December 15, 2014

By Electronic Submission

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 Food for Humans; Docket No. FDA-2011-N-0920; RIN 0910-AG36; 79 Fed. Reg. 58524 (Sept. 29, 2014)

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to share its views on the Food and Drug Administration’s (FDA) supplemental proposed rule on “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Humans” as required by the FDA Food Safety Modernization Act (FSMA). GMA is the voice of more than 300 leading food, beverage, and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

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 more than $1 trillion in added value to the nation's economy.

GMA supported the passage of FSMA and has adopted a comprehensive program to support its implementation. We appreciate FDA providing an opportunity for public comment on its supplemental proposed rule to implement Section 103 of FSMA. We look forward to continuing to work with the agency for successful implementation of this groundbreaking law.

Executive Summary

GMA appreciates the significant changes the agency has made in the supplemental preventive controls proposed rule to make the regulations more systems-based – that is, to include all controls within the food safety system necessary to significantly minimize or prevent food safety hazards. We also appreciate agency effort to make the regulations more risk-based and tailored by allowing
each facility to determine the appropriate level of management oversight required for each preventive control to assure food safety.

GMA also appreciates FDA taking the procedural step to publish for public comment specific proposed codified language for both testing and supplier verification requirements. We believe FDA has taken significant steps toward making both the testing and supplier verification provisions risk-based in allowing food companies the flexibility to design and tailor their own testing and supplier programs as appropriate to the nature of the food, the facility, and the risks presented. For supplier verification, we agree with FDA’s shift on the need to consider both ingredient risk and supplier risk, and the impact of that evaluation on the frequency of supplier audits and other verification activities. We also agree with FDA’s recognition that audit reports should be kept confidential in order to incentivize suppliers to permit open and transparent audits.

Thus, GMA finds that the agency and the food industry are in general agreement regarding the overall framework for the regulations: they should both set a high bar for food safety and be workable for the food industry. It also appears that GMA and FDA fundamentally agree that a hazard analysis and preventive controls system should be both systems-based and risk-based. Indeed, in the preamble to this supplemental proposed rule FDA explicitly recognizes the need for the regulations to be risk-based and able to accommodate a range of food safety needs. It is imperative that this intent be carried out in the final regulatory language. Therefore, the changes GMA recommends in the comments that follow are designed to “fine-tune” the proposed regulations, to carry out the agency’s intended flexibility as stated in the preamble, and to make sure that they improve food safety and are workable in the decades to come, long after the final rule is published.

Areas for Further Clarification and Fine-Tuning to Make the Regulations Risk-Based

GMA highlights the following recommendations to make the final regulations more risk-based.

- **“Significant Hazard”**: We strongly support FDA’s decision to remove “reasonably likely to occur” from the regulations. Though we support FDA’s proposed definition for the term, we respectfully suggest FDA use a phrase or term other than “significant hazard,” given the term’s longstanding meaning outside of FSMA. “Food safety hazard,” as used in international food standards, is one possibility for FDA to consider.

- **Risk-Based Management Components**: We strongly support FDA’s proposal to provide flexibility in the oversight and management of preventive controls. Nevertheless, changes are necessary to carry out the agency’s intent and to ensure the regulations recognize that management components depend not only on the “nature of the preventive control” itself, but also on the role of the preventive control for ensuring food safety. For example, a degree or two of fluctuation in refrigeration temperature above a designated parameter is unlikely to have a negative impact on food safety.

- **Product Testing**: The regulatory text should include the same flexibility described in the preamble that would allow each facility to design an appropriate product testing program, including scenarios in which no product testing is required because it is not a relevant or useful verification activity. We agree with FDA’s adoption and use of the term “product testing” – consistent with the statutory text – to include testing of incoming raw materials and ingredients, in-process testing, and finished product testing.
- **Environmental Monitoring:** The regulatory text should likewise include the same flexibility, as described in the preamble, to design an appropriate environmental monitoring program, including designing corrective actions as appropriate to the nature of the test organisms and location in the facility where they were found. FDA also should state clearly in the preamble to the final rule that a company will not be cited on a FDA Form 483 when its environmental monitoring programs have identified positive findings, so long as the facility takes appropriate, necessary, and timely corrective actions.

- **Supplier Verification Programs:** Supplier verification programs should be required to address suppliers based upon both ingredient and supplier risk. Factors such as which party controls the hazard(s) should affect the extent of supplier verification, but not whether an assessment to determine supplier oversight is needed.

- **Record Reviews:** Recordkeeping requirements should accommodate the creation, maintenance, and implementation of certain food safety programs, such as supplier verification, at corporate headquarters. When FDA is allowed the opportunity to review such programs at a non-facility corporate location, there should be no need to duplicate that review repeatedly during inspections at each of the corporation’s manufacturing facilities within any given FSMA-mandated inspection cycle.

- **Economically Motivated Adulteration:** The agency has proposed to require facilities to consider economically motivated adulteration (EMA) as part of the facility’s hazard analysis. GMA disagrees with this proposed requirement because EMA is not a good fit with the hazard analysis and preventive controls framework and would be best deferred until after FDA completes rulemaking on the seven major FSMA regulations. As this is a cross functional issue affecting the Foreign Supplier Verification Program and Hazard Analysis and Preventive Controls for Animal Food, GMA will address this issue in detail in a separate document posted to all three supplemental rules’ dockets.

- **Recall Plans:** Recall plans should be facility-wide, rather than product-specific. A facility can and should use the same recall process for any product being recalled. FDA should require all registered facilities to have recall plans, regardless of whether they are subject to preventive controls requirements.

These recommended changes are intended to ensure the regulations reflect the current leading practices and also to support the sustained implementation of the regulations across a broad range of products. Another basic principle underlying our recommended changes to make the regulations even more risk-based is that the regulations should encourage adoption of a food safety culture at all regulated facilities. Regulatory requirements should encourage facilities to use expert judgment and scientific and technical data to identify controls and make fact-based and risk-specific decisions about how to manage those controls that protect the public health and can be justified to FDA. In this respect, the changes GMA is recommending, if adopted, would ensure the regulatory scheme encourages facilities to adopt a culture of food safety, which goes well beyond just complying with regulations. A food safety culture is present when a facility thinks critically about and has a clear understanding of food safety needs rather than simply checks boxes. Conversely, FDA should streamline the regulations in areas where proposed requirements would not add a net food safety benefit.
Implementation
We 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 the regulatory requirements, inspectional procedures, and the types of observations that are appropriate to include on 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 C.F.R. § 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 a regulatory requirement. Inspectors should treat guidance as a safe harbor that represents one acceptable compliance approach but not the only compliant approach. The agency should take particular precautions to educate its inspectors about this limitation.

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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.
Executive Vice President Science and Regulatory Affairs & Chief Science Officer
GMA Feedback and Recommendations on Proposed Rule:
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Humans
21 CFR Part 117

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Comments on Proposed Regulatory Framework

Executive Summary

GMA appreciates the significant changes the agency has made in the supplemental preventive controls proposed rule to make the regulations more systems-based – that is, to include all controls within the food safety system necessary to significantly minimize or prevent food safety hazards. We also appreciate the agency’s efforts to make the regulations more risk-based and tailored by allowing each facility to determine what level of management oversight for each preventive control is needed for food safety.

GMA also appreciates FDA taking the procedural step to publish for public comment specific proposed codified language for both testing and supplier verification requirements. We believe FDA has taken significant steps toward making the testing and supplier verification provisions risk-based in allowing food companies the flexibility to design and tailor their own testing and supplier programs as appropriate to the nature of the food, the facility, and the risks presented. For supplier verification, we agree with FDA’s shift on the need to consider both ingredient risk and supplier risk, and the impact of that evaluation on the frequency of supplier audits and other verification activities.

Thus, GMA finds that the agency and the food industry are in general agreement regarding the overall framework for the regulations: they should both set a high bar for food safety and be workable for the food industry. It also appears that GMA and FDA fundamentally agree that a hazard analysis and preventive controls system should be both systems-based and risk-based. Indeed, in the preamble to this supplemental proposed rule FDA explicitly recognizes the need for the regulations to be risk-based and able to accommodate a range of food safety needs. It is imperative that this intent be carried out in the final regulatory language. Therefore, the changes GMA recommends in the comments that follow are designed to “fine-tune” the proposed regulations, to carry out the agency’s intended flexibility as stated in the preamble, and to make sure that they improve food safety and are workable in the decades to come, long after the final rule is published.

Areas for Further Clarification and Fine-Tuning to Make the Regulations Risk Based

GMA highlights the following recommendations to revise the regulations to make them more risk-based.

- **“Significant Hazard”:** We strongly support FDA’s decision to remove “reasonably likely to occur” from the regulations. Though we support FDA’s proposed definition for the term, we respectfully suggest FDA use a phrase or term other than “significant hazard,” given the term’s longstanding meaning outside of FSMA. “Food safety hazard,” as used in international food standards, is one possibility for FDA to consider.

- **Risk-Based Management Components:** We strongly support FDA’s proposal to provide flexibility in the oversight and management of preventive controls. Nevertheless, changes are necessary to carry out the agency’s intent and to ensure the regulations recognize that management components depend not only on the “nature of the preventive control” itself, but also on the role of the preventive control for ensuring food safety. For example, refrigeration...
only a degree or two outside a designated parameter may not have a negative impact on food safety.

- **Product Testing:** The regulatory text should include the same flexibility described in the preamble that would allow each facility to design an appropriate product testing program, including scenarios in which no product testing is required because it is not a relevant or useful verification activity. We agree with FDA’s adoption and use of the term “product testing” – consistent with the statutory text – to include testing of incoming raw materials and ingredients, in-process testing, and finished product testing.

- **Environmental Monitoring:** The regulatory text should likewise include the same flexibility, as described in the preamble, to design an appropriate environmental monitoring program, including designing corrective actions as appropriate to the nature of the test organisms and location in the facility where they were found. FDA also should state clearly in the preamble to the final rule that a company will not be cited on a FDA Form 483 when its environmental monitoring programs have identified positive findings, so long as the facility takes appropriate, necessary, and timely corrective actions.

- **Supplier Verification Programs:** Supplier verification programs should be required to address suppliers based upon both ingredient and supplier risk. Factors such as which party controls the hazard(s) should affect the extent of supplier verification, but not whether an assessment to determine supplier oversight is needed.

- **Record Reviews:** Recordkeeping requirements should accommodate the creation, maintenance, and implementation of certain food safety programs, such as supplier verification, at corporate headquarters. FDA inspections of such corporate programs should be conducted once during the FSMA mandated inspection cycle, rather than repeatedly at each of the corporation’s facilities.

- **Economically Motivated Adulteration:** The agency has proposed to require facilities to consider economically motivated adulteration (EMA) as part of the facility’s hazard analysis. GMA disagrees with this proposed requirement because EMA is not a good fit with the hazard analysis and preventive controls framework and would be best deferred until after FDA completes rulemaking on the seven major FSMA regulations. As this is a cross functional issue affecting the Foreign Supplier Verification Program and Hazard Analysis and Preventive Controls for Animal Food, GMA will address this issue in detail in a separate document posted to all three supplemental rules’ dockets.

- **Recall Plans:** Recall plans should be facility-wide, rather than product-specific. A facility can and should use the same recall process for any product being recalled. FDA should require all registered facilities to have recall plans, regardless of whether they are subject to preventive controls requirements.

These recommended changes are intended to ensure the regulations reflect the current leading practices, and also to support the sustained implementation of the regulations across a broad range of products. Another basic principle underlying our recommended changes to make the regulations even more risk-based is that the regulations should encourage adoption of a food safety culture at all regulated facilities. Regulatory requirements should encourage facilities to use expert judgment and
scientific and technical data to identify controls and make fact-based and risk-specific decisions about how to manage those controls that protect the public health and can be justified to FDA. In this respect, the changes GMA is recommending, if adopted, would ensure the regulatory scheme encourages facilities to adopt a culture of food safety, not one of simply complying with regulations. A food safety culture is present when a facility does not simply check boxes, but thinks critically about food safety needs. Conversely, FDA should streamline the regulations in areas where proposed requirements would not add a net food safety benefit.

I. Hazard Analysis Framework

In the supplemental proposed rule, FDA has proposed to eliminate the term “hazard reasonably likely to occur” from the regulations and to replace it with a new term – “significant hazard” – and a new definition. GMA strongly supports FDA’s proposal to eliminate the term “hazard reasonably likely to occur” throughout proposed Subpart C, and we also strongly agree with the definition for the new term. However, we respectfully suggest FDA use a phrase or term other than “significant hazard,” given the term’s longstanding meaning outside of FSMA. The term “food safety hazard” is one such term for FDA to consider to be more in-line with international terminology.

A. Hazard Analysis Requirements Should Avoid Using Terms that are Used in the HACCP Context

GMA strongly supports FDA’s proposal to eliminate the term “hazard reasonably likely to occur” from proposed Subpart C because, as the agency acknowledges, “it could be confusing to use the same phrase “reasonably likely to occur” in both [the Hazard Analysis and Critical Control Point] HACCP regulations and in the regulations [the agency] is proposing to establish to implement FSMA’s requirements . . . because the phrase “reasonably likely to occur” has been used as the basis for determining hazards that need to be addressed in a HACCP plan at CCPs.”


However, it also would be confusing to use the agency’s proposed term “significant hazard,” because as the agency also notes in the preamble, “[t]he term ‘significant hazard’ has sometimes been used in the context of HACCP to refer to the hazards to be addressed in a HACCP plan through CCPs.”


Thus, we recommend the agency avoid using terms that are used in the HACCP context in the proposed hazard analysis requirements.

GMA agrees with FDA’s proposed definition for “significant hazard” (though not the term itself) which would mean:

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

379 Fed. Reg. at 58,542; proposed 21 C.F.R. § 117.3.

This definition is effective in clarifying those food safety hazards that should be addressed in the food safety plan. Further, the definition is clear that hazards addressed in the food safety plan are...
based on the outcome of a hazard analysis and that controls established for these hazards must be managed as appropriate to the food, the facility, and the control. We also strongly agree that the hazard analysis should consider both the severity and the probability of the potential hazards.

Nonetheless, as a practical matter, the term “significant hazard” itself could be confusing to food manufacturers who are familiar with the term’s use and meaning in the HACCP context and, in fact, may currently use the term and its HACCP meaning in their existing food safety plans as a gateway to CCPs. For example, facilities that are familiar with the term “significant hazard” as used in the National Advisory Committee on Microbiological Criteria for Foods HACCP guidance\(^4\) are likely to be confused by FDA’s proposed use of the term. Likewise, facilities that are subject to both FDA and USDA jurisdiction will face challenges implementing FDA’s proposed requirements for their FDA regulated products because USDA uses the term “significant hazard” in its HACCP guidance documents\(^5\) in a manner different from FDA’s proposal under FSMA. The same can be said for facilities that ultimately will operate under Part 117 and FDA’s juice and/or seafood HACCP regulations (Parts 120 and 123). Even facilities not familiar with the term’s use in HACCP may nonetheless focus on the word “significant” and address a far narrower set of hazards within their food safety plans than FDA intends.

Rather than use an existing term with a historically different meaning and wide use in existing HACCP regulations, GMA recommends that FDA eliminate use of a term altogether. In our view, the definition cited above that is used to frame the hazard analysis is sufficiently clear; a succinct term like “significant hazard” is not necessary. GMA respectfully suggests that the regulations state the hazard analysis must determine whether there are “hazards for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.”\(^6\) We have included this and other suggested revisions to the regulations in Appendix 1.

Alternatively, if the agency concludes that a term is necessary, we suggest the term “food safety hazard.” This term clearly conveys that the hazard analysis determines those hazards that should be addressed through preventive controls in the food safety plan. “Food safety hazard” also conveys the inclusive nature of the regulatory scheme – that is, the various hazards and preventive controls that can be employed to address them within the food safety plan – while at the same making clear that preventive controls are those needed for food safety. “Food safety hazard” also is a term used in ISO 22000,\(^7\) which would help harmonize FDA’s requirements with international standards. Regardless of the specific term chosen, we recommend that if a term is needed, FDA use a new term that is not used elsewhere in food safety regulatory documents as being linked closely with CCPs and which expresses the broad scope of a food safety plan.

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\(^6\) Alternatively, GMA recommends FDA consider the language we suggested in our comments to the original proposed rule, which would state that the hazard analysis must determine “whether there are 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.”

\(^7\) In section 3.3, ISO 22000:2005(E) defines a food safety hazard as a “biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect.”
II. Preventive Control Management Components

In the preamble to the supplemental proposed rule, FDA recognizes the need for the regulations to be risk-based and able to accommodate a range of food safety needs. GMA strongly endorses this risk-based approach, and we believe it is imperative to make sure this intent is carried out in the final regulatory language. Therefore, additional changes to the regulations are necessary to ensure that the level of management oversight applied is commensurate with the nature of the risk and the type of control being used. Under FSMA, preventive controls must be risk-based and therefore must be managed differently depending on the specific circumstances; to make this possible, the regulations must expressly provide for such tailored management.

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

In the preamble to the supplemental proposed rule, FDA acknowledges some of the concerns expressed by GMA and others in the food industry in response to the original proposed rule. Namely, FDA’s original proposed requirements did not sufficiently emphasize the risk-based nature of each component of the overall framework for hazard analysis and preventive controls, including monitoring, corrective action procedures, and verification activities. In response to these concerns, FDA notes that although the 2013 proposed rule would not have limited a facility’s ability to develop and implement a risk-based food safety system, specific changes to the regulatory text could help clarify the risk-based nature of all provisions in Subpart C.

To that end, the agency has proposed several revisions to make clear that the preventive control management components (i.e., monitoring, corrective actions, and verification) depend on the nature of the control. As detailed in attached Appendix 1, GMA supports these changes. In the preamble, FDA also has provided several examples, set forth in Table 6, of the flexibility that a facility would have complying with requirements that would be established in Subpart C. The agency provides examples of:

- Controls that would not be a CCP;
- Monitoring activities that would not require monitoring records;
- Corrections that would not require records;
- Preventive controls that would not require validation; and
- Corrective actions that would not require verification.

We support these examples and agree with the agency’s intent that the management components of preventive controls be risk-based.

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

As FDA recognizes in the preamble, 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 what level of management oversight is needed to accomplish the food safety goal of significantly minimizing and preventing hazards. Therefore, to carry through FDA’s intent in the preamble, changes are needed to the proposed regulatory language to make

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clear that facilities must manage individual preventive controls commensurate with the nature of the control and its role in the food safety system.

In general, to allow facilities to address a wide range of food safety needs, GMA asserts that the regulations for management components should convey not only that the application of a particular element be appropriate (i.e., 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). Therefore, we strongly support the addition of proposed section 117.140, which states that preventive controls “are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control.” Other similar changes are needed, however, to ensure the regulations addressing each individual management component reflect this risk-based approach. These are discussed in more detail below and in Appendix I. Examples of management elements and verification activities applicable to various preventive controls from our 2013 comments to the original proposed rule are included in Appendix II.

1. Parameters Are Not Necessary for All Process Controls to Significantly Minimize or Prevent Hazards

The proposed regulations state that process controls “must include as appropriate to the applicable control . . . parameters associated with the control of the hazard; and, [t]he maximum or minimum value, or combination of values, to which any . . . parameter must be controlled to significantly minimize or prevent a significant hazard.” We appreciate FDA’s decision to tie parameters to process controls and not to all controls, as there are many controls for which parameters would not be possible (e.g., allergen storage). Nonetheless, the regulation remains overly prescriptive because of the emphasis created by the term “must,” and the fact that “as appropriate to the applicable control” could be understood to mean “if possible” or “if feasible,” 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 process control or the specific food safety need.

Assigning a parameter and associated minimum and maximum values may be possible 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 for a product such as a dry spice blend that 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. As another example, the conditions of many baking processes to achieve a finished product 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.

Further, the regulations should account for the different roles that parameter values can play in the food safety system. GMA urges the agency to avoid an interpretation that a facility has failed to significantly minimize or prevent (SMOP) a hazard, a legal requirement, solely because a parameter

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9 Proposed 21 C.F.R. § 117.140(a).
10 Proposed § 117.135(c)(1) (emphasis added).
is outside of specified minimum or maximum values. Rather, when a parameter’s value is outside of the specified max/min values, the impact on food safety needs to be assessed, consistent with the role of the process control in the overall food safety system. This evaluation is necessary to determine if hazards have been significantly minimized or prevented, and it is the resultant food safety risk (or not) that should ultimately be determinative.

For example, if the non-compliance to a parameter min/max is at a CCP, the non-compliance has most likely created a clear food safety issue. In contrast, for some process controls, such as refrigerated storage, further evaluation may be needed to assess the consequences of non-compliance. The fact that a food has been held one degree outside of its maximum value does not necessarily mean that the food is adulterated. There also are instances where a variety of parameters may work collectively to SMOP a hazard and non-compliance to any one parameter will not necessarily result in unsafe product. A formulation used to SMOP the biological hazard of vegetative pathogens, for example, could utilize a combination of moisture, pH, titratable acidity, and salt level. It is the combination of these factors working in conjunction with each other that will SMOP the hazard. If one of the parameters is out of the specification limit, it would require analysis and review, but the product could still be safe due to antimicrobial contributions of the other factors. Consequently, it may not be plausible to list one set of minimum and maximum parameters for food safety.

Consistent with FDA’s stated intent in the preamble and with the flexibility provided in proposed section 117.140, GMA recommends that FDA revise the requirements regarding parameters to make clear that parameters should be tailored “as appropriate to the nature of the applicable control and its role in the food safety system.”

2. Not all Monitoring Activities Need to be Documented

GMA appreciates FDA’s recognition in the preamble to the supplemental proposal that some monitoring activities may not require records (such as monitoring for foreign material with x-rays). We agree that some oversight activities may not be documented at all, may only be documented in the case of exceptions, or may not be amenable to written records. For example, a facility may have continuous monitoring of cold storage through an automated control system that sounds an alarm if room temperature specifications are exceeded, but records of monitoring are generated only if the temperature exceeds a pre-set maximum value (i.e., when an alarm is sounded). Therefore, there would only be monitoring records for the exceptions.

Nonetheless, the necessary flexibility FDA intends to provide is not sufficiently clear in the regulatory text that states “All monitoring of preventive controls in accordance with this section must be documented . . . .” To provide consistency between FDA’s stated intent and the regulations, GMA recommends FDA revise the regulatory text to make clear that not all monitoring activities must be documented.

3. It is Not Necessary to Validate Each Preventive Control in a Food Safety System

Although the preamble states that not all preventive controls require validation, the proposed regulation states that, unless a specific exemption applies, all preventive controls must be validated: “[e]xcept as provided by paragraph (b)(3) of this section you must validate that the preventive
controls...are adequate...as appropriate to the nature of the preventive control." Paragraph (b)(3) provides exemptions only for allergen controls, sanitation controls, the supplier program, and recall plans. And although the regulation includes the phrase "as appropriate to the nature of the preventive control," this could be interpreted to mean that only the validation act itself can be tailored and that the facility does not have the flexibility to conclude that validation isn’t necessary. Yet, in the preamble, FDA is clear that preventive controls such as zoning, refrigerated storage, and preventive maintenance do not require validation. Thus, the proposed regulation’s prescriptive approach is inconsistent with the agency’s stated intent.

Further, not only could the regulation 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 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 for the specific hazard.

Therefore, in Appendix 1, GMA proposes an amendment to proposed section 117.160 to make clear that not all preventive controls need to be validated. GMA provides suggested factors for the regulation to help facilities determine which controls need to be validated, consistent for the justifications provided for the specific exemptions FDA has outlined.

4. Corrections Are Not Limited to Sanitation and Food Allergen Controls

GMA appreciates FDA’s recognition that that not all actions to address issues in the manufacturing environment require the formal procedures and documentation contemplated for “corrective actions,” and that FDA has proposed the term “corrections” to address these situations. Nonetheless, the concept of “corrections” is not limited to sanitation and allergen cross-contact controls. Further, the term “corrections” could be confusing in the regulations, given the term’s established meaning and use in ISO 22000.

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). As we discussed in our original comments, if an employee who should not be in a high hygiene zone used to reduce the risk of microbial cross-contamination (a GMP) mistakenly enters it, for example, the employee is asked to leave immediately. This is a correction, not a corrective action. Therefore, the concept of corrections should be expanded to include controls in addition to sanitation and allergen cross-contact controls.

In addition, because the term “corrections” is used in ISO 22000 and has a well-established meaning in many food facilities here and internationally, GMA recommends that FDA eliminate the term from the regulations. Instead, GMA recommends that the regulation be revised to clarify those types of actions that are exempted from the requirements applicable to corrective actions. In accordance with both of our recommendations, GMA suggests that section 117.150(c) be revised to state:

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11 Proposed § 117.160(a) (emphasis added).
12 ISO 22000:2005 Definition of “correction:” Action to eliminate a detected nonconformity. A correction relates to the handling of potentially unsafe products, and can therefore be made in conjunction with a corrective action. A correction may be, for example, reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labeling).
13 As used in ISO, corrections apply to process controls. In the context proposed by FDA, they do not.
“Prompt actions to address isolated deviations that do not directly impact product safety. You do not need to comply with the requirements of paragraphs (a) and (b) of this section for prompt actions taken to address minor and isolated conditions and practices that are not consistent with, for example, food allergen controls designed to protect food from allergen cross-contact, sanitation controls, preventive maintenance controls, or other controls as appropriate.” These changes would make the regulations clearer.

C. Risk-Based, Flexible Requirements Improve Food Safety

Based on FDA’s statements in the preamble to the supplemental proposed rule, GMA understands FDA to support a risk-based approach to the management of preventive controls and that the changes GMA is proposing would merely carry through the agency's intent into the regulatory text. Nonetheless, GMA believes it is important to have the record show that this is the right approach for food safety. First, the need for a variety of management approaches makes sense when you consider the diversity of preventive controls within the food safety system. By their very nature, not all controls can be managed the same way. Second, a risk-based approach allows facilities to focus their resources where they are needed for food safety. Third, because it requires critical thinking, a risk-based approach promotes a culture of food safety.

The FSMA framework and FDA’s supplemental proposed rule are systems-based. Both address all controls within the food safety system necessary to produce safe food and significantly minimize or prevent food safety hazards, as judged by qualified food safety experts. This includes controls at critical control points and those controls not at critical control points. It also includes controls that could range from pasteurization to pest control, from formulation to foreign material management, from employee training to allergen change over procedures, and many more. All controls as determined through the hazard analysis should be part of the facility’s food safety system. Consequently, they are subject to some level of management oversight by both the facility and FDA. Yet, given the diversity of preventive controls within the food safety system, the need for a variety of management approaches is readily apparent. For example, many sanitation measures are validated, but zoning programs are not. All controls within the system cannot be managed the same way. Thus, a systems-based food safety framework necessitates a risk-based framework. Systems-based and risk-based are two sides of the same coin.

Further, risk-based regulatory requirements allow facilities to focus their resources where they are needed for food safety. In contrast, regulatory requirements that are not necessary for food safety divert the focus away from measures that are proven effective for ensuring food safety. Under a one-size-fits-all framework where everything is important, nothing is. A risk-based approach to managing controls is, therefore, essential, because we know there are some hazards that are of greater severity and probability than others and thus deserve more attention in the food safety system.

Finally, a risk-based approach to the management of controls promotes a culture of food safety. A food safety culture is present when a concern for food safety exists throughout the work in a facility, employees are continuously aware of potential hazards, and employees are responsive to changes within the facility and their potential impact on food safety. Rather than manage each control using a pre-determined checklist of management elements, under a risk-based approach facilities must proactively assess food safety needs and make risk-based decisions that protect the public health. Additionally, facilities must be able to justify the management strategies they have chosen and
answer questions FDA may have. Thus, a risk-based regulatory scheme encourages facilities to think critically about food safety needs, and not simply check boxes.

III. Recall 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 should be required for all registered facilities, not just those subject to preventive controls. As discussed in III.C below, FDA has the legal authority to move recall plan requirements to Subpart B, GMPs.

A. Recall Plans Should be Facility-Wide

Recall plans are facility-wide programs. 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 are often administered corporately as well. Recall plans are a crisis management tool and are used after an adulterated or noncompliant product is released into the marketplace. In contrast, the food safety plan’s goal is to prevent a potentially-adulterated or misbranded 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 that is managed through the supply/distribution chain.

It would be unnecessary and confusing for each facility to have a separate recall plan for each food. Accordingly, FDA’s regulations should require each facility to have a recall plan, but should not require a plan “for each food.” Similarly, the regulatory requirement to have a recall plan should not be limited to foods with “significant hazards.” Although the scope of “significant hazard” is broad, any product can be subject to a recall. Therefore, all facilities should have recall plans.

B. All Registered Facilities Should Be Required to Have a Recall Plan

FSMA requires all food processors to be responsible for recalling their goods when the public health might be threatened. However, the requirement for a recall plan is in proposed Subpart C and certain firms are exempt from these provisions. Therefore, registered firms such as very small businesses, facilities with juice and seafood products, and warehouses, would not be required to maintain recall plans. If the requirement for a recall plan is part of the GMPs, these same firms would be required to have a recall plan. Ensuring that all facilities can conduct effective recalls is a better outcome for the public health.

C. FDA Has the Legal Authority to Require Recall Plans Outside of Preventive Controls

FDA has the legal authority to move the requirement for recall plans to the GMP regulations. We recognize that FSMA identifies recall plans as an example of a preventive control and agree with FDA that because recall plans cannot be treated as a control, they should be exempt from the management components associated with preventive controls (monitoring, corrective actions, verification, and validation). FDA’s authority to require recall plans, however, is not limited to Section 418 of the Federal, Food, Drug and Cosmetic Act (FFDCA).
GMA asserts that FDA has the legal authority to require recall plans (and to impose a requirement for recall plans in Subpart B – the GMPs – of Part 117). When FDA issued guidelines for product recalls in 1978, the agency relied upon Section 701(a) of the FFDCA, which authorizes regulations for the efficient enforcement of act, and Sections 301, 351, and 361 of the Public Health Service Act (PHSA). In particular, Section 361 of the PHSA authorizes the agency to make and enforce regulations “necessary to prevent the introduction, transmission, or spread of communicable diseases.” In that rulemaking, FDA stated:

FDA does have the authority under both the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to prescribe mandatory procedures and requirements that among other things, facilitate the conduct of recalls. The agency is not fully exercising this authority in this document in that the provisions set forth are merely guidelines rather than mandatory requirements. The agency has the authority to prescribe mandatory procedures and requirements concerning the conduct of recall because such procedures and requirements prevent the introduction into commercial channels, or facilitate the removal from commercial channels, of adulterated, misbranded, or otherwise violative food. . . .

Therefore, FDA has the legal authority to make the current recommendation in 21 C.F.R. § 7.59 that firms prepare and maintain a recall plan a mandatory requirement.

Further, FDA has the authority to require recall plans as part of the GMP regulations. When issuing the current GMP requirements, FDA relied on several statutory provisions including Sections 402(a), which sets forth the adulteration standards, as well as Section 701(a) of the FFDCA and Section 361 of the PHSA. The same statutory provisions that provide FDA with the authority to require recall plans provide the agency with the authority to require GMPs and thus extend the scope of those GMP requirements to cover recall plans.

Finally, we note that FSMA specifically amended the FFDCA to provide FDA with the authority to mandate a food recall. Prior to issuing an order to a firm to cease distribution and recall a product, the agency must provide the firm with an opportunity to voluntarily recall the product. It would be reasonable for FDA to conclude that in order to efficiently carry out this provision the agency should issue requirements governing the conduct of recalls (e.g., having a strategy for each recall, notifying customers of the recall, and having a current written plan affecting recalls).

IV. Testing

GMA appreciates FDA taking the important step to publish proposed codified language for both product testing and environmental monitoring in the supplemental proposed rule, as neither was included in the original proposed rule. In general, GMA agrees with the approach FDA has taken, which is to provide facilities with flexibility to design their own product testing and environmental

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15 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, 44 Fed. Reg. 33,238, 33,239 (June 8, 1979).
16 FSMA § 206; FFDCA § 423.
17 FFDCA § 423(a). In National Confectioners Association v. Califano, the court stated “we believe that the voluntary nature of recalls does not foreclose their regulation.” 569 F.2d 690, 694 (D.C. Cir. 1978).
monitoring programs, as verification activities, and as appropriate to the nature of the food, the facility, and the nature of the preventive control(s) being verified.

We refer back to our original comments at the initial proposed rule stage to provide added detail supporting the basis of our comments, without repeating that detail here.

GMA also looks forward to collaborating with FDA on the development of applicable guidance documents that may be needed to further expand on leading industry practices in this area.

A. Specific Areas of Support

GMA supports the following points from the supplemental proposal with respect to product testing and environmental monitoring:

- The proposed definition of "product testing" as including raw material and ingredient testing, in-process testing, and finished product testing.

- FDA’s acknowledgement that there are limitations to product testing and that the implementation of any such programs needs to be appropriate to the facility, the food, and the nature of the preventive control(s) being verified. As explained in our comments on the original proposed rule, finished product testing is of limited utility for products and processes that are under control, but may be relevant where information from verification activities raises concerns about the hygienic status of a processing line or ingredient. In most cases, finished product testing is not a reliable or resource-effective tool and other verification activities are more appropriate to verify the effectiveness of control measures.

- The proposed clarification of the definition of “environmental pathogen” by linking contamination of the food from the environment with the potential of the food to cause human illness. We also agree with FDA that not all pathogens are environmental pathogens. For example, \textit{C. botulinum} spores in the environment, as FDA noted, generally do not pose a risk to human health.

- The proposed definition of “pathogen” to mean “microorganism of public health concern” and the use of “pathogen” throughout the regulation.

- The proposal to allow facilities to design the timing, location, and frequency of environmental monitoring programs in a risk-based manner, and in not prescribing specific locations or sample quantities for testing (e.g., product contact surfaces (PCS) or “zone 1”). Per our earlier comments, routine testing of PCS for the presence of environmental pathogens, as part of an environmental monitoring program, is not preventive in nature nor the best approach for routine sampling, as it is unlikely to detect incidental contamination.\textsuperscript{18} Resources are best focused on areas of the environment at risk of ingress or harborage to prevent pathogens from reaching PCS. We also support the flexibility provided to use indicator organisms in testing programs as appropriate.

\textsuperscript{18} See pages 10-11 and 23-24 of 56 of our November 15, 2013, comments.
• Providing that corrective actions arising from positive environmental testing findings (i.e., detection of a pathogen or presence of an indicator above a certain threshold) need to be tailored "as appropriate to the preventive control" being verified.

We also agree that environmental monitoring should be required to verify effectiveness of preventive controls when Ready-to-Eat (RTE) products are exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. Our support is predicated on our understanding that "treatment" in this context applies not only to heat treatments (i.e., kill steps), but also to compositional properties that would inactivate pathogens (e.g., flavors in alcohol, antimicrobials). We ask FDA to confirm that understanding.

B. Recommendations for Fine-Tuning in the Final Rule

GMA recommends some fine-tuning changes to the text of the final rule to ensure that the codified language fully reflects the flexibility articulated by FDA in the preamble to the supplemental proposal.

1. Conforming codified language to explanatory statements in preamble to the supplemental proposal

We strongly agree with FDA's statements in the preamble to the supplemental proposal that the agency intends to afford "flexibility for a facility to make risk-based decisions on when product testing would be appropriate by providing that the facility can take into account the facility, the food, and the nature of the preventive control."19 We understand this to mean there are circumstances when product testing, particularly finished product testing, would not be necessary or relevant in routine sampling programs—such as for pasteurized milk when a validated pasteurization process has been properly implemented and the hygienic status of the post-process environment is under control.

Nevertheless, the text of the proposed codified language is ambiguous and by use of the word “must” in proposed section 117.165(a)(2) (i.e., “To do so you must conduct activities that include . . . product testing”) could be interpreted to mean that product testing in some form is always required. We believe it is essential that FDA modify the codified language to clearly reflect the flexibility articulated in the preamble. This could be accomplished by rewording the sentence in either of the following ways:

• “To do so you must evaluate the need to conduct activities that include the following, if as appropriate . . . “; or

• “To do so you must conduct activities that include the following, if and when as appropriate and necessary . . .”

These changes would result in codified language that reflects FDA’s explanatory statements in the preamble.

In addition to product testing, environmental monitoring is also listed in the proposed codified language as a verification activity, and the same type of changes should be made to the codified language so that it reflects the agency’s statements recognizing the flexibility to design a risk-based

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environmental monitoring program. By making the changes suggested above, FDA would also clarify that facilities have the flexibility to make risk-based decisions regarding environmental monitoring results.

We also request conforming changes to the provision (section 117.165(a)(4)) for a qualified individual to review the completeness of testing records (both product testing and environmental monitoring) by striking references to “product testing” and “environmental monitoring” records and replacing them with “verification testing (e.g., product testing and/or environmental monitoring as applicable), . . . .” This is because the qualified individual cannot be expected to ensure the completeness of records that do not, and are not required to, exist.

2. Definition of "scientifically valid" testing procedures.

We also request modification of the provision in section 117.165(b)(2)(i) and (3)(i) that product testing and environmental monitoring procedures need to be “scientifically valid." Although we agree with the principle, we are concerned that the word “valid" could be construed to mean “validated" and not all testing protocols can be validated within the traditional meaning of the term. For example, some elements of environmental monitoring programs, such as target microorganisms, are developed based on data and scientific information, such as the associated risk of similar products that have been implicated in food borne illness outbreaks, and would fall within the traditional meaning of the term “validated." Other elements, such as sampling sites, are selected based on historical knowledge of the product, the facility, and the manufacturing process. GMA recommends that FDA expand its definition of “scientifically valid" in this context to include these additional considerations beyond the traditional use of the term “validated." We believe what FDA intends is for these testing programs to be technically sound.

3. Proportionality of corrective actions

Proposed section 117.150 would direct registered facilities to establish, in advance, corrective action procedures to address the following situations: (A) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with section 117.165(a)(2); and (B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with section 117.165(a)(3).

GMA agrees that facilities should take corrective actions in response to certain testing results and that it is useful to have established procedures to address those results. Corrective actions, however, are not limited to testing programs. GMA is concerned that by specifically requiring corrective action procedures in response to testing results, some facilities may not understand the need take corrective actions in other circumstances, in response to other non-conformances, or for other types of verification activities. It would be better for food safety if the regulatory requirements took a more principled approach and generally required corrective action procedures. FDA could address the importance of corrective action procedures as part of testing programs through guidance.

If FDA concludes that specific requirements for corrective action procedures in response to testing are necessary, it is important for FDA to clarify in the final rule that the nature and extent of any corrective actions should be proportional to the nature of the test findings. For example, some
organisms (both pathogens and indicators) have threshold levels that need to be taken into account when assessing potential concern for human health. There are some pathogens that are only of concern to human health if they are present in food at high levels and/or their toxin is consumed. Examples of these pathogens include *Staphylococcus aureus*, *Clostridium perfringens* and *Bacillus cereus*.²⁰

In addition, information regarding the sample location that yielded environmental monitoring results would play a significant role in determining what follow-up actions, if any, are needed. The key concept here is proportionality. Corrective actions, if any, need to take into account the nature of the hazard (i.e., particular testing results, including the type of organism, the sample location, and the levels found) and the nature of the control measure(s) being verified. For example, areas distant from the food contact surfaces and outside the manufacturing area can be sampled and tested to gather information regarding prevalence and the potential impact on product manufacturing areas (e.g., raw product areas could be tested for surveillance purposes). Also, the finding of an indicator may lead to a correction instead of corrective action (e.g., an isolated finding of high indicator levels in the drain in a zone 4 area.) Further, it is crucial that the regulations and FDA’s enforcement of them account for the fact that strong environmental monitoring programs incorporate a “seek and destroy” approach and are incentivized to find and address issues. Should FDA conclude that specific requirements for corrective action procedures in response to testing results are necessary, GMA recommends that FDA modify the text in proposed section 117.150 to be clear that corrective actions are to be proportionate to the nature of the test findings and the nature of the control(s) being verified. Specific language is offered in Appendix I.

V. Supplier Verification Programs

GMA contends that a supplier program is a vital component of an effective overall food safety system. We appreciate that FDA has issued a supplemental proposed rule for Preventive Controls that includes proposed supplier verification program requirements. We also appreciate the significant revisions made by the agency, to the requirements for the Foreign Supplier Verification Program (FSVP) as many of the requirements in §117.136 are very similar to those for FSVP. The original proposed rule did not contain these provisions, and we are pleased to see that the supplemental proposal appears to be risk-based and flexible. Nevertheless, the proposed rule still requires several additional changes in order to be workable and to better align with the existing practices of food companies with a long record of producing safe food. It is crucial however, that FDA recognizes that supplier verification is a verification activity and not a preventive control.

Under the FSVP proposal, a facility is deemed in compliance with the FSVP requirements if it is also in compliance with the supplier verification requirements in the preventive controls rule §117.136. GMA agrees with this approach, as it avoids imposing redundant regulatory requirements on importers who are also receiving facilities subject to the preventive controls requirements.

²⁰ The FDA Bad Bug Book (2nd Edition, 2012) outlines the infectious dose for these organisms, which exceeds $10^5$ colony forming units per gram (CFU/g) (leading to toxin formulation for *S. aureus*, $10^6$ cells or spores per gram for *C. perfringens* and $10^4$ CFU/g (toxin formation) for *B. cereus*. See [http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf](http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf).

In some cases it may be acceptable to have a microbiological criterion for these organisms that is a CFU/g. For example, Australian and New Zealand Food Standards recognize that <100 CFU/g is a “satisfactory” result for all three of these organisms in RTE foods. See [http://www.foodstandards.gov.au/publications/documents/Guidelines%20for%20Micro%20exam.pdf](http://www.foodstandards.gov.au/publications/documents/Guidelines%20for%20Micro%20exam.pdf). Other countries also have permissible levels for all or some of these organisms. Furthermore, in some circumstances *S. aureus* testing is used to indicate hygiene, and not food safety (for example, in a food that does not support its growth).
A. Areas of Agreement with Supplemental Proposed Rule

GMA strongly supports a number of the provisions in the supplemental proposed rules that are designed to provide needed flexibility to make the rules more practical and more effective in preventing food safety issues:

- **Confidentiality of Audit Reports.** GMA agrees with FDA that receiving facilities need not provide the full audit report to the agency, and need only provide documentation that demonstrates the audit was conducted and that significant deficiencies were addressed through corrective actions. Confidentiality of audit reports promotes food safety by encouraging suppliers to be open and honest about their facilities and records so that any issues can be identified and corrected and it encourages auditors to be robust in their efforts.

- **Flexibility to Determine Appropriate Supplier Verification Activity and Frequency.** We strongly support FDA’s proposal to provide flexibility for receiving facilities to determine the appropriate supplier verification activities and the frequency with which the activities must be conducted, based on the risk evaluation for the food and supplier (i.e., “Option 2” under the original proposal), for hazards that do not present a risk of serious adverse health consequences or death to humans or animals (SAHCODHA). As explained in our initial comments, receiving facilities need flexibility to determine the appropriate verification activities based on their assessment of both food and supplier risk. Option 2, as applied to non-SACODHA hazards, appropriately recognizes that making a determination of the appropriate verification activities to apply is the role of qualified individuals, who have knowledge of their ingredients and product applications and therefore are in the best position to design effective food safety programs.

- **Flexibility to Take a Different Approach if Appropriate for SAHCODHA Hazards.** GMA agrees with FDA’s proposal that a receiving facility should be able to document its determination that a verification activity other than annual onsite audits is appropriate for a supplier with a SAHCODHA hazard. Overall, this approach to supplier verification has a greater likelihood of delivering safe food in a cost-effective manner.

- **No Mandatory Written List of Suppliers.** GMA agrees that instead of maintaining a written list of suppliers, receiving facilities should be required to establish and follow procedures to ensure that they use only approved suppliers (or, when necessary and appropriate, unapproved suppliers on a temporary basis). Given the logistical challenges of maintaining a list of suppliers when the list of approved suppliers is constantly changing, many of our members do not maintain a single supplier list but instead have corporate-wide systems in place to confirm ingredients are received only from approved suppliers.

- **Deemed Compliance.** Under the FSVP proposal, a facility is deemed in compliance with the FSVP requirements if it is also in compliance with the supplier verification requirements in the preventive controls rule. GMA agrees with this approach, as it avoids imposing redundant regulatory requirements on importers who are also receiving facilities subject to the preventive controls requirements.

B. Areas Where Revisions are Needed to Make the Regulations More Flexible

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21 As explained in our comments dated January 27, 2014, a significant deficiency would be one that triggers a Reportable Food Registry report. See p. 37 of 67.
GMA appreciates that the supplemental proposals provide receiving facilities with ability to select the appropriate verification activities and the frequency of those activities for each facility. We are concerned, however, that other aspects of the regulations remain overly prescriptive. Greater flexibility within the regulatory requirements is needed to accommodate different approaches to supplier verification that can all result in safer food.

In particular, greater flexibility is needed to accommodate current leading practices that result in successful programs. As we commented to the original proposed rule, the Agency’s regulation of supplier verification should not establish a new paradigm, but rather should account for current successful industry-developed practices.

Further, greater flexibility is needed to account for the diversity and complexity of the food supply chain. There are many different kinds of ingredients and food materials that are procured, and there is a diverse range of end uses for those ingredients and food materials. There are also many different types of suppliers and different relationships between customers and suppliers. In addition, large companies procure thousands of food materials from thousands of suppliers from locations both domestic and foreign. Codified requirements for supplier verification programs need to be flexible enough to address these complex and diverse situations and allow companies to tailor their supplier verification activities to the particular circumstances at hand. At the same time, the regulations should not be overly burdensome with respect to documentation for each scenario. This would not advance the public health, yet would add consume considerable resources.

1. Supplier Verification Should be Broader Than Simply Verifying Control of Discrete Hazards

The supplemental proposed rules continue to suggest that the primary purpose of supplier verification is to verify the supplier’s control of a particular hazard (see proposed 117.136(a)(3)(ii) and (a)(4)). Rather than focusing on this one element, companies typically look at the supplier’s system as a whole to ensure it is producing a safe product. FDA’s enforcement of supplier verification programs should account for this practice.

In our members’ experience, verification programs often focus on the supplier’s overall food safety system, rather than focus only on a supplier’s control of ingredient-specific hazards. The latter approach could overlook significant aspects of a supplier’s program that could have an important impact on food safety. For example, receiving facilities may assess compliance with prerequisite programs like GMPs and sanitation, which are foundational to enable a company to make safe food, as well as a supplier’s food safety culture, knowledge, and their management’s commitment to continuously improving their program. If supplier verification only considers whether the supplier appropriately applies its CCPs, it may overlook basic deficiencies for essential foundational programs. As a result, supplier verification activities are often systems-based, and not solely hazard-based.

Revisions to the codified language are not necessary to address this issue, but we request that FDA recognize the documentation for supplier verification may not reflect a specific confirmation that the company has “verified that supplier is controlling for X hazard.” Further, we ask FDA to recognize that the records may not show an itemized listing of each hazard and a corresponding verification activity for each supplier. Rather, documentation may reflect a holistic look at the supplier and their overall food safety system.
2. **Supplier Verification Programs are Often Established and Implemented at a Corporate Level**

For companies with multiple facilities, supplier verification programs are often established, implemented, maintained, and reviewed at the corporate level, rather than at each individual receiving facility. Similarly, not all contract manufacturing facilities establish their own supplier verification programs; instead, their supplier verification programs may be established and managed by their customer (the brand name company). This affects FDA’s recordkeeping requirements, but also FDA inspections of supplier verification programs. For example, the knowledgeable individuals who developed and implement the program, as well as the relevant records, may reside at corporate headquarters rather than at the facility. We discuss these issues further in part VI of these comments. We ask that FDA recognize the often corporate nature of supplier verification programs in the final rule, and conduct inspections accordingly. In addition, however, a change to the regulations is needed to appropriately recognize that an individual facility may not always create the supplier verification program and that it may instead be established by corporate headquarters.

3. **Intra-Company Shipments Should be Exempt from Supplier Verification**

GMA continues to recommend that FDA should provide a complete exemption from supplier verification for intra-company shipments. Although we support the flexibility in the proposed rule, which provides that performance history and “other factors” are to be considered in determining the verification activity, this is not the same as a complete exemption based on intra-company status.

As explained in our previous comments on the original preventive controls for human food proposed rule and FSVP proposed rule, we strongly recommend that FDA exempt intra-company shipments (i.e., shipments between two business units owned by the same corporate parent) from supplier verification, as any ingredients or materials will already have been verified by another division of the receiving company. It would be duplicative and not benefit public health to require a company to verify itself. This applies to both international shipments (e.g., importation from a foreign affiliate) as well as domestic shipments (e.g., from a domestic affiliate). FSVP is intended to establish a mechanism for companies to have additional insight to their suppliers to ensure safe food enters the country. Supplier verification considers risks presented by the supplier and the food. Companies already have full insight about the foods they make themselves as well as their own history in supplying the food/ingredients within the company.

4. **The Regulations Should Outline the Factors to be Considered When Approving a Supplier, Rather than the Factors that Must be Considered to Select the Appropriate Verification Tool**

The supplemental proposed rule sets forth the specific factors the importer or receiving facility must consider when selecting verification activities, which include both ingredient risk factors as well as supplier risk factors (proposed 117.136(b)). GMA supports a requirement to consider both ingredient risk and supplier risk, as this is a key element of a successful supplier verification program. We appreciate FDA’s inclusion of supplier risk as a factor to consider. In practice, however, not all of the factors enumerated in the proposed regulation may be reviewed for each supplier or for each ingredient as part of the analysis to determine or select the appropriate verification activity. Several
of these factors may be considered later in the process as part of the decision to approve the supplier or revisit the verification activities selected.

In determining the verification activities, companies typically focus on the hazard, how it is controlled, who is controlling it, and other factors, as appropriate to the particular supplier (i.e., the factors specified in Sections 117.136(b)(1)(2), and (3)), and 117.136(b)(4) and (5)). Compliance status and performance history may not be considered in determining the verification activity to conduct, but may be considered at other points in the supplier verification process before ultimately deciding whether to approve a particular supplier. For example, companies typically would not review a supplier’s compliance with FDA regulations as an initial screening activity to determine the verification activity; rather, the supplier’s compliance may be considered later as part of the actual verification and qualification of the supplier (e.g., when conducting the audit or when reviewing their food safety plan records). We therefore request more flexibility with respect to the utilization of the specified factors (i.e., as part of determining the verification activities or as part of determining whether to approve the supplier).

Therefore, GMA recommends the regulations provide more flexibility as to which factors are to be considered as part of the risk evaluation and when they must be considered. One option is to revise the language in proposed Sections 117.135(b) to clarify that both supplier and material risk must be considered as part of the company’s decision to approve a supplier and provide flexibility in the specific factors considered:

**Proposed 117.136(b) Determination and documentation of appropriate verification activities whether to approve a supplier.** In determining and documenting the appropriate verification activities whether to approve a supplier, whether to approve a supplier, the receiving facility must consider both food and supplier related risks, including the following as appropriate:

5. **Letters of Assurance from Customers Controlling Food Safety Hazards Are Not Necessary for Food Safety**

FDA has proposed that where the customer is controlling any hazard, the importer or receiving facility must annually obtain a letter of assurance from the customer that it is controlling the hazard. GMA is concerned that securing such a letter each year is not necessary for food safety, but would be a burdensome paperwork exercise. Significantly, a letter is no guarantee that the customer is appropriately controlling the hazard (e.g., through a proper cook procedure). Furthermore, while suppliers can communicate the hazards associated with a food and the proper mitigation steps to reduce or eliminate this hazard; fundamentally, facilities are not able to police their customers (i.e. receiving facilities downstream in the supply chain). It is the responsibility of each party in the supply chain to understand the products and ingredients it receives, analyze the potential hazards in those materials, and manage them appropriately. This is the fundamental principle of FSMA. A letter from the customer is not necessary for food safety because the customer has an independent legal responsibility to assess and control hazards within its facility.

Further, a food manufacturer could potentially have thousands of different end-users (e.g., retailers) of one product, and in some cases may not know the identity of all end-users. As an example, a manufacturer could sell a raw cookie dough product to a food distributor, which might then sell the product to thousands of retailer customers, which are responsible for performing a cook step to kill the microbiological hazard. It would be extremely burdensome for the manufacturer to obtain
documentation from each retailer. (It is also unlikely the food distributor would issue a letter because they are not the entity performing the cook step). Accordingly, even if obtainable, such a letter is not necessary to food safety and would simply add undue cost and burden. Therefore, GMA recommends FDA delete the proposed requirement for documentation that the customer is controlling the hazard(s).

6. **The Receiving Facility Should Not be Required to Obtain Letters of Assurance from Farms that Their Suppliers and Are Exempt from the Produce Safety Rule**

The receiving facility should not be required to obtain a letter of assurance every two years from farms exempt from the produce safety rule that they are in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA) (see proposed Section 117.136(c)(4)). Such a requirement would be burdensome and would not contribute to public health. FDA exempted these farms from the produce safety rule precisely because it considered them to present a very low risk. For example, FDA stated that foods that are rarely consumed raw or that receive commercial processing that adequately reduces the presence of microorganisms of public health significance “pose minimal or no risk” (see 78 Fed. Reg. 3504, 3527 (Jan. 16, 2013)). Consistent with this recognition, it is appropriate to exempt such farms from supplier verification activities as well.

Further, in many situations it would not be feasible to trace the specific farm that supplied produce due to industry handling practices. Sometimes our members are not able to ascertain the specific farm that harvested a given food. For example, our members often purchase ingredients from brokers, cooperatives, distributors, or traders rather than directly from the ingredient harvester. One example of this challenge is with certain commingled raw agricultural commodities, like spices and coffee. For example, many hundreds of small farmers may grow a certain crop and then deliver it to a co-op where the food is commingled and shipped to the importer. Sometimes the importer is unable to determine the specific identity of each individual farmer to engage in supplier verification (e.g., to audit their program for appropriate application of pesticides) or the number of individual suppliers is resource-prohibitive to verify directly.

Accordingly, GMA recommends that FDA delete the proposed requirements in Section 117.136(c)(4) to document assurances from farms exempt from the produce safety rule, as this would be an exercise in paperwork with no benefit to food safety.

7. **Supplier Verification is a Verification Activity; Not a Preventive Control**

Finally, it is crucial that FDA recognizes that supplier verification is a verification activity and not a preventive control. The activities that are part of a supplier verification program do not directly significantly minimize or prevent hazards. For example, conducting an onsite audit of a supplier does not itself control any hazards, but rather provides confidence in (or raises questions about) the supplier’s food safety system. Because supplier verification programs do not directly control hazards, they are not preventive controls. The regulations should be revised to reflect that supplier verification programs are not preventive controls. Specifically, FDA should delete “supplier controls” from the list of “Preventive Controls” in proposed Section 117.135(c)(4) and should revise the title of proposed Section 117.136 (“Supplier program”) to read “Supplier verification programs.”

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22 A requirement to provide documentation from each customer also becomes a business confidentiality issue as a letter from each customer would reveal a company’s entire customer base.
VI. Records

GMA’s review of the agency’s proposed codified regulations for testing and supplier verification programs highlighted some additional concerns with respect to the records for those and other programs. Specifically, FDA should recognize that these and other programs often are administered corporately, not at individual facilities. Therefore, FDA should develop inspection procedures that take this into account. In addition, FDA should modify the requirement that all records be identified with the name and location of the facility with which they are associated (e.g., if the record is a company-wide record that applies to multiple facilities). Further, records associated with testing and supplier verification programs raise the same concerns we discussed in our previous comments regarding compliance with Part 11 for electronic records as well as concerns about remote access to records. Finally, GMA expresses its support for the agency’s proposal to allow existing records to satisfy food safety plan related recordkeeping requirements.

A. FDA Should Recognize that Some Food Safety Activities are Administered Corporately

FDA should be aware that for companies with more than one manufacturing facility and companies that use co-manufacturers, many food safety activities are administered at the corporate level, not at individual facilities. Hence, records for these activities are housed corporately not necessarily at each facility. For example, supplier oversight, recall plans, and some testing and validation documentation are typically handled at the corporate level, not at an individual facility. Further, requiring every facility to maintain entire programs on the above examples would create an unnecessary burden on food manufacturers and agency investigation personnel without any enhancement of the public health.

1. Inspection Procedures Should be Tailored to Address these Activities

As we discussed in our comments to the original proposed rule, GMA advocates for reviewing records where it makes the most sense to do so. With respect to those corporately administered programs, this is not always at the facility. In the preamble to the supplemental proposed rule, FDA suggests that because supplier verification records are likely kept in electronic form, they would be available at the facility level and thus it would be appropriate to review those records during facility inspections. GMA appreciates the flexibility to store records electronically, but is concerned FDA may expect each facility to have a direct portal or connection to access electronic records stored elsewhere. Facilities often must contact the corporate personnel familiar with the relevant data to identify records that will be responsive to specific requests; as a result, individual facility operators usually will not be able to call up requested records on their own. Rather, the records may only be available electronically upon consultation with an expert in a central office.

Furthermore, access to records at the facility is not the same thing as understanding programs and interpreting verification activities, which is best performed by the subject matter experts managing the programs, who may be at corporate headquarters or another facility. GMA asserts that it would not be a good use of facility resources to train employees in the components of programs that they are not implementing. With respect to supplier verification, the facility should be able to show the inspector the program for ensuring materials are received from approved suppliers and to be able to

show the inspector they are following the program. How the supplier was verified and how the verification activity was chosen or carried out is not known by employees at local facilities.

For these and similar programs, FDA should develop implementation procedures that take into account these centrally organized activities. The goal should be for FDA to inspect these aspects of a company’s FSMA compliance activities just once during each inspection cycle (3 years for some facilities, 5 years for others). For example, for a company that has 20 manufacturing facilities, but only one common corporately administered supplier verification program, it would be extremely inefficient for FDA, and extremely burdensome for the company, to inspect the same program during multiple inspections of the same company's facilities. Further, reviewing centrally administered programs one time, rather than 20, will help prevent inconsistencies in the way different district offices assess programs.

Additionally, centralized inspections can provide FDA with an overview of a company’s programs and standards before it conducts facility inspections and can identify those areas where it would be appropriate to review the facility’s records and procedures in light of the corporate program. This would be especially helpful for those inspectors who are new or new to the particular process used at the facility. They will better understand the programs, practices, and procedures they are reviewing at the facility level and the implementation of those programs if they have an overview of them beforehand.

As there are different ways to address this problem, GMA requests that FDA collaborate with the food industry as the agency’s FSMA inspection procedures are developed. Training or instructing FDA personnel to address such activities at the facility level will not be a good use of agency resources.

2. Recordkeeping Requirements Should Accommodate these Activities

FDA has proposed to require all records to include the name and location of the plant or the facility.\(^\text{24}\) Not all food safety related records, however, are associated with an individual facility. For example, supplier verification program records are typically administered and maintained at corporate headquarters and therefore would not have the name and location of a facility on them. Likewise, some testing related records, such as laboratory procedures or procedures for collecting sampling would not have an individual facility name and location listed on them. For these and other food safety records, including the name and location may not add value. These records may also have limited room on them on which to identify the facility name and location. Further, it is not uncommon for a firm to have more than one facility in the same city.

Accordingly, GMA recommends that FDA modify the requirements in part (f) of section 117.305 such that records only need to include details such as the name and location, the date and time, and the signature of the person performing the activity “as appropriate” or “where appropriate.” Alternatively, FDA could modify the requirement to allow companies to use an alternative method to link the record to the facility in lieu of requiring facilities to change existing records and recordkeeping systems. For example, records may be associated with the facility because they are stored or filed with other records that do have the facility name and location on them (because they are specific to the facility, such as monitoring records). And for some records, it may be possible to use a unique identifier to link the record to the location, such as a plant number or other identification code. Nonetheless, it is

\(^{24}\) Proposed § 117.305(f)(1).
important to keep in mind that for some corporately administered programs, such as supplier verification, records may not be linked to individual facilities.

**B. Electronic Record Security**

Supplier verification program records are often maintained electronically, as are many testing records (such as laboratory results which are communicated to the company and facility electronically, rather than by paper). Thus, compliance with 21 C.F.R. Part 11, which sets out rules for ensuring the security of electronic systems used to meet recordkeeping requirements, raises the same concerns we discussed in our comments to the original proposed rule. Compliance with Part 11 would be burdensome and costly without a corresponding public health benefit and is not necessary to ensure that electronic records are secure. GMA strongly recommends that FDA remove the reference to Part 11 in the proposed regulations. Instead, the regulations should allow facilities to maintain electronic records so long as the system they use is trustworthy, reliable, and generally equivalent to paper records.

**C. Remote Records Access**

In addition to the legal and security concerns with remote access to records that we discussed in our comments to the original proposed rule, our practical concerns with submitting records to the agency electronically are reinforced by the proposed requirements in the supplemental rule. For example, agency review of testing records outside of a facility would lack the context necessary to explain their meaning, relevance, and significance. It would not be clear whether the results were the signal of a trend, the significance of the location sampled, or whether and what kind of corrective actions the facility took in response to the testing results. Those testing results would not tell the agency whether the facility had designed a sound testing program and the role of the testing program within its food safety system. Therefore, GMA reiterates its position that companies should not be required to provide records remotely (e.g., submit records to FDA through the mail or electronically), as this practice will likely lead to confusion and misunderstanding and will not enhance foods safety oversight.

In addition, we refer the agency to our comments to the original proposed rule in which we discussed the lack of a legal basis in FSMA for a remote access requirement. The statutory language of FSMA does not provide FDA with authority for remote access in any circumstances, nor was there such authority in the FFDCA prior to FSMA's enactment. Had Congress intended to expand the scope of FDA's records access to include a submission requirement, it would have explicitly mandated such action in the statute. In sum, it would be inconsistent with the statutory framework to exercise remote access to food safety records.

**D. Use of Existing Records**

GMA supports FDA's proposal to allow companies to use existing records to satisfy the recordkeeping requirements. For example, the ability to use records created for compliance with California's canning requirements to satisfy the recordkeeping requirements in Part 117 is helpful. It prevents companies from having to duplicate records or create new records solely to satisfy recordkeeping requirements. So long as the existing records contain all of the required information, use of existing records is appropriate. As result, some facilities will use one form for compliance with multiple regulatory requirements. At the same time, GMA cautions the agency that its records
reviews should be limited to issues under its jurisdiction, regardless of the other information that may be contained in the record.
Appendix I

GMA Feedback and Recommendations on Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

21 CFR Part 117

Detailed Comments

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.

Proposed Rule

§ 117.3 Definitions

Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

GMA Comments:

- GMA supports the agency’s proposal to establish a definition for the term “allergen cross-contact” rather than the term “cross contact.”
- GMA agrees that the term “allergen cross-contact” may reduce the potential for confusion with the term “cross contamination.”

GMA Recommends:

None.

Proposed Rule

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

GMA Comments:

- We are satisfied with this new definition, as it includes a link between contamination of the food from the environment and illness.
- GMA also agrees that the term should not include the spores of pathogenic sporeformers.
GMA Recommends:
None.

Proposed Rule

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

GMA Comments:
- See below regarding the hazard analysis requirement.

Proposed Rule

Pathogen means a microorganism that is of public health significance.

GMA Comments:
- GMA supports this proposed definition and agrees that pathogen is a term preferable to “microorganism of public health significance.”

GMA Recommends:
None.

Proposed Rule

§ 117.130 Hazard analysis

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

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

GMA Comments:
- GMA strongly supports the definition proposed for the term “significant hazard.”
  - It clearly states that hazards addressed in the food safety plan are based on the outcome of a hazard analysis.
  - It states that those hazards addressed in the food safety plan are those that knowledgeable persons commonly recognize as food safety hazards.
• GMA supports the agency’s proposal to eliminate the term “reasonably likely to occur” as we share the agency’s concern, as noted in the preamble, for “… the potential for a misinterpretation that all necessary preventive controls must be established at critical control points.”

• However, it also would be confusing to use the agency’s proposed term “significant hazard,” because, as the agency also notes in the preamble, “[t]he term ‘significant hazard’ has sometimes been used in the context of HACCP to refer to the hazards to be addressed in a HACCP plan through CCPs.”

• Thus, we recommend the agency avoid using terms that are used in the HACCP context in the proposed hazard analysis requirements.

• GMA suggests that because the definition of “significant hazard” is sufficiently clear, the use of a term such as “significant hazard” is not needed. The regulation would be equally strong if it used the definition, instead of the term itself.

• If the agency feels a term must be used, we propose the term “food safety hazard.” The proposed definition is similar to “food safety hazard” as defined by ISO 22000.

GMA Recommends:

• FDA modify the language in proposed § 117.130(a)(1) as follows:
  (a) Requirement for a hazard analysis. (1) You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are significant food safety hazards for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.

• Alternatively, FDA could replace the word “significant” with “food safety.”
  (a) Requirement for a hazard analysis. (1) You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are significant food safety hazards.

Proposed Rule

§ 117.130 (b) Hazard identification. The hazard identification must consider:
(1) Hazards that include:
(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
(ii) Chemical hazards, including radiological hazards,

GMA Comments:

• GMA supports the proposed change to include radiological hazards as a subset of chemical hazards.

GMA Recommends:
None

Proposed Rule
§ 117.130(b) Hazard identification. The hazard identification must consider:
(2) Hazards that may be present in the food for any of the following reasons:
(iii) The hazard may be intentionally introduced for purposes of economic gain.

GMA Comments:
• GMA disagrees with this proposed requirement because EMA is not a good fit with the hazard analysis and preventive controls framework and would be best deferred until after FDA completes rulemaking on the seven major FSMA regulations.

GMA Recommends:
FDA modify the proposed language as follows:
§ 117.130(b) Hazard identification. The hazard identification must consider:
(2) Hazards that may be present in the food for any of the following reasons:
(iii) The hazard may be intentionally introduced for purposes of economic gain.

Proposed Rule
§ 117.130 (c) Hazard evaluation. (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

GMA Comments:
• GMA agrees that an analysis of potential hazards must include probability (likelihood) of occurrence as well as severity of potential illness or injury.

GMA Recommends:
None.

Proposed Rule
§ 117.135 (c) Preventive controls include, as appropriate to the facility, and the food:
(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls include, as appropriate to the applicable control:
(i) Parameters associated with the control of the hazard; and
(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

GMA Comments:
• GMA finds the requirement for parameters overly prescriptive because of the emphasis created by the term “must,” and the fact that “as appropriate to the applicable control” could
be understood to mean “if possible” or “if feasible,” 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 process control or the specific food safety need.
- Assigning a parameter and associated minimum and maximum values may be possible 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.
- Food safety plans utilize a variety of preventive controls, often in combinations, to significantly minimize or prevent (SMOP) hazards.

GMA urges the agency to avoid an interpretation that a facility has per se failed to SMOP a hazard, a legal requirement, solely because a parameter is outside of specified minimum or maximum values. Rather, when a parameter’s value is outside of the specified max/min values, the impact on food safety needs to be assessed, consistent with the role of the process control in the overall food safety system. For example,

- If the non-compliance to a parameter min/max is at a CCP, the non-compliance has most likely created a clear food safety issue; however, for some process controls, such as refrigerated storage, further evaluation may be needed to assess the food safety consequences of the non-compliance. The fact that a food has been held one degree outside of its maximum value does not necessarily mean that the food is adulterated.
- There are cases where a variety of parameters may work collectively to SMOP a hazard and non-compliance to any one parameter will not result in unsafe product. Consequently, it may not be plausible to list one set of minimum and maximum parameters for food safety. A formulation used to SMOP the biological hazard of vegetative pathogens, for example, could utilize a combination of moisture, pH, titratable acidity, and salt level. It is the combination of these factors working in conjunction with each other that will SMOP the hazard. One of the parameters could be out of the specification limit, but with the combination of the other parameters, the product could still be safe from the antimicrobial contributions of the other factors.

GMA recommends that the regulations be revised to make clear that not all process controls parameters have max/min values and the facility must consider the role of those parameters within the context of the food safety system.

- When referring to appropriate applicable controls, FDA should consistently use the term “nature of the control” as has been done throughout the preamble.

**GMA Recommends:**

- FDA modify the language in § 117.135(c) as follows:
  
  § 117.135(c) Preventive controls include, as appropriate to the facility and the food:
  
  (1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to nature of the applicable control and its role in the food safety system:
  
  (i) Parameters associated with the control of the hazard; and
(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled, to significantly minimize or prevent a significant hazard.

Proposed Rule:
§ 117.135 Preventive controls.
(c) Preventive controls include, as appropriate to the facility and the food:
...
(4) Supplier controls. Supplier controls include the supplier program as required by § 117.136.

§ 117.136 Supplier program.
(a) Supplier program.

GMA Comments:
- GMA agrees that a supplier program is a vital component of an effective overall food safety system.
- However, it is crucial that FDA recognizes that supplier verification is a verification activity and not a preventive control.

GMA Recommends:
- FDA modify §§ 117.135 and 117.136 as follows:

  § 117.135 Preventive controls.
  (c) Preventive controls include, as appropriate to the facility and the food:
  ...
  (4) Supplier controls. Supplier controls include the supplier program as required by § 117.136.

  § 117.136 Supplier verification program.
  (a) Supplier verification program.

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Proposed Rule
§ 117.136 Supplier Program.
(a) Supplier program. (1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.

GMA Comments:
- FDA should amend the regulations to state that each importer or receiving facility “must establish, or have established for it, and implement a risk based supplier program.” This approach appropriately recognizes that the facility may not always create the program and that it may instead be established by corporate headquarters. This revised language also recognizes that where contract manufacturers are used, the brand-name company may in some cases establish the supplier verification program and prescribe for the contract manufacturer which suppliers are approved and are to be used.
GMA Recommends:
- FDA modify the language in proposed § 117.136(a)(1)(i) as follows:

  (a) Supplier program. (1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish, or have established for it, and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.

Proposed Rule
§ 117.136 Supplier Program.
(a)(1)(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

  (C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).

  (3) The annual written assurance that a receiving facility’s customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

GMA Comments:
- GMA recommends that FDA delete the requirement for documentation that the customer is controlling the hazard(s) since a letter is no guarantee that the customer is appropriately controlling the hazard (e.g., through a proper cook procedure). Even if a letter was obtainable, such a letter would not augment food safety, but would simply consume resources. While suppliers can communicate the hazards associated with a food and the proper mitigation steps to reduce or eliminate this hazard; fundamentally suppliers cannot police or control their customers. It is the responsibility of the customer to understand the food it is receiving, analyze it for potential hazards, and implement the proper steps to reduce or eliminate the hazard.

GMA Recommends:
- FDA should delete the requirement in proposed § 117.136(a)(ii)(C) as follows:

  (a)(1)(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

  ... (C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.
and delete the language in proposed § 117.136(g) as follows:

(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).

... (3) The annual written assurance that a receiving facility’s customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

...

Proposed Rule

§ 117.136(b) Determination and documentation of appropriate verification activities. In determining and documenting the appropriate verification activities, the receiving facility must consider the following:

GMA Comments:

- The regulations should provide more flexibility as to which factors are to be considered as part of the risk evaluation and when they must be considered. Through this flexibility and risk-based approach there will be a greater likelihood of delivering safe food in a cost-effective manner.

GMA Recommends:

- FDA modify the language in proposed § 117.136 as follows:

  (b) Determination and documentation of appropriate verification activities whether to approve a supplier. In determining and documenting the appropriate verification activities whether to approve a supplier, the receiving facility must consider both food and supplier related risks, including the following as appropriate:

Proposed Rule

§ 117.136(a) Supplier Program

(3) The supplier program must include:

(i) Verification activities, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use);

§ 117.136(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).

... (4) Documentation demonstrating that products are received only from approved suppliers.
GMA Comments:
- GMA agrees that instead of maintaining a written list of suppliers, receiving facilities should be required to establish and follow procedures to ensure that they use only approved suppliers (or, when necessary and appropriate, unapproved suppliers on a temporary basis).

GMA Recommends:
- None

Proposed Rule
§ 117.136 Supplier verification activities for raw materials and ingredients. (1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document one or more of the supplier verification activities as determined by the receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

GMA Comments:
GMA strongly supports FDA’s proposal to provide flexibility for receiving facilities to determine the appropriate verification activities and the frequency with which the activities must be conducted, based on the risk evaluation for the food and supplier. Overall, there will be a greater likelihood of delivering safe food through this flexible regulatory approach.

GMA Recommends:
None

Proposed Rule
§ 117.136(c)(1)
(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.

GMA Comments:
- We agree that testing can be conducted by either the importer or the foreign supplier.
- Verification testing is often more efficient and effective when conducted by the supplier, rather than the importer or receiver, because, among other factors, lot control can be maintained.

GMA Recommends:
- FDA should consider collaboration with other industry stakeholders to possibly develop guidance on “test and hold” procedures and when such procedures could be implemented.

Proposed Rule
§ 117.136(c) Supplier verification activities for raw materials and ingredients.
(2)(i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.
(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurances that the hazards are controlled.

**GMA Comments:**
- GMA agrees with FDA’s proposal that a receiving facility can document its basis for concluding that an audit of a supplier providing a food with a hazard that could cause serious adverse health consequences or death to humans can be conducted less frequently than annually.
- This determination, however, may be made by a corporate parent or by the brand-name company in the case of a contract manufacturing arrangement.

**GMA Recommends:**
- FDA should modify the language in proposed §117.136(c)(2)(ii) as follows:

  §117.136(c)(2)(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurances that the hazards are controlled.

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**Proposed Rule**

§117.136(c) Supplier verification activities for raw materials and ingredients.

(4) If a supplier is a farm that is not subject to the requirements in part 112 of this chapter in accordance with §112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

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

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

(g) Records. The receiving facility must document the following in records and review such records in accordance with §117.165(a)(4).

…

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

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

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

**GMA Comments:**
- FDA should delete the proposed requirement to document assurances from farms exempt from the produce safety rule, as this would be an exercise in paperwork with no benefit to food safety.
GMA Recommends:
- FDA modify the language in proposed § 117.136(c)(4) as follows:

  § 117.136(c) Supplier verification activities for raw materials and ingredients.
  (4) If a supplier is a farm that is not subject to the requirements in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:
  (i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
  (ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

- And modify the language in proposed § 117.136(g)(11) as follows:

  (g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).
  ...
  (11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:
  (i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and
  (ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

Proposed Rule
§ 117.136(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).
...
(5) Documentation of an onsite audit. This documentation must include
(i) Documentation of audit procedures;
(ii) The dates the audit was conducted;
(iii) The conclusions of the audit;
(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and
(v) Documentation that the audit was conducted by a qualified auditor.

GMA Comments:
- GMA agrees with FDA that the full audit report should remain confidential.

GMA Recommends:
- None

Proposed Rule
§ 117.305 General requirements applying to records. Records must:
…
(f) Include the following:
(1) The name and location of the plant or facility;
(2) The date and time of the activity documented;
(3) The signature or initials of the person performing the activity; and
(4) Where appropriate, the identity of the product and the production code, if any.

GMA Comments:
- The record keeping provisions in proposed Section 117.305 should be revised to exempt
  supplier verification records from the requirements in paragraph (f) to provide the plant name,
  plant location, and product/production code. This change would make the supplier
  verification requirements under the preventive controls rules the same as those under the
  FSVP rule, which requires only that supplier verification records be “signed and dated by the
  owner, operator or agent in charge of the facility.”

GMA Recommends:
- FDA modify the language in proposed § 117.305(a)(1) as follows:

  § 117.305 General requirements applying to records. Records must:
  …
  (f) Include the following, except that supplier verification records are exempt from the
  requirements in subparagraph (f)(1) and (f)(4) of this section:
  (1) The name and location of the plant or facility;
  (2) The date and time of the activity documented;
  (3) The signature or initials of the person performing the activity; and
  (4) Where appropriate, the identity of the product and the production code, if any.

___________________________

Proposed Rule
- N/A

GMA Comments:
- We strongly recommend that FDA exempt intra-company shipments (i.e., shipments
  between two business units owned by the same corporate parent) from supplier verification,
  as any ingredients or materials will already have been verified by another division of the
  receiving company. It would be duplicative and would not benefit public health to require a
  company to verify itself.

GMA Recommends:
- FDA adopt the following language to exempt intra-company shipments:

  § 117.3 Definitions
  Affiliated party means, with respect to an entity, any other entity that (i) directly or indirectly
  controls or is controlled by, or is under common control with that entity, and (ii) is subject a
  comparable food safety control framework, including but not limited to, adhering to the same
  corporate food safety policies, risk assessment processes, and corrective action procedures
  as the controlling entity. For purposes of this definition, “control” means (i) the direct or
  indirect ownership of more than fifty percent (50%) of the total voting security of every class
  or other evidences of ownership interest of the entity, or (ii) the possession, directly or
indirectly, of the power to direct or cause the direction of the management and policies of an entity. For purposes of this definition “entity” means any individual, general partnership, limited partnership, limited liability company, corporation, or joint venture.

§ 117.136(a)(1)(ii) Supplier program.
(a)(1)(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

(D) The receiving party receives the raw material or ingredient from an affiliated party.

Proposed Rule
§ 117.137 Recall plan
For food with a significant hazard:
(a) You must establish a written recall plan for the food.
(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:
(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 Comments:
- GMA recommends removing the requirement for recall plans from this section from Subpart C and adding it to the GMP section (Subpart B).
- When establishing requirements for firms to maintain recall plans, the agency should be aware that such plans are typically facility-wide, not product and process specific, and should be required for all registered facilities, not just those subject to preventive controls.
- FDA’s regulations should require each facility to have a recall plan, but should not require a plan “for each food.” Similarly, the regulatory requirement to have a recall should not be limited to foods with “significant hazards.” Although the scope of “significant hazard” is broad, any product can be subject to a recall. Therefore, recall plans should cover all foods.

GMA Recommends:
- Remove § 117.137 from Subpart C and require recall plans in Subpart B.
- Modify the language in proposed as follows:
  § 117.135(c)(5) Recall plan. Recall plan as required by §117.137.
  §117.137 Recall plan.
  For food with a significant hazard:
  (a) You must establish a written recall plan for the food.
(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

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 Preventive control management components
(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control:

1. Monitoring in accordance with § 117.145;
2. Corrective actions and corrections in accordance with § 117.150; and
3. Verification in accordance with § 117.155.

GMA Comments:
- GMA agrees that verification activities must be both appropriate to the nature of the control and necessary for food safety (to ensure the effectiveness of the control).

GMA Recommends:
None.

Proposed Rule
§ 117.145 Monitoring
(a) As appropriate to the preventive control, you must:

1. Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and
2. Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).

GMA Comments:
- GMA agrees with the agency’s statement in the preamble at Table 6 that not all monitoring activities require monitoring records.\(^27\)
- FDA should modify the regulation to conform with this statement because monitoring records are not appropriate for all preventive controls.

\(^27\) 79 Fed. Reg. at 58,543.
GMA Recommends:

- FDA should modify the language in § 117.145(b) as follows:
  
  § 117.145(b) As appropriate to the nature of the preventive control and as necessary, All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).

Proposed Rule

§ 117.150 Corrective actions and corrections.

(a) Corrective action procedures. As appropriate to the preventive control and hazard, except as provided by paragraph (c) of this section:

(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(A) The presence of a pathogen or appropriate indicator organism at a level of concern for food safety in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and

(B) The presence of an environmental pathogen or appropriate indicator organism detected at a level and/or location of concern through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(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 that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you 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 Comments:

- GMA does not believe specific corrective action requirements should be codified such as the agency has done with regard to testing. GMA is concerned that by specifically requiring corrective action procedures in response to testing results, some facilities may not understand the need take corrective actions in other circumstances, in response to other non-conformances, or for other types of verification activities.

- To keep the regulation flexible and not overly prescriptive, our first preference is for FDA to delete the references to testing within the corrective action provisions.

- GMA believes it is important for FDA to clarify in the final rule that the nature and extent of any corrective actions should be proportional to the nature of the findings. For example, some microorganisms (both pathogens and indicators) have threshold levels that need to be taken into account when assessing potential concern for human health. There are some pathogens that are only of concern to human health if they are present in food at high levels.
and/or their toxin is present and consumed. Examples of these pathogens include *Staphylococcus aureus*, *Clostridium perfringens* and *Bacillus cereus.*

- In addition, the sample location and level of concentration (i.e., CFU/swab) of any environmental monitoring result would play a significant role in determining what follow-up actions, if any, are needed.
- Therefore, corrective actions, if any, need to take into account the nature of the hazard (i.e., particular testing results, including the type of organism, the location and the levels found) and the nature of the control measure(s) being verified.

**GMA Recommends:**

- FDA should modify the language in proposed § 117.150 as follows:
  - (a) Corrective action procedures. As appropriate to the preventive control and hazard, except as provided by paragraph (c) of this section:
    - (1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.
    - (ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:
      - (A) The presence of a pathogen or appropriate indicator organism at a level of concern for food safety in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and
      - (B) The presence of an environmental pathogen or appropriate indicator organism detected at a level and/or location of concern through the environmental monitoring conducted in accordance with § 117.165(a)(3).

- Should the agency retain these sections, the agency should modify them as follows:
  - (a) Corrective action procedures. As appropriate to the preventive control and the hazard, except as provided by paragraph (c) of this section:
    - (1)(i) You must establish and implement written corrective action procedures, as appropriate to the nature of the hazard, the nature of the control measure, and the extent of the deviation that must be taken if preventive controls are not properly implemented.
    - (ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:
      - (A) The presence of a pathogen or appropriate indicator organism above actionable levels in accordance with the written testing program in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and
      - (B) The detection of an environmental pathogen or appropriate indicator organism detected above actionable levels and/or at identified critical environmental locations which have been established through the environmental monitoring conducted in accordance with § 117.165(a)(3).

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28 The FDA Bad Bug Book (2nd Edition, 2012) outlines the infectious dose for these organisms, which exceeds $10^7$ colony forming units per gram (CFU/g) (leading to toxin formulation for *S. aureus*, $10^6$ cells or spores per gram for *C. perfringens* and $10^6$ CFU/g (for toxin formation) for *B. cereus*). See [http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf](http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf).

In some cases it may be acceptable to have a microbiological criterion for these organisms that is a CFU/g. For example, Australian and New Zealand Food Standards recognize that <100 CFU/g is a “satisfactory” result for all three of these organisms in RTE foods. See [http://www.foodstandards.gov.au/publications/documents/Guidelines%20for%20Micro%20exam.pdf](http://www.foodstandards.gov.au/publications/documents/Guidelines%20for%20Micro%20exam.pdf). Other countries also have permissible levels for all or some of these organisms. Furthermore, in some circumstances *S. aureus* testing is used to indicate hygiene, and not food safety (for example, in a food that does not support its growth).
• Alternatively, with respect to section 117.150(a)(1)(ii)(B), our second most preferred language is:

(B) The detection presence of an environmental pathogen or appropriate indicator organism detected at a level and/or location of concern that have been established through the environmental monitoring conducted in accordance with §117.165(a)(3).

Proposed Rule
§117.150(c) Corrections applicable to food allergen controls and sanitation controls. You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the food allergen controls in §117.135(c)(2)(i) or the sanitation controls in §117.135(c)(3)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

GMA Comments:
• GMA appreciates FDA’s recognition that that not all actions to address issues in the manufacturing environment require the formal procedures and documentation contemplated for “corrective actions,” and that FDA has proposed the term “corrections” to address these situations.
• Nonetheless, the concept of “corrections” is not limited to sanitation and allergen cross-contact controls.
• Further, the term “corrections” could be confusing in the regulations, given the term’s established meaning and use in ISO 22000, which is considerably different than the agency’s implied definition.
• Instead of using a specific term, FDA should revise the regulation to clearly state the conditions in which corrective action procedures would not be necessary.

GMA Recommends:
• FDA should modify the language in §117.150(c) as follows:

§117.150(c) Corrections applicable to food allergen controls and sanitation controls. You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the food allergen controls in §117.135(c)(2)(i) or the sanitation controls in §117.135(c)(3)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices. Prompt actions to address minor and isolated deviations that do not directly impact product safety. You do not need to comply with the requirements of paragraphs (a), (b) and (d) of this section for prompt actions taken to address minor and isolated conditions and practices that are not consistent with, for example, food allergen controls designed to protect food from allergen cross-contact, sanitation controls, preventive maintenance controls, or other controls as appropriate.

(d) Documentation. All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with §117.155(a)(3) and records review in accordance with §117.165(a)(4)(i).

Proposed Rule
§117.155 Verification
(a) Verification activities. Verification activities must include, as appropriate to the preventive control:
(1) Validation in accordance with § 117.160.
(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).
(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).
(4) Verification of implementation and effectiveness in accordance with § 117.165; and
(5) Reanalysis in accordance with § 117.170.

GMA Comments:
- GMA’s 2013 comments recommended validation activities be included in a section of the proposed regulations separate from verification because of the common confusion between these two activities.
- The agency has partially addressed this confusion by providing separate sections for verification (§ 117.155) and for validation (§ 117.160).
- However, § 117.155(a) states “Verification activities. Verification activities must include, as appropriate to the preventive control (1) Validation in accordance with § 117.160.” A regulation that refers to validation as a type of verification activity will continue the common confusion between activities and procedures 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 its component control elements are operating as planned.
- GMA requests that the agency consider using clearly separate definitions of validation and verification, to help to avoid confusion about activities related to these important processes.
- A working group of the Codex Alimentarius Food Hygiene Committee is considering separating out the two concepts. In their discussion paper, ftp://ftp.fao.org/codex/Meetings/ccfh/ccfh46/CRDs/fh46_CRD2e.pdf, they state, “Validation is an important part of HACCP systems. There is a need to more clearly distinguish validation from verification within Principle 6.”

GMA Recommends:
- FDA should modify the language in § 117.155 as follows:
  § 117.155 Verification
  (a) Verification activities. Verification activities must include, as appropriate to the preventive control:
  (1) Validation in accordance with § 117.160.

Proposed Rule
§ 117.160 Validation
(a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the significant hazards are adequate to do so where necessary and as appropriate to the nature of the preventive control.

GMA Comments:
- Although the preamble states that not all preventive controls require validation, the proposed regulation states that, unless a specific exemption applies, all preventive controls must be validated: “[e]xcept as provided by paragraph (b)(3) of this section you must validate that the preventive controls . . . are adequate . . . as appropriate to the nature of the preventive
control."\textsuperscript{29} Paragraph (b)(3) provides exemptions only for allergen controls, sanitation controls, the supplier program, and recall plans.

- There are many controls for which validation is not appropriate or necessary in addition to the four explicitly referenced in the proposed rule as noted in Table 6.
- To be consistent with the agency's statements in the preamble, FDA should revise the regulation to clarify that not all preventive controls must be validated.

GMA Recommends:
- FDA should modify the language in § 117.160 as follows:
  § 117.160 Validation.
  (a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the significant hazards are adequate to do so \textit{where necessary and} as appropriate to the nature of the preventive control.

\textbf{Proposed Rule}

§ 117.160 (b) The validation of the preventive controls:
(1) Must be performed (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 inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards; and
(3) Need not address:
(i) The food allergen controls in § 117.135(c)(2);
(ii) The sanitation controls in § 117.135(c)(3);
(iii) The supplier program in § 117.136; and
(iv) The recall plan in § 117.137

\textbf{GMA Comments:}
- GMA is concerned that codifying a list of preventive controls that do not need validation as done in 117.160(b)(3)(i)-(iv) makes that list exclusive, both today and for the duration of this regulation. Effective preventive measures may be identified in the future that are not amenable to validation and it would be counterproductive for them not to be employed in food safety plans because they cannot meet the validation requirements of § 117.160.
- The list of preventive controls in § 117.160(b)(3)(i)-(iv) is not an exclusive list of controls that would not require validation by FDA's own analysis. In addition to the above preventive controls, FDA lists in Table 6 of the preamble zoning, training, preventive maintenance, and refrigerated storage as "Preventive controls that would not require validation."\textsuperscript{30}
- Regulatory terminology should address exempting from § 117.160 those preventive controls that, due to the nature of the control, cannot be validated., for example, according to

\textsuperscript{29} Proposed § 117.160(a) (emphasis added).
\textsuperscript{30} 79 Fed. Reg. at 58,543.
guidelines such as Codex Alimentarius Commission Guidance CAG/GL 69 2008 Validation of Food Safety Control Measures.

- Certain control measures are not suitable for validation activities for a variety of reasons.
  - The nature of the activity is not conducive to validation activities;
  - Validation is not necessary (e.g., has been performed by another entity (e.g., supplier)); or
  - Specific methods are not available that enable validation.

GMA Recommends:
- FDA should modify the language in § 117.160 as follows:

  § 117.160 Validation.
  (a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the significant hazards are adequate to do so where necessary and as appropriate to the nature of the preventive control.
  (b) The validation of the preventive controls:
     (1) Must be performed (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 inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards;
       and
     (3) Need not address:
       (i) The food allergen controls in § 117.135(c)(2);
       (ii) The sanitation controls in § 117.135(c)(3);
       (iii) The supplier program in § 117.136; and
       (iv) The recall plan in § 117.137.
       (v) Other controls, as determined in § 117.160 (a)

Proposed Rule

§ 117.165 Verification of implementation and effectiveness.
(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so you must conduct activities that include the following, where necessary and, as appropriate to the facility, the food, and the nature of the preventive control:
  (1) Calibration of process monitoring instruments and verification instruments;
  (2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;
  (3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and

GMA Comments:
- We strongly agree with FDA’s statements in the preamble to the supplemental proposal that the agency intends to afford “flexibility for a facility to make risk-based decisions on when
product testing would be appropriate by providing that the facility can take into account the facility, the food, and the nature of the preventive control.” We understand this to mean there are circumstances when product testing, particularly finished product testing, would not be necessary.

- Nevertheless, the text of the proposed codified language is ambiguous and use of the word “must” in proposed section 117.165(a)(2) (i.e., “To do so you must conduct activities that include . . . product testing”) could be interpreted to mean that product testing in some form is always required. We believe it is essential that FDA modify the codified language to clearly reflect the flexibility articulated in the preamble.

GMA Recommends:

- FDA should modify the language in §117.165(a) as follows:

  §117.165 (a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so you must evaluate the need to conduct activities that include the following, as if appropriate to the facility, the food, and the nature of the preventive control:

  Or-

  §117.165 (a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so you must conduct activities that include the following, as if and when appropriate and necessary to the facility, the food, and the nature of the preventive control:

Proposed Rule

§117.165(a)(4) 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 created.

(ii) Records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

GMA Comments:

- We have included Table 4 from GMA’s 2013 comments as examples of relevant verification activities for various preventive controls.

- GMA understands the language “...and appropriate decisions were made about corrective actions” to mean that corrective action procedures were followed as described in the food safety plan. In other words, the intent of “appropriate decisions” in this section is to verify that the corrective actions are implemented as devised. This does not mean that, for example, a facility submitting a thermal process deviation to a process authority would seek an additional opinion from a second process authority to ensure the recommendations of the first authority were “appropriate.”

- Review of records should be required within seven working days instead of one week, to account for holidays and scheduled facility down-time.

GMA Recommends:

- FDA should modify the language in § 117.165(a)(4) as follows:
  § 117.165(a)(4) 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 actions records within a week, seven working days after the records are created.

Proposed Rule

§ 117.165(b) Written procedures. As appropriate to the facility, the food, and the nature of the preventive control, you must establish and implement written procedures for the following activities:
(1) The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.
(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:
  (i) Be scientifically valid;
  (ii) Identify the test microorganism(s) or other analyse(s);
  (iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;
  (iv) Include the procedures for sampling, including the number of samples and the sampling frequency;
  (v) Identify the test(s) conducted, including the analytical method(s) used;
  (vi) Identify the laboratory conducting the testing; and
  (vii) Include the corrective action procedures required by § 117.150(a)(1).
(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:
  (i) Be scientifically valid;
  (ii) Identify the test microorganism(s);
  (iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;
  (iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;
  (v) Identify the test(s) conducted, including the analytical method(s) used;
  (vi) Identify the laboratory conducting the testing; and
  (vii) Include the corrective action procedures required by § 117.150(a)(1).

GMA Comments:

- GMA is pleased that these requirements give facilities the flexibility to make risk-based decisions regarding sampling locations and frequency. As we discussed in our previous comments, routine testing of product contact surfaces is not preventive in nature. It also hampers the effective implementation of a “seek and destroy” approach to environmental monitoring programs.
• Although we agree with the principle, we are concerned that the word “valid” could be construed to mean “validated” and not all testing protocols can be validated within the traditional meaning of the term.
• We believe what FDA intends is for these testing programs to be technically sound.

GMA Recommends:
• FDA should modify the language in as follows:
  § 117.165(b)(2)(i) and (3)(i)
  Be scientifically valid. Be technically sound.

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Proposed Rule
§ 117.170 Reanalysis
(b) You must complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production.

GMA Comments:
• 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 a period of “90 days” be provided, which is also consistent with USDA-FSIS requirements.

GMA Recommends:
• FDA should modify the language in § 117.170(b) as follows:
  § 117.170(b) You must complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks 90 days of production.

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Proposed Rule
§ 117.170(e) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

GMA Comments:
• GMA agrees with FDA that a reanalysis of the food safety plan is required to respond to newly identified hazards and to significant developments in scientific understanding of known hazards as determined by the Commissioner of Food and Drugs. GMA believes that such determinations should be communicated from the agency to the appropriate product category. This would assure that all affected facilities receive the same message and that it is scientifically based.

GMA Recommends:
• FDA should modify the language in § 117.170(e) as follows:
  (e) You must conduct a reanalysis of the food safety plan when FDA the Commissioner of Food and Drugs determines it is necessary to respond to new hazards and developments in scientific understanding.
Proposed Rule

§ 117.305 General requirements applying to records.

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

GMA Comments:
- Not all food safety related records are associated with an individual facility. For these and other food safety records including the name and location may not add value. In addition, other records may have limited room on them on which to identify the facility name and location. Further, it is not uncommon for a firm to have more than one facility in the same city.

GMA Recommends:
- FDA should modify the requirements in part (f) of 117.305 so that records only need to include details such as the name and location, the date and time, and the signature of the person performing the activity “as appropriate” or “where appropriate.”
- Alternatively, FDA could modify the requirement to allow companies to use an alternative method to link the record to the facility in lieu of requiring facilities to change existing records and recordkeeping systems. For example, records may be associated with the facility because they are stored or filed with other records which do have the facility name and location on them (because they are specific to the facility, such as monitoring records). And for some records, it may be possible to use a unique identifier to link the record to the location, such as a plant number or other identification code.

GMA Recommends:
- FDA should modify the language in section 117.305(f) as follows:
  117.305 General requirements applying to records.
  Records must:
   (f) Include, as appropriate:
      (1) The name and location of the plant or facility;
      (2) The date and time of the activity documented;
      (3) The signature or initials of the person performing the activity; and
      (4) Where appropriate, the identity of the product and the production code, if any.
- Alternatively, FDA could modify the language as follows:
  117.305 General requirements applying to records.
  Records must:
(f) Include:
(1) The name and location of the plant or facility, or other unique identifier that links the record to the plant or facility;
# Appendix II

## Table 1. Examples of Management Elements Applicable to Various Preventive Controls
(Examples only, may not be appropriate to all manufacturing facilities)

<table>
<thead>
<tr>
<th>Control</th>
<th>Preventive Control Management Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parameter with max/min?</td>
</tr>
<tr>
<td><strong>GMP</strong></td>
<td></td>
</tr>
<tr>
<td>Shoe change</td>
<td>No</td>
</tr>
<tr>
<td>Distinctive clothing</td>
<td>No</td>
</tr>
<tr>
<td>Hygenic-Zoning controls</td>
<td>No</td>
</tr>
<tr>
<td>Pest control</td>
<td>No</td>
</tr>
<tr>
<td>Training</td>
<td>Yes</td>
</tr>
<tr>
<td>Transportation (refrigerated)</td>
<td>Yes</td>
</tr>
<tr>
<td>Storage (refrigerated)</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Allergen control</strong></td>
<td></td>
</tr>
<tr>
<td>Segregation</td>
<td>No</td>
</tr>
<tr>
<td>Labeling</td>
<td>No</td>
</tr>
<tr>
<td>Changeover cleaning</td>
<td>Situational(^b)</td>
</tr>
<tr>
<td><strong>Sanitation</strong></td>
<td></td>
</tr>
<tr>
<td>CIP</td>
<td>Yes</td>
</tr>
<tr>
<td>COP</td>
<td>Yes</td>
</tr>
<tr>
<td>Manual clean</td>
<td>No</td>
</tr>
<tr>
<td><strong>Foreign materials</strong></td>
<td></td>
</tr>
<tr>
<td>Glass management</td>
<td>No</td>
</tr>
<tr>
<td>Preventative maintenance</td>
<td>No</td>
</tr>
<tr>
<td>Detection systems</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Process controls</strong></td>
<td></td>
</tr>
<tr>
<td>Pasteurization</td>
<td>Yes</td>
</tr>
<tr>
<td>Addition of acid</td>
<td>Yes</td>
</tr>
<tr>
<td>Drying</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Addition of humectant | Yes | Situational* | Yes | Yes | Yes | Yes

- Documentation of performance / operation of control measure. Validation, verification and corrective actions are documented when conducted.
- The applicability of parameters and associated monitoring depend upon the nature of the cleaning activity.
- The ability to validate changeover cleaning depends upon the nature of the activity, the availability of monitoring procedures, and existence of thresholds.
- FDA has exempted because validation is done by the chemical / equipment manufacturer; however for CIP, operational qualification may be conducted by the operator.
- Implementation of control may be confirmed through monitoring (such as confirmation of the addition of acid, humectants or conditions of drying) and/or through verification that the product parameters are reached.

Table 4. Examples of Verification Activities for Various Preventive Controls
(Examples only, may not be appropriate to all manufacturing facilities)

<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*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GMP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoe change</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Distinctive clothing</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Situational</td>
<td>No</td>
</tr>
<tr>
<td>Zoning controls</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Situational</td>
<td>Yes</td>
</tr>
<tr>
<td>Pest control</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Situational</td>
<td>No</td>
</tr>
<tr>
<td>Training</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Situational</td>
<td>No</td>
</tr>
<tr>
<td>Transportation(refrigerated)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Storage (refrigerated)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Allergen control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Segregation</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Labeling</td>
<td>No</td>
<td>Yes (labels)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Sanitation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIP</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>COP</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Manual clean</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Foreign materials</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glass management</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Situational</td>
<td>Yes</td>
</tr>
<tr>
<td>Preventative maintenance</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Detection systems</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Process controls</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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<td>----</td>
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<td>----</td>
<td>----</td>
</tr>
<tr>
<td>Pasteurization</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Addition of acid</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Drying</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Addition of humectant</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

\(^a\) 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.