Dear Sir or Madam:

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

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

GMA strongly supported the FDA Food Safety Modernization Act (FSMA) and looks forward to working with FDA for successful implementation of this groundbreaking law. GMA applauds FDA for the considerable efforts to reach out to stakeholders during the pre-rulemaking stage of the proceedings and for the Agency’s willingness to continue that dialogue during the public comment period. We appreciate the Agency’s desire to develop a regulatory framework that is protective of public health, risk-based, and practical. We all share a common goal of providing safe food to American consumers.
GMA is filing seven separate comments in response to the proposed rule, which address (1) the food safety plan; (2) testing; (3) supplier verification; (4) recordkeeping; and (5) current Good Manufacturing Practices (cGMPs), as well as (6) the economic analysis and (7) information collection burdens. The attached comments address aspects of the proposed rule involving Subpart B (cGMPs).

Executive Summary of Comments

GMA applauds FDA for proposing to modernize the cGMPs to reflect current practices in the food industry. The association is generally supportive of FDA’s approach of separating cGMPs from those activities typically included in a food safety plan. Accordingly, the comments that follow are primarily aimed at clarifying the proposed provisions and further aligning them with industry practices that are proven to ensure delivery of safe food products.

1. Application of cGMPs to low moisture foods: GMA strongly recommends that FDA clarify how the proposed cGMP requirements would impact low-moisture food operations.

2. Recall plans (§ 117.126(b)(6)): Recall plans should be part of the cGMP requirements rather than part of Subpart C to ensure that firms exempt from preventive controls are required to maintain recall plans.

3. Storage of raw agricultural commodities for further processing (§ 117.93): GMA asks FDA to clarify that bulk outdoor storage of raw agricultural commodities for further processing are exempt from the cGMPs.

4. Definition of cross-contact (§ 117.3): FDA should change the term “cross-contact” to the term “allergen cross-contact” in order to clarify that the term cross-contact, is not to be confused with the term “cross contamination.”

5. Definition of packaging (§ 117.3): FDA should clarify that protection of packaging from cross contamination or allergen cross-contact means protection of food-contact packaging or packaging that is in direct contact with the food.

6. Food-contact surfaces (§ 117.35(d)(1)); definition of sanitize (§ 117.3): GMA strongly urges FDA to clarify that the proposed requirement to maintain food-contact surfaces in a sanitary condition is not a requirement to sanitize all product contact surfaces, and asks the Agency to add language allowing the continued use of cleaning methods based on a risk assessment, including dry cleaning with no sanitizing step. GMA also asks that FDA adopt a definition of the term “sanitize” similar to that found in the Pasteurized Milk Ordinance (PMO), which recognizes that cleaning and sanitizing do not always have to be separate, sequential steps.

7. Defect action levels (117.110): FDA should clarify that compliance with the requirement to reduce natural or unavoidable defects to “the lowest level currently feasible” does not amount to a requirement for facilities to exceed cGMPs or go beyond the preventive controls identified through a hazard analysis.
In the attached comments, GMA also responds to FDA’s request for comments on how best to revise the current provision on employee training requirements (§ 110.10(c)). GMA believes FDA should establish employee training requirements, but that any requirements must be sufficiently flexible to allow facilities to tailor the training needed to their employees’ duties, facilities, equipment, processing conditions, specific food product category risk concerns and needs, etc. With respect to frequency, GMA believes that employees should be trained initially and periodically thereafter. Any training requirements should be located in subpart B as part of cGMPs.

Additionally, GMA requests that FDA correct a number of redundancies in the proposed rule or use clarifying language in a number of instances, including in the following proposed provisions: §§ 117.35(d)(3) and (f); 117.40(a)(6); 117.40(g); 117.80(b)(3) and (c)(3), (4), (10), (11), (14), (15).

GMA also lists a number of proposed provisions with which it agrees, including FDA’s proposed approach to establish a performance standard for hand-washing facilities (§ 117.37); and a number of the provisions that would establish requirements in the place of current guidance, such as for sanitation of non-food contact surfaces (§ 117.35(e)).

Implementation

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

- **The Final Rule Should Be Cost Neutral for Food Companies with Advanced Food Safety Programs:** We agree with FDA’s stated goal of issuing regulations on preventive controls that would be essentially cost neutral for food companies that already have advanced food safety systems. As part of our comments on the preventive controls proposal, we are submitting proposed alternate regulatory language that will ensure the final rule is consistent with this goal – as well as consistent with both the letter and purpose of FSMA and the corresponding Preliminary Regulatory Impact Analysis (PRIA). The implementation cost estimates should accurately reflect the true costs the food industry will incur. GMA encourages the FDA to adopt the approach to preventive controls outlined in the comments based on our analysis that they are more cost effective and are aimed at preventing the diversion of resources from important food safety activities.

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

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

* * *

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

Sincerely,

Leon Bruner, DVM, Ph.D.
Senior Vice President for Scientific and Regulatory Affairs &
Chief Science Officer
GMA’s Comments on Proposed cGMPs, 21 CFR §117 Subpart B

General

GMA concurs with FDA’s approach which presumes that, generally, cGMPs are separate from those activities typically found as part of a food safety plan. Procedures typical of cGMPs create an environment that results in many hazards being unlikely but are not usually specific to an explicit hazard in a particular food. Therefore, GMA agrees with FDA when they state in the preamble to the proposed rule that, “CGMP controls are traditionally considered to be part of prerequisite programs, essential to effective preventive controls but often not part of them. FDA expects that compliance with those requirements in proposed part 117, subpart B will be sufficient.” 78 Fed. Reg. 3744.

Unique requirements for low moisture foods

GMA strongly recommends that the Agency be clear on how proposed GMP requirements would impact low moisture food operations.

GMA applauds the Agency for modernizing the GMPs to be more pertinent to current challenges in the food processing industry. In doing so it is apparent that the FDA used 21 CFR § 110 as a foundation document and proceeded to make changes to § 110 to bring the 1986 regulation up to date. This is a logical approach.

In 1986, foodborne illness reports associated with low moisture foods were virtually nonexistent and unforeseen. Unfortunately, 27 years later, we know that low moisture foods can be subject to pathogen contamination and be a vector for foodborne illness. More importantly, we know low moisture foods have their own unique set of requirements and challenges, especially the necessity to minimize the presence of moisture at all times. This prerequisite for food safety must be maintained both during operations and when cleaning and sanitizing the low moisture manufacturing facility.

GMA has provided discussion and recommendations to the proposed § 117 Subpart B in an attempt to make the proposed regulations amenable to the food safety requirements unique to low moisture food safety. Accordingly, we strongly recommend that the Agency be clear on how proposed GMP requirements would impact low moisture food operations and the impact that the final regulation will have on food safety plans for such facilities.

Recall plans

Requirements for firms to maintain recall plans should be facility-wide, not product and process specific and therefore moved to Subpart B, cGMPs. The current proposed rule, § 117.126(b)(6), lists recall plans as a required component of the food safety plan. GMA highly recommends that the requirement for a recall plan be moved to Subpart B, cGMPs, for the following reasons:

- Recall plans are often tailored to a given facility or company, not to a given product, process or production line.
For companies with more than one production facility, recall plans are often written at the corporate office and recall activities administered corporately as well.

Recall plans are a crisis management tool and are used after an adulterated product is released into the marketplace. In contrast, the food safety plan’s goal is to prevent a potentially-adulterated product from being produced and/or entering commerce.

A facility may process several categories of food in one building and have several food safety plans to do so. However, such a facility typically has one recall plan.

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

Structure of GMA’s comments on proposed cGMPs (Subpart B)

GMA has provided a structured approach to the comments below, the format of which is described here. First the section of the proposed rule or issue to be discussed is presented. This is followed by a section entitled “GMA Feedback” where general comments and suggestions on the proposed rule are presented. This is followed by a section entitled “GMA Recommends” where specific recommendations are made. These include recommended changes to the proposed rule language, if any. The proposed changes to 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).

There are slight modifications to this format for GMA’s response to FDA’s request for comments on how to best revise current §110.10(c): training requirements (78 Fed. Reg. 3729), and Table 11 of the proposed rule: Potential Revisions to Establish Requirements in Place of Current Guidance (78 Fed. Reg. 3728).
GMA’s Detailed Comments on Proposed cGMPs (Subpart B)

**Proposed Rule or Issue:** Storage of raw agricultural commodities for further processing. § 117.93 Warehousing and distribution: “Storage and transportation of food must be under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and the container.”

**GMA Feedback:**

- FDA states in their preamble that all food should be protected throughout the food chain: “FDA is proposing to delete the term ‘finished’ before ‘food’ because the requirements in this provision must apply to all food being held for distribution regardless of whether it is a raw material or ingredient or in its finished state. To ensure food safety throughout the food chain, food, whether a raw material or finished product, must be protected against contamination.” 78 Fed. Reg. 3727.

- While we agree with this basic concept except for the inclusion of radiological hazards (see GMA comments to the Food Safety Plan proposed requirements), GMA wants to ensure that the apparently minor change to existing regulation § 110.93, the removal of the word “finished” before the word “food,” does not transform a common and safe transportation method that has been used for over a century into an unacceptable practice.
  
  - For over 100 years, the frozen and canned produce industry has transported raw produce from the field, or from packing houses, to the processing factory in open top containers such as field boxes, totes and gondola trucks.
    
    - Fresh product transported this way is not protected against biological or physical contamination; birds can fly overhead and excrete on the produce or sticks and stones may fall onto the goods.
    
    - However, all of these commodities destined for frozen or canning processors will undergo processing that renders them safe for the consumer as evidenced by the trillions of servings consumed over the last century or more.
    
    - These uncovered containers are also often staged in a processor’s yard for a period of time until they are processed.

  - These two industries accounted for $11 billion in sales in 2008. Elimination of these practices would be a severe financial cost to a large segment of the food industry with no improvement to the consumer’s health.

- The same situation exists for raw produce transported to other processors of non-canned or non-frozen products such as fresh, refrigerated salads and salsas.

- GMA contends that this specific practice would not be affected by § 117.93 as it would fall under the exemption from the GMP requirements that FDA proposes to extend to the “holding or transportation of one or more raw agricultural commodities.” Proposed 21 CFR§
117.5(k)). GMA also understands that the practice described above is not subject to the requirements of proposed §117.20(b)(3) due to the exemption specified in proposed §117.5(k). Further, we read §117.20(b)(3) to provide flexibility and allow for various methods to be used to protect outdoor bulk vessels.

**GMA Recommends:**
- The Agency clarify the exemption of bulk, outdoor storage and transportation of raw agricultural commodities for further processing from GMP requirements with discussion in the preamble of the final rule.
- §117.93 be rewritten as follows: §117.93 Warehousing and distribution: Storage and transportation of food must be under conditions that will protect against allergen cross-contact and biological, chemical, and physical, and radiological contamination of food, as well as against deterioration of the food and the container.

**Proposed Rule or Issue:** Refinement of the definition for “cross-contact”

**GMA Feedback:**
- GMA commends the Agency for modernizing §110 GMPs (new proposed §117 Subpart B) with provisions to protect allergen sensitive consumers.
- GMA has reviewed the incorporation of the term “cross-contact” in the proposed regulation and finds its use consistent with practices employed today by GMA members to protect allergen sensitive consumers.
- FDA has defined “cross-contact” in proposed §117.3 as “Cross-contact means the unintentional incorporation of a food allergen into a food,” but GMA suggests that the overall goal of protecting these consumers would be enhanced if the term were changed to “allergen cross-contact.” This would further clarify what appears to be the Agency’s intention to address allergen-related cross-contact and not confuse the term with “cross contamination.”
  - This definition would serve to demarcate the two terminologies, cross-contact and cross contamination, which are often erroneously used interchangeably in the food processing community.

**GMA Recommends:**
- §117.3 Definitions be modified as follows:
  - **Allergen** cross-contact means the unintentional incorporation of a food allergen into a food.
  - Cross-contact means the unintentional incorporation of a food allergen into a food.
**Proposed Rule or Issue:** Definition of food-contact packaging

**GMA Feedback:**
- FDA should revise the final rule to include a definition indicating that protection of packaging from cross contamination or allergen cross-contact means protection of *food-contact* packaging.
  - The language used throughout the preamble seems to indicate this, but nowhere is “packaging (the noun)” specifically defined.
  - There is a definition of packaging when used as a noun in the regulations implementing the recordkeeping requirements of the Bioterrorism Act, but this definition states, “Packaging (when used as a noun) means the *outer packaging of food that bears the label and does not contact the food.* Packaging does not include food-contact substances as they are defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(6)).” Although this definition is not included in proposed § 117, it does confuse things and further illustrates why FDA should add language to the proposed GMPs clarifying that protection of packaging means protection of food-contact packaging.
  - We urge further clarification that “packaging (the noun)” does not refer to non-food-contact packaging such as shipping cases, over-sleeves, shrink wrap, labels, etc.
  - A common term used throughout the industry for food-contact packaging is “primary packaging.”
    - On page 2 of FDA’s Guidance for Industry – Container Closure Systems for Packaging Human Drugs and Biologics, (http://www.fda.gov/downloads/Drugs/Guidances/ucm070551.pdf) there is a definition for primary packaging that appears to be simple and could be adapted to food.
    - The Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children states that “Primary packaging is packaging that comes in direct contact with the product.”
  - Table 9 lists five provisions in current § 110 where “food-packaging materials” would be added resulting in proposed § 117 regulations. 78 Fed. Reg. 3717.
    - § 110.20(b)(4) (Plant Construction and Design)
    - § 110.35(d)(3) (Non-food-contact surfaces)
    - § 110.35(d)(4) (Food-contact surfaces)
    - § 110.37(a) (Water supply)
    - § 110.37(f) (Rubbish and offal disposal)

**GMA Recommends:**
- §117.3 contain a definition of “primary packaging” as follows: **Primary packaging means packaging that is in direct contact with the food.**
- Applicable portions of proposed § 117 would hence be changed accordingly.
Proposed Rule or Issue: Food-contact surfaces §117.35(d)(1): “Food-contact surfaces used for manufacturing/processing or holding low moisture food must be in a clean, dry, sanitary condition at the time of use.” 78 Fed. Reg. 3803.

GMA Feedback:
- GMA agrees with this statement insofar as “clean” is understood to mean free from foreign matter and unadulterated. Once an operation begins production, of course food-contact surfaces will not appear visibly spotless and pristine. Also, not all food-contact surfaces are kept dry, for example some food-contact surfaces of steam or water cookers may normally be wet during production.

- For the continued optimization of the public health, GMA contends that maintaining a sanitary condition is not a requirement to sanitize all product-contact surfaces. In the production of low moisture foods, facilities have areas that are designated “dry clean only” for food safety reasons, and include inaccessible areas of conveying equipment, such as transfer piping. These areas are kept dry to ensure that any existing pathogenic microbes, if present, cannot grow. Adding an aqueous-based cleaning and sanitizing procedure could increase public health risk in these certain operations such as low moisture foods production. These areas are cleaned with a variety of dry cleaning methods: vacuuming, wiping, scraping, push-through of other food or food-grade material (e.g., hot food-grade oil, salt, dry products, etc.). The resulting equipment, while sanitary, may not always be visibly clean, or suitable for aqueous chemical sanitizers.

GMA Recommends:
- The Agency clarify that maintaining a sanitary condition is not a requirement to sanitize all product-contact surfaces.

- The addition of language that would allow the continued use of cleaning methods determined by a risk assessment, which include dry cleaning without a sanitizing step.

Proposed Rule or Issue: The term “sanitize” proposed in § 117.3 is: “Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.”

GMA Feedback:
- The word “cleaned” is added to the proposed definition from the original in § 110.

- FDA explains in the preamble to the proposed rule that it is well established that sanitizers can be inactivated by organic material and, thus, are not effective unless used on clean surfaces. 78 Fed. Reg. 3697.

- While GMA agrees with this general and broad concept as it applies to chemical sanitizers used in wet cleaning, we note that:
o Adding an aqueous-based cleaning and sanitizing procedure could increase public health risk in certain operations such as low moisture food production.

o Cleaning and sanitizing do not always have to be separate, sequential events. They can be performed simultaneously and there is regulatory precedent for this approach at the federal and state levels.

  ▪ Appendix F of the Pasteurized Milk Ordinance (PMO), for instance, permits the use of hot water or steam as sanitation measures. The proper use of this procedure will result in a clean and sanitary surface in one step.

  ▪ Wisconsin Agriculture, Trade & Consumer Protection section 80.16 states, “Returnable glass bottles cleaned in an automatic bottle washer shall be sanitized while in the washer. Bottles cleaned in an automatic bottle washer may be sanitized by being soaked in a caustic solution.” (Emphasis added.) This is a codified example requiring cleaning and sanitizing in one simultaneous step.

• FDA may find the following language from section 12P of the PMO useful: “The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use.” This language would permit the use of methodology that cleans and sanitizes in one simultaneous step or sequential steps.

• GMA also reminds the Agency that food processors routinely sanitize areas and objects besides food-contact surfaces such as drains or employee footwear. Accordingly a definition of sanitize similar to that found in the PMO may be more appropriate: “the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable.”

• As stated above, GMA also has concerns with a requirement to sanitize all product-contact surfaces. In the low-moisture foods segment of the industry, for food safety reasons, facilities have areas where only dry cleaning methods are employed and include inaccessible areas of conveying equipment, such as transfer piping. These areas are kept dry to ensure that any existing pathogenic microorganisms, if present, cannot multiply and are cleaned with a variety of dry cleaning methods: vacuuming, wiping, scraping, push-through of other food or food-grade material (e.g., hot food-grade oil, salt, dry products, etc.). This results in equipment that while sanitary, is not visibly clean, nor suitable for aqueous chemical sanitizers. GMA highly encourages the addition of language that would allow the continued use of cleaning methods determined by the risk assessment, which might include dry cleaning with no sanitizing step needed for manufacturing product on a routine basis. Adding routine aqueous-based cleaning and sanitizing procedure to such operations may increase microbiological risk to consumers and require significant additional cost to industry.

GMA Recommends:
• The Agency clarify that maintaining a sanitary condition is not a requirement to sanitize all product-contact surfaces.

• The addition of language that would allow the continued use of cleaning methods determined by a risk assessment, which include dry cleaning with no sanitizing step needed.

• FDA adopt a definition of “sanitize” similar to that found in the PMO.

Proposed Rule or Issue: § 117.80(c)(10) “Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact and contamination. Food should be protected from contaminants that may drip, drain, or be drawn into the food.”

GMA Feedback:
• Although GMA agrees that processing conditions should be managed to protect against contaminants that may drip, drain, or be drawn into a food, making this sentence mandatory would create a redundant requirement to protect food from allergen cross-contact and contamination.

• GMA suggests the wording is equally effective when stated as, “Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and contamination.”

• Consistent with FDA’s approach as defined in the preamble to the proposed rule, the Agency should provide flexibility to industry by retaining the performance standard in current § 110.80(b)(12) (i.e., protection against contamination) but deleting the examples of mechanisms to achieve compliance rather than proposing to establish these recommendations as requirements. 78 Fed. Reg. 3716.

• Finally, in many cases the practice of “protecting” a food must be weighed against the severity of potential contamination that could result in such “protection.” For example, many frozen baked items use conveying time between the oven exit and the freezer entrance to pre-cool the hot baked goods. Installing covers over such conveyor lines could likely result in condensation, which is both insanitary and a potential vector for contamination by environmental pathogens, should any be present.

GMA Recommends:
• § 117.80(c)(10) should read as follows: “§ 117.80(c)(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and contamination. Food should be protected from contaminants that may drip, drain, or be drawn into the food.”
Proposed Rule or Issue: § 117.80(c)(9) “Food, raw materials, and ingredients that are adulterated must be disposed of in a manner that protects against the contamination of other food or, if the adulterated food is capable of being reconditioned, it must be reconditioned using a method that has been proven to be effective.”

GMA Feedback:
- FDA removed the language from current § 110.80(b)(9): “…or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.”
- FDA states in the preamble, “FDA is proposing to delete the option for reexamination so that adulterated food can only be disposed of or reconditioned if the food is capable of being reconditioned. FDA is proposing this deletion because a food may test positive for a contaminant in one test and negative in one or more additional tests although the food continues to be contaminated. For example, the distribution of a pathogen in a food may not be homogeneous.” 78 Fed. Reg. 3726.

  - GMA agrees with this statement and its intent as pertaining to pathogenic microorganisms.
  - However, GMA notes that many instances of product being placed “on hold” are not always due to contamination with pathogenic microorganisms.
  - For example, when a metal detector is used to detect potential metal contaminants, and is found to be inoperative, a common corrective action is to isolate affected product and pass it through a properly operating metal detector at a later time.

- GMA contends that such product has not been determined to be adulterated, and is therefore not subject to the restrictions outlined in proposed § 117.80(c)(9).

  - It simply has not been manufactured consistent with the overall food safety plan.
  - The processor has no intention of releasing the product to commerce without confirming it has no metal contamination.
  - Applying a corrective action as above simply completes the manufacturing process as reflected in the food safety plan.
  - This practice protects the public health as well as the originally intended process of passing product through the metal detector at the time of manufacture.
  - However, the product has not been “reconditioned” per se.
    - No material change has affected the product
    - It has not been re-cooked, used as an ingredient in another product, etc.

GMA Recommends:
• The Agency should include explanatory language in the preamble to the final rule to clarify that this and similar situations would not be covered by § 117.80(c)(9) because the product has not been determined to be adulterated.

Proposed Rule or Issue: Equilibrium pH. §117.80(c)(15) would state that, “Food, including acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.”

GMA Feedback:
• GMA cautions FDA that different regulations affecting a large segment of the industry contain conflicting language when addressing pH.
• GMA thoroughly understands the science and intention of that proposed text.
• GMA recommends however, that the proposed text be closer to that in 21 CFR §114.80(a)(1), which uses the term “equilibrated pH.”
• For clarification GMA offers the definition found in FDA’s Guide to Inspections of Acidified Food Manufacturers, which states that equilibrated pH is, “The condition achieved when the solid and liquid parts of the product have the same pH.”

GMA Recommends:
• § 117.80(c)(15) be worded as follows: “Food, including acid and acidified food, that relies principally on the control of equilibrated pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.”
• § 117.3 contain the following definition: “Equilibrated pH is the condition achieved when the solid and liquid parts of the product have the same pH.”

Proposed Rule or Issue: §117.80(c)(14) Manufacturing operations, water activity and moisture. Food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

GMA Feedback:
• Water activity (aw) and moisture do not measure the same attributes.
• Moisture level is not an adequate food safety control measure.
  o It may be an indicator of food safety effectiveness when it is correlated to aw.
• The wording should be changed to reflect that proper maintenance of aw will prevent growth of undesirable microorganisms.
GMA Recommends:

- § 117.80(c)(14) be worded as follows: §117.80(c)(14) Manufacturing operations, water activity and moisture. Food, including dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of water activity ($a_w$) for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe level.

Proposed Rule or Issue: § 117.80(c)(3) and (4), Manufacturing operations to prevent adulteration.

Proposed text for § 117.80(c)(3) reads, “Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding.”

Proposed text for § 117.80(c)(4) reads, “Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling $a_w$ that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.”

GMA Feedback:

- GMA contends that requirements in § 117.80(c)(3) are duplicated in § 117.80(c)(4) since § 117.80(c)(4) includes freezing and refrigerating (holding at temperatures that will prevent the food from becoming adulterated).

GMA Recommends:

- FDA modify the proposed regulatory language as follows:
  
  - § 117.80(c)(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing and holding.
  
  - § 117.80(c)(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling $a_w$ that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

Proposed Rule or Issue: §117.35(f) Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination.
GMA Feedback:
- GMA contends that the manner in which this equipment is stored includes the location and therefore such wording is redundant.

GMA Recommends:
- FDA modify the proposed regulatory language as follows: §117.35(f) Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and contamination.

Proposed Rule or Issue: §117.40(a)(6) Food-contact surfaces must be maintained to protect food from cross-contact and from being contaminated by any source, including unlawful indirect food additives.

GMA Feedback:
- GMA contends that the wording is equally effective when placing a period after the word “source.”
- This results in a stronger and more absolute requirement.

GMA Recommends:
- FDA modify the proposed regulatory language as follows: §117.40(a)(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source including unlawful indirect food additives.

Proposed Rule or Issue: §117.40(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

GMA Feedback:
- Similar to our discussion regarding § 117.40(a)(6), equipment and utensils, GMA contends that the wording in §117.40(g) is equally effective when placing a period after the word “contaminated.”
- This results in a stronger and more absolute requirement.
- We also advocate for the inclusion of the word “the” between “that” and “food.”

GMA Recommends:
- The Agency modify proposed language for §117.40(g) as follows: Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that the food is not contaminated with unlawful indirect food additives.
Proposed Rule or Issue: § 117.80(b)(3) Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.

GMA Feedback:
- Aflatoxin is a natural toxin, thus the term “aflatoxin or other natural toxins” is redundant.

GMA Recommends:
- The Agency modify proposed language for § 117.80(b)(3) as follows: “Raw materials and ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current FDA regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food.”

Proposed Rule or Issue: § 117.80(c)(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

GMA Feedback:
- GMA is concerned that this list could be interpreted as an exhaustive list of processing methods and consequently be a hindrance to the development of new technologies.

GMA Recommends:
- Accordingly GMA recommends modification of § 117.80(c)(4) as follows: “Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w, or other measures that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.”

Proposed Rule or Issue: Hand washing, § 117.37(e)

GMA Feedback:
- GMA agrees with the Agency’s approach that establishing a performance standard for hand-washing facilities similar to the one found in § 111.15(i) is a better approach than mandating the current recommendations in § 110.37(e).
- This approach is consistent in recognizing the diversity of modern food processing operations and the different approaches to address similar vectors of contamination utilized across the industry.
Mandating provisions of § 110.37(e) could be counterproductive as processors would seek compliance with those mandates and might pass up superior methods as they become available.

GMA Recommends:
- The Agency establish a performance standard for hand-washing facilities similar to the one found in § 111.15(i).
- FDA not mandate the current recommendations in § 110.37(e).

**Proposed Rule or Issue:** § 117.110 Defect action levels. Natural or unavoidable defects in food for human use that present no health hazard:

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods when it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food not be prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or the requirements in this part that food manufacturers, processors, packers, and holders must observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, processor, packer and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.
GMA Feedback:

- GMA recommends the discussion of defect action levels (DALs) should include a reference(s) where specific DAL information can be found, such as a URL.

- Similar language was included in § 110.110(e) and found useful by industry.

- With respect to § 117.110(c), a facility subject to proposed § 117.110(c) will implement current GMPs (proposed 117, Subpart B) and a food safety plan (proposed 117, Subpart C) as guiding “quality control operations” appropriate for this purpose.

- Importantly, we contend that reducing natural or unavoidable defects to “the lowest level currently feasible” does not require a facility to exceed current cGMPs or go beyond preventive controls identified through a hazard analysis; doing so would run contrary to the risk-based principles that underlie FSMA and leading food safety programs by requiring that all hazards be managed equally without considering the outcomes of the hazard analysis.

- Successful, responsible food safety programs allocate resources to hazards commensurate with their potential impact to the public health.

GMA Recommends:

- FDA include language in the preamble to the final rule clearly indicating that required compliance with § 117.110(c) does not constitute a requirement for facilities to exceed current cGMPs or go beyond preventive controls identified through their hazard analysis.

Other Comments on Proposed Subpart B

GMA response to FDA’s request for comments on how to best revise current §110.10(e), training requirements. 78 Fed. Reg. 3729.

- GMA believes that FDA should establish employee training requirements, but that any requirements should be sufficiently flexible to allow facilities to tailor the training needed to their employees, duties, facilities, equipment, processing conditions, etc. In general, GMA supports the tentative training and education requirements that FDA originally proposed in the version of the proposed rule that was submitted to the Office of Management and Budget for review, but which were not included in the published proposed rule. That regulation would have stated:

  “(1) Each person engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof, must receive training, as appropriate to the person’s duties upon hiring and periodically thereafter. The training must include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility.
  (2) Each person engaged in manufacturing, processing, packing or holding food (including temporary and seasonal personnel), or in the supervision thereof, must
have the training, in combination with education or experience, to perform the person’s assigned duties.

(3) Plant management must establish and maintain records that document required training of personnel, including the date of the training, the type of training, and the person(s) trained.”

- With respect to the level of detail in any training related regulation, GMA responds to FDA’s questions as follows:
  
  o “Specifying that each person . . . receive training as appropriate to the person’s duties. GMA agrees that appropriate training should be delivered. The decision as to appropriate training should be determined by the facility. Each facility is unique and will need to tailor training to the particular operations of the facility, and the culture and languages of its work force, as well as to the person’s duties.

  o Frequency of training. GMA believes that employees should be trained “initially” and “periodically thereafter.” FDA should recognize that a certain percentage of a facility’s workforce may be on extended leave at any one time. For those employees who are not “active,” annual training may be delayed until their return to the active workforce. Further, employees are not necessarily trained immediately upon hiring, but shortly after they commence work.

  o “Specifying that training include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene as applied at the facility.” GMA agrees that the training should include the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility.

  o “Records documenting training and minimum requirements for documentation.” GMA agrees that training should be documented and those records should show the date of training, a description of the training and the name of the person trained. FDA should understand that the way these records are kept may vary from facility to facility. Some facilities may use manual, sign-in sheets. Other facilities may conduct some training electronically and records of the training are stored in an electronic format. In the case of electronically provided training, FDA should accept print-outs of training reports as sufficient documentation of training as long as the print-out includes the necessary information concerning the date of training, a description of training and the name of person trained.

  o Whether training requirements should be in cGMPs, preventive controls or both. GMA believes that training requirements should be in cGMPs. All facilities should be compliant with the basic training requirements described above and maintain appropriate records.

  o Training to perform the employee’s assigned duties should not be limited to a narrow class of food processors.
Training also does not lend itself to being treated as a preventive control since it is not subject to the kinds of parameters or monitoring as would certain preventive controls. While training should be verified, the cGMP rule requiring training could include this as part of the record-keeping requirements.

GMA comments to items in Table 11 of the proposed rule, Potential Revisions to Establish Requirements in Place of Current Guidance. 78 Fed. Reg. 3728.

- § 117.10(c): As stated in our comments above, GMA agrees that appropriate training should be delivered.
  - GMA contends that the type and frequency of training should be determined by the facility since each facility is unique and will need to tailor training to the particular operations of the facility, and the culture and languages of its work force, as well as to the person’s duties.
  - This is consistent with FDA’s approach as defined in the preamble to the proposed rule where the Agency cites emphasis in section 418(o)(3) of the FD&C Act on the importance of both training in preventing hazards from occurring in foods, and with recommendation in the CGMP Working Group Report. 78 Fed. Reg. 3720.
  - GMA maintains that incorporating further specificity as suggested by the bulleted items in section XI.M.3 of the proposed preamble would be counter to the Agency’s intentions as stated above.

  - The resulting sentence from Table 11 incorporating this change would be, “Single-service articles ... must be stored in appropriate containers and must be handled, dispensed, used and disposed of in a manner that protects against cross-contact and contamination of food...”
  - GMA contends that using “must” and “appropriate” in the same sentence will result in protracted discussions regarding the definition of “appropriate” in each individual situation. These activities will add nothing to protection of the public health.
  - GMA further notes that Dictionary.com defines handling as “the manner of treating or dealing with something; management; treatment.”
    - Consistent with this definition, “handling” would include appropriate storage, dispensing, usage and disposal.
    - Thus, GMA recommends the requirements of this section be changed to something similar to: “Single-service articles must be handled in a manner that protects against allergen cross-contact and contamination of food.”

- § 117.35(e): Sanitation of non-food-contact surfaces. GMA agrees with this concept and supports such a change as proposed in Table 11.
o GMA still contends that comments made previously in this document on § 117.35(e) are appropriate.

- § 117.35(f): GMA has commented on this section above and would agree with the change from “should” to “must.”

- §117.40(a)(3) – Note, 78 Fed. Reg. 3728 version of Table 11 cites this incorrectly as §117.40(a)(1) - Equipment and Utensils.
  o GMA recommends the following wording: “All equipment must be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces as needed to protect against allergen cross-contact and contamination.”

- § 117.80(1)(b) Container and carrier inspection.
  o GMA encourages the addition of language that would be less prescriptive and narrow, such as: “Containers and carriers of raw materials must be inspected as necessary to ensure that their condition has not contributed to allergen cross-contact, contamination or deterioration of food that will not be mitigated by the manufacturing process.”

- § 117.80(c)(10): GMA has provided extensive comments above.

- § 117.80(c)(11): Current proposed regulation states, “Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.” FDA is proposing replacing the italicized words “should” above with “must.”
  o GMA contends that this entire section is redundant and not needed since these requirements are covered in proposed §117.80(a)(4), which states, “All reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.”
  o Accordingly, GMA recommends removing this redundant section.
  o However, if the Agency does not feel this is a prudent recommendation, and is intent on replacing the two instances of “should” with “must,” we suggest the following language: “Heat blanching, when required in the preparation of food, should must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay that could result in growth of pathogenic microorganisms. Thermophilic growth and contamination in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning, as necessary.”