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 Supplier Approval and Verification Program

Dear Sir or Madam:

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

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

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

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

Executive Summary of Comments

GMA supports establishment of supplier verification requirements as part of the preventive controls regulation, provided the Agency offers an opportunity to comment on specific codified language before publishing a final rule. We feel strongly that FDA’s approach to supplier verification should incorporate current leading practices in place today that result in successful food safety programs. A responsible manufacturer will engage in some level of due diligence for nearly all of their suppliers. The regulations should be sufficiently flexible to allow facilities to tailor their programs based on risk, evolve their programs in the years to come, and strive for continuous improvement in food safety without requiring future modification to the regulations to adapt to new developments.

We encourage the Agency to consider the following guiding principles for the regulation:

- **FDA’s supplier verification regulations should encourage appropriate behavior.** Everyone in the supply chain is responsible for making safe food and the regulation should require activities that will improve public health outcomes. FDA’s regulation should incentivize companies to work with their suppliers and customers to drive continuous improvement in food safety.

- **Supplier verification does not control hazards.** Rather, supplier verification is successfully applied today as a prerequisite program, verifying that suppliers are following effective food safety programs. We are concerned that FDA’s approach in the OMB Redline and the Foreign Supplier Verification Program (FSVP) proposed rule takes too narrow of an approach.

- **Supplier verification should be based on a holistic assessment of risk (both ingredient and supplier).** Supplier verification programs should identify and evaluate the risks presented by the food and the supplier based on multiple factors, including the historical track record of the supplier. FDA’s hazard-based approach is too narrow by focusing only on the risks presented by the ingredient.

- **The role of audits needs to be placed in proper perspective: Audits are an important verification tool, but they only offer a “snapshot” of a supplier’s performance at a given time.** Audits should not be overemphasized and also should not be narrowly tied to a supplier’s application of specific controls. Rather, effective audits are risk-based, assess a supplier’s food safety system as a whole, and occur at a frequency tailored to the risks presented by a supplier and ingredient.

- **Audits need to assure confidentiality so as to promote food safety.** Confidentiality protections also are necessary for supplier audits to be effective and to encourage robust scrutiny and an open dialogue without creating fears about consequences from FDA
review of the resulting paper trail. FDA’s records access should focus on information that demonstrates that significant corrective actions were taken as needed to assure food safety.

- **Supplier verification should not be a “check the box” exercise.** A regulation that imposes regulatory requirements without encouraging thoughtful analysis and dialogue will miss an important opportunity to move food safety forward across the industry. Requiring mandatory annual audits and a detailed review of a supplier’s regulatory compliance will result in a culture focused on compliance rather than prevention and continuous food safety improvements.

- **Supplier verification is typically managed on the corporate level.** It would be inefficient for FDA to inspect these programs at the facility level, which could mean that a company with 20 facilities has its supplier verification program inspected 20 different times. Instead, inspections of supplier verification programs should be corporate-based if that is how the company manages this program. The regulatory language should reflect the fact that supplier verification can be managed company-wide.

- **FDA inspections of supplier verification programs should focus on ensuring receiving companies have and implement strong supplier verification programs.** The goal of FDA’s inspections should be to ensure receiving companies have well-functioning systems in place. Unless there is cause, FDA should not routinely question the receiving company’s determinations about individual suppliers, such as assessments of risk and decisions about what verification activities to apply and the frequency for those activities.

- **A receiving company should not be required to verify the same supplier twice.** FDA should exempt receiving companies from supplier verification under preventive controls if the supplier has already been verified under that company’s FSVP. This approach will eliminate redundancy.

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

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

Comments on Supplier Approval and Verification Program

I. Introduction and Overview

GMA supports establishment of supplier verification requirements as part of the preventive controls regulation and feels strongly that the U.S. Food and Drug Administration (FDA)’s approach to supplier verification should incorporate current leading practices in place today that result in successful food safety programs. The regulation needs to be carefully developed with input from supply chain management experts to ensure the new requirements are practical to implement and will function to improve food safety.

To help inform FDA’s rulemaking and educate the Agency about how supplier verification works today, these comments provide an overview of practices implemented by GMA members that result in successful food safety programs. GMA comments also respond to FDA’s approach on supplier verification in the draft preventive controls proposed rule submitted to White House’s Office of Management and Budget (OMB) that was not published in the actual proposed rule (referred to hereinafter as the “OMB Redline”).1 There is some cross-over between these comments and our forthcoming comments on the Foreign Supplier Verification Program (FSVP) proposed rule given that there are similarities between the FSVP proposal and OMB Redline; however our separate comments on the FSVP more directly comment on the intricacies of that proposal and the overlap between the two regulations. As an Appendix to these comments, we are providing proposed codified language for the preventive controls proposed rule that illustrates our main points and how they can be incorporated into the Agency’s regulations.

We think it is important for FDA to conduct further study of current leading supplier verification practices so that the final rule is not a significant diversion from the well-established programs that are known to be effective today. The Agency’s regulation of supplier verification should not establish a new paradigm, but rather should codify current successful industry-developed practices. FDA should regulate supplier verification in a comprehensive and meaningful, but flexible, manner. We encourage the Agency to consider the following guiding principles for the regulation:

- FDA’s supplier verification regulations should encourage appropriate behavior. Everyone in the supply chain is responsible for making safe food and the regulation should require activities that will improve public health outcomes. FDA’s regulation should incentivize companies to work with their suppliers and customers to drive continuous improvement in food safety.

1 Docket Id. No. FDA-2011-N-0920-0016. Despite “foreshadowing” in the preventive controls preamble, the Agency has made it quite difficult for industry to interpret the Agency’s intended direction for supplier verification with the sporadic release of different information about the intended approach to supplier verification (i.e., the brief preventive controls appendix, followed by the outdated OMB redline, superseded by the FSVP proposed rule).
• **Supplier verification does not control hazards.** Rather, supplier verification is successfully applied today as a prerequisite program, verifying that suppliers are following effective food safety programs. We are concerned that FDA’s approach in the OMB Redline and the FSVP proposed rule misses the mark by taking too narrow of an approach.

• **Supplier verification should be based on a holistic assessment of risk (both ingredient and supplier).** Supplier verification programs should identify and evaluate the risks presented by the food2 and the supplier based on multiple factors, including the historical track record of the supplier. FDA’s hazard-based approach is too narrow by focusing only on the risks presented by the ingredient.

• **The role of audits needs to be placed in proper perspective: Audits are an important verification tool, but they only offer a “snapshot” of a supplier’s performance at a given time.** Audits should not be overemphasized and also should not be narrowly tied to a supplier’s application of specific controls. Rather, effective audits are risk-based, assess a supplier’s food safety system as a whole, and occur at a frequency tailored to the risks presented by a supplier and ingredient.

• **Audits need to assure confidentiality so as to promote food safety.** Confidentiality protections also are necessary for supplier audits to be effective and to encourage robust scrutiny and an open dialog without creating fears about consequences from FDA review of the resulting paper trail. FDA’s records access should focus on information that demonstrates that significant corrective actions were taken as needed to assure food safety.

• **Supplier verification should not be a “check the box” exercise.** A regulation that imposes regulatory requirements without encouraging thoughtful analysis and dialogue will miss an important opportunity to move food safety forward across the industry. Requiring mandatory annual audits and a detailed review of a supplier’s regulatory compliance will result in a culture focused on compliance rather than prevention and continuous food safety improvements.

• **Supplier verification is typically managed on the corporate level.**3 It would be tremendously inefficient for FDA to inspect these programs at the facility level, which could mean that a company with 20 facilities has its supplier verification program inspected 20 different times. Instead, inspections of supplier verification programs should be corporate-based if that is how the company manages this program. The

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2 These comments use the words “food” and “ingredient” interchangeably.

3 Throughout these comments, we use the phrase “receiving company” to emphasize that supplier verification is typically managed on the corporate level, not on a facility-by-facility basis. We suggest addressing this issue through the definitions in the regulation itself by defining “receiving facility” as “a facility or corporate parent of a facility” that is subject to subpart C and manufactures/processes a raw material or ingredient that it receives from a supplier.” This will clarify that the supplier verification activities can be managed on the corporate level.
regulatory language should reflect the fact that supplier verification can be managed company-wide.

- **FDA inspections of supplier verification programs should focus on ensuring receiving companies have and implement strong supplier verification programs.** The goal of FDA’s inspections should be to ensure receiving companies have well-functioning systems in place. Unless there is cause, FDA should not routinely question the receiving company’s determinations about individual suppliers, such as assessments of risk and decisions about what verification activities to apply and the frequency for those activities.

- **A receiving company should not be required to verify the same supplier twice.** FDA should exempt receiving companies from supplier verification under preventive controls if the supplier has already been verified under that company’s FSVP. This approach will eliminate redundancy.

Although we are disappointed that FDA did not propose specific codified language on supplier verification as part of the preventive controls proposed rule, we appreciate the position explained in the FSVP preamble that the Agency intends to take a parallel approach to domestic supplier verification under preventive controls. This is important to facilitate implementation by industry and comply with World Trade Organization (WTO) obligations. We are submitting detailed comments on the FSVP proposed rule and encourage the Agency to consider both sets of our supplier verification comments in tandem when working on the final regulations. While we support inclusion of a supplier verification requirement in the preventive controls regulation, we strongly urge the Agency to allow another opportunity for public comment before those requirements are finalized and implemented.

Our comment emphasizes that FDA’s supplier verification regulations should be built on successful practices in place today, rather than the Agency’s proposed “hazard based” approach. A responsible manufacturer will engage in some level of due diligence for nearly all of their suppliers. The regulations also should be sufficiently flexible to allow facilities to tailor their programs based on risk, evolve their programs in the years to come, and strive for continuous improvement in food safety without requiring future modification to the regulations to adapt to new developments.

**II. FDA’s Approach to Supplier Verification Should Incorporate Successful Industry Practices**

Recognizing that supplier verification is an essential part of a food safety system, GMA members have invested significant resources in developing robust and effective supplier verification programs. Our experience has taught us that supplier verification verifies whether the food has been produced under a strong food safety program, but does not itself function to make food safe. Rather, it is a foundational, prerequisite program: one component of an integrated system of controls that operate collectively to deliver safe food. Our members manage their supplier verification programs on the corporate level, as they apply company-wide. The comments that follow explain current leading practices in more detail.
A. Supplier Verification is a Foundational, Prerequisite Program

Under the traditional HACCP framework in place today, supplier verification is applied as a prerequisite program. Like GMPs, pest control, or other prerequisite programs, supplier verification establishes the foundation a HACCP program is built on. Supplier verification is a foundational food safety program. Therefore, our members believe that it is critical to have a level of visibility into their supply chains and they perform some degree of supplier due diligence for most ingredients, regardless of whether the incoming ingredients will be subject to a kill step. Food safety issues can be created by hazards other than pathogens. Our experience has taught us that food safety programs are most effective when applied across the board, as both the largest and smallest suppliers are still subject to the same risks if appropriate controls are not in place.\(^4\) Our members engage in some level of supplier verification for most suppliers, no matter their supplier’s size or sophistication.

This approach is consistent with guidance from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) HACCP Principles and Guidelines document, which describes “supplier control” as a prerequisite program. NACMCF states: “Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.”\(^5\) Thus, NACMCF recognizes that supplier verification programs should focus on the supplier’s food safety system, rather than specific hazards and controls. As a prerequisite program, supplier management programs are focused on verifying that a supplier implements a robust food safety system and that its management is committed to food safety. Supplier management programs do not necessarily only verify a supplier’s routine control of specific hazards. Sometimes a supplier’s specific preventive controls are assessed but, more likely, an assessment will focus on a supplier’s complete food safety system.

B. Supplier and Ingredient Risk Both Should Be Assessed

Before determining what verification activities should be applied to an individual supplier, our members typically assess the level of risk presented by (1) the supplier and (2) the incoming raw material/ingredient and its intended use. Our members generally assess whether the supplier and ingredient risk are significant based on severity (i.e., seriousness of the effects) and probability (i.e., likelihood). This assessment of risk enables our members to take a consistent risk-based approach when determining appropriate verification activities. Based on this assessment of risk, verification activities are applied on a “sliding scale” where more robust verification is applied to suppliers and foods that present higher risks. Given the large number of suppliers our members oversee, the assessment of supplier and ingredient risk is not necessarily documented for each supplier. Rather, some companies use risk-grouping to assist with categorizing suppliers.

\(^4\) There are some limited very low-risk situations where our members do not typically engage in supplier verification, such as for intra-company shipments between business units owned by the same corporate parent. Also, as discussed further in sections II.7 and III.2.i herein, certain commingled raw agricultural commodities should be exempt from supplier verification because of the complex nature of the supply chain and low food safety risk.

The following types of information may be considered when assessing ingredient risk:

1. Risks presented by the ingredient’s inherent hazards
2. Intended use in finished product
3. Material is a known source of potential contamination
4. Vulnerable consumer base for finished product
5. Presence or lack of kill step in material or finished product
6. Material may or may not support survival/growth of pathogens
7. Source of allergens
8. Packaging/transportation/storage (e.g., potential for temperature abuse for refrigerated products)
9. Risks associated with consumer use (e.g., potential for consumer misuse)

The following types of information may be considered when assessing a supplier’s food safety risk:

1. Performance history (e.g., audit history, responsiveness, on-time deliveries, sanitary transportation issues)
2. Culture of food safety and quality management (e.g., recent management changes, recalls)
3. Country of manufacture/location of manufacturing facilities (e.g., infrastructure; volatility; impact of events on material [e.g., Japan/radiation]; inconsistent enforcement of regulations)
4. Quantity involved for purchase or use in finished product
5. U.S. regulatory compliance (e.g., Warning Letters, Import Alerts)
6. Personnel skill base and training

C. There is a “Sliding Scale” of Verification Activities

The results of the supplier/ingredient assessment of risk determine the verification activities that our members perform. There are a wide range of supplier verification activities employed by our members. We implement supplier verification activities on a “sliding scale,” such that the activities applied are commensurate with risk – both food and supplier risk. This enables us to focus our resources in the areas where they will have the biggest impact for food safety. We employ more supply chain management resources to the suppliers and ingredients that present a higher level of risk. That is, we subject our higher-risk suppliers and foods to more oversight through application of additional verification activities. For example, because some suppliers providing ingredients with inherent risk may have a strong food safety program and performance history, we may consider these suppliers to be lower risk and thus apply fewer verification activities. Conversely, some ingredients without inherent risk may need more robust verification based on risks presented by the supplier itself (e.g., country of origin, audit history).

How frequently our members perform verification activities for a given supplier depends on the results of our assessment of risk. Also, our assessment of risk will inform us as to what verification activities are appropriate and whether more than one verification activity is needed.
Based on the results of our assessment of risk, the verification activities applied for a given supplier may include the following:

1. Successful completion of a third-party audit;
2. On-site audits conducted by the customer/purchaser (i.e., second-party audits);
3. Lot-by-lot Certificates of Analysis (COAs);
4. Reviewing supplier’s HACCP/food safety plan, GMPs, and other food safety records;
5. Receiving testing results for shipments (through certificates of analysis);
6. Conducting verification testing to confirm testing results, when appropriate and necessary; and
7. Supplier surveys.

In addition to conducting verification activities, our members typically convey their supplier expectations through specifications, supplier expectation manuals, and contracts.

D. Audits are an Important Tool, but Have Some Limitations

Second- and third-party audits can be important verification tools. There is a wide diversity of second- and third-party audits. Some audits are scheduled and some are unannounced. Some audits last a few hours and some last several days. Some audits focus on specific aspects of a food safety system and some conduct an overall systems assessment. Our members need the flexibility to determine what type of audit is most appropriate to conduct for their suppliers, so that they can implement a tailored, risk-based program. No matter the nature of the audit, it is important that it be conducted by an appropriately qualified individual and that appropriate checks be in place to account for conflicts of interest.

Audits help receiving companies assess a supplier’s application of its food safety program, so they can gain additional visibility into a facility’s actual operations. The important role of audits is demonstrated by our members’ experience: suppliers who are expected to be low-risk based on the results of a paper-based review sometimes are found to have significant food safety problems when an audit is conducted.

Third-party audits are conducted by an individual that works for an independent entity, rather than the supplier or the company receiving the raw material or ingredient. Many third-party auditors issue certifications that demonstrate suppliers are meeting specified food safety standards (e.g., Global Food Safety Initiative (GFSI)-benchmarked accredited certifications), but

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6 GMA’s Food Supply Chain Handbook includes sections on each of these verification activities; however it also makes it clear that no one activity is mandatory. Rather, the manual explains that it represents a “tool chest” for companies and “[n]ot every example will be applicable for all suppliers. Companies should always implement those practices that will best serve the production of safe foods in their individual operations.” http://www.gmaonline.org/downloads/wygwam/GMA_SupplyChain2.pdf

7 This is one of the many reasons why GMA does not support a requirement to submit facility profiles to FDA that itemize a facility’s hazards and controls. Such information is best understood within the context of the facility. A company can easily hire a third-party to write them a great food safety plan but only an in-person visit can confirm that the facility applies the program appropriately to consistently make safe food. Please see our comments on the inspection-related issues in the proposed rule for additional comments on this issue.
the quality of third-party auditors is not uniform. Our members view third-party audits as an important tool to enable efficient supplier verification. These audits also help prevent duplication, as a single third-party audit of a supplier can be used to satisfy the requirements of multiple customers (although some customers may determine that additional verification activities are needed and may choose to conduct their own second-party audit in addition to reviewing the results of a third-party audit).

Our members ensure that third-party auditors hired to assess their suppliers are subject to controls for conflicts of interest and are appropriately independent. Because widespread reliance on third-party audits for supplier verification has only developed in the last several years, our members expect that the reliability of and confidence in third-party audits will increase over time.

Second-party audits are conducted by the company that is purchasing the raw material or ingredient (i.e., the receiving company, such as a GMA member). These audits may be used instead of or as a supplement to third-party audits. Receiving companies often use second-party audits as a primary or second layer of verification, performing their own audit when appropriate based on risk after the supplier has successfully passed a third-party audit. This is based on recognition that in some cases more insight may be needed into some suppliers’ practices and programs.

Second-party audits are very resource intensive. Therefore, our members tend to focus second-party audit resources on auditing suppliers or ingredients that present a higher level of risk or are new to the company. For example, a receiving company may source an ingredient that presents a risk of *Salmonella* that will not be subject to a kill-step during manufacturing of the finished product. In this situation, the receiving company may determine that it is appropriate to engage in a second-party audit in addition to requiring the supplier to provide documentation of a successful third-party audit, given the high risk presented by the ingredient and the importance of ensuring the supplier has a robust food safety program in place.

Currently, receiving companies sometimes experience push-back from suppliers when seeking to conduct second-party audits, as some suppliers are hesitant to allow customers into their facilities and would prefer audits to be conducted by neutral third-party auditors. For a robust second-party audit to be conducted, a receiving company needs to give assurance to its supplier that information obtained during the audit will be maintained confidentially. Without confidence and adequate assurances from the receiving company that confidential information will not be disclosed (often in the form of a nondisclosure agreement), suppliers will decline to allow their customers sufficient access to their facility and records to engage in a comprehensive food safety audit. Accordingly, as described further below, it is essential that FDA not have routine access to the underlying audit reports, as this would discourage suppliers from being open with auditors. Instead, the regulations should limit FDA’s access to information demonstrating that any significant corrective actions necessary to assure food safety were made.

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8 We note that not all “accredited” audits have the same level of independence. Some auditors are accredited by an entity that lacks external oversight. The level of reliance that can be placed on a third-party audit is linked to the quality of the auditing firm.
Although supplier audits are an important verification activity, they have inherent limitations and additional verification activities also may be necessary. Supplier audits do not control hazards or change the inherent risk of an ingredient. Supplier audits also only represent a “snapshot” of a supplier’s performance. Nevertheless, audits are a valuable tool because they give receiving companies insight into the function of a supplier’s food safety system with the goal of better understanding a supplier, its performance, and the risks the supplier presents.

The fact that problems can still occur with a supplier that passes an audit is illustrated by high-profile recent situations where companies with passing audit scores still were involved in outbreaks and recalls. For this reason, GMA’s members are careful not to over-rely on audits and to structure their supplier verification programs in a manner that recognizes the inherent limitations of audits. Accordingly, sometimes an audit alone will be determined to be a sufficient verification activity, while in other situations an audit may need to be coupled with additional verification activities that provide assurance a supplier has the appropriate controls and food safety program in place.

Consider the following examples that illustrate how our members tailor their programs based on risk, and why they need the flexibility to tailor their programs accordingly:

- If a receiving company’s facility is controlling a Salmonella hazard, it would not focus its supplier verification efforts based on whether the supplier is controlling that hazard although it may assess the supplier’s GMPs to ensure they are not increasing the risk presented by the pathogen. It also may be responsible for the receiving company to engage in verification of non-microbiological hazards that the supplier’s activities can mitigate, such as foreign material control. Indeed, a number of costly product recalls have been due to physical hazards that are not adequately controlled by the supplier. The specific program applied to the individual supplier will depend on the supplier and ingredient’s risk.

- A receiving company may conduct a third-party audit and also require a COA regarding a certain hazard that is inherent to an ingredient and controlled by the supplier (e.g., Salmonella). The receiving company also may have other controls in place to address the hazard, such as hygienic zoning, enhanced GMPs, and a lethality step because the receiving company knows that supplier verification itself has not been able to adequately control the hazard.

- Additional verification activities beyond a third-party audit may not be required for a supplier with a long history of safely supplying a moderate risk ingredient, even if the supplier is responsible for controlling some hazards, or for a supplier of an ingredient that has a low inherent risk.

- Even if a supplier has a long history of safely supplying an ingredient, additional steps beyond a third-party audit may be necessary if the ingredient has a high inherent risk or may be subject to other uncertainties (e.g., crop year variation).

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9 For example, the Peanut Corporation of America received a “superior” rating in several third-party audits. More recently, Sunland, Inc. received high ratings from an audit under a GFSI-benchmarked accredited certification and Jensen Farms received a “superior” rating from Primus Labs.
• Additional verification steps beyond an audit may be required for a new supplier of an ingredient, even an ingredient with low inherent risk, until an acceptable performance history can be established.

As with all verification activities, determining the appropriate approach to follow requires evaluating risk-factors specific to the supplier. Professionals with experience in supplier verification are best situated to make these assessments.

E. Verification Activities May Need to Be Reassessed Over Time

The verification activities a receiving company employs for a given supplier may vary over time. All of the factors that play a role in how receiving companies assess supplier and ingredient risk can change, resulting in modifications to the way the company employs supplier verification activities. Our members reassess suppliers when appropriate, though not necessarily at specified intervals, to determine if their risk-profile has changed and whether a different program of verification activities is necessary. Reconsideration of risk and a corresponding change in verification activities may be appropriate following a “triggering event” or if a receiving company receives information that materially affects their prior risk-assessment. However, unlike a food safety plan or HACCP program, it does not make sense to routinely reassess suppliers at a set time interval.10

For example, if regulatory action is taken against a supplier for a food safety violation (e.g., a supplier receives a Warning Letter related to a material food safety issue), a receiving company may determine that additional verification activities are needed. Events like a change in ownership/management or a natural disaster (e.g., flood resulting in non-potable water) also may trigger a receiving company to engage in additional verification activities for a supplier.

F. Some Companies Have Different Tiers of Supplier Approval

Our members understand that not all suppliers have the same level of experience. Accordingly, many of our members have different levels of supplier approvals with different significance for the approved uses of an ingredient (e.g., “approved,” “approved with conditions,” “provisionally approved”). Our members use varying tiers of approval because they are committed to assisting suppliers in improving their programs.

For example, a supplier may be approved on a temporary basis with the understanding that certain aspects of their program need improvement if they want to continue the business relationship in the longer term. This is particularly important in emerging markets or for ingredients with limited availability, where none of the available suppliers are currently able to meet a customer’s standards. Provisional approval enables our members to work with suppliers to improve their programs. In turn, this helps improve supplier performance. Our members often

10 As will be discussed in more detail in our FSVP comments, FSMA does not require reassessment for supplier verification programs. Additionally, supplier verification is simply one operational aspect of a larger food safety plan that does not make sense to reassess on its own. Just as other prerequisite programs like GMPs are not reassessed periodically, it also does not make sense to require reassessment of supplier verification programs as set intervals.
work with suppliers to improve their programs and assist with execution, providing expert personnel as consultants on issues like sanitation and testing.

If a supplier is provisionally approved, the receiving company may decide to employ additional verification activities, such as conducting third-party laboratory testing to confirm COA results or implementing a more aggressive sampling plan. Our members view supplier development as an important role for leading food companies, so as to drive continuous improvement throughout the supply chain.

When emergency situations arise, it may be necessary to source from suppliers that have not been through a receiving company’s full approval process and therefore are only conditionally approved. As with provisionally approved suppliers, additional verification steps are applied in these situations in order to address the higher level of risk presented by such a supplier. For example, in times of natural catastrophe, when a supplier location is not able to supply materials on time or in full, a “spot buy” purchase may be made from a supplier that has not undergone the normal qualification process. In this case, a site audit from an approved third party organization, indicating no critical quality or food safety concerns exist at the manufacturing location, and verification of critical functional specifications, either on a pre-shipment sample or upon receipt might be necessary.

Sometimes only some of a supplier’s facilities are approved, but a receiving company will conclude that it is appropriate to source from other facilities owned by the same company. For example, a receiving company may receive 90% of its flour from five facilities owned and operated from Company X, but when necessary based on business needs will source small amounts of flour from several other facilities owned and operated by the same Company X. Although the receiving company determined that third-party audits are necessary for flour received from Company X and only the five primary facilities have been audited, the receiving company’s risk analysis may support sourcing from the other Company X facilities on occasion. Similarly, sometimes a supplier is only approved to supply a certain ingredient to a receiving company, but the receiving company’s assessment of risk may support receipt of other ingredients on occasion as needed.

G. Commingled Raw Agricultural Commodities are Unique

Suppliers of many commingled raw agricultural commodities (excluding those subject to the new produce safety regulation) are not amenable to being verified given the way in which the markets work. At the beginning of that supply chain, at any given receiving facility, hundreds of trucks daily deliver commodities to country elevators/warehouses. It is not possible to verify the supplier of each truckload. Nor, given the lack of agricultural production GMPs or HACCP requirements for these raw agricultural commodities,11 is there any standard against which to assess a commodity supplier’s food safety performance. Given practical space limitations, the commodities are commingled at the first receiving facility and are subsequently further traded and commingled domestically and globally.

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As a result, food-based commodities are not directly traceable to thousands of farm level producers. Complex financial and logistical mechanisms are in place to help balance inventories and move these commodities to match manufacturing needs around the world. This market deals with products such as sugar, oils, grains, oilseeds, coffee beans, cocoa beans and other vital food products. Receiving facilities for these raw agricultural commodities can and do assess the risks inherent in these raw agricultural commodities as part of their food safety plans. For example, a facility receiving corn will monitor aflatoxin levels in the drawing area for the facility and implement – as necessary – an aflatoxin screening protocol to minimize the risk of receiving corn with unsafe levels of aflatoxin. It is just not feasible to verify the individual suppliers for such materials.

**H. In Some Situations, it is Difficult or Impossible to Determine the “Supplier”**

Similar to the above situation with commingled raw agricultural commodities, sometimes we are not able to ascertain the specific entity or farm that manufactured, processed, or harvested a given food. For example, sometimes our members purchase ingredients from brokers or distributors rather than directly from the ingredient supplier. In these situations, receiving companies need the broker’s assistance to verify the supplier. A broker should either provide the receiving companies with the name, address, and contact information of the supplier, so that the supplier can be verified directly, or provide assurance of the supplier’s performance based on verification conducted by the broker (e.g., demonstrating a robust supplier verification program is executed by the broker, providing blinded documents like third-party certification certificates). Unfortunately, our members have found that sometimes brokers are hesitant to provide information about suppliers in order to maintain confidentiality to protect the broker’s business relationship with the supplier.

**III. OMB Redline Document Response**

In light of the fact that FDA did not offer proposed codified language on supplier verification in the preventive controls proposed rule, we have reviewed the language FDA initially submitted to OMB. The comments that follow specifically address the approach FDA set forth in the OMB Redline document. We recognize that FDA’s approach to supplier verification likely has

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12 Commodity that are bought and sold may never actually leave the location of storage or may change destination en route depending on circumstances. As an example, a flood or other calamity will cause commodities to move to the area of need to fill the void.

13 Brokers help facilities procure ingredients but typically do not take possession of actual raw materials or ingredients. Rather, brokers provide a service by managing import requirements and connecting manufacturing facilities with suppliers. Traders often play a similar role. Another similar entity is a distributor, which may provide for warehousing of raw materials or ingredients as a conduit between suppliers and manufacturers.

Another example of this challenge is with certain commingled produce. For example, many hundreds of small farmers may grow a certain fruit and then deliver them to a co-op where they are commingled and shipped to the receiving company. Sometimes the receiving company is unable to determine the specific identity of each individual farmer to engage in supplier verification (e.g., to audit their program for appropriate application of pesticides) or the number of individual suppliers is resource-prohibitive to verify directly.

14 Although we are providing comments on the OMB Redline, we do not consider its release to provide adequate notice under the Administrative Procedure Act (APA) such that a direct final rule would be a logical outgrowth of this document.
evolved considerably since the time the OMB Redline was created over two years ago, and, therefore, we first provide a summary of what the OMB Redline would have proposed, which is followed by our specific comments applicable to only the OMB Redline and our specific comments applicable to both the OMB Redline and the FSVP proposed rule.

A. Overview of the OMB Redline Approach

The OMB Redline document shows that FDA’s intended proposed rule on supplier verification would have required every raw material or ingredient manufacturer or processor (referred to by FDA as a “receiving facility”) to have a dedicated supplier verification program as part of its food safety plan. The program would focus on verifying the supplier’s control of specific food safety hazards that are “reasonably likely to occur,” rather than the overall performance of the supplier’s food safety system. The regulation would have provided that some hazards may need more than one verification activity. FDA’s draft approach would place a heavy emphasis on supplier audits as a verification activity (conducted by either the manufacturer or a third-party). Such audits would be required to focus on the supplier’s control of specific hazards, not the supplier’s food safety program as a whole.

Under the draft approach set out in the OMB Redline, the Agency would establish a four-tiered system of supplier verification requirements, which would hinge first on whether the supplier is subject to designated FDA food safety regulations (i.e., regulations regarding preventive controls, cGMPs, produce safety, seafood or juice HACCP, low acid or acidified foods, infant formula, dietary supplement cGMPs, bottled water cGMPs, and shell egg safety):

- For the first two tiers—suppliers subject to an applicable FDA food safety regulation—an initial on-site audit would be required for all suppliers. Raw materials or ingredients that present hazards that could potentially result in a Class I recall also would be subject to annual audits (i.e., first tier). Audits would be required at least every two years for all raw materials or ingredients that present hazards that could potentially result in a Class II or Class III recall (i.e., second tier).

- The third tier of requirements would be for suppliers that are not subject to an FDA food safety regulation (e.g., producers of raw agricultural ingredients, such as wheat, that are exempt from the produce safety rule; food packaging material suppliers). For these suppliers, receiving facilities would have considerable flexibility to determine the applicable verification activities and the frequency of verification activities for these suppliers.

- Finally, the fourth tier of suppliers would be subject to minimal or no verification requirements. No verification activity is needed if there are: (a) no hazards reasonably likely to occur; or (b) if a hazard is effectively controlled by the receiving facility.

We reserve our right, if necessary, to pursue all available legal remedies in the event the Agency proceeds to issue a final rule on preventive controls that includes supplier verification.
FDA would have access to records of verification activities, including a list of approved suppliers. There would only be minimal supplier verification required for qualified facilities (i.e., very small businesses). The supplier approval and verification program would be a component of a facility’s food safety plan, but would not be subject to monitoring, corrective actions, or verification/validation.

**B. Response to Issues Unique to OMB Redline**

We offer the following comments on issues presented by the OMB Redline that are not also reflected in the FSVP proposed rule:

1. **Designated Food Safety Regulations**

The OMB Redline shows that FDA intended to establish regulatory requirements that differ based on whether a supplier is subject to designated food safety regulations. In our members’ experience, supplier and ingredient risk do not depend on whether a product is subject to a certain regulatory scheme.

Although we agree with FDA that different suppliers should be subject to different verification activities depending on risk, we do not support a regulation that codifies that assessment of risk rather than leaving this determination to each receiving company. We do not believe that the determination of the appropriate verification steps for a supplier should depend solely on whether the supplier is subject to designated food safety regulations. Our experience shows us that whether a product is subject to regulation is not the main issue for our assessment of risk. In fact, this issue is rarely determinative when assessing risk.

Nearly all suppliers are subject to designated food safety regulations on FDA’s list, with the exemption of suppliers of certain raw agricultural commodities (e.g., grains) and food contact packaging. This dividing line seems arbitrary, as many other factors affect risk besides being subject to regulation. We agree that whether a supplier is subject to food safety regulation is a factor that may be considered as part of a risk analysis, but this should not be the primary issue considered in an assessment of risk. Whether a supplier is subject to a regulation is much less meaningful than the supplier’s performance, food safety culture, and adherence to robust food safety practices.

FDA’s draft proposed approach also is unnecessarily complex, requiring receiving companies to carefully analyze each supplier separately to determine whether they are subject to a designated food safety regulation. This activity does not add any value for food safety and is simply a “check the box” exercise. Correspondingly, we do not believe that food safety would benefit from requiring receiving companies to maintain a list of all designated food safety regulations governing each supplier. A requirement to maintain a list of the regulations applicable to each supplier would be an exercise in paperwork, rather than a meaningful activity with a tie to prevention. Many receiving companies have thousands of suppliers who each are likely subject to at least two designated food safety regulations (cGMPs and a food-specific regulation). It would take considerable effort to develop and maintain this list, which is not a good use of resources because the list will not help improve food safety outcomes.
2. Role of Supplier Verification in Preventive Controls Framework

We agree with FDA’s approach in the OMB Redline regarding the role of supplier verification in the preventive controls framework. That is, supplier verification should not be subject to monitoring, corrective actions, verification, or validation. This approach makes sense because supplier verification is typically applied as a prerequisite program. Our Food Safety Plan comments discuss the core premise that the application of management elements for preventive control (i.e., monitoring, verification, and corrective actions) should be commensurate with the risk(s) they mitigate. Requirements for receiving companies to engage in monitoring, verification, and corrective actions simply do not apply for a supplier verification program.\(^ {15} \)

Accordingly, we agree with the Agency’s intended approach that would exempt supplier verification from monitoring, verification, and corrective actions even though it is a preventive control that is part of a food safety plan.

3. Testing

We agree that testing can be an important verification activity in some situations. Ingredient testing often more effective and appropriate when conducted by the supplier rather than the receiving company. Suppliers generate COAs using valid analytical methods to evaluate conformance of the specific lot to the receiving company’s requirements. Sometimes receiving companies verify the results of the COA by conducting their own testing of the incoming ingredient. The need for and frequency of such testing is determined based on inherent material risk, intended use of the material by the receiving facility, and the supplier’s performance history.

Requiring receiving facilities, as opposed to shipping companies, to test incoming ingredients could result in unnecessary duplication of testing of the same production lot. Materials destined for multiple companies would be subject to multiple analyses that would not have been needed if the shipper conducted the testing and provided a COA.\(^ {16} \) Moreover, recalls can be prevented if testing is conducted by the supplier before shipping because the problem will be identified before the food reaches any consumers. We also oppose a requirement to test all incoming ingredients, as this would result in unnecessary testing for materials for which the relative risk is low and/or supplier confidence is high.

As discussed in our comments on the testing aspects of this proposed rule, testing is a verification activity and does not directly prevent the conditions that lead to contamination with or growth of pathogens. Testing programs are constrained by the statistical limitations of selecting a defective sample in a consignment or lot and results are only reflective of the sample or sample location evaluated at the time the sample was collected. Ingredient testing cannot

\(^{15}\) Notably, the Agency recognizes its statutory authority to provide flexibility on this point by exempting recall plans from these management elements. This flexibility also is demonstrated by the OMB Redline’s approach of exempting supplier verification from this management oversight.

\(^{16}\) Furthermore, if the receiving company tests a sample of an incoming ingredient and gets positive results, other product shipped from the same lot (which may be in the control of other facilities) also will be implicated. Testing by the shipper can prevent the need for a multi-company recall.
ensure the hygienic status of a product lot. Ingredient testing is most effective as a component of a supplier verification program that includes other activities to verify a supplier’s program.

C. Response to Issues Overlapping in OMB Redline and FSVP Proposed Rule

We have the following comments on issues that appear in both the OMB Redline and the FSVP proposed rule. Our comments on the FSVP proposed rule will provide more detailed feedback on some of these issues.

1. Assessment of Supplier Risk

GMA feels strongly that a successful food safety program requires supplier verification for almost all suppliers, not just for suppliers that present hazards that are “reasonably likely to occur” (RLTO). As discussed in our Food Safety Plan comments, the term RLTO has typically been used as a HACCP filter for determining critical control points (CCPs).\footnote{We also note that the term RLTO does not appear in the statute.} Just as this term does not fit with a Food Safety Plan hazard analysis, it makes little sense here for a prerequisite program like supplier verification.\footnote{FDA appears to apply its “reasonably likely to occur” framework differently in the deleted supplier verification preamble than it does in the preventive controls proposed rule. The deleted preamble stated “a supplier would likely determine there are no hazards reasonably likely to occur in salt.” We disagree, as the analysis under the “reasonably likely to occur” approach would likely identify physical hazards, such as rocks, in the salt. More importantly, however, this conclusion underscores why supplier verification should focus on risk, rather than just hazards. Even if salt does not present any hazards that are “reasonably likely to occur,” the supplier itself (e.g., because of factors like its compliance history) may present an adulteration risk that warrants supply chain oversight.} The phrase RLTO focuses on a supplier’s specific hazards, whereas a robust supplier verification program focuses on a supplier’s overall food safety system. In the preventive controls Appendix, FDA notes several high profile supplier-related recalls that are a result of failures in prerequisite programs, not CCPs. A supplier verification framework that only requires verification of hazards that are RLTO misses out on an important opportunity to improve the safety of the supply chain.

Our members view FDA’s draft approach as too narrow by limiting supplier verification requirements to only suppliers that present risks that meet a certain threshold. We agree that supplier verification needs to be risk-based, with verification activities tailored for each supplier, but believe FDA’s approach will inadvertently create gaps in the food safety system by focusing only on ingredient hazards that will not be addressed by the receiving company. Risks also can be presented by the supplier itself (e.g., GMP failures) or by aspects of an ingredient that will not be addressed by a kill step (e.g., foreign material; undeclared allergens). Even if all hazards presented by an ingredient will be controlled at the receiving company’s facility, our members would engage in some level of supplier verification to ensure the supplier has an appropriate food safety program and does not introduce any unanticipated hazards. Notably, FSMA provides that preventive controls “may include” “supplier verification activities that relate to the safety of food,” without limiting this to only suppliers that present certain hazards.

The determination of what verification steps apply for a supplier should be based on the risk presented by the ingredient and the supplier. There is no way to effectively manage food safety using a one-size-fits-all standard.
2. Role of Regulatory Information for Assessing Supplier Risk

As discussed in section I.2. above, our members often consider both supplier and ingredient risks when assessing a supplier. Receiving companies need flexibility to conduct their own assessments of risk and this is not something that can be codified without significantly limiting the efficacy of supplier verification programs. Regulatory information such as Warning Letters or Import Alerts can be a helpful tool to consider when assessing supplier risk, but review of such information—which speaks to potential supplier risk—is only one information input that should be considered as part of an assessment of risk. Overemphasis of this information could result in less sophisticated companies assuming that because a supplier has not received a Warning Letter and is not on Import Alert, they are making safe food. This is certainly not the case in our experience.

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

We agree that reconsideration of a supplier’s risk and a corresponding change in verification activities may be appropriate following a “triggering event” or if a receiving company receives information that materially affects their prior risk-assessment. This type of information may include a Warning Letter or Import Alert regarding that supplier. Although such information is clearly relevant to the assessment of supplier risk, FDA should not identify review of a supplier’s U.S. regulatory compliance history as a distinct requirement for supplier verification and instead this should be incorporated within the broader assessment of supplier risk. Moreover, receiving companies should have the flexibility to determine what responsive action is appropriate based on the significance of such regulatory actions for their intended use, such as the ingredient being supplied, the nature of the regulatory findings, and whether the supplier has instituted effective corrective actions.

3. Verification Activities

The Agency’s approach in both the OMB Redline and FSVP proposed rule would designate appropriate verification activities based on whether a supplier controls a hazard that could result in a Class I recall (i.e., the hazard presents a “SAHCODHA” risk of serious adverse health consequences or death to humans or animals). We agree that it is appropriate to apply different supplier verification requirements based on risk. However, rather than prescribing risk by regulation, individual facilities should have the flexibility to determine what verification activities are appropriate based on their own assessment of risk – both food and supplier risk.

As discussed above, our members consider more factors than just whether a supplier or an ingredient presents a hazard that could result in food safety problems when they assess risk.
There are a wide range of possible outcomes that can result when balancing ingredient and supplier risk, which are not readily quantifiable in a regulation. There are situations where a supplier should be subject to stringent verification activities even though they do not control a hazard that presents a Class I recall risk. Conversely, there are situations where a supplier needs less verification even though they do control a hazard that presents a Class I recall risk. Receiving companies need flexibility in this regard. It is unnecessarily prescriptive to codify risk analysis; specific direction of the factors that trigger more rigorous verification activities are better left for guidance issued by FDA. Codifying the risk analysis rather than requiring companies to engage in critical thinking will inhibit development of experience and innovation in this area over the longer term. We also are concerned that less sophisticated facilities may simply expect that because their suppliers do not control a Class I recall hazard, less verification is needed and this is not always the case. Additionally, FDA should incentivize suppliers with robust food safety programs so that suppliers who appropriately manage the risk of the ingredients they produce receive the benefit of reduced customer oversight.

Accordingly, we agree that the frequency of supplier verification activities should be risk-based. Beyond a foundational requirement to assess supplier and ingredient risk before use, receiving companies should have the flexibility to determine the appropriate frequency of verification activities for each supplier based on their unique risk-profile. This is a core principle that is essential for supplier verification to function effectively.

4. Role of Audits

We agree that supplier audits are an important verification activity, but believe FDA’s approach in both the OMB Redline and FSVP proposed rule puts too much focus on audits at the expense of a fuller picture of supplier verification activities. We support a requirement to engage in audits when appropriate and necessary. Not all suppliers need to be audited before use, depending on the type of hazard they may control. It is important to recognize that supplier audits are not the only tool available to verify suppliers. Other verification activities, as listed above in Section I.3. of these comments, also serve an important function for supplier verification.

A requirement to audit suppliers at a set frequency is too prescriptive and does not allow the necessary flexibility to tailor a supplier verification program based on risk. Certainly some suppliers are subject to audits at least annually, but other suppliers may not need to be audited that frequently. For example, a finished, fully cooked bakery product supplied by a well-known and responsible supplier may not require an annual or bi-annual audit because of the low-risk it presents—even though the supplier is controlling certain microbiological hazards through their baking process. Resources are better expended on conducting more in-depth verification activities for higher risk suppliers.

Over-reliance on audits can provide a false sense of security about a supplier’s performance. Audits are only a tool used to gain more information about a supplier. We agree with FDA’s recognition that additional verification activities besides an audit, such as a supplier COA or periodic testing by a receiving facility, may be necessary depending on the risk presented by an
ingredient and the supplier. Conversely, routine audits may not be needed at all for some suppliers, depending on risk. For example, if a supplier is providing a low-risk ingredient and the company has a long history of successfully providing that ingredient without any food safety concerns, the receiving company may not audit the supplier or may only conduct an audit intermittently (but not routinely). The same may be true for even a “high risk” ingredient where the supplier controls a hazard, such that it may be appropriate to audit a supplier less often than annually.

Audits, like all other supplier verification activities, do not control hazards. Rather, they capture the performance of a supplier’s system at a specific point in time. An audit is a “snapshot” in time that provides insight on a supplier’s program at the time the audit was conducted. This is why it is important to recognize that supplier verification is just one aspect of a broader food safety program—because a prerequisite program alone cannot make food safe.

Our experience has taught us that the most effective audits focus on a supplier’s overall food safety system. It appears that FDA’s proposed approach in the OMB Redline would focus only on a supplier’s control of specific hazards. (That is, the audits would be tailored to assessing certain hazards but would not consider the supplier’s overall program.) This approach could overlook important aspects of a supplier’s program that could have an important impact on food safety. For example, audits typically assess compliance with prerequisite programs like GMPs and sanitation, which are foundational to enable a company to make safe food. If an audit only considers whether the supplier appropriately applies its CCPs, it may overlook basic deficiencies for these essential programs.

When audits are used, it is important that auditors be appropriately qualified through education, training, or experience.\(^{19}\) We support use of either second- or third-party auditors that have appropriate technical expertise obtained by a combination of training and experience appropriate to perform the auditing function. We agree that it is important to establish protections for auditors to ensure independence, such as certain protections against conflicts of interest.

5. List of Approved Suppliers

We agree with the principle underlying FDA’s approach that a list of approved suppliers is a useful tool to ensure only materials from verified suppliers are received. However, many of our members do not maintain a single supplier list but instead have another corporate-wide system in place to confirm ingredients only are received from approved suppliers. FDA should simply require receiving companies to have a procedure in place to ensure ingredients are only received from approved suppliers.

Maintaining a single standalone list of suppliers presents numerous logistical challenges given that the suppliers who are approved are constantly evolving. In particular, some ingredients are sourced from brokers, traders, or distributors that do not disclose the name of the individual supplier that manufactures the ingredient. Similarly, the approved suppliers may be conditionally approved, such that it could be misleading to simply put their name on a list of

\(^{19}\) In some situations, it may be appropriate for an auditor to have education, training, or experience with the specific food category or process being audited.
approved suppliers that implies all suppliers are equally acceptable. A supplier also may be approved to provide some ingredients, but not all ingredients they manufacture.

Instead of maintaining a facility specific list, many receiving companies have centralized, controlled processes that ensure only approved suppliers can deliver products to their facilities.\(^{20}\) FDA should require companies to maintain and implement procedures to ensure only approved supplier facilities are permitted to supply ingredients or raw materials, rather than maintaining a written “list” that can soon become out of date. There are multiple ways that a receiving company can achieve this goal other than maintaining a single list. We agree that it is important that this information be maintained in real time, so that there is no delay between a supplier’s disapproval and a facility’s discontinuance of using that supplier’s ingredients.

6. Response to Supplier Nonconformance

FDA’s regulations should provide flexibility to determine the appropriate responsive action to take in the event of non-conformance. We agree that receiving companies should take appropriate measures in response to a supplier non-conformance, but believe discontinuing use of a supplier is an extreme response that should be reserved for only the most serious situations, when other solutions that would protect the public health are not available.

There are many different levels of supplier non-conformance. For example, a supplier may fail to deliver goods on time, which may result in business concerns but would not necessary raise concerns related to food safety. On the far other end of the spectrum, a supplier may supply repeated shipments that test positive for a pathogen that the supplier is responsible for controlling, which may result in the receiving company deciding to discontinue use of the supplier. Our members recognize the importance of investing resources in supplier development. Oftentimes supplier non-conformance is an indication that further supplier development resources are necessary. We believe that a culture of continuous improvement needs to be encouraged under FSMA. Requiring receiving companies to discontinue use of a supplier simply because of a single non-conformance would be a disincentive for receiving companies to invest resources in supplier development.

Because food safety is not controlled through supplier verification, many types of nonconformances do not trigger the need to discontinue use of a supplier. Our members regularly work with their suppliers to identify the root cause of the problems and to help develop programs the supplier can implement to improve their processes. For example, if periodic testing conducted by the receiving company as an additional verification step finds problems with the supplier’s product, responsible companies would work with the supplier to identify why the problem occurred and how it can be prevented in the future. Certainly the receiving company would make any required Reportable Food Registry reports and would not use the lot that tested positive in its own production (unless they can control the hazard or recondition the ingredient). However, working together with the supplier to improve their processes will have a more beneficial result for food safety, by driving improvement throughout the supply chain, than simply discontinuing use of the supplier following a nonconformance. Provided that a supplier

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\(^{20}\) These processes are centralized because supplier verification typically is managed company-wide on the corporate level.
implements appropriate corrective actions following a nonconformance it should be permissible to continue to source from that supplier.

Follow-up actions based on supplier non-conformance can be affected by business issues, such as unavailability of an adequate replacement vendor. If a supplier provides non-conforming goods but an adequate replacement vendor is not immediately available, it should be permissible to continue to source from that supplier. Follow-up actions based on supplier non-conformance can be affected by business issues, such as unavailability of an adequate replacement vendor. If a supplier provides non-conforming goods but an adequate replacement vendor is not immediately available, it should be permissible to continue to source from that supplier. If a supplier provides non-conforming goods but an adequate replacement vendor is not immediately available,21 a receiving company may continue to purchase from the supplier but also may engage in additional verification activities and oversight. In our members’ experience, it often is better to continue receiving goods from a supplier who has experienced a nonconformance but took appropriate corrective actions (and for which additional verification steps may be applied), than to switch to using a new supplier with whom we may have less or no experience or confidence.

We encourage FDA to develop guidance explaining its recommendations for appropriate responses in instances of supplier nonconformance in order to help less sophisticated manufacturers, but we do not believe any specific cause/response requirements should be included in the regulation itself. Companies should be given the flexibility to determine the appropriate action to take if they have the knowledge and expertise to do so. Receiving companies should document their responses to supplier non-conformances and this documentation should be available for FDA’s review.

7. Documentation

FDA’s documentation requirements should not provide a disincentive for engaging in robust supplier verification programs. It is important for receiving companies to document their supplier verification programs in a manner that enables production of safe food, but records should not simply be created for the purpose of facilitating inspections to assess compliance.22 Further, we are concerned that sharing certain supplier verification information with FDA could discourage open, honest, and complete audits. Thus, we agree receiving companies should be required to establish and follow supplier verification procedures and FDA should have access to these procedures. In contrast, companies should not be required to create documents such as lists of suppliers simply for regulatory compliance purposes.

Our members also are particularly concerned about any potential requirement to share audit reports with FDA. Among other things, requiring audit reports to be shared with FDA could undermine the receiving party’s ability to conduct the robust type of audits that may be necessary as a verification activity. If a receiving company wishes to conduct a second-party audit of a supplier, this supplier still has the discretion about whether to voluntarily allow their customer into their facility. Suppliers usually only allow their customers to conduct an audit on the condition of confidentiality. If the receiving company is required to share its audit report with

21 Sometimes it is necessary to purchase goods from a non-approved supplier in emergency situations, such as when there are serious food safety concerns with an approved supplier. FDA’s regulations should provide flexibility to purchase from non-approved suppliers when necessary, to avoid production disruptions. This would be consistent with current third-party audit standards. For example, SQF’s code states: “The receipt of raw materials, ingredients, and packaging materials received from non-approved supplier shall be acceptable in an emergency situation provided they are inspected or analyzed before use.”

22 As discussed below in section IV, we urge FDA to inspect supplier verification programs company-wide, on the corporate level.
FDA, the supplier will inevitably resist the audit or seek to severely restrict the scope of the 
second-party audit. Without a promise of confidentiality, receiving companies could lose the 
ability to conduct a candid and thorough audit.

Further, audits of customers often include confidential business information and may include 
findings that indicate the audited facility may be out of compliance. This is important 
information that enables the receiving company to assess appropriate verification activities for a 
supplier. However, if a supplier knows that the audit report will be available to FDA they may 
be less likely to allow the audit. The fact that public disclosure of these audits would be 
protected by the Freedom of Information Act (FOIA) is not enough to ensure that suppliers will 
continue to allow receiving companies to conduct audits of their facilities. It is not only a 
supplier’s concern about public disclosure that could have a chilling effect, but also their fear of 
disclosure of these reports to FDA.23

Protection of audit reports will encourage cooperation and visibility by suppliers, allowing for 
receiving companies to conduct full due diligence. Complete and candid audits are an essential 
part of the food safety system because they allow receiving companies to learn from first-hand 
assessments of their suppliers’ systems. Confidentiality is an important part of these audits to 
courage suppliers to allow their customers open access to their facilities. If suppliers cannot 
be assured of the confidentiality of audits, they are less likely to allow receiving companies to 
conduct these assessments. This will mean that receiving companies will lose an important 
opportunity to identify problem areas for their suppliers. Sharing audit reports with FDA could, 
therefore, chill the behavior that supplier verification activity is designed to encourage.

Of note, Congress has recognized the importance of maintaining confidentiality for food-related 
audit reports in the context of infant formula. The Drug Enforcement, Education, and Control 
Act of 1986 (Pub. L. No. 99-570) required FDA to establish regulations regarding retention of 
records of routine mandatory audits to confirm regulatory compliance, but also specified that a 
manufacturer need only provide written assurances that the regularly scheduled audits are being 
conducted by the manufacturer, “and need not make available to the Secretary [of Health and 
Human Services] the actual written reports of such audits.”24 Accordingly, FDA’s regulations 
require firms to maintain “audit plans and procedures,” but not the actual written reports of the 
audits.25

FDA also recognizes the value of protecting audit confidentiality in the medical device industry 
where it is the Agency’s policy generally not to review quality audit reports.26 The Agency’s 
medical device Quality System Regulation provides that facilities must prepare a report with the 
results of each internal quality audit and document their supplier evaluations and control

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23 To the extent that FDA disagrees and concludes that audit reports will be accessible to the Agency, we urge the Agency 
to reaffirm its intent to protect the content of these audits from public disclosure under FOIA because they contain 
confidential commercial information and/or trade secret information that is exempt from disclosure. 5 U.S.C. § 552; 21 
25 21 C.F.R. § 106.100(j).
26 61 Fed. Reg. 52602, 52613 (Oct. 7, 1996). (FDA “believes that refraining from routinely reviewing these reports may 
help ensure that the audits are complete and candid and of maximum use to the manufacturer”).

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activities. However, this documentation (including supplier audit reports) are not subject to review and copying by FDA. Rather, upon request of FDA “an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.”

We encourage FDA to follow the precedent established in the medical device and infant formula context and to exempt audit reports from disclosure to the Agency. The Agency should be able to review (1) documentation that demonstrates an audit was conducted (i.e., the date(s) of the audit and name(s) of auditor(s)), and (2) documentation that demonstrates any corrective actions in response to any significant deficiencies were completed. However, FDA should not have access to the content of the audit report itself. Such disclosure would provide a disincentive against thorough auditing. If necessary, FDA can access the content of audit reports under its broader emergency records access authority under FDCA section 414.

8. Substitution of Regulatory Inspections for Supplier Audits

Regulatory inspections may be taken into account when assessing supplier risk, but should not be permitted to substitute for supplier audits. Regulatory inspections have a very different purpose than a supplier audit and therefore should not be used as a substitute. There also are a wide-range of different types of regulatory inspections conducted by either FDA or state agencies under contract with FDA. It is unlikely that FDA’s investigators will focus on the same issues that a second- or third-party auditor would consider when conducting a supplier audit, especially considering that audits sometimes are tailored to focus in-depth on a particular ingredient made by a given facility (while also taking account of issues like GMP compliance and allergen cross-contact from other lines). Regulatory inspections also are difficult to obtain copies of and often are highly redacted. The issue of regulatory inspections substituting for supplier audits will be discussed in more detail in our FSVP comments.

9. Exemptions and Modified Requirements

We agree with FDA’s limitation in the OMB Redline on the scope of supplier verification to only facilities that are manufacturers or processors. However, we encourage the Agency to take account of several other issues, discussed below, when considering the scope of supplier verification regulation.

Non-Duplication of Effort and Overlap with FSVP. As will be discussed in more detail in our FSVP comments, we support an exemption from supplier verification under preventive controls of any suppliers that have already been verified under the FSVP. This approach will eliminate redundancy. For example, if a U.S.-based facility verified an ingredient under FSVP, it should not be required to verify this ingredient again under preventive controls (and vice versa). Similarly, if a U.S.-based facility buys an ingredient from a U.S.-based distributor that verified the ingredient under their FSVP, the U.S.-based facility should not be required to engage in

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27 21 C.F.R. §§ 820.22, 820.50(a).
28 21 C.F.R. § 820.180(c).
supplier verification for this ingredient under their own preventive controls obligations. Rather, the U.S.-based facility should only be required to verify and document that the entity from whom the food was purchased implements a risk-based supplier verification program.

**Commingled Raw Agricultural Commodities.** We propose exempting commingled raw agricultural commodities (excluding those subject to the produce safety regulation) from the regulation’s supplier verification requirements for several reasons. First, supplier verification is not feasible for commingled raw agricultural commodities. FDA’s draft proposed rule assumes that a supply chain exists only in a linear fashion: a need is identified, a supplier is approved, and product is shipped to the manufacturer. This is not necessarily the case with many raw agricultural commodities as discussed in Section II.7. The traditional model of verifying each supplier just does not fit for these ingredients.

Second, supplier verification activities should be proportional to the food safety risk. Since there are no GMP or other FSMA requirements that apply to suppliers of these raw agricultural commodities, FDA has already determined that food safety requirements/controls are not warranted for such suppliers and/or the cost of implementing such requirements/controls is not justified by the cost of implementation. As such, there is no value or improvement to public health achieved if receiving facilities are required to conduct verification of suppliers such as grain and oilseeds farms, handlers, traders, or storage sites. Further support for this proposed exemption, including discussion of the scientific support for this approach, is discussed in comments being filed to this docket by other trade associations that specialize in these commodities.

**Intra-Company Shipments.** As will be discussed in more detail in our FSVP comments, we recommend that FDA exempt intra-company shipments (i.e., shipments between two business units owned by the same corporate parent) from supplier verification, as any ingredients will already have been verified by another division of the receiving company. It would be duplicative and would not benefit public health if a company has to verify itself. This applies to both international shipments (e.g., importation from a foreign affiliate) as well as domestic shipments (e.g., from a domestic affiliate).

**Contract Manufacturers of Branded Products.** Supplier verification should not be required when a contract manufacturer (i.e., “co-manufacturer”) is receiving an ingredient from the company for whom they are manufacturing a product (i.e., the contracting company) and the finished product will be sold under the contracting company’s name. For example, if a contracting company manufactures and provides its co-manufacturer with cookies to use as an ingredient in a cookie-bit ice cream sold under the contracting company’s name, the co-

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29 When we refer to commingled raw agricultural commodities in this context, we are referencing any commodity that is combined or mixed after harvesting but before processing.

30 Under the Bioterrorism Act and FDA’s implementing regulations, a facility is only required to be able to trace food “one-step back.” Requiring receiving companies to engage in supplier verification further back to the source of the food would be contrary to the Bioterrorism Act and the traceability provisions in FSMA. Notably, FSMA specifically restricts FDA from requiring facilities to maintain records of the full pedigree of a food and also limits traceback requirements for commingled raw agricultural commodities to the immediate previous source of the food. FSMA § 204(d)(1)(L). Going further back simply is not feasible.

31 In the alternative, we suggest that commingled raw agricultural commodities should only be required to be assessed for risks on the ingredient level, not risks presented by an individual supplier.
manufacturer should not be required to engage in supplier verification for the cookies. The co-
manufacturer should be required to engage in supplier verification for other ingredients in the ice
cream, like milk, cream, and sugar. The unique nature of this co-manufacturing relationship
provides that supplier verification is not necessary because, in many ways, it is akin to an intra-
company shipment.

**Broker/Distributor Purchases.** As noted above, a receiving facility may not be able to ascertain
the specific manufacturer or processor of a specific food because that food is purchased from a
broker or distributor rather than directly from the ingredient supplier. Because a
broker/distributor will often refuse to disclose the specific manufacturer or processor, a receiving
facility should not be required to verify more than that the broker/distributor has a documented,
risk-based supplier verification program that is consistently implemented.

**Who to Verify.** Supplier verification should only be required to go “one-step back” (i.e., to your
supplier, rather than to your supplier’s supplier). We are concerned that deleted preamble
discussion in the OMB Redline implies an obligation to review a supplier’s suppliers. The
document explains that a receiving company may determine it is appropriate to periodically
review a supplier’s food safety records, which may include “records of a supplier’s audit of its
supplier’s hazard control activities.” While we agree that records review can be an appropriate
verification activity, we are concerned by the implication that supplier’s suppliers need to be
reviewed.

Every company is responsible for verifying its own direct suppliers. Requiring duplication of
these efforts creates unnecessary redundancy in the system. A receiving company does not
typically have sufficient knowledge about their supplier’s supply chain to fully evaluate the
adequacy of a supplier’s suppliers. However, we do support review of a supplier’s suppliers
records in limited, unique situations involving “middle men” (e.g., brokers and distributors).
When a receiving company verifies that its broker/distributor implements an appropriate supplier
verification program, it may be appropriate to review specific supplier verification records from
the broker or distributor’s program to ensure their system is adequate.

**Small Quantities Intended for Research and Evaluation.** Consistent with the requirements for
the foreign supplier verification program, supplier verification should not be required for small
quantities of raw materials or ingredients intended for research and evaluation purposes where
the finished product will not be available for retail sale and will not be sold and distributed to the
public. This exemption in section 301 of FSMA reflects Congress’s recognition that there is
not a significant need for supplier verification of these foods given that they will have limited
consumption by a small, controlled group of consumers. For consistency, FDA should take the
same approach in the preventive controls regulation.

This exemption also makes practical sense because it is common to test samples from several
suppliers before deciding which one meets requirements during the research and development
process. It would present a significant burden if all research and development suppliers had to
be verified with no commensurate public health benefit. We consider that food is not
“distributed to the public” if it is consumed by a small number of consumers in a controlled

32 FSMA § 301(a); FDCA § 805(f).
testing environment, such as taste tests conducted at the manufacturer’s facility or a controlled in-home use test. In such situations, there is direct traceability over the product and consumption is only by a limited group of consumers who have given informed consent recognizing that the food is necessarily experimental. This exemption would not apply to situations where the product is sold to the public, including regional test marketing, as we agree in that case full supplier verification is necessary and appropriate.

**Food Contact Substances.** We urge FDA to exempt food contact substances, so that receiving companies are not required to engage in supplier verification for these materials. Our FSVP comments will discuss our rationale for this proposal.

**IV. FDA Inspections of Supplier Verification Programs**

GMA commends FDA on its goal of modernizing the way the Agency conducts inspections under FSMA, shifting its approach to ensuring consistent implementation of FSMA’s modern prevention measures rather than being narrowly focused on identifying legal violations. As part of this transformation, we encourage FDA to pay particular attention to developing a thoughtful and effective approach to inspecting and enforcing new supplier verification requirements. As most supplier verification programs are managed on the corporate level, it may be appropriate for FDA to conduct targeted inspections at corporate headquarters that focus only on the company’s supplier verification programs, rather than inspection the same company’s supplier verification program again and again through facility inspections. This also would enable FDA to inspect supplier verification programs using investigators with specialized experience in this area. GMA welcomes the opportunity to work with FDA to develop such an inspection program.

During inspections, FDA should focus efforts on ensuring a company has a documented, risk-based supplier verification program that is consistently implemented. The goal of inspections for supplier verification should be to ensure receiving companies have a well-functioning system in place. Individual companies and/or facilities are best situated to assess the risks presented by their suppliers and supply chains. Thus, when FDA conducts an inspection of a supplier verification program, the Agency should ensure the company has developed and implemented such a program but should only scrutinize the specific rationales or reasoning underlying the program when there is good cause for doing so. Certainly we agree that it would be appropriate for FDA to take action if a program is clearly deficient. However, FDA should not routinely focus its limited inspection resources on questioning the specific verification activities applied for a given supplier if the firm being inspected has a robust supplier verification program in place.

Just as FSMA should provide companies with the flexibility to develop their food safety plans in the manner their experts determine are most effective to make safe food, the same should be true for supplier verification programs. FDA should ensure companies have programs in place and that the programs are consistently and effectively implemented. GMA appreciates that some companies, especially smaller companies may not yet have the same in-house expertise on supplier verification programs that GMA members have. We believe it important that the qualified individual preparing or overseeing preparation of a facility food safety plan possess the necessary expertise in supplier verification to enable all facilities to achieve the appropriate
supplier verification plan based on an assessment of risk. Even with less experienced companies, we believe FDA should focus on whether the company has a truly qualified individual overseeing supplier verification, rather than conducting a de novo review of the supplier verification program itself.

As discussed above, it is particularly important that FDA establish and maintain protections for the content of audit reports during inspections. Inspections should ensure audits have been conducted as required by a company’s supplier verification program, but should not second-guess the reasoning underlying these programs or scrutinize the content of these audit reports. Consistent with the Agency’s approach in the medical device regulations, we support a requirement to provide FDA with documentation of corrective actions for significant deficiencies observed during audits.

V. FDA Should Offer Another Opportunity to Comment on Supplier Verification

We urge FDA to allow stakeholders an opportunity to review and comment on the Agency’s codified language for supplier verification under preventive controls before any such requirements are included in a final rule. We understand that FDA intends to take a similar approach for preventive controls as for the FSVP, consistent with its WTO obligations; however, we feel this statement in the FSVP preamble does not allow industry adequate due process. Although we support a final regulation that includes supplier verification requirements, the Agency has not laid adequate groundwork to go from this proposed rule to a final rule that includes such a requirement. We question whether including a supplier verification requirement in the preventive controls final rule would be logical outgrowth of this proposed rule given the preamble’s cursory discussion of supplier verification. This is why an opportunity to comment on codified language is needed. Although we are providing comments on the OMB Redline document, the release of this document does not mitigate our procedural concerns. (Further, we understand that the Agency’s thinking has evolved in the past two years since the OMB Redline was developed and expect that the final rule could look very different than the draft regulation in the OMB Redline, such that it would not be a “logical outgrowth” of this document.)

Given that FDA did not propose specific codified language on supplier verification, the Agency should publish the supplier verification aspect of the preventive controls final rule as a tentative or interim final rule in order to allow an opportunity for public comment. We also would support an approach whereby FDA provides some other interim mechanism to solicit public comments. This aspect of the regulation should not be enforced until after consideration of these comments and publication of a final rule.
Appendix I: GMA Recommended Regulatory Language

§ 117.3 Definitions.

Receiving facility means, for an article of food, a facility or corporate parent of a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

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

§ 117.152 Supplier verification program.

(a) Supplier verification program.

(1) Except as provided in paragraphs (a)(4) and (a)(5) of this section, the owner, operator, or agent in charge of a receiving facility must establish and implement a supplier verification program for all incoming raw materials and ingredients.

(2) The supplier verification program must evaluate the risks presented by each supplier and by each incoming raw material and ingredient. This assessment of risk must consider the effect of the following on the safety of the finished food for the intended consumer:

   (i) The known or reasonably foreseeable hazards in the food;
   (ii) The ingredients of the food;
   (iii) The condition, function, and design of the supplier’s establishment and equipment;
   (iv) Transportation practices;
   (v) Harvesting, raising, manufacturing, processing, and packing procedures;
   (vi) Packaging and labeling activities;
   (vii) Storage and distribution;
   (viii) Intended or reasonably foreseeable use;
   (ix) Sanitation, including employee hygiene;
   (x) The supplier’s U.S. regulatory compliance status; and
   (xi) Any other relevant factors.

(3) The supplier verification program must include:

   (i) Procedures to ensure products are received only from approved suppliers; and
   (ii) Risk-based verification activities, as required by paragraph (b) of this section, when necessary and appropriate, to verify the incoming raw material or ingredient is:

      (A) Produced in compliance with the requirements of 21 CFR Part 117 or 21 CFR Part 112, as appropriate; and
(B) Not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(4) The owner, operator, or agent in charge of a receiving facility is not required to establish and implement a supplier verification program for:

(i) Commingled raw agricultural commodities intended for further processing;
(ii) Small quantities of food intended for research and evaluation purposes that are not intended for retail sale and will not be sold and distributed to the public;
(iii) Intra-company shipments, including shipments between facilities with common corporate or corporate-parent ownership;
(iv) Suppliers of food who (a) are under different corporate ownership than the receiving facility, (b) have contracted with the receiving facility to produce finished products on the supplier’s behalf, and (c) are supplying food that will be used in the manufacture of finished products sold under the supplier’s brand name; and
(v) Food contact substances.

(5) In instances where the identity of the supplier cannot be determined because the food was purchased from a co-op, broker, distributor, trader, or other third-party, a receiving facility need not engage in supplier verification of the supplier but instead must verify and document that the entity from whom the food was purchased implements a risk-based supplier verification program.

(b) Supplier verification activities. The owner, operator, or agent in charge of a receiving facility must conduct supplier verification activities as determined to be necessary and appropriate for each supplier, unless the supplier is exempted under paragraph (a)(4) of this section. The nature and frequency of supplier verification activities must be based on the risk associated with both the supplier and the ingredient, as assessed under paragraph (a)(2) of this section. In some situations, depending on risk, it will be necessary to conduct more than one supplier verification activity and/or to increase the frequency of one or more supplier verification activities.

(1) Supplier verification activities. The owner, operator, or agent in charge of a receiving facility must conduct one or more of the following supplier verification activities periodically, as necessary and appropriate based on risk as assessed under paragraph (a)(2) of this section:

(i) Onsite audits conducted by the receiving company or a qualified third-party auditor.
(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.
(iii) Review by the receiving company of the supplier’s relevant food safety records.
(iv) Other appropriate supplier verification measures based on the risk associated with the ingredient.
(c) Records. All supplier verification activities conducted in accordance with this section must be documented. Records of audits must include documentation of audit procedures, the dates audits are conducted, corrective actions taken in response to significant deficiencies identified during supplier verification audits, and that audits are conducted by appropriately qualified auditors, as provided by paragraph (d) of this section. The owner, operator, or agent in charge of a receiving facility is not required to make written reports of audits or other materials specific to an individual supplier available to FDA, except as provided by 21 C.F.R. § 1.361.

(d) Qualifications to perform verification activities.  
(1) Supplier verification programs under this section, including onsite audits, must be developed and implemented by a person who has the necessary education, training, and experience to perform the required activities. This person may be, but is not required to be, an employee of the receiving facility; and
(2) Onsite audits must be conducted by a person (1) with appropriate technical expertise to perform the auditing function and (2) that does not have a financial interest in the supplier. Payment must not be related to the results of the activity. This does not prohibit the owner, operator, or agent in charge of the receiving facility from conducting an audit of a supplier.

(e) Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, or otherwise that the supplier is not producing food that is suitable for the receiving facility’s intended use, the receiving facility must take or cause the supplier to take prompt corrective action to ensure that the food produced by the receiving facility is suitable for its intended use. This action must be documented.
Appendix II: Sperber, Food Control 16 (2005) 511-514
HACCP does not work from Farm to Table

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Abstract

Because of its inability to detect hazards that occur a low incidence, the quality control system was supplanted by the HACCP system to provide assurance of food safety. The global use and success of the HACCP system in the food processing industry created false expectations that it could be used successfully in all steps of the food supply chain, from Farm to Table. However, the lack of definitive critical control points that could eliminate or control identified hazards prevents the effective use of HACCP in all steps of the supply chain. Food safety measures can be used at each step in the supply chain, but most of these measures will be prerequisite programs rather than critical control points from a HACCP system. To better focus on the application of effective food safety control measures, we must communicate in terms of “Farm to Table Food Safety”, rather than “Farm to Table HACCP”.

Keywords: HACCP; Prerequisite programs; Quality control; Farm-to-table

1. Introduction

For more than twenty years, food safety professionals have promoted the HACCP system of food safety so vigorously that they have, in fact, oversold the utility of the HACCP concept. As a result, the interactions between food safety professionals, consumers, and regulators are not entirely transparent. Expectations of food safety throughout the food supply chain have been raised. Confusion, fear, and anger mount when the expectations are not met. In order to understand my claim, it is necessary to consider briefly how HACCP system of food safety grew to global dominance.

2. Limitations of quality control systems to assure food safety

The quality control (QC) system had been used in manufacturing industries for decades before the HACCP concept was developed. QC systems functioned in the same manner in all industries, whether automobiles, radios, or consumer foods were being manufactured. Products were manufactured for an entire shift or day and placed in a storage area. A QC technician collected samples and sent them to a laboratory for analysis (except for the automobiles). The samples were analyzed for defects. Statistical sampling plans were used. Production lots that exceeded the maximum allowable number of defects in the sample set were rejected, the remaining “good” lots were accepted and shipped.

After World War II, serious food safety incidents occurred in the nascent food processing industry. These typically involved Salmonella contamination of dried egg or dairy products, or Clostridium botulinum growth or presence in canned foods. The QC system for quality assurance was applied to food samples to provide food safety assurance. The limitations of QC systems to assure food safety (or quality, for that matter) soon became obvious.

Based upon end product inspections and lot acceptance criteria, QC systems were costly and, worse, inaccurate. QC systems were inaccurate because of their inability to detect defects that occur at a low incidence. For example, at a defect rate of 0.1% (a rate typical for foods that might be contaminated with a microbial pathogen), 3000 product samples would need to be analyzed in order to detect one positive sample with a 95% level of confidence (Fig. 1). QC systems are similarly inaccurate at substantially higher defect levels. If one analyzed 10 samples from a production lot that had a 10% defect rate, one would have only a 35% probability of finding a single positive sample (Table 1,
ICMSF, 2002). QC systems are clearly ineffective and almost totally incapable of detecting food safety defects that occur at a low incidence.

3. The evolution of the HACCP system

The Pillsbury Company encountered this dilemma in the 1960s in its attempts to fulfill several food production contracts with the US Army and the National Aeronautics and Space Administration (NASA). NASA in particular had very stringent microbiological acceptance criteria, not wanting to risk the illness of an astronaut during a space mission (what an inopportune time for a “two-bucket” illness!). In essence, nothing short of 100% product testing could assure NASA that a particular packet of food was safe to consume. It was obvious to all involved that product testing could not be used to guarantee food safety. A much better system of food safety assurance was required.

Thus, the genesis of the HACCP concept, a joint development by The Pillsbury Company, the US Army, and NASA. Unlike QC systems, HACCP is a preventive system in which food safety can be designed into the product and the process by which it is produced. It is a system of product design and process control. The HACCP system of food safety is very effective at controlling identified hazards. Most importantly, it does not rely upon product testing to assure food safety.

Over the next three decades, the HACCP system spread into the food processing industry of the US, and into other countries. Toward the end of this period, government regulatory agencies began to replace their inspection programs, based upon infrequent plant visits, with audit programs, based upon a review of continuous HACCP records; a development that led to the promulgation of several HACCP-based food safety rules.

During the 1990s, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission Committee on Food Hygiene (CACCFH) expanded the early HACCP applications and published documents on HACCP principles and guidelines for their implementation (NACMCF, CACCFH, 1997).

4. Farm to Table HACCP

The long, global evolution and use of HACCP in food processing plants provided overwhelming documentation that the HACCP system of food safety was very effective at controlling identified foodborne hazards. Its ability to assure food safety was vastly superior to that of the quality control system which it replaced. The widespread success of HACCP led to increasing calls by regulators, politicians, and consumers to use this remarkable tool more effectively by applying it along the entire food chain, from “Farm to Table”.

In simple terms, the supply chain consists of seven steps: animal or crop production, slaughter or harvest, raw product production, processed product production, distribution, food service or retail operations, and consumption (Fig. 2). The processed product production is at the center of this supply chain.

It is no accident that HACCP evolved at the food processing step of the Farm to Table supply chain. It is at this step that effective controls, such as cooking, drying, acidification, or refining are available to eliminate significant hazards. Two categories of processed food exemplify this fact superbly—pasteurized dairy products and canned foods. Note that, with both of these food categories, food safety is assured by process control, not by finished product testing.

The most pressing food safety issues in the food industry today are caused by the presence of Escherichia coli O157:H7 and salmonellae in raw meat and poultry products and in produce. Attempts to control these pathogens, either at the “Farm” or “Table” ends of the supply chain have been disappointing because of the lack of effective control measures at these steps that are available at the food processing step. Despite many efforts to reduce or control pathogens in animal or produce production, successful interventions have not yet been realized. Examples of prospective interventions include clean water, pest control, worker hygiene, competitive exclusion, vaccines, bacteriophage and hide cleaning. Similarly, effective pathogen control is not realized at the consumption step even when reliable
control measures are available. In the handling of raw ground beef patties, for example, it is well known that frying or grilling the patties to a minimum internal temperature of 71 °C will eliminate the potential hazard of *E. coli* O157:H7 infections. Yet, there are many illnesses each year attributed to the consumption of cooked hamburger patties. With millions of servings per day, there are ample opportunities for mistakes to be made. Some of the patties will be unintentionally undercooked, some will be deliberately undercooked as a matter of personal preference. Cross-contamination and other poor food handling practices can also lead to foodborne illnesses. Thus, the idea that HACCP can be effectively applied from Farm to Table must be reexamined.

### 5. Farm to Table food safety

In our zeal to promote the HACCP system, we food safety professionals have oversold its ability to assure food safety. Despite the widespread use of HACCP in the food industry, many outbreaks of foodborne

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outbreaks still occur. However, these food safety failures are rarely HACCP failures. Rather, they are frequently failures of cleaning and sanitation practices or the lack of management awareness and commitment to provide the necessary training and resources. We must recognize that HACCP is a necessary, but insufficient, condition to assure food safety. That is, HACCP cannot be effective when applied as an isolated system. It must be supported by prerequisite programs, examples of which are listed in Table 2 (Sperber et al., 1998).

In arguing that HACCP does not work from Farm to Table, I am not suggesting that efforts to improve food safety at supply chain steps other than the food processing step should be abandoned. I am, however, suggesting that at all supply chain steps we must pay attention and apply the appropriate prerequisite programs. The US meat industry is focusing on a number of prerequisite programs and intervention technologies that could reduce the level of pathogens in live animals, yet would not reduce them to insignificant levels (Table 3). Similarly, the US produce industry is requiring the use of good agricultural practices (GAPs) as part of its prerequisite programs for the growth and harvesting of fresh produce (Table 4, FDA, 1998).

Food safety is not synonymous with HACCP. Food Safety is HACCP plus prerequisite programs. It is time for us to stop talking about “Farm to Table HACCP”. Rather, we should talk about “Farm to Table Food Safety” (Fig. 3). This essential change in emphasis will allow us to focus on effective interventions and CCPs to protect the public health and it will eliminate the false expectations that HACCP alone can provide food safety assurance.

References


