November 15, 2013

Submitted Electronically via Regulations.gov

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

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

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments on 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 records and registration.

Executive Summary of Comments

FDA and industry have a shared interest in effective Agency oversight through meaningful record-keeping and access requirements, efficient inspections, and consistent enforcement. In that regard, the proposed rule raises a number of important inspection and enforcement issues that must be worked through to ensure these important goals are met. As discussed further in our attached comments:

- **Facility Profiles:** If FDA decides facility profiles will be useful, they should be voluntary and limited to key basic information (e.g., facility size and schedule) that can be used for risk-based allocation of inspection resources. Facility profiles should not include hazard and control-related information because FSMA does not provide the Agency with authority to require submission of such information. If FDA desires to create an integrated database, GMA believes Agency and industry resources would be best spent in updating the content and format of Establishment Inspection Reports (EIRs) with facility-specific information collected by Agency investigators during inspections.

- **Part 11:** GMA appreciates FDA’s recognition that electronic systems may be used to meet the recordkeeping requirements proposed in Part 117 regulations. FDA should require facilities that utilize electronic records to have secure systems, but we believe compliance with 21 CFR Part 11 is unnecessary, would lead to considerable cost and complexity, and should not be required.

- **Facility Registration:** Pilot plants and similar product development operations are very different from manufacturing and other facilities that handle products intended for commercial distribution. To prevent confusion and ensure that Agency and industry resources are not spent unnecessarily on these low risk operations, the regulatory framework should recognize their unique status and exempt them from facility registration so that they do not have to comply with the food safety plan requirements. In the alternative, FDA should allow these operations to address food safety in a way appropriate to the limited and research-oriented work they do.

- **Storage of Food Safety Records:** The final rule should allow flexibility for the storage of food safety records, as many are currently kept in centrally located corporate files. For example, records relating to suppliers, raw materials, consumer comments, validation, and similar topics that are relevant to multiple facilities routinely are kept in a central location. Requiring such records to be kept also at individual facilities for a period of time would not enhance public health, but rather would be duplicative and unnecessary to allow timely FDA access.
• **Remote Records Access:** Facility records should be reviewed on-site in order to understand their meaning, significance, and context. Facilities should not be required to provide records remotely (e.g., submit records to FDA through mail or electronically) as this practice will likely lead to confusion and misunderstandings and will not enhance food safety oversight. Furthermore, FSMA does not provide a legal basis for a remote access requirement.

• **Efficient Inspections:** FDA should develop a plan for efficiently implementing the records access authority included in the final regulation. Carefully focused records requests by investigators will help with quick identification of information most relevant for public health protection.

• **Freedom of Information Act (FOIA):** FDA should amend the regulatory language regarding FOIA protections to make it clear that trade secret and confidential commercial information are not subject to public disclosure.

**Implementation**

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). If FDA were to adopt GMA’s proposed language, we believe the costs outlined in the PRIA would more accurately approximate the costs the food industry will incur to implement the final rule. However, if the Agency adopts the proposed rule as currently written, the costs would far exceed the estimates in the PRIA. As a result, we strongly encourage FDA to adopt GMA’s alternate preventive controls regulatory language.

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

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

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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.
Senior Vice President Science and Regulatory Affairs &
Chief Science Officer
GMA Comments on Records- and Registration-Related Issues

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GMA Comments on Records- and Registration-Related Issues

FDA and industry have a shared interest in effective Agency oversight through meaningful recordkeeping and access requirements, efficient inspections, and consistent enforcement. The proposed rule raises a number of important inspection and enforcement issues that must be worked through to ensure these important goals are met. As discussed further in our comments below:

- If FDA decides facility profiles will be useful, they should be voluntary and limited to key information (e.g., facility size and schedule) that can be used for risk-based allocation of inspection resources. GMA believes Agency resources would be best spent, however, in updating the content and format of Establishment Inspection Reports (EIRs) to permit FDA to harness important facility-specific information collected by Agency Investigators during inspections in an integrated database.

- GMA appreciates FDA’s recognition that electronic systems may be used to meet the recordkeeping requirements proposed in part 117 regulations. FDA should require facilities that utilize electronic records to have secure systems, but compliance with 21 CFR part 11 is unnecessary, would lead to considerable cost and complexity, and should not be required.

- Pilot plants and similar “product development” operations are very different from manufacturing and other facilities that handle products intended for commercial distribution. To prevent confusion and ensure that Agency and industry resources are not spent unnecessarily on these low risk operations, the regulatory framework should recognize their unique status and allow them to address food safety in a way appropriate to the limited and research-oriented work they do.

- The final rule should allow flexibility for the storage of food safety records, as many are currently kept in centrally located corporate files. For example, records relating to suppliers, raw materials, consumer comments, validation, research and development work, and similar topics that are relevant to multiple facilities routinely are kept in a central location. Requiring such records to be kept at individual facilities for a period of time would not enhance public health, but rather would be duplicative and unnecessary to allow timely FDA access.

- Facility records should be reviewed on-site in order to understand their meaning, significance, and context. A requirement for facilities to provide records remotely (e.g., submit records to FDA through mail or electronically) is likely to lead to confusion and misunderstandings and will not enhance food safety oversight. GMA is also unaware of a legal basis for a remote access requirement.

- FDA should develop a plan for efficiently implementing the records access authority included in the final regulations.
• FDA should clarify the regulatory language regarding Freedom of Information Act (FOIA) protections by explaining the basic nature of those protections in plain language.

GMA has been a strong supporter of FSMA since early in the legislative process and looks forward to continuing to work with FDA to ensure the law is implemented successfully and in a manner consistent with the statutory framework constructed by Congress.

I. Facility Profiles Should Be Voluntary and Limited to Key Facility Information Useful to Allocating Inspection Resources

FDA has asked for comment on whether to require submission of “facility profiles” with a subset of information from food safety plans. For example, FDA has suggested such information could include data elements such as contact information, facility type, products, hazards identified for each product, preventive controls established for each of the identified hazards, third party audit information (whether a facility has had one, and if so, which audit firm), employee training, facility size, and operation schedule (including whether the facility is full time or seasonal). According to FDA, such information could be submitted through an electronic form, creating a searchable database. FDA believes having such information in advance of an inspection may provide the following benefits:

• Help FDA better target inspecional activities to facilities that produce food with an increased potential for contamination (particularly with biological hazards)
• Improve on-site inspections by focusing attention on hazards and preventive controls for which a facility appears to have deficiencies
• Help FDA respond to identified food safety problems by focusing inspections on facilities that make food at increased risk, that may have controls insufficient to prevent a problem, or that may be using a control FDA considers to be ineffective

FDA asks for comment on the utility and necessity of such an approach, on specific types of information that may be useful in developing a facility profile, and on any potential concerns with a facility profile requirement.

GMA supports the Agency’s efforts to make inspections effective and risk-based. GMA appreciates and has availed itself of multiple opportunities offered by the Agency to provide input about ways to accomplish these important goals, which include comments GMA filed in July 2012 (see attached) to address FDA’s consideration of voluntary facility profile submissions and the June 2013 facility profile usability test that GMA hosted and in which several GMA members participated. GMA also supports FDA’s decision, explained in the preamble to the proposed preventive controls rule, that it is not practical to require industry submission of food safety plans.¹ These comments reflect GMA’s previous input and provide additional insight based on more recent information, including the June 2013 usability test.

GMA believes strongly that collection of facility profile information, as explained in the preamble, cannot achieve FDA’s stated goals. Certain information such as facility location, product category, size and operating hours may be useful to know ahead of an inspection, but information about a facility’s hazard analysis, process controls, and other information cannot be fully understood, is subject to misinterpretation, and is of little value when examined outside of the processing facility context. The food industry is diverse and there are many examples of operational differences, product differences and differences in the approach to food safety that cannot be assessed without an inspection of the facility. Likewise, there are examples of facilities that have written food safety plans that might appear compliant at first glance but when reviewed in practice would reveal numerous gaps and deficiencies. GMA believes that the deficiencies that were exposed during the FDA usability test GMA members participated in during June of 2013 are confirmation that the facility profile proposal is highly unlikely to advance FDA’s goals.

GMA also has considered the resources that would be required to comply if FDA were to mandate submission of facility profiles, particularly if they include hazards, controls, and verification inputs. GMA has determined—confirmed through participation in the recent usability study—that FDA’s facility profile plan would require significant resources to collect and assemble the necessary information into a standard template for submission. Additionally, GMA has examined the potential legal basis for a facility profile requirement, and has been unable to identify any authority that would permit such a system to be mandated, as opposed to the voluntary system FDA had previously suggested.

Although the facility profiles discussed in the preamble are problematic, there is much FDA can do to develop better tools to assess risk and determine where best to spend resources in enforcing FSMA and advancing the law’s goals of improving foods safety and public health. GMA believes that the most important information for FDA to use in evaluating risk and prioritizing inspections is collected by its investigators and contracted state inspectors. Instead of investing in a facility profile system of limited utility, now is the time to update the EIR process to assure that EIRs are capturing useful information and that the information is readily accessible through an integrated data system. In support of GMA’s analysis and suggestions, these comments offer several specific examples below to illustrate why the current proposal will not meet FDA’s goals, explain why the requested information will be extremely resource-intensive to collect and submit, outline why GMA believes the proposal is without legal authority, and share an approach that GMA believes will be far more effective and protective of public health.

A. Because of Process and Product Variations, Reviewing Hazards, Controls, and Similar Information Out of Context Will Be of Limited Value to FDA

FDA appears to intend facility profiles to help the Agency use limited resources more effectively. For example, FDA has explained that profiles could help FDA decide which facilities to target if a problem with a particular kind of preventive control has been identified. Similarly, FDA believes facility profiles may help to focus onsite inspections by helping FDA identify possible deficiencies in advance. These are laudable goals, but
interpreting hazards and controls information is far more complex than FDA may realize, for at least two reasons. First, across the broad range of GMA members, we know that multiple approaches to process control can result in the same high level of food safety. We know that to be effective, preventive controls must be tailored to each particular product, process, and facility and there are many different preventive controls that a facility may choose to use to manage a given hazard. Thus, it is very problematic to make judgments about a facility based on a general list of that facility’s hazards and controls.

Second, the food industry is extremely diverse in terms of the variety of products made and the way those products are processed. An almost infinite number of variables make review of hazard and control information of limited use without an accompanying visit to the facility.  

1. Multiple Approaches Can Result in the Same Level of Food Safety

Facilities may use entirely different controls to address similar hazards, leading to multiple approaches that can provide the same level of food safety. For example, there are several ways to control foreign material hazards including filters, magnets, metal detectors, and x-ray.

The same is true for biological hazards. In salad dressing, biological hazards can be controlled through formulation, pasteurization, or fill temperature. In chocolate, biological hazards may be controlled through bean roasting, nib roasting, or debacterization (subjecting cocoa beans to a high temperature/pressure process). A peanut butter facility may use wet cleaning or dry cleaning or both.

GMA is concerned that FDA intends to compare facility profiles for the purpose of identifying facilities that appear to be deficient in one or more respects. Such comparisons could lead to improper assumptions that a facility has not taken the necessary steps to address a food safety hazard when there may be valid product- or process-specific reasons for the approach chosen. Adding the necessary context (e.g., factors like the placement of filters, formula considerations, pack size) to the portal would be unworkable due to the amount and complexity of information involved, but relevant steps and controls can be readily observed and investigated during an inspection.

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2 In recent years, many GMA member companies have introduced increasingly robust supplier management programs. In large part, these programs seek to accomplish the same goals that FDA seeks in its facility profile proposal. GMA member companies evaluate risk in their supply chains and allocate limited resources based on risk. GMA’s approach to supplier risk assessment is discussed at length in GMA’s comments on supplier verification. One universal truth from GMA member experiences is that hazard analysis and preventive controls cannot be adequately evaluated out of context.
2. Numerous Variables in Products and Processing Require Context Before Hazards and Controls Information Can Be Reviewed in a Meaningful Way

Before and after the facility profile usability test, GMA members carefully considered how facility-specific information might be used to help allocate inspection resources. Numerous examples revealed a common theme: a simple listing of hazards and controls does not provide sufficient information to permit a reasonable assessment of food safety, but the kind of detail that would be necessary to identify possible deficiencies is not practical to assemble (indeed, even the foundational information FDA has requested is extremely time and resource-intensive to collect). This result stems from the numerous variables that can affect a hazard analysis and selection of preventive controls, such as the type of processing used to make a product, operational differences among facilities, differences in product formulations, prior treatments for ingredients, the use of multiple steps to address the same hazard, the need for the same control to be used repeatedly in multiple steps, and the mix of ingredients processed in a facility.

Type of processing affects hazards and controls. The facility profile portal GMA evaluated called for hazards and controls to be identified by product category (e.g., “hard cheese”). This is problematic because individual products within the same product category can have different controls depending on the nature of the manufacturing process used to make them. Illustrative “manufacturing” scenarios include making product from entirely raw materials, further processing of in-process materials, blending of otherwise finished products together, and physically converting the form of a food (e.g., grating, cutting). It is impossible to tell from a “manufacturing” entry exactly what a facility is doing.

For example, a parmesan cheese plant that makes parmesan from milk is likely to have different controls than a “conversion” plant that simply grates and packages cheese made in another facility. The conversion plant will not have a thermal process step, but it is not necessary at this stage in the process because the thermal step occurred during cheese manufacture. If viewed out of context, this information could mislead an inspector to think that the conversion facility missed an important hazard and control because they are making cheese, but didn’t identify a biological hazard and thermal processing step.

As another example, consider that manufacturers of spice blends may use either raw or treated spices (i.e., spices treated to reduce microbial hazards) as ingredients. A manufacturer using raw spices may include a treatment step (e.g., fumigation, irradiation) in their food safety process, while a producer using treated spices may simply rely on enhanced hygiene controls. Without context, an inspector may think that the facility using treated spices has a deficient program because they do not apply a treatment step.

It would be difficult (if not impossible) to add more details to the facility profile portal to address these kinds of omissions because numerous variations of these situations exist across the broad food industry. The basic nature of the operation will be immediately apparent, however, during an inspection.
Operational differences affect hazards and controls. Within the same product category, facilities can differ in important ways that will not be captured in a facility profile. As just one example, facilities may have different equipment due to the size of the operation, the facility’s individual history, or other factors. Different processes may sound similar, but may trigger a need for different preventive controls.

For example, corn milling processes are very different depending upon whether they are wet or dry. Controls for syrups and starches from wet milling include chemical additions/reactions, high temperatures and multiple filtration steps, whereas dry milling control steps involve sifting, magnets and metal detectors. In a facility profile, all such diverse operations would all be lumped together as similar operations because they part of the same product category.

Another example is that canning facilities without cooling canals may need special equipment to detect cans with low fill levels (an important food safety issue for canned foods). In contrast, at facilities with cooling canals, the containers float, so under filled containers can be readily detected and removed without special equipment. Although low acid canned food facilities are partially exempt from FSMA, GMA finds this example helpful to illustrate what a significant difference equipment can make to a hazard analysis and selection of preventive controls.

Yet another example is that a large scale cheese operation may have an interim holding tank that has a rinsing step that needs to be controlled for food safety, but a smaller facility may not have such a tank and would be fine with routine daily cleaning. Such diverse operations may be used to make the same product safely, but in different ways that cannot be reasonably assessed outside of the production environment.

As a result of these and other operational differences, an inspector reviewing facility profile information in the proposed portal will not have enough details to assess whether a control related to equipment, operational scale, or similar factors is needed. Adding more specificity to the portal would be unworkable due to the amount and complexity of information involved, but facility-specific details such as equipment can be easily observed during an inspection.

Differences in product formulations affect hazards and controls. The facility profile database must group hazards and controls by category, not by formula. As the food industry is diverse there are an endless variety of possible formulas for foods within the same category. A product’s formulation will necessarily impact the hazards and appropriate controls.

For example, parmesan cheese may take a dry or fresh shredded (full moisture) form. For dried parmesan, the risk of Clostridium botulinum and Bacillus cereus is inherently low because of water activity. But for fresh shredded parmesan, those organisms are controlled by refrigeration and the presence of starter cultures.

As another example, consider that manufacturers of refrigerated, non-shelf stable salsas may take differing approaches. A producer that simply cold mixes and packs the salsa
may aggressively wash and chemically sanitize the fresh vegetables used in this product. The vegetable wash/sanitizing procedure is a strictly managed preventive control identified in this firm’s hazard analysis. In contrast, a processor who pasteurizes the finished salsa might only lightly rinse the same vegetables going into a very similar finished product. The pasteurization greatly reduces the potential for pathogenic contamination, but the product still is held, transported, and sold under refrigeration.

Plants making any of these products may or may not have the right controls in place, but this could not be assessed from the portal information. Adding more specificity to the portal would be unworkable due to the amount and complexity of information involved, but product-specific details can be easily observed and investigated during an inspection.

Prior treatment and end use of product may affect hazards and controls. For many foods, such as spices, steps needed to address microbial issues will vary depending on the food itself as well as customer-specific requirements. For example, a processor might receive red pepper that has been treated with ethylene oxide prior to importation (so it does not need to be treated again); in another case, red pepper might be treated or used in a thermally processed canned chili product at the manufacturing facility; in yet another case, it might be treated at an external irradiation facility in lieu of other treatments. All are legitimate preventive controls, and all are driven by unique logistical and other circumstances that the proposed portal cannot reasonably reflect.

Nuts provide another helpful example. One processor may receive nuts that have been treated by the nut supplier, while another processor may utilize nuts that were not treated prior to receipt. Hazards revealed by a proper hazard analysis would be different for the two processors. Comparing the hazards and controls between these processors without context would be of no value. Upon visiting the processors, however, FDA will be able to evaluate readily the hazards and controls in place.

The same hazard may (or may not) need to be addressed in multiple steps. Within the same process, a specific hazard may need to be addressed multiple times, but it isn’t possible to assess complexities of this type without visiting the facility.

For example, a vegetable fritter factory (battered, fried and frozen mushrooms or cauliflower) might address hazards associated with *Staphylococcus aureus* in three places: (1) raw ingredients such as dairy powders pose a risk, (2) the hand addition of ingredients (human handling) is a potential risk, and (3) the process step of holding a batter slurry prior to heat treatment can lead to growth of *Staphylococcus aureus* and potential toxin development. The first two risks are controlled by the thermal process but the last risk (holding the slurry) is controlled by holding conditions such as time and temperature. This holding step is critical because if it is not properly controlled, *Staphylococcus aureus* growth and toxin production could result. Further heat treatment cannot eliminate the toxin.

While one plant may include all three *Staphylococcus aureus* controls in its facility profile, another facility might not. One of two things might be possible. Slurry holding may not be listed because the facility might not realize the need to control slurry holding,
or the facility may not have a holding step. It wouldn’t be possible without actually visiting the facility to determine whether the control was improperly overlooked or simply unnecessary. Adding process-specific information to the portal would be unworkable due to the amount and complexity of information involved, but relevant steps like product holding practices can be easily observed and investigated during an inspection.

The same controls may (or may not) need to be used in multiple process steps. The proposed portal includes thermal processing, which is a wide and diverse category of controls. Some processors may have two or more operation steps that are thermal process controls. For a sauce manufacturer, there may be both a product cook step and a hot fill process step. Depending on the process, assessing a food safety plan may require consideration of not only whether a thermal process step is in place, but precisely where that control is and how it is managed.

A facility profile would not provide information sufficient to assess whether a facility has identified controls like thermal processing in all places where they may be necessary. In the example above, if a facility did not identify hot filling as a thermal process step, the only way to assess the food safety implications would be an inspection. Failure to identify a hot fill step could be an oversight or could simply mean that the facility uses a cold fill process that is managed in other, equally appropriate ways. If a facility was improperly managing a hot fill step, FDA will miss that red flag if the Agency is simply looking to see whether some kind of “thermal process” is in place. Adding process-specific information to the portal would be unworkable due to the amount and complexity of information involved, but relevant steps like filling practices can be readily observed and investigated during an inspection.

Mix of products and ingredients processed in a facility can affect hazards and controls. Without knowing the mix of products and ingredients in a facility, the rationale for identifying (or not identifying) particular hazards may be difficult to understand and could lead to incorrect assumptions. For example, in a facility that processes only dairy products and does not handle any other allergen, the facility may not manage dairy allergens as a CCP or other control. On the other hand, a dairy facility that also includes a tree nut in some of its products may have controls for both the dairy and tree nut allergens.

As with the other examples above, adding the necessary context to the portal would be unworkable due to the amount and complexity of information involved. In contrast, relevant information such as the kinds of products and ingredients handled can be readily observed and investigated during an inspection.

Many facilities handle numerous product categories with shared (or unique) controls. Many facilities will process a wide variety of products within a particular category (e.g., “bakery” or “dairy” products). Certain universal controls will be implemented for all products across a facility, but many of the products also will have unique processing conditions, hazards, and controls.
For example, a facility might process 30 SKUs of the same product, with only one SKU packaged in glass containers. The proposed facility profile would group all hazards and controls by category, making it impossible to understand which hazards and controls are in place for which kinds of products. The facility profiles for certain facilities may be quite confusing if they identify all different products, hazards, and controls as applicable for their broad range of operations. Consequently, identifying hazards and controls by SKU may be unworkable due to the amount and complexity of information involved, but relevant information can be readily observed and investigated during an inspection. For example, facility personnel can quickly identify for FDA exactly where various allergens are handled, glass containers are used, or similar details that may be relevant to analyzing hazards and controls.

**B. Hazards, Controls, and Similar Information Are Not Only of Limited Value Outside a Facility, but Also Extremely Resource Intensive to Collect, Assemble, and Submit**

GMA members have evaluated the resources that would be necessary to collect and submit the data elements listed in the FDA request for comment. Participation in the June 2013 facility profile study was especially enlightening and confirmed that this information would be extremely resource intensive to collect, assemble into a standardized format, and submit.

As explained in our July 2012 comments on a voluntary facility profile system, GMA members usually handle information such as facility registrations with centrally located corporate employees. To submit facility profiles, these employees would need to work with facility food safety experts to review the applicable food safety plans and prepare a collective list of the hazards, controls, and other information for each product category. Food safety plans can be complex and extensive, so compiling this information would require several hours, at least, per plan. Facilities frequently have multiple food safety plans in effect, making the total time a function of the hours needed to collect and standardize information from each plan multiplied by the total number of plans for each facility.

Because the scope of “preventive controls” is unclear and has not been finalized, GMA members used a variety of approaches to assess resource needs when preparing for the usability test. To test a range of possibilities, one company included only CCPs as preventive controls; another assessed CCPs plus targeted prerequisite programs; another included all possible controls, including both specific (e.g., CCPs) and general controls. In all cases, a need for significant resources was clear.

For example, a GMA member that included only specific controls (i.e., CCPs and targeted prerequisite programs) in its analysis estimated that simply collecting and assembling the information required to enter hazards and controls data could take 262.5 hours or 44 days. This number is calculated based on an assumption that each of 35 production facilities has five food safety plans (with a range of one to 12 plans) and that it would take one to three hours per plan to collect the information, review it, and
assemble it into a data collection template for use in data entry. The estimate of 262.5 hours does not include data entry time.

The necessary time will be significantly affected by the ultimate scope of “preventive controls” that FDA defines in the final rule. The statute, GMA’s comments on food safety plans, and FDA’s analysis in the preamble all point to a broad definition of preventive controls. For example, most of the “preventive controls” listed in the statute are prerequisite programs or programs other than CCPs (e.g., hygiene training, good manufacturing practices); GMA’s comments on food safety plans propose that the preventive control requirements address the food safety system in a holistic, seamless way; and FDA’s discussion in the preamble cites programs such as preventive maintenance as examples of preventive controls. GMA noted that this theme was continued in the draft portal evaluated in the usability test, which listed numerous prerequisite programs as possible preventive controls. As a result, GMA expects that our facility profile resource estimates likely underestimate the actual time that would be required.

Moreover, as shared with FDA during the usability test, many elements of the draft portal suggest that data entry may also require a significant amount of time. GMA appreciates that technology solutions may address some of the challenges, such as the ability to save ongoing work, but others are likely to be more difficult to resolve, as explained in detailed feedback provided during the test.

C. GMA is Unaware of a Legal Basis for Requiring Facility Profiles

Prior to the preventive controls proposal, FDA had considered a voluntary process for submission of facility profiles. In the preamble to the proposed rule, FDA made clear it is seeking comments on whether submission of facility profiles should be mandatory. As a result, GMA has considered the potential legal basis for a mandatory facility profile process, as well as similar requirements FDA has suggested, such as remote records access authority. After a careful review, GMA has concluded that neither FSMA nor other provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) provide authority to require submission of facility profiles or remote access to records. Because the same analysis is relevant to both kinds of authority, the basis for this conclusion is explained below in Section V of these comments, which address remote records access.

D. Rather than Pursuing Facility Profiles, FDA Should Update the Content and Format of EIRs to Harness Key Information in an Integrated Database

Much of the information that FDA seeks to include as part of its facility profile proposal is already collected by FDA as part of the inspection process and recorded in the Establishment Inspection Report (EIR). As part of the EIR process, FDA routinely collects information related to facility contact information, facility type, products produced, facility size and operation schedule. The EIR also captures additional data that would be relevant to assessing risk and targeting inspectional resources. Examples of
additional information collected by FDA include notes about inspectional observations and comments, consumer complaints and food safety documents and systems reviewed.\(^3\)

The EIR process is very capable of capturing key information about hazards and controls. Under current law, FDA has been asking facilities for access to HACCP plans, pest control, sanitation, training and other records. While they may not be required legally to do so, many facilities have provided this information voluntarily. Once the preventive control rules are final and enforced, FDA will easily be able to collect details regarding potential gaps in a facility’s hazard analysis or controls (GMA would expect FDA to focus on potential gaps or especially sensitive controls rather than compiling exhaustive lists of all hazards and controls, which would not be practical and are not likely to provide valuable insight). The EIR is especially advantageous because it offers immediate context to the information collected, in contrast to a facility profile. As explained above, GMA believes strongly that only by including the inspectional context can FDA effectively evaluate the hazard analysis and controls. Even when trying to mine this data to assess risk across broad categories of facilities, products or processes, information will be of little or no use without consideration of the context of the inspection.

An additional category of information that FDA mentions in the preamble is third party audit information. Because confidentiality is the key to a full, open and robust audit process, the fact that an audit occurred could be recorded, along with the result of the audit, but the audit report itself should be kept confidential and not included in an EIR in whole or in part. As GMA explains in greater detail in comments addressing the supplier verification aspects of this proposal and the proposed rule on foreign supplier verification programs, food safety requires facilities to have the freedom to conduct audits that encourage continuous improvement without the potentially chilling effect of regulatory review.

The EIR process is comprehensive as FDA should have data on nearly every facility registered with FDA. Also, as part of FDA’s directive under section 201 of FSMA, FDA is to complete inspections of all domestic high-risk facilities “not less often than once in the 5-year period following the date of enactment of” FSMA. FDA is nearly three years into this cycle which is to be complete by January 2016.

GMA recognizes that the current EIR form used by FDA has been in place since 1997 and may not be database friendly. GMA urges FDA to devote the technological resources it has planned for facility profiles to revise the EIR format to make it more “database” friendly. For example, FDA should consider use of drop-down menus and fields so that EIR information could be more readily searchable. Now is the time to update and modernize the EIR process so it can be used as a more effective tool by FDA to accomplish its goals of targeting inspection resources, looking for gaps in preventive controls, and providing guidance.

In addition to making the EIR form database friendly, another opportunity for improvement of the EIR process is to provide an opportunity for each facility to correct EIR information that may be incomplete or incorrect. Allowing facilities to help FDA improve the accuracy of the EIR data will enhance FDA’s database and its ability to assess risk. FDA should provide notice and an opportunity for facilities to comment on the EIR before FDA finalizes the EIR.

FDA also can use an updated EIR process to develop an integrated database that links EIR data with other FDA data on food facilities (e.g., registration, reportable food registry, 483 observations). Simply by inputting a product type, company name, facility registration number etc, FDA should be able to pull up a robust profile of a facility that includes not only basic information about the facility (e.g., location, hours, type of products) but also information about its overall regulatory history. The end result will be usable and searchable databases that can truly help target inspectional resources and achieve FDA’s goals. FDA will get more value from the IT Resources that the FDA was planning to spend on a new facility profile system by upgrading the existing EIR process and creating an integrated database system. GMA notes that FSIS manages a similar system in which inspectors input facility information and inspected establishments have the opportunity to review the data entered by the inspectors.4

Although GMA believes an EIR-driven database would be the best use of Agency resources in this area, if FDA continues to believe some form of a facility profile submission would be useful, it should be voluntary and limited to data elements most likely to help FDA target inspectional resources. Of the categories noted in the preamble to the proposed rule, this would include details about facility type and size, operation schedule, and number of employees. It should not include hazards, controls, or verification inputs. Where information is already required as part of the facility registration process, such as product categories, that data should be drawn directly from the registration portal and not required to be entered a second time.

II. FDA Should Require Facilities to Have Appropriate Systems for Electronic Records, Where Used; Compliance with 21 CFR Part 11 Is Unnecessary and Should Not Be Required (Proposed § 117.305)

Under the proposed rule, the general requirements for records (proposed 21 C.F.R. § 117.305(a)) identify key principles that facilities must adhere to in keeping FSMA and GMP related records under proposed part 117. For example, the proposed regulations advise that records must contain actual values; be accurate, indelible, and legible; be created concurrently with performance of documented activities; and be as detailed as necessary. GMA strongly supports the good recordkeeping principles FDA has identified for key food safety records. GMA agrees that recordkeeping systems used to document key food safety activities must be trustworthy and reliable.

The proposed requirements would permit facilities to keep electronic records, but specify that such records would need to be kept in accordance with FDA’s regulations addressing

electronic records and electronic signatures (21 C.F.R. part 11). In the preamble, FDA notes that the Agency “tentatively concludes” that it is appropriate to apply part 11 to FSMA and GMP records; however, FDA also asks whether there are any circumstances that would warrant not applying part 11 requirements. For example, FDA asks whether a part 11 requirement would trigger a need to recreate and redesign existing systems, which FDA previously determined to be the case when deciding to exempt records kept in compliance with other regulations from part 11. For this reason, FDA previously determined that part 11 compliance was not necessary for records relating to Bioterrorism Act requirements (21 C.F.R. § 1.329) or FDA Bovine Spongiform Encephalopathy (BSE) regulations (21 C.F.R. § 189.5(c)(7)).

GMA strongly recommends that FDA remove the reference to part 11 in the proposed regulations. Part 11 contains requirements that are unnecessary to produce secure and reliable records. Consequently, industry would be required to significantly redesign and replace existing systems without any corresponding benefit or risk reduction. The cost and time involved would be significant and burdensome, and would not advance food safety. In addition, the inclusion of part 11 compliance would result in an unnecessary enforcement burden for FDA in the area of electronic systems security.

Along with removal of the requirement for part 11 compliance, GMA encourages the Agency to partner with key stakeholders to develop guidance that describes the kinds of systems that can be used to assure the integrity of select electronic records without imposing specific technical requirements that may be unnecessary or inappropriate. This guidance should clarify that specific security needs will depend on the circumstances, including the system at issue, its intended use, the criticality of the preventive control or other food safety measure it is used to manage, and other relevant factors.

A. The Same General Recordkeeping Principles Apply to Critical Food Safety Records Regardless of Whether They Are Generated on Paper or by Electronic Means

GMA believes that the same basic principles that apply to handwritten food safety records also apply to records generated or maintained by electronic means. For example, for both paper and electronic records, essential data elements include authenticity, security, and integrity of the record(s). In addition, recording must take place at the time of the observation either automatically or by trained individuals.

To ensure records are authentic and secure, it may be necessary for certain computerized systems to have limited access with user names, passwords, and time stamps to trace records to those who originated, changed, or reviewed records (when required). Records in a computerized system also must be protected, backed up, and retained as per regulatory requirements and company record retention policies. In all cases, the specific needs will be dictated by the circumstances.

Because the same general principles apply, it is unnecessary for the regulations to adopt a more prescriptive approach for electronic records than for paper. If desired to confirm expectations for electronic systems, however, FDA could add a principle-based
requirement for industry to use electronic systems that are trustworthy, reliable, and generally equivalent to paper records. For example, FDA could strike the part 11 phrase in proposed § 117.305 (“which must be kept in accordance with part 11 of this chapter”) and replace it with “which must be kept using a system that assures records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.” This would bring in the key principles behind part 11 without imposing specific requirements that may not be necessary or appropriate, either now or in the future.

B. Some Part 11 Requirements are Unnecessary and Burdensome

GMA is concerned that some of the requirements in part 11 are unnecessary for the secure operation of many systems currently in use and would create the need to redesign and recreate existing systems. For example, an expectation for validation of electronic recordkeeping software and hardware would be particularly problematic because software patches and security updates are distributed on a nearly weekly basis. Validation activities would be difficult to maintain and would not deliver added value. Validation procedures are most appropriately applied before use of a new system and after major software changes or updates.

It would be costly and burdensome to modify or replace existing electronic systems to achieve part 11 compliance and would require specialized resources. As an example, one GMA member company shared that it took over nine months to upgrade one system alone to achieve part 11 compliance. It would not be unusual for companies to employ multiple systems, so the burden and cost would exponentially increase. It is GMA’s strong belief that full part 11 compliance is not required to have complete confidence in the integrity of food safety electronic records.

GMA appreciates that FDA recognized in the Bioterrorism Act rulemaking that “a requirement that records kept under this subpart comply with part 11 would hinder the ability of persons subject to these regulations to utilize existing systems and records to satisfy the requirements of these proposed regulations...”. See 68 Fed. Reg. 25188, 25199 (May 9, 2003). FDA acknowledged during the Bioterrorism Act rulemaking process that “large numbers of already existing electronic records and recordkeeping systems would have to be recreated and redesigned” in order to become part 11 compliant. Including part 11 compliance in the Preventive Controls proposed rule (21 C.F.R. § 117.305) would result in an analogous situation—indeed, since the scope of FSMA and Preventive Controls is much broader than the Bioterrorism Act rulemakings, the expected impact could only be larger and more significant. GMA strongly encourages FDA to take the same position and exempt the food industry from compliance with part 11, 69 Fed. Reg. 71568 (Dec. 9, 2004).

GMA believes it would be especially inappropriate to build part 11 compliance into new regulations at the present time. Major advances in software technology have been made since part 11 published in 1997, and such advances would need to be carefully considered in evaluating any potential expansion or new applications of part 11. Indeed, FDA is already in the process of reevaluating part 11 for the regulations for which it currently
applies. In industry guidance issued in 2002 and 2003, FDA acknowledged that part 11 is unworkable in many respects and decided to exercise enforcement discretion for part of the regulations. In addition, FDA has announced plans to reexamine part 11 as a whole.

C. GMA Recommends the Development of Additional Recordkeeping Guidance

While GMA does not believe that preventive controls records should be subject to part 11, GMA agrees that it is important for these records to be secure. As explained above, GMA recommends that FDA consider specifying that food safety records must be equivalent to their paper counterparts, meaning that they must have appropriate authenticity, security, and integrity. GMA recommends that FDA develop guidance, with input from key stakeholders, to describe the kinds of systems and steps that can be used to assure records meet the required standard. This guidance should clearly establish that specific security needs will depend on the circumstances, including the system at issue, its intended use, the criticality of the preventive control or other food safety measure it is used to manage, and other relevant factors. For example, a quality system used to manage critical control point (CCP) documentation will have greater security needs than a COA review for a non-sensitive ingredient.

In addition, GMA recommends the development of guidance on practical and simple protocols to assure that electronic recordkeeping systems are secure and working as intended. The guidance should recognize the wide range of systems currently in use in the industry and take into consideration the potential for technological advances in software design and development. A risk-based approach should differentiate between systems that directly collect, transport, analyze, or report records vs. systems that interact with or manage these direct systems.

In summary, GMA believes that industry can continue to practice good recordkeeping principles for critical food safety records, both paper and electronic, without a requirement for part 11 compliance.

III. Pilot Plants and Similar Product Development-Related Operations Should Not Be Subject to the Full Range of Preventive Control Requirements

Under the proposed rule, preventive control requirements will apply to all registered facilities unless a specific exemption applies. This raises a question about operations that many companies have historically registered, but for which the full range of preventive control requirements are unnecessary and impractical, such as pilot plants, test kitchens, or corporate offices that hold product samples. Such operations perform a wide range of research and product development activities that do not warrant a traditional food safety plan—for example, pilot plants frequently make test products that are not consumed in any form, test kitchens may make products consumed as part of sensory or similar research under tightly controlled conditions, or sales offices may hold small amounts of fully packaged products for limited use by sales personnel in communicating with retail customers. Requiring these operations to implement the full range of preventive control requirements is impractical, would be disproportionate to their potential impact on public health, could have the undesirable effect of diverting important Agency and industry
resources that could be put to better use elsewhere, and could pose a barrier to innovation in the food industry.

GMA understands that FDA currently considers these kinds of operations to be subject to facility registration, which triggers a requirement to adopt food safety plans compliant with part 117 of the proposed regulations. GMA urges FDA to reconsider their status as the Agency prepares to implement and enforce FSMA. Specifically, as explained below, GMA believes these facilities can be reasonably understood to not produce “food for consumption in the United States” within the meaning of the facility registration requirement in section 415 of the FFDCA and FDA’s implementing regulations (21 C.F.R. § 1.225(a)). As a result, the facilities should not be required to register and should not be subject to the FSMA food safety plan requirements.

In the alternative, if FDA believes product development operations are making “food for consumption” and therefore registration is required, FDA should take steps to recognize their unique status and food safety needs. The most straightforward approach would be for FDA to exercise enforcement discretion and not generally enforce the FSMA framework with respect to these operations so long as the necessary food safety measures are in place. This would result in a specific framework for regulating food safety in these operations, allowing oversight of food safety without harming innovation or adding unnecessary complexity. Alternatively, if the FSMA framework must be applied, FDA should make clear that FSMA obligations will be determined by the specific characteristics of each operation and commensurate with the relevant food safety risk. The “food safety plan” for such operations, therefore, will be risk-based and tailored to meet the specific food safety needs, and will be very different from plans for facilities that make or hold food for commercial purposes.

A. Product Development-Related Operations Are Unique and Do Not Produce or Hold Food for Consumption by the General Public

GMA members manage several types of operations well outside the range of traditional activities undertaken by facilities that manufacture, process, pack, or hold food for general distribution through typical retail or other channels. GMA considers these operations, all of which generally relate to product development in one way or another, to include the following:

- Pilot plant facilities that make food solely for product development purposes, which is often not consumed in any form, or consumed in very limited amounts under controlled conditions
- Test kitchens that make food for internal evaluations or other kinds of limited, tightly controlled sensory testing
- Domestic and foreign sales or other field offices that hold small amounts of packaged products, some of which may hold products made by competitors (e.g., a foreign sales office that ships competitive products to the United States for testing purposes)
- Corporate headquarters that hold food such as sales samples for controlled distribution
- Corporate and other private food testing laboratories

Although these operations are diverse, all share a common theme in that their activities are research oriented, are usually highly variable, are carefully controlled, and involve no sale or other distribution of product to the general public. For example, many pilot plant facilities are used daily, yet the same product is rarely produced exactly the same way on each production run. Food is made in small batches using varying ingredients, formulas and processes. As another example, sales offices may maintain small amounts of fully packaged products, such as sales samples, for use in educating retail customers about new products. Similarly, corporate headquarters may occasionally bring in a new product or a competitive sample for evaluation, including limited taste testing by one or more company officials.

Food made or held by product development operations often is not consumed in any form. If it is consumed, it is consumed under tightly controlled conditions, such as internal tests or business to business product evaluations that present minimal public health risk. Significantly, GMA is not aware of any food-borne illness outbreaks or other health issues that have occurred as the result of food produced by pilot plants or similar operations.

GMA is concerned that requiring such operations to implement a preventive control program would be an extremely poor use of industry and Agency resources. The limited amounts of product prepared and the controlled conditions under which food might be consumed make the food safety risk from these operations miniscule. Moreover, developing a full scale food safety plan for every product made in a pilot plant is infeasible due to the inherent nature of the work done in these kinds of operations. For example, pilot plants are experimental by design, so the same facility may make X one day, five different kinds of Y another day, and Z on a third day, all in the same week. During a single day on a single run of a development project, a developer may decide to substitute ingredients multiple times, vary cooking temperatures, and make multiple process changes. If a developer were required to undertake a formal hazard analysis, identify preventive controls, conduct monitoring and verification, and perform similar activities, he or she would be required to spend a significant portion of a day (or even multiple days) writing and re-writing multiple food safety plans for food that may never be consumed.

In an effort to assure that industry and Agency resources are used wisely to best promote food safety, GMA has reviewed whether product development operations should be subject to the food safety plan requirements. As a threshold question, GMA considered whether such facilities are truly required to register with FDA, which is the FSMA trigger for requiring a food safety plan. GMA understands that FDA has previously advised that facilities handling only samples are “facilities” required to register under section 415 of the FFDCA, which was added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). For example, in the
interim final rule implementing the facility registration requirement, FDA explained that “R&D facilities and sample facilities that manufacture/process, pack, or hold food that is consumed in the United States either by the facility’s employees or others are required to register.”\(^5\) GMA respectfully suggests that this determination should be revisited and evaluated for compatibility with the FSMA rulemaking.

In addressing the registration status of product development operations, FDA appeared to consider food to be “for consumption in the United States” within the meaning of the facility registration requirement in section 415 of the FFDCA if it is actually eaten, regardless of the amount (e.g., even if it is eaten by only one person) or the surrounding circumstances. This is one interpretation of “consumption,” but it is not ideal because it makes the term “for consumption” redundant with “food” and thus superfluous. Under the FFDCA, an article is “food” if it is “used for food” (i.e., it is consumed). Had Congress intended ingestion to be the standard, the law could have simply said that facilities must register if they are “engaged in manufacturing, processing, packing, or holding food in or destined for the United States.” As a result, it’s reasonable to understand the term “for consumption” to mean something more than just ingestion. GMA believes the term in this context means an operation is making or holding food for external distribution to third parties, whether for sale or otherwise. In other words, “consumption” means third parties will receive and use the product without the facility’s direct involvement and oversight, and for a purpose other than product development.

Significantly, this clarified interpretation would reduce confusion that has arisen around the status of registered “facilities” that do not distribute food to third parties. GMA members are aware of FDA inspectors arriving at corporate headquarters, R&D centers, and similar operations simply because they are registered facilities, expecting to see a manufacturing or similar commercial operation, and then being surprised at the research-oriented nature of the activities undertaken there. Similarly, GMA members are aware of situations where FDA notified a foreign facility of an intent to inspect the facility, and then expressed surprise (and sometimes, disapproval) upon being informed that the facility does not routinely ship product to the United States (e.g., the facility was registered because it may occasionally ship samples to the United States). These kinds of experiences reflect confusion, even within FDA, about the scope and nature of the registration requirement. They also unnecessarily consume resources for all involved. FDA can resolve this confusion by excluding product development-related operations from the facility registration framework, and can do so without compromising bioterrorism preparedness or food safety.

**B. Even if the Facility Registration Requirement Applies for Bioterrorism Act Purposes, FDA Should Recognize the Unique Status of Product Development-Related Operations and Exercise Enforcement Discretion with Respect to Food Safety Plans**

If FDA is not persuaded that it can or should revisit its prior interpretation of the facility registration requirement in section 415 of the FFDCA, GMA urges the Agency to

consider other approaches that will ensure critical Agency and industry resources are put to the most effective use in protecting public health. GMA believes the status and nature of product development operations can be best addressed through a framework that speaks directly to the unique range of activities they undertake and the extremely low food safety risks they pose.

FDA could reasonably develop such a framework in two ways. The first and preferred approach would be for FDA to exercise enforcement discretion and generally not take enforcement action against product development operations based solely on a failure to register under FFDCA section 415. This would make the relevant operations not “required to register” within the meaning of FFDCA § 418(o)(2), making a FSMA compliant food safety plan unnecessary. Alternatively, FDA could decide to exercise enforcement discretion and generally not take enforcement action against product development operations based solely on a failure to have and implement a food safety plan (i.e., to comply with section 418). Consistent with existing FDA practices, the grant of enforcement discretion would carefully describe the products covered and the conditions that must be met to qualify. Additionally, the enforcement discretion would be subject to revision or revocation as the need arises.

In both cases, the exercise of enforcement discretion would be conditioned on the operations having appropriate food safety controls in place. For example, basic sanitation and current good manufacturing practices would be expected in a pilot plant, a test kitchen would need to follow important food safety practices such as cooking food adequately, and a corporate office storing food in need of temperature control for food safety would need to follow good refrigeration practices. Any facilities that make or handle food for sampling would need to address potential allergen concerns, either by affirmatively screening participants in advance or by clearly labeling samples to inform of the potential presence of one or more allergens. Simple, straightforward steps such as these would ensure that product development operations follow all necessary food safety practices.

C. If Food Safety Plans Are Required, They Must Be Risk-Based and Tailored to Meet the Food Safety Needs Unique to Each Operation

GMA contends that mandatory food safety plans for product development-related operations are not a good use of food safety resources. Moreover, FSMA demands that food safety plans be risk-based and tailored to meet the food safety needs unique to each operation. This means that a food safety plan for an operation like a pilot plant or a sales office would be—and look—very different from a plan for a commercial manufacturing operation.

As GMA has noted in comments addressing FDA’s proposed food safety plan requirements, food safety requires facilities to analyze hazards in a fact-specific way and select and manage preventive controls to meet diverse food safety needs. As part of those comments, GMA is proposing regulatory language to make clear that facilities will manage controls using the types of management criteria experts consider appropriate and necessary to achieve the FSMA food safety objectives. In other words, controls must be
monitored if monitoring is appropriate and required for food safety; they must be validated if validation is appropriate and required for food safety; and so on. CCPs and similar controls (e.g., certain prerequisite programs that target specific hazards) will continue to require all the potential management criteria, as they do today. Other controls may require a very different combination of the criteria, depending on expert judgment.

Because it is risk-based and operation-specific, the FSMA framework is adaptable and can be applied to facilities of all types, from commercial operations to pilot plants to corporate offices that handle occasional samples. As described above, however, the process of analyzing hazards, selecting preventive controls, and creating the relevant documentation for product development operations will be very different from the process used by food manufacturing facilities that make food for commercial distribution. For example, a “food safety plan” for a test kitchen might be nothing more than general guidelines outlining key food safety considerations, examples of important controls, and periodic reviews to verify the plan is being implemented appropriately. Because of the unique and highly variable activities of these operations, a policy that treats them like food manufacturing facilities would provide no public health benefit, would be extremely burdensome, and would likely lead to significant disruption to research and development activities.

GMA appreciates FDA’s consideration of the status of these important product development related operations and stands ready to work with FDA to ensure they are appropriately regulated.

IV. The Regulations Should Provide Flexibility for Records Retention (Proposed § 117.315)

FDA proposes that, with the exception of the food safety plan, offsite storage of records would be permitted after 6 months following the date the record was made, provided that the record can be retrieved and provided onsite within 24 hours of a request for official review (proposed § 117.315(c)).6 The food safety plan would always be required to remain onsite. Additionally, electronic records would be considered to be onsite if accessible from an onsite location.

GMA recommends that the final rule permit offsite storage of records other than the food safety plan upon their creation and simply specify expectations for efficient record availability. Regardless of whether the records are stored on- or off-site, FDA should focus on ensuring records are available promptly upon an inspector’s request during an inspection.

GMA’s members typically keep many important records at corporate headquarters or other central locations, not at individual facilities. For example, records relating to

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6 Also with respect to records retention, we request that the Agency clarify in the preamble to the final rule that the two year record retention requirement in section 117.315 only applies for records created after the compliance date for the final rule. When the rule takes effect, facilities may not have two years of historical records on-hand because such records are not legally required prior to the effective date. Under FSMA, facilities only have to maintain the records that FSMA requires them to create.
suppliers and raw materials may be relevant to multiple facilities and are often maintained in a central location. Similarly, validation studies and support (e.g., microbiological, thermal processing, and other scientific materials that support a process or control point) often are kept in corporate files. Pilot plant, research and development data, and recall-related materials are additional examples of materials that often are not stored at an individual facility.

Requiring all these records to be kept at individual facilities would be duplicative and unnecessary to ensuring a manufacturing plant is making safe food. Establishing a 6-month on-site retention policy is arbitrary, particularly given the breadth of records that must be maintained. Instead of prescribing a specific location for storage of the records, FDA’s regulations should simply require that the records must be produced promptly for official review within 24 hours of an appropriate request. Specifying the location for record storage will increase costs but will not contribute to improvements in public health.

The proposal says electronic records will be considered “to be onsite” if they are accessible from an onsite location. GMA appreciates this flexibility, but is concerned that this wording could be read to suggest each facility needs 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.

Accordingly, GMA asks that the final rule simply provide that records must be made available to FDA within 24 hours of an on-site request for official review. Ensuring that facilities respond to requests for required records in a timely manner should be a higher focus for the Agency than mandating specific locations for record storage.

V. Records Are Best Reviewed and Understood in an Inspected Facility; FDA Lacks Legal Authority to Access Food Safety Plan Records Remotely (Proposed § 117.320)

The proposed rule requires all mandatory records to be made promptly available to FDA upon oral or written request (proposed § 117.320). In explaining this requirement, FDA notes the regulation does not explicitly require a facility to send records to FDA rather than making the records available for review at a facility’s place of business. The Agency, however, requests comment on whether the regulation should “explicitly address this circumstance, and if so, whether FDA should require that the records be submitted electronically.”\footnote{78 Fed. Reg. 3783.} The Agency explains that “[o]btaining a facility’s food safety plan without going to a facility could be useful to FDA in a number of different circumstances, such as to determine whether a recently identified hazard is being addressed by affected facilities.” Id. As explained further below, GMA opposes remote records access by FDA for both practical and legal reasons.
A. Practical Concerns: Records Are Best Reviewed and Understood in an Inspected Facility

Remote records review will not give the Agency the information it needs to understand the meaning and significance of information received. As explained in detail in GMA’s facility profile comments in Section I above, facility information of all types, including records, is most effectively reviewed onsite and in person, where the full context and most current information can be provided. Furthermore, the volume of records associated with food safety plans and the fact they will undoubtedly be maintained in various file formats makes remote access and review impractical.

The same is true for information such as testing results. If FDA simply asks a facility to send its positive testing results for *Listeria*, for example, the Agency likely will receive various records without any meaning or context. Only within the facility will the Agency be able to understand the difference between testing records that signaled a potential problem that was appropriately addressed through corrective actions and testing records that signal a significant food safety issue that has not been resolved.

In our members’ experience, advance review of all food safety plans and related records, prior to performing a supplier visit, is of limited value. Food safety plan documents may be well-written, but only direct observations at the facility can provide assurance that the records reflect the facility’s actual food safety practices. Additionally, food safety plans can change frequently. The resources required to remotely review large volumes of food safety plan documents, which may be current for only a limited period of time, would be better used reviewing the most up to date documents at the facility.

GMA also has practical concerns regarding document security. Food safety plans contain confidential business information and need to be appropriately protected. It could be a significant challenge to validate the credentials of a person requesting remote access to a food safety plan so as to ensure the request actually comes from an authorized Agency representative. Similarly, information sent electronically is much more prone to unapproved access via hacking or leaks. In contrast to in-person inspections, where it is possible to validate inspector credentials (through badge and photo identification review) at the beginning of the inspection, credential validation for remote requests are more challenging. This is further complicated when considering that state and local agencies conduct inspections on behalf of the Agency. Our concerns are heightened by recent reports of impersonation of FDA officials via e-mail and during a fraudulent foreign plant inspection.8

If the Agency’s interest in remote records access stems from a desire to respond more quickly to identified situations (e.g., to speed outbreak investigations in order to more rapidly identify potentially impacted facilities), there are much better ways to achieve this goal. The Agency has a great deal of information currently available that can assist in pinpointing establishment types in the event of an outbreak, which could be better organized internally to expedite traceback investigations. Similarly, if the Agency’s

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intent is to be better prepared for inspections, better information technology efforts also could provide a solution.

As suggested in GMA’s facility profile comments in Section I above, FDA also can use an updated EIR process to develop an integrated database that links EIR data with other FDA data on food facilities (e.g., registration, reportable food registry, 483 observations). Simply by inputting a product type, company name, facility registration number etc, FDA should be able to pull up a robust profile of a facility that includes not only basic information about the facility (e.g., location, hours, type of products) but also information about its overall regulatory history. Linking the Agency’s current databases and files into an integrated system would provide substantial quantities of information that would enhance inspection efficiency and assist in the event of an outbreak. If FDA believes the Agency lacks the resources to manage its information in this manner, we are concerned that remote records access will exacerbate the Agency’s challenges in organizing and maintaining data effectively given the huge influx of information that could result.

**B. GMA Is Unaware of a Legal Basis for Remote Access Authority**

Regardless of whether remote records access would be useful to enhance food safety, the Agency must identify appropriate legal authority before it can implement new records access requirements. 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. For the reasons explained below, it would be inconsistent with the statutory framework to exercise remote access to food safety records.

First, section 418(h) of FSMA requires that records must “be made promptly available . . . upon oral or written request.” The plain language of this section does not suggest anything that implies an ability to access records outside of a facility—for example, it does not require facilities to “submit,” “send,” or “provide” records to FDA. Furthermore, the phrase “made promptly available” does not reasonably suggest any kind of submission of records. There is a significant difference between making records available (a passive act that necessarily implies a physical presence) and submitting records (an affirmative act). 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. Instead, it chose the word “available,” rather than “submit” or a similar term, when it drafted the records access language in section 418.

Second, the legislative history of FSMA indicates that Congress did not intend to provide FDA with remote access authority. The food safety bill passed by the House of Representatives would have expressly granted FDA remote access to certain food records, including remote access in emergency situations and remote access to food safety plans, without cause.9 In contrast, the Senate food safety bill, which ultimately

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9 FDA would have been provided with remote access in emergency situations when the Secretary “has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death.” H.R. 2749, 111th Cong. § 106(a) (2009). FDA would have been granted remote access to records related to food safety plans, without cause.
became law, did not contain either of these provisions. The fact that the Senate did not adopt the language of the House passed bill into its legislation is indicative of Congressional intent against providing FDA with remote access authority to food safety plan records.\footnote{The Supreme Court has held that selection of one chamber’s version of legislation over that of the other is indicative of legislative intent. \textit{See, e.g., INS v. Cardoza-Fonseca}, 480 U.S. 421, 441-42 (1987) (rejecting Senate language limiting the Attorney General’s discretion in granting asylum in favor of House language authorizing grant of asylum to any refugee); \textit{United States v. Riverside Bayview Homes}, 474 U.S. 121, 136-37 (1985) (attaching significance to the conference committee’s choice of the Senate version of legislation, retaining the broad definition of “navigable waters” then in current law, over a House version that would have narrowed the definition).} Moreover, the House of Representatives would not have written legislation to authorize FDA to have “remote access” to records if it already viewed FDA as having such authority, because Congress is expected to consider its bills in the context of the existing statutory scheme.

Third, FDA’s emergency records access authority under FFDCA Section 414(a) also does not grant the Agency legal authority for remote access of records. Given that Congress could have, but did not, grant FDA such authority for these emergency situations, we believe it would go beyond the statute to grant the Agency authority to remotely access records routinely.

Fourth, GMA notes that there is one section of FSMA that \textit{does} grant FDA with remote records access, using very specific language. FSMA expressly permits FDA to require an accredited third-party auditor that conducts a regulatory audit to submit records to the Agency upon request, stating:

\begin{quote}
Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an onsite audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of such auditor. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.\footnote{FSMA § 307 (emphasis added). Under the statute, this provision does not extend to reports or documents resulting from a consultative audit.}
\end{quote}

This provision reinforces that FDA does not have remote access authority for food safety plans. Where Congress wants to provide such authority, it clearly does so through use of terms like “submit.” Congress did not include such a term or similar phrase in the preventive controls provision of FSMA or any other section of the FFDCA.

Finally, FDA does not appear to have any other legal authority to impose a remote records access requirement, including the general authority provided under FFDCA section 701(a), which grants the Agency authority to “promulgate regulations for the efficient enforcement” of the Act. As also discussed in our comments regarding the Foreign Supplier Verification Program proposed rule, courts have recognized that “the broad language of Section 701(a) does not give the FDA unlimited regulatory powers; regulations issued under that section must effectuate a Congressional objective expressed elsewhere in the Act.” \textit{Pharm. Mfr. Ass’n v. FDA}, 484 F. Supp. 1179, 1183 (D. Del.)
Moreover, whether FDA has authority to issue a regulation depends in part on “whether Congress refused to include a specific section of the Act authorizing such [action].” *Toilet Goods Ass’n v. Gardner*, 387 U.S. 158, 163 (1967). Given that Congress specifically decided against adopting legislation that would have granted the Agency with remote records access authority, regulatory adoption of remote records access would directly contradict legislative intent.

In summary, even if FDA had the legal authority to implement remote records access—which it does not—implementation of this concept would present numerous practical challenges and would not help improve public health or food safety.

VI. FDA Should Develop a Plan for Efficiently Implementing the Records Access Authority Included in the Final Regulations

FDA and industry have a shared interest in efficient and productive inspections. Once FSMA is implemented, FDA will have access to a wide range of industry records. Based on the volume and complexity of records, as well as differences in terminology and record keeping systems, carefully focused records requests will help quickly identify information most relevant for public health protection. Clear communication between FDA and industry will be essential to quickly identify important records, prevent confusion, and ensure FDA gets truly responsive information in an efficient way.

GMA urges FDA to develop a strategy for efficiently implementing the records access authority in FSMA. To help ensure that required records are produced in a responsive and timely way, GMA suggests the strategy recognize the important role of dialogue in identifying required records. In our experience, in more effective inspections, investigators are open to discussing what documents are most responsive to the investigator’s needs, recognizing that some back-and-forth exchanges may be necessary to identify the records that are most helpful, appropriate, and authorized for disclosure.

For example, in some circumstances, it may be helpful to identify not only the type of record the investigator believes is needed, but why that record is being requested. A company can more easily respond to a specific request for proof of shipments in interstate commerce than a broad request for all products shipped from a facility. In other cases, it may be helpful to put record requests in writing, to help easily identify clarifications that may be needed and minimize the potential for misunderstanding.

In addition to addressing good inspection practices, GMA believes a sound implementation strategy should consider the types of records that will be available for Agency review during inspections. In proposed § 117.175, FDA identifies the record

12 FDA has recognized that “a deliberate refusal by Congress to authorize a specific program would be at least one factor to be weighed in determining the validity of a regulation” promulgated under Section 701(a). 60 Fed. Reg. 65096, 65099 (Dec. 19, 1995) (seafood HACCP). Furthermore, this situation differs from precedent where Congress considered but did not enact legislation that would have granted authority to FDA, given that here the legislature specifically elected to adopt a version of the legislation that did not grant FDA with remote records access authority. Cf. Nat’l Confectioners Ass’n v. Califano, 569 F.2d 690, 693 (D.D.C. 1978) (rejecting an argument that the existence of legislation that was not enacted indicated that Congress intended to exclude such authority from the Act as it was then written).
categories the Agency intends to require to show compliance with the preventive control regulations, including the following:

- The written food safety plan (including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, and verification procedures);
- Records documenting monitoring of preventive controls, corrective actions, and verification; and
- Records documenting applicable training for qualified individuals.

GMA supports these categories as well as proposed § 117.320, which states that required records must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services upon oral or written request. As FSMA is implemented, questions will undoubtedly arise as to whether particular records are or are not included in the above categories. Due to the potential for uncertainty and confusion, GMA urges FDA to consider providing initial guidance to inspectors about the scope of the FSMA records access, and to refine this guidance as necessary to stay current with emerging issues. GMA is committed to working with FDA to help facilitate the implementation process as it pertains to records issues.

Examples may help to illustrate the potential nuances of records access. For instance, responsible companies routinely review and process complaints, and review of complaints can be an appropriate verification procedure, but FSMA does not provide access to the underlying complaint documents. There are both practical and legal reasons for this. As a practical matter, complaints are unique inputs that can be critical to investigate but are often highly subjective, unclear, incomplete, and otherwise factually uncertain. Complaint investigation can be as much art as science, requiring not only food safety skills, but knowledge of particular product attributes, product history, consumer behavior, and trends. Their value, therefore, lies in interpretation and trend spotting undertaken by an expert; a review by outside parties, including regulators, is unlikely to lead to useful insights. Legally, complaints do not fall into any of the record categories identified in FSMA. FSMA and FDA’s proposed regulations call for documentation of verification, but this addresses documents that show complaints were considered as part of the verification process, where relevant and appropriate – it does not extend to the complaints themselves.

GMA appreciates that FDA investigators and facilities may have different perspectives on whether particular records should be considered part of a food safety plan. If an investigator requests a document that a facility believes is not part of the food safety plan or related documentation, the facility must be prepared to explain the basis for its conclusion.
VII. FDA Should Clarify the Regulatory Language Regarding FOIA Protections (Proposed § 117.325)

The proposal states that all records required by Part 117 are “subject to the disclosure requirements under part 20” (the FOIA rule). This is written in a way that could be confusing to individuals that do not understand the scope and protections of part 20. FDA’s regulation should be revised to clarify the Agency’s intent, using plain language that makes the meaning more understandable.

The lack of clarity in the proposed rule is particularly apparent when comparing it with the seafood and juice HACCP regulations. These similar regulations provide that certain records are generally not available for public disclosure:

- The juice HACCP regulation states: “(1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in § 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter. (2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.” 21 CFR § 120.12(f).

- The seafood HACCP regulation states: “(1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter. (2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.” 21 CFR § 123.9(d).

We recognize that the more recent shell egg rule (21 CFR 118.10(f)) is written in the same manner as the proposed rule, but the HACCP regulations cited above are much more analogous to the proposed preventive controls rule. We also understand that the Agency did not follow the model of the seafood and juice HACCP regulations because of a potential concern that those rules may have suggested disclosure protections that differed from FOIA, when in fact the protections would be the same.
It would be helpful to industry if the preventive controls regulation was clearer in explaining the scope of the protections provided by part 20. We suggest that the regulation be revised to state:

“Records required by this part are subject to the disclosure requirements under part 20 of this chapter, including protections for trade secrets and privileged or confidential commercial or financial information.”

This revision would be consistent with the Agency’s proposed approach and legal requirements, but also would provide needed clarity to regulated parties.

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APPENDIX I  GMA Prior Comments on Facility Profiles (Docket No. FDA-2012-N-0430) dated July 10, 2012
July 10, 2012

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

Re: Docket No. FDA-2012-N-0430; Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Submission of Food/Feed Facility Profile Information; Federal Register Notice; (77 FR 27779); May 11, 2012

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA’s) proposed collection of “Facility Profile” information on a voluntary basis during the FDA food facility registration process. 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 over $1 trillion in added value to the nation’s economy.

FDA is proposing to collect voluntary information from registered facilities, including information about the facility type, size, and schedule; the foods handled by the facility; and the facility’s food safety programs. FDA has explained that the information in these “Facility Profiles” will help the Agency better allocate inspection resources—for
example, by helping inspectors prepare for inspections (potentially reducing inspection time), and possibly guiding decisions about a facility’s risk status (i.e., whether a facility should be classified as high risk). We support the Agency’s efforts to make inspections more effective and appreciate the Agency’s efforts to explain its proposal and outline the thoughts behind it.

We understand that the Facility Profile information collection is an alternative to the Agency’s original plan to require electronic submission of Food Safety Plans. As GMA had previously commented, electronic submission of food safety plans raised significant logistical, legal, and policy concerns. GMA appreciates the time FDA has spent in carefully considering these and other comments and refining the idea to now focus on the voluntary submission of Facility Profile information. Some of the voluntary information FDA is planning to collect is very well suited to meet FDA’s goal of better allocating inspection resources; GMA has significant concerns, however, that other information, particularly hazards and controls information, will not be useful, will impose a significant collection burden, and presents issues similar to the previous idea of submitting Food Safety Plans. As explained in greater detail below:

- Voluntary information that is likely to be useful includes details about facility type and size, operational schedule, number of employees, and products; in contrast, details about hazards and controls will not have practical utility and will be difficult and time consuming to collect and to enter;

- The proposal significantly underestimates the time necessary to collect the desired information;

- FDA can enhance the quality, utility, and clarity of the voluntary information collected in several ways, and more specific details about FDA’s plans for using the Facility Profiles would be helpful to identify additional ideas for enhancing the collection;

- To minimize the burden of information to be collected, FDA should take steps to avoid asking for duplicate information, streamline definitions and terminology that will be used as part of any data entry procedures, ensure that information collected will be kept confidential, design the system to allow in-process work to be saved on an ongoing basis, and consider similar steps as necessary.

In keeping with the Paperwork Reduction Act framework, our comments respond to the specific questions FDA has raised in the Federal Register Notice announcing the proposed collection of information.
I. Is the proposed collection of information necessary for the proper performance of FDA’s functions? Will the information have practical utility?

GMA has reviewed the draft form FDA intends to use to collect Facility Profile information as part of the facility registration process (Form FDA 3797). We believe that some of the information FDA proposes to request has the potential to be useful, if properly framed, but are concerned that the hazards and controls information will not add value for reasons noted later in this document and will be burdensome to collect.

A. Basic Facility Information Offers Potential Value

Draft Form FDA 3797 requests several pieces of basic information about the registered facility. These include the facility type (e.g., manufacturer, warehouse, labeler); products handled by the facility (e.g., beverages, dairy, seafood); facility size; operation schedule; and number of employees. GMA believes that these basic pieces of information will help FDA inspectors prepare for inspections – they will know what type of facility they will be visiting, how large it is, whether it is in operation, and the types of products handled. The Agency will be able to better predict how long an inspection might take, how many inspectors to send, and whether to send an inspector with particular expertise or experience.

In addition, to maximize the value of information provided, and avoid collecting data of limited usefulness, we recommend that the facility type (e.g., manufacturer, warehouse, or labeler) determine the kind of subsequent information requested. It makes sense for FDA to know at a very basic level the kinds of operations conducted at a facility, but not all of the details requested in the draft forms are relevant to all kinds of facilities. For example, large distribution warehouses hold a wide variety of products. For these facilities, identifying specific product categories of food handled makes little sense. Similarly, for facilities like grain elevators, research and development facilities, and/or sales offices, questions about product type, third party audits, and training are not relevant. FDA does not need additional information about these facilities to prioritize its inspection resources or prepare for inspections. Knowledge of the type of operations at the facility alone will be sufficient.

B. Hazards and Controls Information Is Unlikely to Be Useful and Will Be Burdensome to Collect

GMA has significant concerns about FDA’s proposal to request that facilities identify the hazards associated with each product type and the controls in place for each hazard. This kind of information is critical to review during an inspection, but offers little, if any, value outside the manufacturing environment. In addition, the information will be difficult and time consuming to collect, and is potentially subject to misinterpretation and misuse. A request to submit hazards and controls information presents very similar concerns to a request for submission of Food Safety Plans.
FDA’s proposed collection of information on hazards and controls is problematic because this kind of information should be reviewed in the context of observing the plant in operation, with the support of people familiar with the system who can answer questions and show an inspector relevant equipment, operations, and procedures. If FDA were to review a simple listing of hazards and controls prior to an inspection, the Agency would be looking at those controls in isolation, not how they interact with each other as part of an overall system of food safety. Only by reviewing the food safety plan and simultaneously observing actual operations can FDA gain an accurate perspective from which to evaluate a facility and determine how it should be classified in terms of risk.

In addition, the voluntary information submitted will be only a snapshot in time. Facilities often change their products, processes, and procedures. It would be overly burdensome to expect companies to continually update the information submitted to FDA. Consequently, FDA may be reviewing inaccurate information and perhaps making flawed decisions when assessing a facility’s profile.

Submitting hazards and controls information is also far more complex than FDA may realize, leading to a significant burden on industry to provide the information. Many facilities handle numerous products, even within the general categories included by FDA in the draft form. For example, a facility may process a wide variety of “bakery” or “dairy” products, some of which will share certain universal controls (e.g., those that apply across a facility, such as basic good manufacturing practices), but many of which will have unique processing conditions, hazards, and controls. To the extent the form requires repetition of universal controls, it asks for redundant information; to the extent that it groups products with unique considerations together, it offers no meaningful value or insight into actual product or line specific conditions. Some facilities may identify so many different products, hazards, and controls as applicable for their broad range of operations the Facility Profile would not allow FDA to readily identify which hazards and controls are applicable for which products produced in the facility. In light of the complexity, it does not seem feasible to amend the form to allow FDA to collect useful information in a non-burdensome way.

In addition to concerns about the lack of utility and the potential burdens, we are also concerned that a hazards and controls database could be subject to misinterpretation and misuse. Across the broad range of GMA members, we know that multiple approaches to process control can result in the same level of food safety. Furthermore, variations in management approaches between products and across plants could cause confusion in a database (e.g., addressing particular hazards with general controls/prerequisite programs as opposed to with critical control points). We also know that to be effective, preventive controls must be tailored to each particular product and facility and there are many different preventive controls that a facility may choose to use to control a given hazard. For example:

1 Preventive controls include both general controls/prerequisite programs and critical control points.
Preventive controls used can vary depending on the facility. For example, Low Acid Canned Food (LACF) facilities without cooling canals may need special equipment to detect cans with low fill levels (an important food safety issue for canned foods), but under filled containers can be readily detected and removed without special equipment at facilities with cooling canals because the containers float.

For many foods, such as spices, steps needed to address microbial issues will vary depending on the food itself as well as customer-specific requirements. For example, a processor might receive red pepper that has been treated with ethylene oxide prior to importation (so it does not need to be treated again); in another case, red pepper might be treated or used in a thermally processed canned chili product at the manufacturing facility; in yet another case, it might be treated at an external irradiation facility in lieu of other treatments. All are legitimate preventive controls, and all are driven by unique logistical and other circumstances that the proposed database cannot reasonably reflect.

Different facilities may use different, but equally effective, cook steps that function as preventive controls. For example, when processing peanut butter, one facility may perform oil roasting, while another may use dry roasting.

Facilities may use entirely different controls to address similar hazards. For example, biological hazards in salad dressing can be controlled through formulation, pasteurization, or fill temperature. The biological hazards in chocolate may be controlled through bean roasting, nib roasting, or debacterization (subjecting cocoa beans to a high temperature/pressure process). A peanut butter facility may use wet cleaning or dry cleaning.

Different processes may sound similar, but may trigger a need for different preventive controls. For example, corn milling processes are very different depending upon whether they are wet or dry – controls for syrups and starches from wet milling include chemical additions/reactions, high temperatures and multiple filtration steps, whereas dry milling control steps involve sifting, magnets and metal detectors.

As these examples show, risks can be managed in many different ways so long as a facility ensures that the controls are effectively minimizing and preventing potential food safety hazards. We are concerned, however, that FDA may view differences in the controls applied in different facilities as suggesting that one facility has better practices than another. Certainly, it would be inappropriate to make a decision about the risk-profile of a facility simply because it uses different preventive controls than other facilities handling the same product type. Such a decision could result in a significant misallocation of limited Agency resources.

FDA has explained that it believes having information about hazards and preventive controls could help inspectors prepare for inspections. For example, an inspector
planning to visit a firm handling nuts would be able to look at the controls the facility is using, and then speak with Agency experts about what the proper controls might be, as well as potential questions to ask the facility about the time and temperature of its roasting process, and about validation for the same. We believe that the inspector can get the same result with the basic information about the product type(s) handled, without details about specific hazards and the controls used. In this example, the fact that the facility is processing nuts would allow the inspector to prepare for the inspection by asking the very same questions of Agency experts. Given the limitations on the information outlined above, the incremental value of knowing specific controls is outweighed by the burden imposed on the facility to collect and submit that information.

Additionally, we understand that FDA aims to use facility profile information to create an electronic database that can identify firms at an increased risk for a food safety problem if, for example, an outbreak occurs with certain types of foods or controls. We believe that the requested information about hazards and controls is not specific enough to assist FDA in identifying firms potentially affected by an outbreak. Rather, the most helpful information will be about the types of products that a firm handles. To develop the proposed database, FDA would need information beyond that requested in the facility profile, such as whether a facility is using a particular ingredient. Such granular information should not be part of the facility profile because it would be overly burdensome for firms to develop and submit. If FDA could provide additional information about instances when it believes this kind of proposed information would be helpful, we can provide additional feedback about how the Agency might meet this need.

C. The Utility of Other Requested Information Is Unclear

We are unclear as to how the other information FDA proposes to collect (i.e., information about third party audits, food safety training, and food defense assessments) fits with the intended purpose of allocating inspection resources. As currently drafted, these questions provide little, if any, useful information. For example, we expect that most facilities voluntarily providing information will state that they have food safety/defense training. Likewise, because FSMA requires identification and evaluation of hazards that may be intentionally introduced and implementation of controls to address those hazards, most, if not all, facilities will say they have a food defense plan.

The value of the audit question as currently drafted is similarly unclear. The question focuses on third party audits, but other kinds of audits (e.g., internal audits) or other methods may equally reflect on the rigor of the facility’s food safety systems. Of potentially greater concern, a facility could report that it has been audited by a third party, but it may have failed the audit or the audit could have been conducted years ago. With additional details as to how these questions fit within FDA’s intended purpose for

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As described previously, large facilities may identify so many different products, hazards, and controls, as applicable for their broad range of operations, that the Facility Profile would not allow FDA to readily identify which hazards and controls are applicable for which products produced in the facility.
collecting the information, GMA could provide more concrete feedback on the value of the information.

II. Is FDA’s estimate of the burden of the proposed information collection accurate? Are the methodology and assumptions used valid?

FDA estimates that submitting a new domestic Facility Profile will take 15 minutes, submitting a new foreign Facility Profile will take 45 minutes, and updating an existing profile will take five minutes. The proposal significantly underestimates the time needed to submit and update Facility Profile information, especially if hazards and controls information is included. If hazards and controls information is not included, FDA may have accurately estimated the time needed to enter information into the electronic form, but not the time needed to collect the requested information. This assumes that the portal is accessible and working properly, and allows users to save in-process work on an ongoing basis.

GMA expects it will take facilities of all sizes much longer than 15 minutes to collect, verify, and submit the proposed information. Many factors affect the time estimate, particularly the time needed to collect the necessary information:

- The registration information is filed on a facility basis, and many GMA members operate facilities that handle numerous products using a wide variety of processes. As a result, simply compiling the list of products handled by a facility will usually take longer than the 15 minutes suggested by the Agency.

- For each product type, the responsible employees (often a combination of centrally located corporate employees and facility subject matter experts) must review the applicable Food Safety Plans and prepare a collective list of the hazards and preventive controls for each product type. Food Safety Plans can be very complex and extensive, so reviewing and compiling this information would require several hours, at least, per plan. Facilities often have multiple Food Safety Plans in effect, making the total time necessary to identify hazards and controls details alone a function of the hours it takes to gather, collect, and extract data from each plan multiplied by the total number of plans for the facility.

- Employee availability will affect the time needed, which will vary depending on the schedules of employees needed to collect the information and facility subject matter experts needed to answer questions with respect to particular products and operations. Availability may be a particular challenge where there are different time zones, not only within the US, but around the world, especially in situations where information is being submitted centrally, and must be gathered from facilities around the globe.

- All of the information collected will need to be organized in a format that aids in actual entry of the details into the portal.
As mentioned, many large food companies collect information and register their facilities centrally, placing primary responsibility on only one or two individuals. GMA urges FDA to consider the potential impact for a large company with several dozen registered facilities, each of which makes numerous products.

The time estimate is also of concern for medium and small companies. Small and medium sized companies may lack the resources needed to assign the task of data entry to an individual who understands hazards and controls, resulting in less efficient collection practices as well as possible miscommunications to the Agency. In contrast, if the Facility Profile requires only basic information, an individual with less training would be qualified to enter the data efficiently and would be less likely to make errors in doing so.

Furthermore, it will take a facility more than five minutes to update an existing food facility profile. Mandatory and voluntary information may need to be updated at different frequencies, increasing the associated time burden. For voluntary information, there should be no expectation or requirement as to the frequency at which facilities update their profiles. However, if a facility were to elect to keep their information up to date on a regular basis, they may need to submit updates several times per year.

Because the Agency has significantly underestimated the potential burden on companies, FDA should revise these burden estimates. Again, we note that the burden on industry will be significantly minimized if FDA eliminates the questions about hazards and preventive controls, as GMA requests.

III. Are there ways to enhance the quality, utility, and clarity of the information to be collected?

As explained above, the greatest value to the Agency will result from voluntary submission of information about the facility type, size, operating schedule, and products. This information will allow FDA to send the appropriate investigators to a facility to conduct inspections and to better assess the time that will be required to complete an inspection. FDA should refine these questions to obtain maximum utility for the information provided, which ultimately will depend on the specific uses FDA intends for the information.

With additional details about FDA’s goals, GMA would be pleased to provide additional recommendations about ways to enhance the quality, utility, and clarity of the information to be collected. In the meantime, we suggest that the following aspects of FDA’s proposed information requests should be clarified to increase their usefulness:

- The question about third party audits is vague. It does not include a time frame, nor does it include a field to indicate whether a certification or other element of a successful audit (as defined by the third party auditor) was received. Furthermore, this question does not consider the fact that other approaches,
including internal audits performed by cross-functional teams, may add rigor to the facility’s food safety system. This question should be clarified or omitted, as the responses are unlikely to provide utility for the Agency as written.

- FDA should consider the complexity that results when more than one operation is located at a single location. It is unclear whether the electronic form will allow for multiple entries if a facility conducts more than one operation, such as processing food and providing storage in multiple warehouses. The online form should provide companies with the ability to make it clear that there are multiple operations at a single location.

- The section of the form that identifies products handled by a facility should distinguish between animal feed and pet food, as these are two very different products.3

- Additionally, to enhance utility, we support FDA’s sharing of voluntary facility profile information with its state partners. This will make contract inspections and state inspections more efficient. Such information should be shared, however, only if it is subject to a confidentiality agreement.

- Before launching the new system, FDA should ensure the software is properly validated using good validation practices and engage in a test run to ensure that the system is operating as intended. Because the Facility Profile system will be used initially by the entire food industry within a 3 month period, it is important that the system functions as intended before launch. Additionally, we encourage FDA to consider engaging in a pilot program before broadly launching the Facility Profile system, to determine whether the requested information actually is useful for its intended purposes.

IV. Are there ways to minimize the burden of the information collection? Is there an opportunity to use automated collection techniques or other forms of information technology?

One of the most significant ways to minimize the burden of the proposed information collection is to avoid asking for the same information more than once. GMA recommends that FDA take steps to ensure that firms do not have to re-enter information that is already accessible to the Agency. The voluntary Facility Profile includes several questions that overlap with information requested voluntarily as part of the existing facility registration system. Specifically, the following information that is proposed to be part of the voluntary Facility Profile is already requested voluntarily as part of the existing facility registration system:

3 As discussed below, the Reportable Food Registry (RFR) uses these same product classifications. For consistency, the RFR should be revised in the same manner to distinguish between pet food and animal feed.
• **Facility Type:** Similar questions about facility type are included in the Registration module and the Facility Profile module.

• **Product Type:** Similar questions about product types are included in the Registration module and the Facility Profile module. Although the product categories listed in the Facility Profile module are identical to the options provided for a RFR report, they differ from the current Registration module, which appears to be more detailed. We encourage FDA to establish consistency for its product categorization lists.

• **Operational Schedule:** The Registration system allows for voluntary submission of a facility’s seasonal dates of operations, including the approximate months during which the facility operates. The proposed voluntary Facility Profile will request similar, but less detailed, information, asking only for the season in which a facility operates.

It is unclear whether FDA intends to retain these questions in the Registration module, creating duplication of the questions asked in the registration and facility profile modules. To prevent duplication and confusion, we suggest that FDA transfer all voluntary questions to the voluntary module. If FDA elects to retain the questions in both places, at a minimum the Agency should harmonize the possible responses to establish consistency and should automatically populate the Facility Profile with information provided as part of the main Registration module. Furthermore, use of consistent terminology across Agency portals can help minimize the potential for confusion when firms are submitting information to the Agency and ensure that the information FDA reviews is consistent and accurate.

Additionally, if the proposed collection is truly voluntary, companies can elect not to submit the requested information, which will minimize the burden for those companies. FDA should ensure that the system does not become a de facto “requirement.” For example, there should not be a penalty, such as a higher risk profile, for firms that choose not to submit facility profile information. Similarly, the Agency should clearly indicate on the profile and all related websites and materials that submission of this information is voluntary, so that firms do not mistakenly assume it is required. FDA also should not penalize a firm for failing to update a facility profile that was voluntarily submitted, for example if an inspector visits a firm and notes that the information provided in the profile does not match the current state of operations.

Finally, we offer the following additional suggestions to minimize the burden of the information collection:

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4 To assist our members with the re-registration process, GMA would appreciate advance notice from FDA as to the specific mandatory questions (and in particular any new questions) that will be asked on the re-registration form. It would be most helpful if FDA can provide this information before re-registration begins, ideally by September 1, 2012 (30 days before the start of re-registration), so that our members can begin to collect the information that will be required to re-register.
• FDA should ensure that information submitted will remain confidential and protected from disclosure under the Freedom of Information Act (FOIA). Companies will be more willing to voluntarily submit information if they have confidence that it will not be made available to their competitors.

• FDA’s Facility Profile registration system should allow facilities to save information before it is submitted. Allowing facilities to save their in-progress work will facilitate gathering and submission of information.

• FDA’s Facility Profile registration system should allow entrants to answer only some, but not all, of the questions provided. This will assist in reducing the burden associated with the information collection. As the entire system is voluntary, this option should not be detrimental to the utility of the information collected.

• It will be less burdensome if the module allows quantitative information to be submitted in ranges, rather than requiring submission of an exact number. For example, facilities should be permitted to submit their approximate number of employees because this number varies regularly. Similarly, facilities should be permitted to submit a size range rather than their exact square footage.

• As noted previously, the “facility type” should govern the subsequent information provided in the registration profile. In the draft screenshots for the module, not all details requested are relevant for all kinds of facilities. For example, the question about third party audits is not relevant for a facility like a grain elevator. The same is true for sales offices and research and development centers, which are different than processing operations but are required to be registered under the statute. Similarly, there is no benefit from providing information about the types of foods held by a warehouse given that the types of foods they hold may change on a daily basis, so the information in the warehouse’s Facility Profile will almost certainly be out of date.

• To improve the connectivity between the registration database and other FDA programs, FDA should consider adding a field to include information that would aid in cross-references that may be relevant, such as the canning establishment number for LACF facilities. Ideally, related databases would be linked and able to reduce the entry of duplicate information (e.g., information already in the LACF system would be recognized by the Facility Profile portal).

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In conclusion, GMA appreciates the opportunity to provide our thoughts on the proposed information collection. We agree that voluntary submission of Facility Profile information could assist FDA in better allocating its resources and preparing for facility inspections; however, we urge the Agency to consider these comments and request only
clearly useful and non-burdensome information before moving forward to implement this plan. We welcome the opportunity to further discuss this issue with the Agency in order to facilitate development of a voluntary Facility Profile that is both useful to FDA and workable for industry.

Sincerely,

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