive controls comments, GMA expects this prescriptive approach would require many preventive controls to be subject to management elements usually reserved for critical control points (CCPs) in HACCP-based systems unless FDA has noted a specific exemption. This is not consistent with current industry practices, and if implemented, it will not improve food safety or provide enhanced public health benefits, and, as discussed in greater detail below, will impose between $352,040 and $512,960 per affected facility in additional costs to the industry that are not identified in the PRIA.

- Because the proposal appears to require preventive controls be managed substantially similar to CCPs, an approach that differs from current industry practices, most affected facilities will need to conduct new hazard analyses and make significant changes to their food safety plans to comply with the proposal as currently written. The PRIA incorrectly assumes that the majority of large manufacturing facilities currently using HACCP models will incur no cost to conduct and devise new food safety systems to comply with the proposed rule. A survey of the GMA membership revealed that most affected facilities will need to conduct new hazard analysis and make significant modifications to their food safety systems at an estimated cost of approximately $12,000 per affected facility.

- The PRIA’s $13,000 per affected facility does not include the costs of implementing testing programs. GMA estimates testing costs to be at least $16,726 per affected facility to test a limited number of environmental samples for Listeria and Salmonella.

11 The $364,040 estimate for each affected facility to implement the preventive controls proposal as it is currently written includes approximately $352,040 to manage an average of 20 prerequisite programs per facility in a CCP-like manner and $12,000 per facility to rewrite each of its food safety plans. A detailed discussion of the costs involved in managing a prerequisite program using the same management criteria currently applied to CCPs is included on pages 117-118. Similarly, the higher end estimate of $524,960 for each affected facility to implement the preventive controls proposal includes $512,960 to manage an average of 20 prerequisite programs per facility in a CCP-like manner and the same $12,000 per facility to conduct new hazard analyses and rewrite each of its food safety plans. None of these costs are included in FDA’s $13,000 per facility estimate outlined in the PRIA for implementing the preventive controls proposal. The $340,320 and $455,807 per affected facility figures do not include other costs associated with implementing the preventive controls proposal such as evaluating radiological hazards as a separate category of hazard in all HACCP plans, mandatory annual onsite audits as part of supplier verification, testing, and Part 11 compliance.
The preventive controls proposal will require companies to evaluate radiological hazards as a separate category of hazard in all HACCP plans. This is not a current industry practice. Currently, radiological hazards are evaluated as chemical hazards and such a requirement would require rewriting and/or amending every food safety plan across the industry. One member company estimated this change would require an initial company-wide expenditure of approximately $35,000. This cost would include technical resources and change management costs. This expense is not included in the PRIA.

The estimated cost for mandatory annual onsite audits as part of supplier verification does not account for any of the indirect costs suppliers will incur during the audit process. We estimate the direct costs of supplier audits to be approximately $5,625 per supplier audit, which is in line with FDA’s cost estimate; however, this number would need to be multiplied by potentially several hundred suppliers per company based on a risk frequency. This figure does not include another $5,000 per audit in indirect costs not included in the PRIA that companies will incur while they are being audited.

Part 11 compliance costs for electronic records are not addressed in the PRIA and will result in significant cost to the industry if required. This expense is not included in the PRIA.

In summary, the PRIA does not accurately capture the true costs of implementing the preventive controls proposal as it is currently written. FDA’s adoption of the proposed modifications to the draft rule outlined in the GMA comments to the preventive controls proposal will bring industry’s true implementation costs considerably closer to those outlined in the PRIA.

Average Implementation Costs Will Far Exceed $13,000 Per Affected Facility

One of the key assumptions in the PRIA is that facilities currently using HACCP-based systems will incur only minimal costs to implement the preventive controls proposal. FDA estimates the average annualized cost per affected facility will be $13,000. Based on a survey of GMA members, GMA’s data indicates that the $13,000 per affected facility figure underestimates the actual costs the food industry will incur to implement the changes mandated by the preventive controls proposal as it is currently written. In fact, the PRIA either does not include, or vastly underestimates, the costs associated with the following implementation activities:

- A prescriptive approach to managing most preventive controls, similar to the way CCPs are handled in HACCP-based systems;
- New hazard analyses for facilities already operating under HACCP models because the proposed rule changes the way these facilities currently access and manage food safety;
- Environmental and finished product testing;
- Assessment of radiological hazards as a separate category of hazard;
- Mandatory onsite audits as a supplier verification activity;
- Part 11 compliance.

As noted above, FDA’s 1995 cost estimate for facilities to comply with seafood HACCP in the years following initial implementation was also $13,000 per facility.
We note also that, while the hourly wage rates identified in the PRIA are largely in line with current industry wages, the number of labor hours and the utilization of cross-functional teams to manage food safety programs are not represented in the PRIA. Accordingly, the actualized labor costs provided in the PRIA are not consistent with industry practice and, as a result, lead to lower than expected cost estimates throughout the PRIA.

Below we provide a more detailed discussion of each of these points to demonstrate how the PRIA either does not include or significantly underestimates the industry’s costs to comply with the preventive controls proposal as it is currently written. FDA’s adoption of the modifications outlined in GMA’s comments on the proposal would address the majority of these issues and ensure that the final rule is aligned with the cost estimates outlined in the PRIA.

1. **Cost of Managing Preventive Controls as CCPs Not Included in $13,000 Estimate**

The proposed rule appears to treat preventive controls – which under FSMA span the entire food safety system – as substantially similar to CCPs. As explained in the GMA food safety plan comments, this treatment is evident both in the way preventive controls are identified (using a “reasonably likely to occur” standard, which is used in regulatory HACCP programs to identify CCPs) and in the way they are managed (using prescriptive management elements similar to CCPs). The PRIA, however, fails to estimate or include any costs associated with managing preventive controls in a CCP-like manner.

To analyze the costs associated with managing preventive controls in a CCP-like manner, we first gathered data from members to understand how much it costs industry to manage CCPs in a HACCP-based system. GMA members indicated they spend between $45,332 and $65,895 to manage one CCP on an annual basis. This cost includes activities related to monitoring, verification, validation, and recordkeeping. GMA members estimated that the average cost for managing other non-CCP controls, such as prerequisite programs (PPs), would range from $10,128 to $14,599 per year per control with an average of approximately 20 PPs per affected facility.

Using the numbers above, the cost of applying CCP-like management criteria to a preventive control such as a PP would range from $35,204 to $51,296.\(^{13}\) If we assume – as stated in the GMA food safety plan comments – that the proposed rule expects preventive controls to be treated as substantially similar to CCPs, assuming an average of 20 PPs per affected facility, we estimate the cost to industry would range from approximately $704,080 to $1,025,920 per affected facility. Even if only half of the current food safety controls contained in prerequisite programs were treated as substantially similar to CCPs, the cost to industry to comply with the proposal as currently written would be between $352,040\(^{14}\) and $512,960 per affected facility.

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\(^{13}\) The $35,204 to $51,296 cost estimate for managing preventive controls in a CCP-like manner is calculated by subtracting the low and high PP management costs provided by GMA members ($10,128 and $14,599) from the low and high CCP management costs ($45,332 and $65,895) to identify the difference between management of a PP and management of a CCP.

\(^{14}\) Multiplying the low-end per affected facility estimate of $352,040 to manage preventive controls in a CCP-like manner by the 51,549 affected facilities identified in the PRIA Option 1 results in an overall cost to industry of approximately $18.1 billion ($18,147,310,000).
Regardless of which estimate is used, the industry will incur significant costs to comply with the proposal – costs that are not estimated or included in the PRIA. Below we offer two examples from GMA members to help further illustrate this point.

- One GMA member operates a facility that manages 2 CCPs and 10 PPs. The establishment spends approximately $52,300 to manage CCPs, and an average of $12,500 to manage each of the 10 PPs for a total expenditure of $229,600 per year. If this facility had to change its food safety approach to comply with the proposal, the increased cost for managing each of the 10 PPs in a CCP-like manner would be $398,000 each year.\(^{15}\) Even if we assumed only a portion, i.e., half, of the PPs would be subject to a management approach usually reserved CCPs, this facility would likely incur close to $200,000 per year in additional costs to implement the preventive controls proposal as it is currently written.

- Another GMA member operates a facility with 17 PPs, each of which cost about $14,600 per year to manage. The facility spends $57,306 each year to manage its CCPs. If this facility applied CCP-like controls to each of its 17 PPs, the cost would be approximately $726,000 in additional costs per year. Even if only half of the PPs were managed using prescriptive criteria similar to CCPs, the cost would still be more than $360,000 per year.

Because none of the costs associated with managing preventive controls in a manner similar to CCPs are included in the PRIA, FDA’s estimate for the industry’s costs to implement preventive controls proposal is flawed. The implementation cost estimates should accurately reflect the true costs the food industry will incur. GMA encourages the FDA to adopt the approach to preventive controls outlined in the comments based on our analysis that they are more cost effective and are aimed at preventing the diversion of resources from important food safety activities.

Below, in Table 1 and Table 2, we provide two additional PP models (condensation and temperature) and one additional CCP model (inline metal detection) using example data to demonstrate how the costs associated with managing these activities are calculated. The two separate examples show a range of data for how CCPs and PPs could be managed. Note that the cost estimates in the models are not used to derive the calculations outlined above for the high and low costs for managing PPs and CCP.

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\(^{15}\) The $398,000 estimate is reached by calculating the difference between the costs for managing a PP ($12,500) and managing a CCP ($52,300) – a difference of $39,800 – and multiplying that by the number of PPs in this company’s facility (10).
### Table 1. Example Costs of Managing a Prerequisite Program on an Annual Basis

<table>
<thead>
<tr>
<th>Prerequisite program: condensation checks</th>
<th>Example 1</th>
<th>Example 2</th>
<th>Prerequisite program: temperature monitoring</th>
<th>Example 1</th>
<th>Example 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of condensation checks per hour</td>
<td>1x</td>
<td>1x</td>
<td>Number of temperature checks per hour</td>
<td>1x</td>
<td>1x</td>
</tr>
<tr>
<td>Amount of time (minutes) for each check</td>
<td>10</td>
<td>10</td>
<td>Amount of time (minutes) for each check</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Labor rate (per hour) for manufacturing production worker. Used FDA labor rate.</td>
<td>$20.00</td>
<td>$20.00</td>
<td>Labor rate (per hour) for manufacturing production worker. Used FDA labor rate.</td>
<td>$20.00</td>
<td>$20.00</td>
</tr>
<tr>
<td>Labor cost for performing each check</td>
<td>$3.33</td>
<td>$3.33</td>
<td>Labor cost for performing each check</td>
<td>$1.67</td>
<td>$1.67</td>
</tr>
<tr>
<td>Number of checks per 24 hour period</td>
<td>16</td>
<td>24</td>
<td>Number of checks per 24 hour period</td>
<td>16</td>
<td>24</td>
</tr>
<tr>
<td>Daily labor costs for condensation checks</td>
<td>$53.33</td>
<td>$80.00</td>
<td>Daily labor costs for temperature checks</td>
<td>$26.67</td>
<td>$40.00</td>
</tr>
<tr>
<td>Yearly labor costs for prerequisite program: condensation check</td>
<td>$13,867 (260 days per year)</td>
<td>$29,200 (365 days per year)</td>
<td>Yearly labor costs for prerequisite program: temperature check</td>
<td>$6,933 (260 days per year)</td>
<td>$14,600 (365 days per year)</td>
</tr>
</tbody>
</table>

NOTE: This cost is only the labor costs associated with maintaining one prerequisite program. This cost does not include the supplies or management oversight for maintaining the prerequisite program. This is an extremely conservative estimate and is not all encompassing of program costs.
Table 2. Example Costs of Managing a CCP (metal detection challenge) on an Annual Basis

<table>
<thead>
<tr>
<th>Monitoring Costs</th>
<th>Verification Costs (Document review by qualified individual (verification))</th>
<th>Validation Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Example 1</td>
<td>Example 2</td>
</tr>
<tr>
<td>Cost per minute of plant associate monitoring CCP</td>
<td>$20.00/60= $0.33 (Rounded PRIA Food Manufacturing Production Worker – Nonsupervisory rate of $19.91)</td>
<td>$20.00/60= $0.33</td>
</tr>
<tr>
<td>Amount of time (minutes) for each metal detection challenge</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>Cost for each challenge</td>
<td>$1.66</td>
<td>$4.95</td>
</tr>
<tr>
<td>Number of metal detection challenges in 24 hour period</td>
<td>48 (assumed 24 hour production schedule with a challenge every 30 minutes)</td>
<td>16 (assumed 16 hour production schedule and 1 challenge per hour)</td>
</tr>
<tr>
<td>Cost of metal detection challenges per 24 hour period</td>
<td>$79.68</td>
<td>$79.20</td>
</tr>
<tr>
<td>Annualized labor cost</td>
<td>$29,200 (assuming 365 days per year)</td>
<td>$20,592 (assuming 260 days per year)</td>
</tr>
</tbody>
</table>

Example 1: Yearly labor costs for managing a CCP (monitoring, verification and validation) $40,337

Example 2: Yearly labor costs for managing a CCP (monitoring, verification and validation) $52,317
2. Costs of New Hazard Analyses Underestimated in $13,000 Estimate

One of the ways FDA supports its $13,000 per facility figure for implementing the preventive controls proposal is to assume facilities currently using HACCP models will not incur any additional costs to conduct and prepare hazard analyses, and make resultant changes to their food safety systems under the proposal. Specifically, the PRIA assumes that affected facilities currently operating using HACCP-based systems will not need to modify their food safety systems because they have already conducted hazard analyses and established preventive controls that comply with the proposal.

Across the domestic food industry, FDA estimates that approximately 66 percent of facilities currently use HACCP systems with the number varying largely according to facility size. FDA estimates that 97 percent of facilities with 100 to 499 employees operate using HACCP systems, and that 100 percent of facilities with more than 500 employees employ HACCP-based systems. Accordingly, for the approximately 4,684 domestic facilities with more than 100 employees, FDA estimates that only three percent – or approximately 140 facilities – are not using HACCP-based systems and thus will be required to conduct hazard analyses to comply with the preventive controls proposal.

We disagree with FDA’s calculation that only those facilities not currently using HACCP models will need to conduct hazard analyses to comply with the preventive controls proposal. As explained above and in GMA’s food safety plan comments, the proposed rule takes an approach that differs from the way successful food safety programs are frequently managed today. For example, in conducting a hazard analysis, successful programs often consider prerequisite programs in concluding that hazards are not “reasonably likely to occur” – an approach the proposed rule does not appear to address or accommodate. Regulatory standards that change the way facilities with HACCP systems manage food safety – for example, the way prerequisite programs are factored into a hazard analysis – would trigger a need for facilities with existing HACCP systems to reexamine their hazard analyses and food safety plans to comply with the proposal.

As outlined below, using FDA’s own numbers from PRIA, we estimate that the 458 facilities with more than 500 employees will incur between $3.3 million and $6.7 million to conduct new hazard analyses and modify their current, successful food safety systems compared with FDA’s estimate of $0. For the 4,226 facilities with between 100 and 499 employees, we estimate the costs to conduct new hazard analyses will be between $18.6 million and $37 million compared with FDA’s estimate of $1.14 million.

For purposes of this exercise, GMA’s example hazard analysis cost estimate uses the following baseline assumptions taken from FDA’s Table 17a in the PRIA (Table 3):

- **12-24 Hours to Conduct a Hazard Analysis**: FDA estimates that facilities will need between 24 and 48 labor hours to conduct an initial hazard analysis, and 12-24 hours to conduct subsequent hazard analyses. We use FDA’s estimate of 12-24 labor hours for conducting subsequent hazard analyses because the majority of these facilities already have experience preparing HACCP plans.
$61 Hourly Wage Rate for Qualified Individuals  We also use FDA’s $61.44 hourly wage rate (rounded to $61) for qualified individuals even though this number does not reflect the cross-functional teams typically used to conduct hazard analyses and write food safety plans.

Median Number of Processes Per Facility  For facilities with between 100 and 499 employees, FDA estimates an average of 3-9 processes per facility and so we use a median number of 6 processes per facility for purposes of this exercise. For facilities with more than 500 employees, FDA estimates an average of 8-12 processes per facility and we use a median figure of 10 processes per affected facility.

Using the baseline assumptions outlined above, for the 4,226 plants with 100 to 499 employees, we calculate the cost of conducting new hazard analyses for a median number of 6 HACCP plans per affected facility to be between $4,392 and $8,784 per affected facility, with a total cost of between $18.5 and $37 million for all manufacturing facilities of this size. For facilities with more than 500 employees, we calculate the cost to rewrite a median number of 10 HACCP plans per affected facility to be between $7,230 and $14,640, with a total cost of between $3.3 and $6.7 million for all 458 facilities of this size. For all facilities with more than 100 employees, we estimate the costs of re-writing HACCP plans would range between $21.9 and $43.8 million. Our analyses are summarized in the table below.

| Table 3. Estimate of Industry Costs to Conduct New Hazard Analyses (using data from PRIA Table 17a) |
|---------------------------------------------------------------|---------------------------------------------------------------|
| Number of domestic affected facilities                       | 100 to 499 employees                                          | ≥ 500 employees                                              |
|                                                               | 4,226                                                        | 458                                                          |
| Hourly wage rate for qualified individuals                   | $61                                                          | $61                                                          |
| Average number of processes per facility                     | 3-9 (use median of 6)                                         | 8-12 (use median of 10)                                      |
| Total per affected facility (12 hrs of labor)                | $4,392                                                       | $7,230                                                       |
| Total per affected facility (24 hrs of labor)                | $8,784                                                       | $14,640                                                      |
| Total all facilities (12 hrs of labor)                       | $18,560,592                                                  | $3,311,340                                                   |
| Total all facilities (24 hours of labor)                     | $37,121,184                                                  | $6,705,120                                                   |

As the table demonstrates, even when using FDA’s own estimates for labor costs and the amount of time needed to prepare a food safety plan for a median number of processes per facility, the resulting cost estimate for facilities with 100-499 employees to conduct new hazard analyses and rewrite their HACCP plans is between $18.5 and $37 million. For facilities with more than 500 employees, the cost would range from $3.3 to $6.7 million. These estimates are quite compelling when compared to FDA’s $1.14 million cost estimate for all facilities with 100-499 employees and $0 estimate for facilities with more than 500 employees.
The cost estimates derived from the example exercise above are consistent with data provided by our member companies indicating that the average cost of conducting new hazard analyses to comply with the preventive controls proposal would be approximately $12,000 per affected facility. When this $12,000 per affected facility figure is multiplied by the 4,684 affected facilities with greater than 100 employees, the resulting cost is approximately $56 million, which is nearly 50 times greater than FDA’s $1.14 million cost estimate.

3. **Testing Costs Not Included in $13,000 Estimate**

The costs associated with environmental and finished product testing, supplier approval/verification activities, and review of consumer complaints were outlined in the PRIA but not included in the total cost calculation for implementing the preventive controls proposal. The Agency determined the average annualized cost per domestic facility to be $13,000 yet this figure is not accurate if the final preventive controls rule requires such activities. Based upon member feedback, GMA has outlined realistic costs associated with environmental and finished product testing (chemical and microbiological), and with supplier approval and verification activities.

The PRIA included substantial data on the cost analysis of environmental and finished product testing. PRIA Table 43 (Table 4) comparing the cost of environmental testing with the actual cost of environmental testing as agreed upon by GMA members is replicated in Table 4:
Table 4. Industry Data on Annual Costs of Environmental Monitoring for Pathogens (15 samples/month) **(PRIA Table 43)

<table>
<thead>
<tr>
<th></th>
<th>Low Volume Pricing</th>
<th></th>
<th>High Volume Pricing</th>
<th></th>
<th>GMA Industry Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Salmonella</td>
<td>Listeria</td>
<td>Salmonella</td>
<td>Listeria</td>
<td></td>
</tr>
<tr>
<td>Hourly labor cost (includes overhead)</td>
<td>$23.34</td>
<td>$23.34</td>
<td>$23.34</td>
<td>$23.34</td>
<td>$49.03 (see wage data table below)</td>
</tr>
<tr>
<td>Time to collect each sample (hours)</td>
<td>0.25</td>
<td>0.25</td>
<td>0.25</td>
<td>0.25</td>
<td>0.33</td>
</tr>
<tr>
<td>Number of samples per facility*</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Total labor cost*</td>
<td>$88</td>
<td>$88</td>
<td>$88</td>
<td>$88</td>
<td>$242.70 (using $49.03 per hour)</td>
</tr>
<tr>
<td>Cost of sampling supplies per sample*</td>
<td>$3.37</td>
<td>$3.37</td>
<td>$3.37</td>
<td>$3.37</td>
<td>$3.37</td>
</tr>
<tr>
<td>Number of samples per facility*</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Total sampling supplies cost*</td>
<td>$51</td>
<td>$51</td>
<td>$51</td>
<td>$51</td>
<td>$51</td>
</tr>
<tr>
<td>Cost of shipping supplies*</td>
<td>$21.76</td>
<td>$21.76</td>
<td>$21.76</td>
<td>$21.76</td>
<td>$21.76</td>
</tr>
<tr>
<td>FedEx standard overnight*</td>
<td>$37.75</td>
<td>$37.75</td>
<td>$37.75</td>
<td>$37.75</td>
<td>$37.75</td>
</tr>
<tr>
<td>Total cost of shipping*</td>
<td>$60</td>
<td>$60</td>
<td>$60</td>
<td>$60</td>
<td>$60</td>
</tr>
<tr>
<td>Lab analysis cost per swab</td>
<td>$28.50</td>
<td>$26.00</td>
<td>$19.50</td>
<td>$17.50</td>
<td>$22.88 (FDA’s average estimate)</td>
</tr>
<tr>
<td>Number of samples per facility*</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Total cost of laboratory analysis</td>
<td>$428</td>
<td>$390</td>
<td>$293</td>
<td>$263</td>
<td>$343.20</td>
</tr>
<tr>
<td>Total cost per shipment</td>
<td>$625</td>
<td>$588</td>
<td>$490</td>
<td>$460</td>
<td>$696.90</td>
</tr>
<tr>
<td>Number of shipments annually*</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Annual environmental testing costs per facility</td>
<td><strong>$7,501</strong></td>
<td><strong>$7,051</strong></td>
<td><strong>$5,881</strong></td>
<td><strong>$5,521</strong></td>
<td><strong>$8,362.80</strong></td>
</tr>
</tbody>
</table>

*This table holds many variables constant for purposes of this exercise such as the number of samples, sampling supplies, total number of shipments per year, shipping costs. We believe many of these variables are conservative estimates, e.g., manufacturing facilities will likely take greater than 15 samples per pathogen each month to have a more extensive data set for trending purposes.

When analyzing FDA’s projected costs associated with environmental sampling (Table 4) GMA members disagreed with the amount of time estimated to collect the samples and the hourly labor rate. In addition, FDA’s financial model only included one employee involved with the environmental sample collection while in many facilities, due to the complexity of the operation, there are multiple employees involved with the program. Typically, for finished product testing and environmental sampling, the following positions are involved in the program: sampling/laboratory technician (obtaining the samples), senior laboratory individual (performing testing) and manager or quality engineer (program oversight and data review/trending). Table 5 represents average salary data, based upon a survey of GMA members, for these positions.

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16 External laboratories such as Silliker use different methodologies to test for *Salmonella* and *Listeria* and the costs for testing vary according to which methodology is used. We found FDA’s average estimate of $22.88 per swab to be extremely conservative. While we use FDA’s average estimate for calculation purposes in this table, GMA members reported that the actual testing costs are closer $25-30 per sample/swab.
Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food (Docket No. FDA–2011–N–0920)—GMA Comments on the Preliminary Regulatory Impact Analysis (PRIA)

Table 5. GMA Member Laboratory Staff Wage Data

<table>
<thead>
<tr>
<th>Position Title</th>
<th>Hourly Rate</th>
<th>Benefits &amp; Insurance (per hour) based on 40% of hourly rate</th>
<th>Total Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling/Laboratory Technician</td>
<td>$27.40</td>
<td>$10.96</td>
<td>$38.36</td>
</tr>
<tr>
<td>Senior Laboratory Staff</td>
<td>$34.00</td>
<td>$13.60</td>
<td>$47.60</td>
</tr>
<tr>
<td>Laboratory Manager</td>
<td>$48.69</td>
<td>$19.48</td>
<td>$68.17</td>
</tr>
<tr>
<td>Quality Engineer</td>
<td>$30.00</td>
<td>$12.00</td>
<td>$42.00</td>
</tr>
<tr>
<td>Average Cost per Hour</td>
<td>$35.02</td>
<td>$14.01</td>
<td>$49.03*</td>
</tr>
</tbody>
</table>

*Utilized average compensation per hour as $49.03 (including benefits and insurance) for industry costs associated with testing program.

Using the more realistic data from GMA members for labor costs, sample collection time, and the cost of laboratory analysis, GMA calculated that the annual cost for an environmental sampling and testing program would be approximately $8,362.80 per pathogen for each affected facility in comparison to the Agency’s estimate of $5,521 to $7,501 annually. In actuality, an annual program cost per facility of $8,362.80 is conservative. Collecting and analyzing only fifteen samples per month for an entire facility may not be sufficient for accurate statistical analysis and valuable data trending purposes. In addition, the number of samples and testing frequency will depend on factors such as the product type, the associated risk of the product, and equipment design. As a result, the PRIA underestimates the cost estimate for a holistic environmental testing program. A cost profile for an environmental program—a more realistic economic model that would allow for adequate monitoring and trending purposes—is shown in Table 6.

Table 6. Example Costs for a Facility with a Comprehensive Environmental Monitoring Program

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hourly labor cost (includes benefits)</td>
<td>$49.03</td>
</tr>
<tr>
<td>Time to collect each sample (hours)</td>
<td>0.33</td>
</tr>
<tr>
<td>Number of samples per month</td>
<td>80</td>
</tr>
<tr>
<td>Total labor costs per month</td>
<td>$1,294.39</td>
</tr>
<tr>
<td>Total labor costs per year</td>
<td>$15,532.70</td>
</tr>
<tr>
<td>Total sampling supplies per year (based on $3.37 per unit)</td>
<td>3,255.20</td>
</tr>
<tr>
<td>Annual shipping costs (based on $60 per shipment)</td>
<td>$720.00</td>
</tr>
<tr>
<td>Annual testing cost (based on $22.88 per test)</td>
<td>$21,964.80</td>
</tr>
<tr>
<td>Total annual cost based on 80 samples per month</td>
<td>$41,452.70</td>
</tr>
</tbody>
</table>

17 While we use an average of 80 samples per month for purposes of this table, we note that many facilities test on a weekly basis and rotate their sample sites. As a result, the 80 sample per month estimate may be conservative for many facilities.
As evidenced by the example above, it costs approximately $41,452.20 annually for a facility to sample and test eighty environmental samples per month. GMA members found this example was more representative of a typical environmental monitoring program.

A similar analysis can be applied to finish product testing costs. In Table 48 of the PRIA for annual costs of food product testing, FDA’s figures underestimate the labor rate, the time to collect the samples is inadequate, and the number of samples collected does not appear technically sound. A more important factor when analyzing the finished product testing is the cost of storing the product while awaiting results of pathogen testing. In Table 49 of the PRIA, FDA estimated the per facility cost of holding product during finished product testing to be $16,000 (facility with <20 employees) to $1,566,013 per facility (>500 employees). For this calculation, the Agency utilized the average daily value of production per manufacturing line but did not include the necessary cost of outside warehousing/storage or the cost to the disruption in the supply chain. The daily value of production is an incorrect assumption when calculating product storage cost, because product storage costs are determined by the number of pallets stored and the type of controlled environment (e.g. ambient, refrigerated, frozen) for storage. In addition, the Agency did not include any testing (environmental or finished product testing) or holding product costs in the overall cost estimate for implementation of the proposal. If these costs were included, the cost per affected facility to implement the proposal would be far greater than the estimated $13,000 per year for domestic facilities.

In the PRIA, FDA included cost estimates for microbiological tests, which are relatively inexpensive tests. The cost of chemical analysis is generally much higher (Table 7) and would be significant if the Agency were to mandate chemical analysis in the final rule.

### Table 7. GMA Member Costs for Chemical Analysis Testing

<table>
<thead>
<tr>
<th>Analyte (s)</th>
<th>Cost Per Sample</th>
<th>Turn Around Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pesticide residues (multi-residue screen) for low to high fat products</td>
<td>$250-$828 depending on which methodology is used</td>
<td>5-10 days</td>
</tr>
<tr>
<td>Allergens by Elisa assay</td>
<td>$130 for each allergen tested</td>
<td>5 days</td>
</tr>
<tr>
<td>Heavy metals screen</td>
<td>$43-80 per metal screened</td>
<td>5 days</td>
</tr>
<tr>
<td>Natural toxin by Elisa assay</td>
<td>$80 per toxin</td>
<td>5 days</td>
</tr>
<tr>
<td>Unapproved food colors</td>
<td>$88 per color</td>
<td>10 days</td>
</tr>
</tbody>
</table>

*Note that these costs are from laboratories that are ISO/IEC 17025:2005 accredited.*

For microbiological testing it is important to consider and recognize some of the difficulties in expecting a microbiological examination of a sample to portray the true microbiological condition of the product lot.\(^{18}\)

With regard to an environmental finished product testing program, several costs such as the hourly labor cost (industry estimated for a benefitted employee the rate was $49.03 per hour), the time to process the samples, and shipping costs for the samples are readily quantified and

\(^{18}\) See, e.g., Microorganisms in Foods 2. Sampling for microbiological analysis: Principles and specific applications. 2\(^{nd}\) Ed. International Commission on Microbiological Specifications for Foods.
relatively standard across the industry; whereas, the cost for holding product during product testing is significant yet difficult to quantify. GMA members rely on the scientific and technical basis for finished product testing, along with the derived benefit of finished product testing; in particular, microbiological testing. The Agency stated that “when the production process does not have a step that will eliminate or reduce hazards to an acceptable level finished product testing may be helpful to verify that the final product does not contain a hazard.” We caution FDA on this assumption as the limitations of lot acceptance sampling – particularly for the microbiological content of the product – are well established and documented.

Chemical testing is significantly more expensive than microbiological testing. As is the case with any testing program, determination of the necessity and design of the program must be risk-based rather than a prescriptive set of mandates applied universally across the industry. A risk-based approach applied to testing is a more efficient use of precious technical resources and has a greater likelihood of having a public health benefit than prescriptive mandates.

The goal of the food industry is to prevent problems before they occur. The goal of effective verification programs is to evaluate the performance and effectiveness of control measures and to detect problems before they affect products. Successful food safety systems conduct root cause analyses at the front end of the process rather than relying on finished product testing to detect a defect once the lot is complete. The costs associated with conducting finished product testing could be more effectively applied to further designing quality into products, e.g., sanitation methods, sanitary designs technologies, more robust preservative systems, and environmental monitoring programs. Investing in preventive risk-based approaches to improve food safety systems will have a greater likelihood of reducing the estimated 1,000,000 annual food related illnesses than sole reliance on quality systems that are more reactive (example: finished product testing).

4. Costs of Separate Assessment for Radiological Hazards are Not Included in $13,000 Estimate

Manufacturing facilities operating under HACCP-based systems currently consider radiological hazards as a type of chemical hazard. The preventive controls proposal, however, requires that radiological hazards be evaluated as a separate category of hazard. As a result, the industry will incur a substantial initial expense to make this change, a cost that is not identified in the PRIA.

Evaluating radiological hazards as a separate type of hazard will not only require each facility to reassess and then either rewrite or revise their existing HACCP plans. One member company estimated that the one-time initial cost of revising their HACCP plans to include radiological hazards as a separate category would be approximately $35,000 company-wide. This figure includes the cost analyzing approximately 250 HACCP plans in all the company’s affected facilities as well as the cost of having qualified individuals rewrite each HACCP plan. The $35,000 estimate does not include the cost of updating corporate HACCP models, training of corporate and local HACCP teams on the new category of hazard, updates to ingredient and finished product specifications, updates to product safety evaluations, and possible resubmission of HACCP plan data to customers.
It is our hope that the FDA is amenable to having radiological hazards treated as a chemical hazard and we strongly encourage that this be reflected in the final preventive controls rule.

5. **Costs for Mandatory Annual Onsite Audits as Part of Supplier Verification are Not Included in $13,000 Estimate**

The PRIA outlines costs associated with supplier approval and verification activities but these costs are not included in the total cost calculation for implementing the preventive controls proposal. The Agency determined the average annualized cost per domestic facility to be $13,000 yet this figure is not accurate if the final preventive controls rule includes such mandatory supplier verification activities.

Estimating the costs associated with supplier verification programs are difficult because these activities are determined based on the risk of not only the raw material but also the supplier’s food safety performance history. As a result, successful food safety systems conduct supplier verification activities at different frequencies and at different intensity levels based upon risk. Therefore, the PRIA’s use of only one economic model to estimate the cost of a supplier approval and verification program can create a distorted view of the economics of implementing and maintaining such programs. We also note that the PRIA is not tied to specific proposed codified language and the detailed requirements FDA adopts will affect costs.

The PRIA estimates the direct annual cost of conducting supplier audits to be, on average, between $3,250 and $5,625\(^{19}\) per supplier (including $625 for auditor travel expenses), depending on facility size. While the $625 estimate for travel costs is quite low, based on a survey of GMA members, our analysis indicates FDA’s high estimate of $5,625 per supplier audit most closely approximates the direct costs the food industry will incur to conduct an audit. It is important to consider that this figure is the cost for one company to audit one supplier. Most large companies source from hundreds of suppliers and, as a result, the $5,625 figure would need to be multiplied by the number of a company’s total suppliers as determined by the need for risk-based auditing.

We note that the PRIA also fails to take into account any of the indirect costs associated with a supplier audit such as the supplier’s need to divert employees and resources while the audit is being conducted. In typical audits, the auditor works intensively with the quality manager (average hourly rate $61)\(^{20}\) for the duration of the audit which can last from 1-5 days. During this timeframe there are often other affected facility employees or cross-functional teams engaged in supporting the audit process, e.g., retrieving and explaining various records, escorting the auditor(s), and other administrative tasks associated with the audit. Our member companies

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\(^{19}\) For the PRIA cost estimate, FDA refers to supplier assessments conducted under the GMA-SAFE requirements which are billed at a rate of $160/hour not including travel. We note that the $160/hour audit rate FDA uses for the PRIA is significantly less than the hourly rate FDA identified in a recent Federal Register notice for facility re-inspections. In particular, FDA’s hourly re-inspection rate, which became effective on October 1, 2013, is $221 not including travel. See Food and Drug Administration, Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2014, 78 Fed. Reg. 46966 (Aug. 2, 2013).

\(^{20}\) For purposes of this discussion, we use FDA’s $61.44 hourly rate for qualified individuals.
estimate the cost of diverting employee time and resources during an audit to be approximately $5,000 per audit, an expense that was not factored into the cost estimate for supplier audits.

Finally, FDA did not account for the cost of any corrective actions resulting from the audit process. While corrective actions are integral to the audit process, and addressing audit non-conformances are a necessity, there is still a cost associated with corrective actions that must be actualized. For example, the supplier must devise a corrective action plan, implement the corrective action, and verify that the corrective action plan has been implemented to the satisfaction of the auditor. All these activities need to be considered and factored into the calculation to derive a more accurate estimate of the cost of a supplier approval and verification program.

6. **Part 11 Costs are Not Included in $13,000 Estimate**

The preventive controls proposal would require that electronic records be kept in compliance with 21 C.F.R. Part 11. FDA requests comment on whether there are any circumstances that would warrant not applying Part 11 to records that would be kept under proposed Part 117. We have substantively addressed this issue in our comments to the preventive controls proposal. Because the PRIA does not address Part 11 costs, however, we want to note the significant costs that would be associated with requiring the food industry to apply Part 11 to all records that will be kept under proposed Part 117.

GMA strongly supports the good recordkeeping principles FDA has identified for key food safety records and agrees that recordkeeping systems used to document key food safety activities must be trustworthy and reliable. We are, however, concerned that an FDA mandate for all Part 117 records be Part 11 compliant would require significant revision and/or replacement of existing electronic document systems which, without a corresponding food safety benefit, does not support the significant implementation cost to industry.

We surveyed GMA members to identify the current scope of Part 11 compliance and learned that current Part 11 compliance is minimal. For example, two large member companies, each with more than 50 affected facilities, reported that none of their systems are currently Part 11 compliant. Another large member company with more than 600 affected facilities indicated only 15-20% of its systems are Part 11 compliant. Typically, modern food manufacturing facilities have multiple systems that could include, but are not limited to, the following: supply chain systems, operating systems, change management and document control systems. Requiring Part 11 compliance for these multiple, interrelated systems would place an undue burden on the food industry. Accordingly, in light of the cost and allocation of specialized resources for upgrading all documentation to be Part 11 compliant and the corresponding lack of public health benefit, GMA strongly recommends that the Agency not require Part 11 compliance as a component of the preventive controls proposal or other rules issued pursuant to FSMA.

7. **Hourly Wage Data Task Cost Estimates are Underestimated in $13,000 Estimate**

We surveyed member companies to determine whether the hourly wage data used in the PRIA accurately reflect the wages used by industry. In some cases, we found that FDA’s hourly wage estimates are close to industry rates. For example, one member company’s fully benefitted
hourly wage rate for a qualified individual is $67 compared to FDA’s estimate of $61.44 for one type of qualified individual (industrial production manager).

As noted above, GMA generally accepts FDA’s wage data estimates. Some member companies even reported paying lower wages (including benefits) for the equivalent of what the PRIA identifies as an industrial production manager/qualified individual. While we largely agree with the wage data estimates in the PRIA, we do believe the amount of time the Agency allocates for conducting various tasks vastly underestimates the actual time needed to complete these tasks, which in turn impacts the accuracy of the total labor costs cited in the PRIA.

In addition, PRIA fails to consider that many activities are often performed by teams of employees or functional departments, rather than individuals. For example, PRIA Table 28a estimates the number of labor hours needed to develop sanitation monitoring procedures as ranging from 4 to 14 hours. According to GMA members, this time estimate is inaccurate because it fails to account for industry practices that involve the deployment of cross-functional food safety teams, including consultants, to develop these types of procedures. Such cross-functional teams are typically comprised of representatives from the following functional areas: quality, maintenance, engineering, production, logistics, supply chain, and R&D. These teams collaborate to either develop new or revise existing food safety procedures and systems, a process which can sometimes take months to complete. In another example, PRIA Table 30a, which summarizes the cost to implement recall controls, estimates the time needed to develop initial recall procedures as ranging from 7 to 19 hours. GMA members, however, indicated that developing an initial recall procedure would involve at least three functions: legal, regulatory and quality, and could require a minimum of fifty hours.

Table 8 provides wage data information from GMA member companies. For future rulemakings, we encourage FDA to consider the differences and similarities between the wage data estimates identified in the PRIA and those below provided by our member companies.

### Table 8. Examples of GMA Member Wage Data

<table>
<thead>
<tr>
<th>Position Title</th>
<th>Function</th>
<th>Company A Hourly Rate (including benefits)</th>
<th>Company B Hourly Rate (including benefits)</th>
<th>FDA Estimated Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affected facility management staff</td>
<td>Oversees facility specific food safety programs, conducts food safety trainings, manages the affected facility HACCP program, manages staff that conducts monitoring and verification activities</td>
<td>$56.63</td>
<td>$48.69</td>
<td>$61.44 (qualified individual)</td>
</tr>
<tr>
<td>Corporate Quality Assurance</td>
<td>May conduct supplier risk assessments, perform supplier audits, oversee 3rd party accreditation programs, implement and review corporate quality programs (e.g., environmental monitoring)</td>
<td>$77.37</td>
<td>$66.71</td>
<td>Not estimated in PRIA</td>
</tr>
<tr>
<td>Affected facility Technician/support staff/quality coordinator</td>
<td>Performs monitoring activities</td>
<td>$24.93</td>
<td>$34.03</td>
<td>$19.91 (closest reference in PRIA was &quot;food manufacturing production worker – nonsupervisory&quot;)</td>
</tr>
</tbody>
</table>
Regardless of facility size, companies will need to actively assess and increase their number of full time employees in order to implement the preventive controls proposal as it is currently written. For example, one of our member companies operates 169 affected facilities in the United States. This company shared that it would need to add at least one additional full-time employee per facility to manage, update and maintain facility documentation to ensure compliance with the proposed preventive controls rule. The need for companies to add non-revenue generating positions and the cost of adding additional personnel are not considered by or reflected in the PRIA.

In conclusion, because the PRIA in many instances underestimates the time needed to complete various tasks and does not consider that these tasks are often performed by cross-functional food safety teams, the realistic financial impact to industry is not captured. FDA’s acceptance of GMA’s proposed regulatory language as outlined in our comments to the proposed preventive controls rule would help to bring the actual implementation cost of the rule closer to the average annualized value sited in the PRIA.

Other Considerations for Future Rulemakings and Administrative Costs

A risk-based approach to food safety regulation is one where regulatory requirements are matched to food safety outcomes. Ideally, risk-based regulations should give regulated establishments maximum flexibility to adapt the required controls to their unique situations. The modifications to the draft preventive controls rule, submitted separately by GMA, are intended to provide flexibility in the current draft regulation while requiring the implementation of provisions that will significantly enhance food safety.

GMA contends that a proper regulatory impact analysis should be based on a risk assessment to define baseline needs. This baseline analysis is needed to properly assess the overall economic impact of the proposed rule and demonstrate how the proposed rule will reduce the risks identified in the baseline analysis (mitigation assessment). To the best of our knowledge, FDA has not conducted such an assessment, which is essential to an accurate cost/benefit analysis. GMA acknowledges the Agency has indicated they used the highly detailed 2010 Nationwide Survey of Food Industry Safety Practices, Draft Final Report in order “to learn about the domestic food industry’s baseline manufacturing practices...” (PRIA page 52). This is only a compilation of practices employed by various industry sectors, which is only one component of the analysis. The missing component of a thorough risk analysis would be for the report to determine the amount of risk reduced by each portion of the regulation, which it does not.

We recommend the Agency conduct an assessment associated with packaged food products. In addition, the risk assessment needs to examine each provision of the proposed regulation, including foreshadowed provisions, i.e., testing, microbial and otherwise, and supplier verification requirements not presented in the current proposed rule, and determine the likely amount of risk reduced by each provision. Information from the baseline survey of practices and new information on types of personnel and hourly wage rates, as well as administrative costs, discussed below, should be fed into a revised cost estimate in the PRIA. In addition, the benefit analysis should be revised based on the above-mentioned risk assessment.
Aside from the added costs of implementing the preventive controls proposal, outlined in the previous pages, there are several other additional costs that, while not required by the proposal, we wanted to highlight. In particular, we would encourage FDA to consider the substantial administrative costs and other costs associated with implementing a sweeping regulation of this kind and keep in mind that these costs do not offer a measureable food safety benefit. Also, many of FDA’s cost estimates are based on facility size which is not always an accurate basis for determining costs.

- **Changes to Reference Part 117 Instead of Part 110** Currently, all quality system documentation and training materials, including HACCP plans and GMP program documents, reference Part 110 of Title 21 in the Code of Federal Regulations. Because the preventive controls proposal transitions from Part 110 to Part 117, the food industry is expected to take on the significant burden of updating all documentation and training materials to reflect this change. While not directly required by the preventive controls proposal, this update will necessarily cause affected corporations and facilities to manage this change through document control and then update of all corresponding manuals, whether electronic or paper, to reference Part 117.

- **Costs of One-Time Label Changes for Qualified Facilities** Another administrative cost associated with the preventive controls proposal is the one-time label change for qualified facilities that do not submit the required documentation to demonstrate they are implementing preventive controls. While this will not directly affect most GMA members, our members do business with many facilities that will incur these costs for making label changes. We believe it is important for FDA to understand that there are costs associated with these types of label changes and those costs need to be a factor when considering the overall costs of major rulemaking such as the preventive controls proposal.

- **Size of Manufacturing Facility Does Not Necessarily Correlate to Cost** The PRIA explains that FDA’s analysis is largely based on the size of the manufacturing facility as a determining factor for the costs of complying with the preventive controls proposal. In some instances facility size may be an accurate measure of cost. For example, large facilities with many lines and HACCP plans are likely to incur more cost to implement the preventive controls proposal than a small facility with just one line and HACCP plan. In other contexts, however, size may not be an accurate predictor of cost. For example, as food manufacturing facilities become more automated, large and complex operations may have very few employees but may have many different product categories, each with distinct HACCP plans, as well as extensive quality systems for managing the associated risks. Accordingly, we believe that facility size is not always an accurate predictor of cost.

Finally, the PRIA should assess current industry practices as represented in this document and how they align with the current proposed regulation because the Agency arrived at the assumption that major food producers with successful food safety programs will not have to change any of their food safety management systems. GMA does not agree with this statement as the proposed rule is currently written.
Break Even Analysis

In order for the preventive controls proposal to provide benefits equal to or greater than the cost of implementation, the rule would need to reduce the monetized cost of the illnesses for Option 1 by about $475 million (page 5 of PRIA). FDA assumes the average cost per illness is $2,063 and so reducing the cost of illness by $475 million would require the number of illnesses to be reduced by at least 230,000 illnesses per year, which is one quarter of the annual illnesses the Agency estimates are attributable to foods covered by preventive controls proposal using its primary methodology.

As discussed above, GMA conservatively estimates that the industry’s costs to implement the preventive controls proposal will be approximately $18.8 billion. This value is nearly 40 times greater than FDA’s breakeven number, defined as the cost reduction in domestic illnesses necessary to cover industry costs, of $475 million per year. Even if GMA’s $18.8 billion estimate were significantly discounted, the food industry would still incur implementation costs that far exceed FDA’s breakeven number and the PRIA’s $13,000 per facility estimate. Because the industry’s costs for implementing the preventive controls proposal as currently written outweighs the benefit of the rule, we encourage FDA to adopt the modifications to the draft rule outlined in GMA’s comments to the preventive controls proposal. Adoption of the industry’s modified regulatory language will ensure that the industry’s actual implementation costs are more consistent with the PRIA. The changes recommended will also ensure that the final rule is aligned with the scope defined in the statute.

Conclusion

While GMA appreciates the difficult task of quantifying the economic impact of a significant and sweeping food safety regulation such as the preventive controls proposal, GMA’s analysis indicates that the PRIA underestimates the food industry’s costs to implement the rule. In particular, our comments have challenged FDA’s estimate that the average implementation cost will be $13,000 per affected facility. GMA has shown that the actual costs will range from $364,040 to $524,960 per affected facility. When calculated for the industry as a whole, the 51,549 (reference table 1a of PRIA) affected facilities would incur upwards of $18.8 billion added cost to implement the preventive controls proposal as it is currently written. Moreover, as discussed above, these figures do not include many other substantial costs associated with implementing the preventive controls proposal such as evaluating radiological hazards as a separate category of hazard, mandatory annual onsite audits as part of supplier verification, testing and Part 11 compliance. Thus, our $18.8 billion cost of implementation is a conservative estimate.

The majority of GMA’s estimated implementation costs – nearly $18.1 billion – are directly related to the proposal’s prescriptive approach to managing preventive controls that does not adequately account for the role of horizontal prerequisite programs in ensuring food safety. As explained above and in our comments on the proposed rule, GMA expects this prescriptive approach will require many preventive controls to be subject to management elements usually reserved for CCPs in HACCP-based systems, except where FDA has noted a specific exemption. Not only does this approach substantially differ from current industry practices, if implemented, it will fail to improve food safety or provide enhanced public health benefits at enormous cost to the industry and ultimately consumers. We are deeply concerned that the PC rule, if our
comments are not taken into account, could have a detrimental impact on the effectiveness of food safety management systems.

FDA’s adoption of GMA’s proposed modifications to the draft rule would significantly reduce the industry’s implementation costs making them more consistent with the PRIA. It would also bring the final rule in line with the statutory language of FSMA while still ensuring the public health benefits expected by FSMA. GMA therefore strongly encourages the Agency to incorporate GMA’s proposed regulatory language into the final preventive controls rule.