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 Testing

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates the opportunity to provide comments on the testing 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 testing.

**Executive Summary of Comments**

Environmental, ingredient, and finished product testing can play an important role in the verification of process and environmental controls in some products and manufacturing facilities. GMA agrees with the Agency that the role of and need for verification testing programs varies depending on the type of products and activities in the facility. We appreciate FDA’s understanding that the regulations should take a risk-based and flexible approach to the design of testing programs.

Our comments highlight the following priority issues:

- **Lack of Proposed Codified Language:** GMA requests that, prior to issuing final regulations requiring testing, FDA provide an opportunity to comment on specific codified language. This is because codified language on testing was not included in the Agency’s proposed rule. Given the importance of this subject, it is necessary that stakeholders have a full and fair opportunity to comment.

- **Testing is a Verification Activity and Not a Control Measure:** Although testing is listed as a preventive control under FSMA, in practice testing is rarely considered a control measure. Testing results only reflect the sample or sample location evaluated at the time the sample was collected. Product testing programs are constrained by statistical limitations. Additionally, product and environmental test results often are not available until several days after the sample was collected. Although testing programs can be important verification programs to identify failures or adverse trends in sanitation, Good Manufacturing Practices (GMPs), or operational controls, product and/or environmental testing cannot directly prevent, reduce, or eliminate microbial hazards from foods.

- **Implementation of Testing Programs Requires Flexibility:** Due to the considerable number of variables that influence the utility, design, and implementation of verification testing programs covered by FSMA, it is impossible to prescribe specific testing requirements for all scenarios in a regulation. Additionally, prescriptive requirements for testing programs may result in some facilities only conducting the testing mandated by FDA, resulting in a failure to tailor or adapt their programs to the facility in ways that would further enhance food safety. The Agency should clarify in the final rule and preamble that effective testing programs need to be tailored to the specific circumstances of each product and manufacturing operation.

- **Finished Product Testing Has a Limited Role in Verification Programs:** GMA agrees with the FDA that the utility of finished product testing depends upon a variety of factors.
Finished product testing is not relevant for many products and processes. For example, it is of limited utility for products and processes that are under control, but may be relevant where information from other verification activities raises concerns about the hygienic status of a processing line or ingredient. In most cases, other verification activities are more appropriate to evaluate the effectiveness of control measures. In particular:

- Environmental (including sanitation) controls are more effectively verified with hygiene audits and environmental monitoring programs;
- Ingredients are more effectively verified through supplier verification activities, which may include ingredient testing by the supplier; and
- Process controls are more effectively managed through monitoring and verification of the operation.

Even if contamination is present in finished products, it often is not possible for testing programs to detect contamination due to statistical sampling limitations. Thus, finished product testing results can give a false sense of reassurance. This is why finished product testing is generally neither a reliable nor cost-effective verification tool. FDA should limit the application of finished product testing to exceptional cases where it is identified as necessary in a facility’s food safety plan based on the relevance for the facility, food, and information from other verification activities.

- **Product Contact Surface Testing Should Be the Exception, Not a Routine Requirement:**
  FDA should not mandate specific requirements for routine testing of pathogens on product contact surfaces. Routine sampling programs should not include sampling product contact surfaces for *Salmonella* or other pathogens because such testing is neither necessary for food safety nor cost-effective. Resources are best focused on areas of the environment at risk of ingress or harborage to prevent pathogens from reaching product contact surfaces. There often is a much lower likelihood of harborage sites on product contact surfaces than other areas of the equipment and in the overall manufacturing environment, as these sites are the focus of hygienic design, cleaning, and sanitation programs. Because systems are designed to eliminate potential harborage areas on or near product contact surface sites, testing in these areas is of little value so long as other verification activities indicate that environmental or operational controls are effectively managed. Product contact testing may be useful in limited circumstances, such as:
  - When a potential harborage point is identified on or near a product contact surface;
  - When information for other verification activities, such as the evaluation of hygiene indicators, calls into question the hygienic status of a processing line; or
  - When a scheduled or unscheduled event could lead to an increased potential for contamination of the line.

The final rule should provide that the necessity, location, and frequency of pathogen testing in the processing environment and on equipment, including product contact surfaces, is based upon the risk of the product, process, and hygienic status of the production environment, as well as information provided from other verification...
activities. Testing of product contact surfaces should be the exception and reserved for circumstances outlined in the facility’s food safety plan.

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). The implementation cost estimates should accurately reflect the true costs the food industry will incur. GMA encourages the FDA to adopt the approach to preventive controls outlined in the comments based on our analysis that they are more cost effective and are aimed at preventing the diversion of resources from important food safety activities.

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

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

*   *   *

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

Sincerely,

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

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMMENTS REGARDING PRODUCT AND ENVIRONMENTAL TESTING</td>
<td>7</td>
</tr>
<tr>
<td>THE ROLE OF TESTING AS A VERIFICATION MEASURE IN A MODERN FOOD SAFETY SYSTEM</td>
<td>12</td>
</tr>
<tr>
<td>RESPONSES TO REQUESTS FOR COMMENTS</td>
<td>35</td>
</tr>
<tr>
<td>RESPONSES TO OMB REDLINE (DRAFT CODIFIED LANGUAGE)</td>
<td>48</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>55</td>
</tr>
</tbody>
</table>
GMA Feedback and Recommendations on Proposed Rule:
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
21 CFR Part 117

COMMENTS REGARDING PRODUCT AND ENVIRONMENTAL TESTING

I. Introduction and Overview

The Grocery Manufacturers Association (GMA) commends the efforts of the U.S. Food and Drug Administration (FDA) in promulgating its proposed rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. 78 Fed. Reg. 3646, Jan. 16, 2013 (“proposed rule”). GMA appreciates the opportunity to comment on testing-related questions published in the proposed rule. The commitment to the production of safe and wholesome food and continued advancement of food safety systems is a shared responsibility and priority for all of us.

GMA believes that environmental, ingredient^1 and finished product testing can play an important role in the verification of process and environmental controls in some products and manufacturing facilities. GMA agrees with the Agency that the role and need of verification testing programs varies depending on the type of products and activities of the facility. GMA appreciates FDA’s focus on developing a risk-based and flexible approach to the design of testing programs, as discussed in the preamble and appendix to the proposed rule.

GMA has carefully reviewed the questions asked by the Agency regarding verification testing requirements in the final rule. GMA has also reviewed the appendix outlining the Agency’s thoughts on testing, and the original draft testing regulation FDA sent to the Office of Management and Budget (OMB) for regulatory review that shows draft codified language that was not included as part of the proposed rule (referred to in our comments as the “OMB redline”).

These comments provide GMA’s analysis and feedback on testing requirements. A brief summary of priority issues is included in Section 1. Detailed feedback and recommendations related to FDA’s discussion of testing in the preamble and appendix to the proposed rule are included in Section 2. Specific feedback and recommendations to FDA’s requests for comment are included in Section 3. Section 4 provides GMA’s recommendations for codified language related to verification testing in the final rule. Section 5 provides references.

GMA has provided a structured approach to our comments, the format of which is described here. First, the section of the proposed rule preamble, appendix or OMB redline language to be

---

^1The FDA notes a difference in the definition of “raw materials” and “ingredients” in the preamble to the proposed rule although both would be considered in a hazard analysis. 78 Fed. Reg. 3737. For this reason GMA’s references to “ingredients” in these comments is encompass raw materials, processed materials, and materials receiving a microbiocidal process that are used in the formulation of a processed food.
discussed is quoted. This is followed by a section entitled “GMA Feedback” where general comments and suggestions on the particular to the FDA discussion, question or codified language are presented. This is subsequently followed by a section entitled “GMA Recommends” where specific recommendations are made to FDA as they consider the development of testing requirements and other related topics. Recommendations related to codified language (Section 4) are based upon OMB-redline language and are presented as follows: text that is recommended as being deleted is noted with a strikethrough (strike-through) and text that is recommended as being added is noted by being underlined (underlined). Italics (italics) are used for emphasis. For further clarity, GMA provides a summary of all the suggested regulatory language changes in response to draft codified language provided in the OMB redline: Draft §§ 110.145(c), 110.150(d)(3) and[(4)].

A. Priority Issues

1. Lack of Proposed Codified Language

GMA welcomes this opportunity to provide feedback in response to the many questions FDA has asked relative to the scope and specificity of requirements for product and environmental testing as verification in the final rule. Although GMA is commenting on the draft proposed regulatory language from the OMB redline, this language was not formally proposed. GMA requests that, prior to issuing any final regulation requiring testing, FDA provide an opportunity to comment on specific codified language. This is necessary to provide a full and fair opportunity for stakeholder comment. It is not possible to provide substantive feedback when FDA has not presented complete language on testing in the proposed rule.

2. Testing is a Verification Activity, Not a Control Measure

In Section 418(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), testing is discussed as a means to verify implementation of preventive controls. Although environmental testing also is a preventive control under the statute, it is important to recognize that preventive controls do not necessarily control hazards. In fact, in the Proposed Rule, FDA acknowledges that “testing is rarely considered a control measure.” Testing programs can identify failures or adverse trends in sanitation, GMPs, or operational controls; however neither product nor environmental testing can prevent, reduce, or eliminate microbial hazards from foods and as such they are ineffective as control measures. Testing is only reflective of the sample or sample location evaluated at the time the sample was collected. As there is a substantial lag between taking the sample, conducting the test, obtaining the result, and acting upon the result, microbiological testing, particularly finished product testing, is retrospective and does not allow corrections to be made to address operational or environmental failures while potentially affected products are manufactured. If food is contaminated with pathogens, the contamination typically occurs at extremely low levels and is not evenly distributed. Due to the limitations of statistical sampling, it is not always possible to detect contamination even if it is present. Therefore, prevention of contamination through the use of validated controls is a more effective means of protecting public health than testing (ICMSF2002; NRC 1985). Process controls are most effectively

\[\text{\footnotesize See, e.g., 78 Fed. Reg. 3776, 3812.}\]
managed through robust oversight of the process itself, including associated monitoring and verification activities to ensure that process controls are properly applied. Testing may play an important role in the verification of these controls; however, reliance on testing in the absence of effective and validated process, environmental, and sanitation controls can provide an incorrect impression that a process is under control.

GMA requests that in the final rule that FDA clarify that, although testing is defined as a “preventive control” under FSMA, it functions as a verification tool rather than a measure that directly controls hazards.

3. Implementation of Testing Programs Requires Flexibility

FDA has acknowledged that requirements for product testing should depend on the type of product and facility, and should be flexible in order to accommodate the wide diversity in the food manufacturing industry.\(^3\) GMA concurs that testing programs play an important role in verification of process and environmental (including sanitation) controls for many products and agrees that in some scenarios testing (e.g., environmental monitoring, ingredient or finished product) should be undertaken. However, there is considerable variability in products and processes that are considered in the design of such programs. GMA therefore believes it is vital to the success of these programs to provide flexibility to implement these programs as appropriate and necessary. GMA requests the Agency to allow flexibility in any requirements for testing programs in the rule. Prescriptive programs may hamper the implementation of appropriate programs in some facilities, as program design may be restricted to only that mandated by law and not adapted to the facility or situation.

Any specific requirements for testing should indicate that (1) testing programs are implemented as verification activities for environmental and process controls, and (2) the relevance of testing, and design of testing programs, is risk-based and adapted to the specifics of the product and operation. FDA should expect that such programs are implemented when they are appropriate and necessary to verify the effectiveness of sanitation, GMPs, or operational controls; however, FDA should not mandate specific program designs. Recommendations on the design of testing programs should be provided in guidance documents specific to the product category or process. Guidance should be developed in cooperation with industry and other relevant experts.

4. Finished Product Testing Has a Limited Role in Verification Programs

Section 418 of the FD&C Act uses the term “product testing,” but does not use the phrases “finished product testing” or “microbiological testing.” In the preamble and appendix to the proposed rule, FDA has acknowledged that “product testing” could mean ingredient or finished product testing. However, in much of the discussion FDA generally interprets “product testing” as “finished product testing.” FDA has acknowledged, “The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such

\(^{3}\) 78 Fed. Reg. 3764, 3766; OMB Redline (“As discussed in section XII.G.5.c of this document, proposed § 110.150(d)(3) would provide flexibility with respect to verification testing of product by not specifying specific products that must be tested, the hazards to test for, the frequency of testing, or the number of samples”).
testing should be performed.” Moreover, Congress specifically elected to use the term “product testing” instead of “finished product testing.” If the law was intended to mandate finished product testing in specific circumstances, the legislation would have been more specific in this respect. Including a requirement for finished product testing in the final rule would exceed statutory authority. GMA urges FDA to establish regulations that reflect the statutory language of “product testing,” which may include ingredient or finished product testing, rather than taking a narrower, prescriptive approach that focuses only on finished product testing.

Finished product testing is not relevant for many products and processes. For example, it is of limited utility for products when processes are under control, but may be relevant where information from other verification activities raises concerns about the operation of the process, the hygienic status of a processing line or ingredient. In most cases, other verification activities are more appropriate to evaluate the effectiveness of control measures. In particular:

- Environmental controls (including sanitation) are more effectively verified with hygiene audits and environmental monitoring programs;
- Ingredients are more effectively verified through supplier verification activities, which may include ingredient\(^4\) testing by the supplier and/or receiving facility and;
- Process controls are more effectively managed through monitoring and verification of the operation.

Even if contamination is present in finished products, it is often not possible for testing programs to detect contamination due to statistical sampling limitations. Thus, finished product testing results can give a false sense of reassurance. This is why finished product testing is often neither a reliable nor cost-effective verification tool. FDA should limit its expectations for finished product testing to exceptional cases where it is identified as necessary in a facility’s food safety plan based on the relevance for the facility, food, and information from other verification activities.

5. **Product Contact Surfaces Testing Should be the Exception, not a Routine Requirement**

GMA does not agree with FDA that sampling product contact surfaces for *Salmonella* must be included in routine sampling programs for low moisture ready-to-eat (RTE) products. Routine testing of product contact surfaces (“PCS” or “zone 1”) for the presence of *Salmonella* or other environmental pathogens such as *Listeria monocytogenes*, as part of an environmental monitoring program, is not preventative in nature or the best approach for routine sampling. Testing of contact surfaces in routine testing programs is unlikely detect incidental

---


\(^5\)The FDA notes a difference in the definition of “raw materials” and “ingredients” in the proposed rule although both would be considered in a hazard analysis. 78 Fed. Reg. 3737. For this reason GMA’s references to “ingredients” in these comments is encompass raw materials, processed materials, and materials receiving a microbiocidal process that are used in the formulation of a processed food.
contamination. There often is a much lower likelihood of harborage sites on product contact surfaces than other areas of the equipment and in the overall manufacturing environment, as these sites are the focus of hygienic design, cleaning, and sanitation programs. Because systems are designed to eliminate potential harborage areas on or near product contact surfaces, testing in these areas is of little value so long as other verification activities indicate that environmental or operational controls are effectively managed. Verification testing is best focused on areas (product or non-product contact) where there is potential harborage or elevated risk of contamination. When routine testing of a PCS is conducted, testing is generally more valuable when it focuses on index or indicator organisms rather than the pathogen of concern.

- Product contact testing may be useful in limited circumstances, such as:
  - When a potential harborage point is identified on or near a product contact surface;
  - When information for other verification activities, such as the evaluation of hygiene indicators, calls into question the hygienic status of a processing line; or
  - When a scheduled or unscheduled event could lead to an increased potential for contamination of the line.

A requirement to test product contact surfaces in all cases could result in testing “clean” surfaces just for the sake of testing a specific number of samples. PCS testing should be risked based and not mandated by the regulation.

The final rule should provide that the necessity, location, and frequency of pathogen testing in the processing environment and on equipment, including product contact surfaces, is based upon the risk of the product, process, and hygienic status of the production environment, as well as information provided from other verification activities. Testing of product contact surfaces should be the exception and reserved for circumstances outlined in the facility’s food safety plan.

6. **FDA Should Reconsider the Cost Estimate for Testing**

FDA has provided cost estimates for microbiological environmental and product testing based on collecting and testing a very limited number of samples (5-15 per month). These cost estimates could change considerably depending on the requirements in the final rule. For some product categories and facilities, these estimates do not reflect a realistic number of samples. Costs associated with holding product, warehousing, training, and other miscellaneous expenses also were not included in the cost estimate. Expenses associated with non-microbial (e.g., allergen, chemical contaminants) testing were not provided. Therefore, the cost to implement testing programs is anticipated to be higher than the published estimates. GMA has provided comments to this issue in our comments on the proposed rule’s Preliminary Regulatory Impact Analysis (PRIA).
THE ROLE OF TESTING AS A VERIFICATION MEASURE IN A MODERN FOOD SAFETY SYSTEM

A. Testing for the Verification of Preventive Controls

Reference
“The safety of food is principally ensured by the effective implementation of scientifically valid preventive control measures throughout the food chain (Ref 34)(Ref 100). Prevention of hazards in food is much more effective than trying to differentiate safe from unsafe food using testing.”

GMA Feedback
GMA agrees with FDA that prevention of hazards through the management of control measures during food production is much more effective than trying to differentiate safe from unsafe food using any form of testing, whether testing for microbial pathogens and hygiene indicators, allergens, foreign materials, or other contaminants. GMA is also in agreement that testing does not directly prevent the conditions that lead to contamination with or growth of pathogens in ingredients, the environment, or finished products. Testing programs can play an important role in verifying the effectiveness of preventive controls that directly impact hazards. For this reason GMA is concerned that FDA’s statement that “such verification testing is important in preventing contamination in food” implies that testing controls hazards. Where feasible, the implementation of process and environmental controls and subsequent monitoring and verification is the most effective way to manage identified food safety hazards, rather than relying solely on verification testing.

GMA agrees with FDA that testing plans include both microbiological and chemical programs. The focus of the requested comments from FDA was on microbiological testing. GMA recommends that any testing, including chemical, allergens, mycotoxins, heavy metals, pesticides, and other contaminants, needs to take into consideration the same principles applied to microbiological testing. Safety cannot be tested into products due to the same statistical limitations discussed for microbiological parameters. For example, testing for mycotoxins in grain based products would not be considered a control program at the finished product level. Testing at some point in the ingredient stream may be a part of an overall surveillance strategy.

Testing programs are constrained by the statistical limitations of selecting a defective sample in a consignment or lot. Testing results are only reflective of the sample or sample location evaluated at the time the sample was collected. It is not always possible to detect contamination by testing, even if it is present, as contamination of pathogens in foods is typically at extremely low levels and in most cases the contamination is not evenly distributed in the food. As there is a substantial lag between taking the sample, conducting the test, and obtaining the result, microbiological testing is retrospective and does not allow corrections to be made to address

---

\(^{6}\)78 Fed. Reg. 3812.  
\(^{7}\)Id  
\(^{8}\)78 Fed. Reg. 3763.  
\(^{9}\)78 Fed. Reg. 3812.
operational or environmental failures during manufacturing. Absolute assurance that a lot is free of defective product cannot be guaranteed simply because test results are within acceptable limits.

GMA believes that testing may play an important role in the verification of the effectiveness of process controls, allergen management, sanitation verification, environmental, and other general ("prerequisite") controls. Effective testing programs for verification should be risk-based and may include environmental monitoring, ingredient, and finished product testing. Examples of the application of microbiological testing for the verification of various products are included in Table 1. GMA has provided information on the design of effective product and environmental monitoring programs in our prior submissions to Docket No. FDA-2011-N-0251 (GMA 2012a, b).

The implementation of an effective testing program is based upon information about the nature of the ingredients, type of product, supplier confidence, history of the hygienic status of the process environment, or implementation of process controls. Due to the considerable number of variables that influence the utility, design, and implementation of verification testing programs for products covered by FSMA, a listing of specific testing requirements in the regulation could not possibly account for all scenarios.

While environmental and product testing may be useful in specific circumstances to verify preventive controls, they are not the only means or always the most appropriate means to verify effectiveness. Other, more appropriate, verification tools may be available. For example, the verification of sanitation control measures can be achieved using visual inspection, ATP bioluminescence, protein tests, or indicator organisms rather than testing for the presence of pathogens, allergens, or contaminants. For foreign material hazards, it is more effective to verify the integrity and effectiveness of sieves, screens, and magnets, conduct a visual inventory of potential sources of glass, metal, or other foreign material, and ensure proper execution of preventive maintenance than to rely on finished product testing to verify the effectiveness of controls.

For companies with multiple facilities, certain aspects of testing programs, such as the development of risk assessment strategies, definition of methods, development of specifications, setting of requirements for program design, and/or analysis of data, may be managed at the corporate level. Responsibility for program implementation is at the factory level.

Additional comments on environmental, ingredient, and finished product testing are included below. Section 3 provides specific feedback and recommendations to FDA’s request for comment.

**GMA Recommends**

- FDA should clarify in the final rule that testing, when necessary and appropriate, is a verification procedure and does not function to control hazards;
• FDA should clarify in the final rule and its preamble that the necessity, design and implementation of effective testing programs needs to be adapted to the specific circumstances of the product and manufacturing operation;
• FDA should recognize reputable existing guidance on relevant testing programs and, where necessary and appropriate, develop guidance in conjunction with industry stakeholders.

Table 1. Examples\(^{10}\) of testing applied as a verification measure for products and process controls (Jackson, 2013. Adapted from GMA 2012b).

<table>
<thead>
<tr>
<th>Product type</th>
<th>Monitoring program applied</th>
<th>Parameters evaluated</th>
<th>Location and Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry mix product or other product assembled without further microbiocidal process</td>
<td>Ingredient</td>
<td>Relevant pathogen and hygienic indicator organisms</td>
<td>Depends upon ingredient risk; for example, testing of each lot of high risk material by supplier and/or receiving factory.</td>
</tr>
<tr>
<td>Environment</td>
<td>Relevant pathogen and hygienic indicator organisms</td>
<td>Areas where ingredients are handled and product is exposed prior to packaging. Weekly or monthly sampling which may involve rotation of sites.</td>
<td></td>
</tr>
<tr>
<td>Finished product</td>
<td>Relevant pathogen and hygienic indicator organisms</td>
<td>For new processing lines or where there is evidence of a hygienic concern for the product and process. Periodic testing according to risk.</td>
<td></td>
</tr>
<tr>
<td>Products receiving a microbiocidal process and exposed to the environment after processing and prior to packaging.</td>
<td>Ingredient</td>
<td>Relevant pathogen and hygienic indicator organisms</td>
<td>For ingredients added after the thermal process. Depends upon ingredient risk; for example, testing of each lot of high risk material by supplier</td>
</tr>
</tbody>
</table>

\(^{10}\)Scenarios outlined are examples only, and may not be applicable in all situations.
| Environment | Relevant pathogen and hygienic indicator organisms | Equipment and environment where products are exposed post-processing; interface between raw and cooked material handling areas. |
| Finished products | Relevant pathogen and hygienic indicator organisms | For new processing lines or where there is evidence of a hygienic concern for the product and process. Periodic testing according to risk. |
| Products that are in-pack pasteurized | Finished product | Total plate count and total coliform or total *Enterobacteriaceae* |
| Hot-filled products | Finished product | Total plate count, mold, yeast or other potential spoilage organisms (for high acid products) |
| Product processed for commercial sterility and aseptically packaged | Finished product | Incubation testing |
| Low-acid products commercially sterilized in hermetically-sealed containers | Finished product | Incubation testing |
A. Scientifically Valid Sampling and Testing

Reference
“…[T]he term ‘scientifically valid’ with respect to testing to mean using an approach to both sampling and testing that is based on scientific information, data or results published in, for example, scientific journals, references, text books or scientific research.”11

GMA Feedback
GMA agrees that analytical methods for testing of products and ingredients need to be validated to confirm that they are capable of detecting or quantifying the analyte/microorganism(s) in the sample matrix evaluated. When ingredient or finished product testing is appropriate and necessary, the sampling plans used should be based upon inherent risk of the product/material, sensitivity of the consumer, other verification information about the hygienic status of the process or production environment, the effect of handling in distribution and by the consumer on the risk and, for ingredients, the effect of process controls at the manufacturer and receiving factory on the identified hazard. Sampling plans applied may be based upon statistical sampling schemes such as the microbiological sampling plans outlined by the International Commission on Microbiological Specifications for Foods (ICMSF) and adopted in Codex and other international standards (ICMSF 2011, Codex Alimentarius Commission 1997, 2007a). GMA concludes that the identification of sampling plans based upon technical evaluation by the manufacturer and statistical sampling schemes such as those identified by ICMSF would meet the definition of “scientific.”

ICMSF (2002) notes that environmental sampling plans are not statistically designed and are based on experience and knowledge of the sites most likely to detect a failure in good hygiene practices (GHP). Therefore it may be difficult for a facility to provide scientific evidence, such as journal articles, to justify choice of sampling locations or the number of samples collected. Another example of an element of testing based upon practical considerations rather than scientific studies is the selection of sampling tools. While the sampling methods and tools should not interfere with the recovery or survival of the analyte or microorganism(s), selection of such tools is generally based on a technical evaluation and not a formal validation relative to the specific analyte or application.

GMA therefore concludes that certain aspects of sampling and testing are scientifically validated and others are not, but all aspects need to be based upon sound technical and practical considerations. To account for the various aspects of testing programs and to avoid confusion with formal validation procedures, GMA proposes the term “technically sound” instead of “scientifically valid” when referring to sampling and testing. However, GMA would agree with the use of “validated” when referring to specific program aspects amenable to scientific validation, such as analytical methods. Such methods need to be formally evaluated to confirm their suitability for use in the specific application.

GMA Recommends
- FDA should use the term “technically sound” rather than “scientifically valid” when referring to sampling and testing programs.

B. Verification Testing of Ingredients

1. Use of Ingredient Testing Programs

Reference
“[I]ndredients are often tested as part of a supplier approval and verification program, as one of the verification activities when a preventive control that is adequate to significantly minimize or prevent the hazard is not applied at the receiving facility.”

GMA Feedback
GMA agrees that a supplier verification program, which may include testing, can help provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in ingredients. Ingredient testing cannot ensure the hygienic status of a product lot and is most effective as a component of a supplier management program that includes other activities to verify the existence and effectiveness of preventive controls at the supplier. (See GMA comments on supplier verification submitted to this docket, as well as our forthcoming comments on the Foreign Supplier Verification Program proposed rule.)

GMA agrees with the Agency’s statement, “the utility and frequency of ingredient testing for verification of supplier controls depend on many factors.” The relevance and application of ingredient testing as a risk management and verification tool depends upon:

- Nature of the material or ingredient (for example raw commodity versus processed ingredient, microbiologically sensitive ingredient versus non-microbiologically sensitive ingredient);
- Identified hazards, their severity and likelihood of occurrence,
- Origin of the material;
- Processing applied to the ingredient by the processor;
- Potential for the pathogen to grow to levels of concern during storage and distribution;
- Final use of the finished product; and
- History of supplier performance.

Testing is typically relevant as a verification procedure for ingredients when a potential hazard exists in the material that is not controlled by the receiving facility, or when the incoming levels of the hazard can impact the effectiveness of process controls or finished product safety. Testing is generally not useful for the verification of ingredients where a process control measure is in place in the receiving factory that is sufficient to eliminate levels of the hazard potentially present in the material.

13Id.
GMA does not agree that ingredient testing is a practical or effective means to protect the processing environment from cross contamination from a hazard present in an incoming ingredient as the Agency suggests.\textsuperscript{14} Statistical limitations make such testing ineffective as a hygienic zoning control. This is especially true for the receiving, storage, and handling of raw commodities that have a high probability of contamination, such as raw meat, raw milk, and fresh vegetables. Food manufacturers assume that the material is a likely source of the hazard(s) and design control measures to ensure that cross contamination does not occur. Such controls include process controls to significantly minimize or prevent the hazard, physical barriers to segregate the ingredient from exposed post-lethality product prior to packaging, and other related zoning controls, such as the management of people, material and equipment traffic patterns; water, waste and air flow to prevent cross contamination; and effective cleaning and sanitation practices. Verification of the implementation and effectiveness of such controls may include environmental monitoring.

GMA has concluded that verification testing by the receiving facility may be useful for ingredients in the following situations:

- To verify the conformance of a new ingredient to agreed-upon specifications;
- As periodic verification of Certificates of Analysis (COA) provided by the supplier at a frequency based upon risk; and/or
- For acceptance of ingredients when there is other information that reduces confidence in the material or supplier. An example of this situation could be when a supplier that is conditionally approved due to minor non-conformance.

GMA contends that the example presented in the Appendix regarding nutmeat testing\textsuperscript{15} does not reflect industry practices. The example of shelled, untreated nutmeats was provided by the Agency to illustrate that testing increases with the receipt of raw nutmeats versus heat treated nuts. It is likely that raw nutmeats will be contaminated to some level with \textit{Salmonella}, and that a validated process to eliminate this risk will be applied by the receiving facility. In practice, raw nutmeats would not be tested upon receipt. The receiving facility must significantly minimize or prevent the hazard with process interventions and effective hygienic zoning to isolate the handling of raw nutmeats and prevent cross contamination of areas where processed nutmeats are exposed. If deemed necessary by the facility risk assessment, testing of the nuts may be conducted after the application of the validated process to verify the effectiveness of process or environmental controls. Testing of an ingredient that is likely to be contaminated might provide more information about prevalence, but would do little to eliminate or reduce the hazard. However, if nutmeats were purchased having been previously subjected to a process that eliminated a pathogen risk, testing upon receipt may be useful to verify the supplier’s process intervention and environmental controls.

**GMA Recommends**

- FDA should not use language in the final rule or the preamble indicating that the application of ingredient testing is appropriate for “protecting the environment from

\textsuperscript{14}78 Fed. Reg. 3813.
\textsuperscript{15}Id.
incoming hazards.” It is the control measures verified by testing, and not the testing itself, that prevents incoming hazards. Likewise, the nutmeat or similar examples should not be used.

2. Location of Ingredient Testing

Reference

“The owner, operator, or agent is making appropriate decisions about corrective actions taken under section 418(e) of the FD&C Act (section 418(f)(3) of the FD&C Act);” “The preventive controls implemented under section 418(c) of the FD&C Act are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means.”

GMA Feedback

Where necessary and appropriate, testing of the supplier’s finished product (i.e., an ingredient manufactured for use by another FDA-regulated facility) is performed to verify the effectiveness of the supplier’s preventive controls. In many cases, verification testing of ingredients is most effectively conducted by the manufacturer of the ingredient (i.e., the supplier). The site manufacturing the material is most able to perform random and event sampling from the production lot and maintain control of the product while testing is conducted. The ingredient manufacturer/supplier also generally is able to react more quickly to find and address the root cause in the event of adverse findings, because analytical results may be available in a shorter time for the supplier than for product sampled at the receiving facility.

Receiving facilities may require a COA from the supplier that includes results of analytical tests conducted by the supplying facility. The results indicated on the COA should be generated using valid analytical methods to evaluate the specific delivered lot. To verify supplier controls (supplier COA results (i.e. conformance to specifications)), the receiving company may conduct its own testing of received lots at a frequency determined based on the material risk, use for the material by the receiving facility, and the history of supplier performance. A requirement that receiving facilities test all lots of incoming material could result in unnecessary duplication of testing of the same production lot if the supplier is conducting their own testing and providing a COA. This also may result in unnecessary testing for materials for which the relative risk is low and/or supplier confidence is high.

GMA Recommends

- FDA should not require the receiving company to be responsible for testing ingredients to verify supplier controls. FDA should acknowledge that verification of information in COAs generated by suppliers, based upon their own testing, can be an appropriate component of a receiving company’s verification testing program.
- FDA should indicate that verification testing programs for ingredients are only required when necessary and appropriate for the material, process, and supplier performance based on an assessment of risk.
- Additional comments are provided in Section 3.

C. Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Environmental Controls, Including Sanitation

1. Definition of Environmental Pathogen

Reference
Proposed §117.3 defines “environmental pathogen” as “microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.”

GMA Feedback
GMA contends that the term “environmental pathogen” is difficult to define and the Agency definition is too broad. Many pathogens of significance to food exist in the environment at a point in time, such as in soil, air, water, or the food production facility. GMA asserts that while some foodborne pathogens may be present transiently in the environment, only a limited number of pathogenic microorganisms, namely Salmonella and Listeria monocytogenes, have been demonstrated to cause foodborne illness via food contaminated from the production environment. The relevant organisms for an effective pathogen environmental monitoring programs are those, such as L. monocytogenes, where the primary manner in which contamination is prevented is through maintenance of a hygienic environment.

Spore forming pathogens, such as Bacillus cereus and Clostridium perfringens, are widespread in nature and may be present in the environment at low levels. They are relevant food safety hazards in products in which they can grow to high levels and are generally not significant in products in which they cannot grow. Such hazards are most effectively managed by process related preventive controls which significantly minimize expected levels, through formulation controls that result in intrinsic product characteristics preventing their growth or through the management of storage and distribution conditions and product shelf life that does not allow growth to levels of concern.

GMA Recommends
- FDA should change the definition of “environmental pathogen” to “foodborne pathogens of public health significance for which their presence or harborage in the food processing environment may result in product contamination that may result in foodborne illness when the product is consumed.”
- FDA should not provide spore-forming pathogens, such as Bacillus cereus and Clostridium perfringens, as examples of environmental pathogens. They have not been demonstrated to cause illness via contamination from the processing environment and they are most effectively managed through process, formulation or storage/distribution controls.
2. Environmental Monitoring for Verification

Reference
“A robust environmental monitoring program for environmental pathogens can detect these strains and enables the facility to eliminate them from the environment which can prevent contamination of food with these pathogens and, thus, prevent foodborne illnesses.”\(^{17}\)

GMA Feedback
GMA believes that environmental monitoring is an appropriate means to verify the effectiveness of specific environmental controls, such as cleaning and sanitation, facility maintenance, hygienic zoning, and personnel practices. Environmental monitoring programs for pathogens and related hygiene indicators should be implemented in facilities where contamination of an ready-to-eat (RTE) product by an environmental pathogen is a hazard that needs to be addressed in the food safety plan. This will be determined by a number of factors, such as the type of food produced, its intrinsic and extrinsic properties, and exposure of product following a lethality process or assembly without the application of a lethality process prior to packaging. Environmental monitoring programs are generally not valuable in food manufacturing facilities where post-processing contamination of RTE foods is not a hazard that needs to be addressed in the food safety plan. Examples of these types of facilities may include operations utilizing a hot-fill process, aseptic processing, or in-pack pasteurization for which post-process contamination is not a risk.

For products exposed to the environment without a lethal step prior to packaging, GMA agrees that that a robust environmental monitoring program can help to identify gaps in certain environmental controls, including sanitation. Other verification procedures such as hygiene audits, hygienic design reviews, or visual observations during production can also identify issues of concern. A facility does not need to rely solely on environmental testing to confirm whether the conditions could contribute to a risk and need to be corrected. Even a robust environmental monitoring program cannot detect pathogens of concern in all cases. GMA believes that the use of index and indicator organisms is important, in addition to other verification procedures, to verify the hygienic status of the processing environment.

Effective environmental monitoring programs are designed to “seek and destroy,” i.e., to identify potential gaps in environmental controls before they impact product safety. A well-designed and executed program will focus on finding and addressing gaps in environmental controls, while enabling an investigation and corrective actions to be made to address issues before they could potentially lead to product contamination. The finding of a pathogen or indicator organism within the environment does not necessarily mean the process or processing environment is out of control or that the product is contaminated.

GMA Recommends
- FDA should recognize that effective environmental monitoring programs are designed to discover the presence of foodborne pathogens and indicator organisms, thereby enabling corrective actions within the environmental control programs. The Agency should regard

\(^{17}\)78 Fed. Reg. 3815.
programs that find issues, which are subsequently addressed, to be successfully implemented.

- Agency inspectors should not penalize facilities for finding potential problems through verification testing if appropriate corrective actions are taken.

3. Indicator and Index Organisms

Reference

“FDA’s current thinking is that *Listeria* spp. may be an appropriate indicator organism for *L. monocytogenes*, because tests for *Listeria* spp. will detect multiple species of *Listeria*, including *L. monocytogenes*. However, FDA’s current thinking is that there is no currently available indicator organism for *Salmonella* spp.”

GMA Feedback

GMA concurs with FDA’s conclusion that *Listeria* spp. is an appropriate pathogen index organism for *L. monocytogenes*, and concurs with FDA’s discussion of the topic in the appendix of the proposed rule. GMA agrees that currently there are no index organisms which are directly indicative of *Salmonella* spp. presence in the manufacturing environment.

Verification for the presence or levels of indicator organisms can demonstrate that conditions exist that could lead to the presence or growth of the pathogen. Monitoring for index organisms is beneficial in that it casts a broader net than specific pathogen testing, allowing an investigation and corrective actions to be taken even when the pathogen has not been detected. The U.S. Department of Agriculture’s Food Safety and Inspection Service (USDA FSIS 2012) has set the precedent that a finding of an index organism for a foodborne pathogen indicates conditions exist that could lead to the presence or harborage of the pathogen; however, a product or food contact surface is not considered adulterated unless the pathogen is detected. Facilities are expected to take corrective action to ensure the root cause is identified and resolved.

Hygiene or sanitation indicator organisms are used to verify that sanitation programs are effective and plant operating conditions are under control. They do not indicate the presence of a pathogen, but their levels can indicate insufficient cleaning and sanitation or operating conditions (such as entry of water into a dry processing facility or insufficient cleaning and sanitation of equipment) that could allow the growth or presence of organisms beyond established baseline limits. Facilities are expected to take appropriate corrective action if results exceed the established control limits. Quantitative microbial indicators, such as *Enterobacteriaceae* or coliforms (or others depending on the type of manufacturing facility and food being processed) may be useful hygiene indicator organisms for verification of hygiene and sanitation, or of the insufficient control of water in dry processing environments. This is because such indicators are ubiquitous and are therefore more likely to be found in the process environment than pathogenic microorganisms. Baseline levels of hygiene indicator organisms can be established that indicate the facility is manufacturing under appropriate GMPs and have effective cleaning and sanitation programs. Identification of levels above the established baseline can provide an early indication of potential issues. Data analysis, including the evaluation of trends, is used by

---

manufacturer/operator to identify root cause, implement corrective actions and proactively address any potential issues before they lead to the contamination of RTE product contact surfaces or finished products.

GMA Recommends

- FDA should differentiate between pathogen index organisms (such as *Listeria* spp.) and hygiene/sanitation indicator organisms (such as *Enterobacteriaceae*, coliforms, aerobic plate count, mold and yeast).
- FDA should recognize the precedent set by the FSIS that product contact surfaces are not considered adulterated due to the presence or level of an index or indicator organism, but rather are considered adulterated due to the presence of a pathogen.
- FDA should recognize the role of hygiene/sanitation indicator organisms as verification of environmental controls. Programs that incorporate only *Salmonella* testing may not effectively identify trends towards loss of control that can be addressed before contamination occurs.

4. Identification and Prioritization of Sample Sites

GMA Feedback

The purpose of monitoring a food processing environment for the presence of pathogens and associated index and indicator organisms is to verify the implementation and effectiveness of controls intended to significantly minimize or prevent the presence of environmental pathogens in food processing areas. Environmental monitoring programs are defined by the test organisms and by sampling location and frequency. GMA supports the concept of sampling zones or other sample prioritization classifications to define sampling locations as indicated in the preamble. Sample site prioritization may be used to determine the proportion of sample sites evaluated at each sampling occasion and the frequency with which samples are collected. As they are widely used in industry, sampling zones are determined based upon the proximity of the area to product and the potential that the contaminant, if present, would lead to product contamination. Sampling zones are differentiated from hygiene zones, which identify barriers, traffic, hygiene, and other GMP controls necessary to prevent ingress, harborage, and growth in processing areas. Although sample sites are determined based upon an evaluation of risk, the number of sample sites may be biased toward the areas at greater risk of contamination of product or product contact surfaces. Sites for sampling programs are selected based upon risks identified in the hazard analysis, including an understanding of the product, process, necessary hygienic zoning, GMPs, cleaning, and sanitation controls. Priority is given to sites that are difficult to clean and thus potential harborage sites, high traffic areas, areas where it is important to control traffic to ensure that pathogens do not enter processing areas where product is exposed after the application of a microbiocidal process, or interfaces between wet and dry cleaning areas. (Examples of sites for dry processing operations are included in GMA 2009, 2010, 2012a; examples for high moisture processing operations are provided in NFI/NFPA 2002, USDA FSIS 2012, and Jackson 2013.)

---

Effective environmental monitoring programs take an investigative approach, including additional sites that were identified during hygiene audits or observations of conditions by the individual collecting the sample.

The frequency of testing a site depends upon the proximity of the site to the processing line, the potential for contamination of product or product contact surfaces if the pathogen were present at the sampling site, and the relative risk of the pathogen being present at the site (for example, a potential harborage site, or a site with a history of problems).

GMA Recommends:

- FDA should not mandate specific sample locations. FDA should recognize sampling programs to be appropriate when they include sites selected based upon an understanding of relevant hazards and environmental controls.
- FDA’s regulations should enable and encourage programs to prioritize sampling frequency based upon an evaluation of the site risk and history. Variation from the sampling program design should be acceptable provided that adequate justification is documented.
- FDA should recognize existing industry and regulatory guidance on effective monitoring programs (GMA 2009, 2010, 2012a; NFI/NFPA 2002, USDA FSIS 2012) and work with industry to develop additional guidance for existing product categories.

5. Testing of Product Contact Surfaces in Routine Analysis

Reference

“The data (discussed in the preamble of this document) available from investigations of food facilities following outbreaks, recalls, or reports to the RFR warrant including food-contact surfaces in a routine environmental testing program for Salmonella spp. However, a routine environmental monitoring program for Salmonella spp. may not contain the same level of food-contact surface testing (including the frequency of testing and number of samples collected) as a routine environmental monitoring program for Listeria spp., because the same benefits may not be achieved.”20

GMA Feedback

GMA contends that the necessity and frequency of testing of product contact surfaces for environmental pathogens and related indicator organisms should be based upon the risk of the product, process, and hygienic status of the production environment. The potential for harborage sites on product contact surfaces is often much lower than other areas of the equipment and the environment as these sites are the focus of hygienic design and cleaning/sanitation efforts. Testing of contact surfaces is unlikely to detect incidental contamination due to cross contamination from the environment or workers. Routine testing of product contact surfaces for indicator microorganisms can provide useful information on the hygienic status of potential harborage sites, or the increase in microbial levels during production. In various situations, the testing of product contact surfaces for pathogens does not provide information that is not already

---

provided through other verification activities such as testing of other sites that are at higher risk of contamination or harborage.

Sampling and testing of product contact surfaces for pathogens is potentially a greater logistical challenge than other environmental sites as corresponding products are often held pending the results of testing. The focus and resources of testing programs is better placed on the evaluation of sites of greater risk of harborage. The testing of product contact surfaces for pathogens is included in routine testing programs only when necessary to evaluate a specific site of concern that cannot be verified through testing of non-contact sites or other verification activities.

Verification testing is best focused on areas (product or non-product contact) where there is potential harborage or elevated risk of contamination. A requirement to test product contact surfaces in all cases could result in testing “clean” surfaces for the sake of testing a specific number of sites.

GMA disagrees with FDA’s conclusion that data from outbreak and recalls indicate that Salmonella testing in a low moisture environments should be included in a routine testing program. In the appendix of the proposed rule FDA cites several examples of outbreaks that resulted from failures in hygienic control of the environment:

- In a 2010 case related to Salmonella in hydrolyzed vegetable protein the Agency investigation recovered Salmonella from product contact surfaces; however FDA also indicated that Salmonella was isolated from the plant environment and that there were “numerous sanitation deficiencies” in the factory.
- In the investigation of a 2008-2009 Salmonella Typhimurium outbreak linked to peanut butter and peanut paste, the FDA indicated that the facilities had a “lack of controls to prevent contamination from pests, from an insanitary air circulation system, from insanitary food contact surfaces and from the processing environment” and that they had isolated several strains of Salmonella from the multiple products and the plant environment.
- An investigation into a 1998 outbreak of Salmonella Agona in a breakfast cereal indicated the presence of Salmonella in “various locations in the plant, including the floor, processing equipment, and the exhaust system of the implicated processing line.” A 2008 outbreak originating from the same Salmonella strain in the same facility was linked to a construction event that re-introduced dormant Salmonella into production areas of the facility.

In these cases, Salmonella did not originate from product contact surfaces, but from cross contamination of Salmonella from the environment. GMA contends that the failures resulting in these incidents would have been most effectively detected through factory hygienic design reviews, audits, and through Salmonella testing in the factory environment that was focused on potential harborage sites. Salmonella testing of product contact surfaces was warranted for these facilities because there was other information from environmental testing and poor factory controls that would elevate the concern that these conditions would lead to Salmonella contamination of processing equipment.

---

In an effectively designed verification program, a construction event such as that that resulted in the 2008 *Salmonella* Agona outbreak, would have led to increased environmental testing to evaluate the impact of the event and the effectiveness of environmental controls in controlling its impact.

GMA concludes that routine testing for *Salmonella* may not be necessary or useful for product contact surfaces of production lines or equipment in processing operations that are maintained under good hygiene practices, and where moisture and traffic are effectively controlled. Resources for pathogen testing in such operations are most appropriately focused on areas of the environment at risk of ingress or harborage. As the Agency notes:

> *Salmonella* harborage sites are less likely to be found on equipment and are more likely to be found in the environment in locations where food particles lodge and escape a dry cleaning process. When these locations get wet, *Salmonella* spp. grows and contaminates other areas of the facility, eventually contaminating food-contact surfaces and food. Equipment used in the production of low-moisture foods where *Salmonella* spp. is the environmental pathogen of concern does not have the moisture to allow *Salmonella* spp. to grow and, thus, sampling of non-food-contact surfaces for *Salmonella* spp. may be more effective in finding the organism than sampling non-food-contact surfaces.\(^\text{22}\)

Environmental controls are verified through hygienic reviews, audits, and observations of the execution of environmental controls and GMPs. The evaluation of the levels of hygienic indicators, such as *Enterobacteriaceae* on product and near product contact surfaces, can indicate where moisture is present and there is an increased risk of *Salmonella* growth if the organism is present.

GMA contends that the necessity, location, and frequency of *Salmonella* testing should be based upon the risk of the product, process, and hygienic status of the production environment.

The testing of product contact surfaces for *Salmonella* is warranted when:

1. A potential harborage site is identified on or near a product contact surface;
2. Information from other verification activities calls into question the hygienic status of a processing line or an increased potential for cross contamination of the line; or
3. Activities have occurred (maintenance events, construction, infiltration of water, etc.) that could increase the risk of *Salmonella* contamination of the environment and processing line.

GMA agrees with the FDA that *L. monocytogenes* in a high moisture environment would be an environmental pathogen of concern in wet manufacturing environments for RTE products where such products are exposed to the environment without the application of a further lethality control measure prior to packaging. Moisture may be present in these operations due to the use of high moisture ingredients and/or the use of water in cleaning and sanitation activities. The control of water in such operations is important for the management of *L. monocytogenes*. However, as FDA notes “*Listeria monocytogenes* frequently establishes itself in a harborage site

\(^\text{22}\)78 Fed. Reg. 3817.
on equipment and grows (increases in number) there, where both food and moisture are available.”  

GMA agrees with the FDA that “it is important to sample areas where the organisms [L. monocytogenes] are likely to be present in relatively high numbers.”  

Effective environmental monitoring programs for Listeria focus on harborage sites such as those that may be found in the environment (drains, gaps between equipment and floor, gaps between floor and wall) or in equipment (hollow bodies on equipment, areas of equipment that are difficult to access and clean, etc.).  Harborage sites should be avoided or eliminated in the design and construction of processing equipment.  Effective hygienic engineering and maintenance programs are focused on preventing potential harborage points.  Routine testing of product contact surfaces for L. monocytogenes or Listeria spp.  may be a part of programs for wet RTE food production equipment where areas with potential product contact have been identified as having design or operational conditions that could allow harborage and growth.  Such testing is focused on the area of potential harborage and is conducted at a frequency relevant to the product risk.

Routine testing of product contact surfaces on equipment for high moisture RTE products may not be of value where there are no potential harborage areas in or near product contact surfaces and when other verification activities indicate that operation and environmental controls are effectively managed.  This is particularly true for products in which L. monocytogenes cannot grow during storage and distribution.  Monitoring of Listeria spp.  should be focused on areas of the environment where there is a potential for harborage or where there is a potential for ingress of the organism through traffic or proximity to high risk activities.

GMA concludes that the necessity, location, and frequency of testing for Listeria monitoring, including product contact surfaces, should be based upon the risk of the product, process, and hygienic status of the production environment, as well as the information provided from other verification activities.  The testing of product contact surfaces for Listeria spp. is warranted when:

1. A potential harborage site is identified on or near a product contact surface;
2. Information from other verification activities calls into question the hygienic status of a processing line or an increased potential for cross contamination of the line; or
3. Activities have occurred (maintenance events, construction, infiltration of water, etc.) that could increase the risk of L. monocytogenes contamination of the processing environment.

More frequent verification of the environment, including periodic testing of relevant product contact surfaces, may be necessary to verify environmental controls for products in which L. monocytogenes can either grow to unsafe levels during storage and distribution prior to consumption by the consumer, or where there is risk for contamination with L. monocytogenes from the environment.  The necessity, location and frequency of such testing will depend upon

---

24Id.
the nature and history of the operation and relevant process and preventive environmental controls.

**GMA Recommends**
- FDA should not mandate specific sampling locations.
- FDA should not mandate the routine sampling of product contact surfaces for *Salmonella* or *L. monocytogenes* and should recognize that routine verification testing is best focused on areas (product or non-product contact) where there is potential harborage or elevated risk of contamination.
- FDA should recognize that testing of index or indicator organisms in routine testing of contact surfaces is generally more valuable than testing for the pathogen of concern.

6. **Other Comments on the Role of Environmental Monitoring in Verifying the Implementation and Effectiveness of Sanitation Controls (Appendix Section I.E.)**

**Reference**
“Corrective actions are taken for every finding of an environmental pathogen or indicator organism in the environment to prevent contamination of food-contact surfaces or food.”

**GMA Feedback**
Corrective actions should be implemented where appropriate and necessary to ensure that conditions that could lead to contamination are addressed to reduce the risk of contamination of food contact surfaces or food. In many cases, the finding of an environmental pathogen or indicator organism above the established baseline would require corrective action. However, in some situations, such as with environmental testing of raw product areas or non-production areas, the findings may be trended and acted upon as necessary but no action may be taken in response to a single finding. Also, the focus and extent of the corrective action applied will depend on a number of factors, such as the location of the positive test sample and whether it is a single or recurring finding.

Corrective actions are discussed in more detail in Section 3.

**GMA Recommends**
- FDA should not mandate specific corrective actions to be taken upon a finding of a pathogen or hygiene indicator in the environment. (See discussion in Section 4)
- FDA should account for the fact that necessary corrective actions in response to environmental testing results are based upon a number of factors, including site location, root cause analysis, and implications of contamination present at the site on product contamination.

---

“Another example of an investigative procedure is conducting molecular strain typing such as pulsed-field gel electrophoresis (PFGE), ribotyping, or polymerase chain reaction (PCR) analysis to determine if particular strains are persistent in the environment.”

GMA Feedback
There is the potential for many new typing methods to be developed in the future, so these methods should be listed as examples, but not limited to PFGE, ribotyping, or PCR.

GMA Recommends
FDA should limit the presentation of specific subtyping methodologies as examples only, understanding that additional subtyping technologies may be developed in the future.

E. The Role of Finished Product Testing in Verifying the Implementation and Effectiveness of Preventive Controls

Reference
“Finished product testing could be appropriate if an environmental pathogen is detected on a non-food-contact surface, such as on the exterior of equipment, on a floor or in a drain.”

GMA Feedback
If a pathogen is recovered from a non-food contact surface environmental sample, the determination of whether to test finished product in response should be based upon the risk of transferring that pathogen to a product or product contact surface. Facilities would evaluate factors such as proximity of the site to a product contact surface or the potential for transfer via debris water, personnel or equipment. Finished product testing may be triggered following recovery of a pathogen in a sample from certain near-product-contact surface sites, but not from other sampling sites farther away from exposed products. In the absence of pathogen findings in other locations, a finding on the floor or in a drain would be a relatively low risk and would not typically initiate sampling of finished products, although it may result in increased cleaning and sanitation efforts and additional environmental testing to investigate the source of the contamination and the effectiveness of corrective actions. The finding of a pathogen or index organism on a near-product contact surface, such as an equipment surface next to a product contact surface, will also result in additional cleaning and sanitation efforts and investigative sampling. This finding also may trigger finished product testing to verify the extent of the contamination.

GMA Recommends
- The final rule or preamble should not require finished product testing when an environmental pathogen is found on a non-product contact surface. The Agency should

---

27 Id.
provide for testing to be conducted where necessary and appropriate when verification information, including information from environmental monitoring, indicates a risk of contamination of the product or product contact surface. The number of samples collected for verification will depend on the degree of confidence needed to ensure that finished product is not affected.

1. “Product Testing”

Reference

- “The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed. FDA believes that the role and need for these [product testing] measures varies depending upon the type of products and activities of a facility. FDA further believes that the owner, operator, or agent in charge of a facility could consider a number of factors to establish a product testing program.”
- “…[T]he frequency of testing and the number of samples tested must be determined and needs to take into account a variety of hazard/commodity/facility considerations.”
- “The facilities that would adopt a testing and holding regime are facilities producing products for which finished product testing would be particularly useful as a verification measure.”

GMA Feedback

Section 418 of the FD&C Act uses the phrase “product testing” and does not stipulate finished product testing or microbial testing. In the preamble and appendix to the proposed rule, FDA has acknowledged that “product” could mean ingredient or finished product, however in much of the discussion FDA has chosen to generally interpret “product testing” as “finished product testing.” The statute does not indicate the specific circumstances when product testing would be required or the specific manner in which such testing should be performed. Moreover, Congress specifically elected to use the term “product testing” instead of “finished product testing.” If the law was intended to mandate finished product testing in specific circumstances, the legislation would have been more specific in this respect. Including a requirement for finished product testing in the final rule would exceed statutory authority. FDA has acknowledged that “The statute does not indicate the specific circumstances where product testing would be required or the specific manner in which such testing should be performed.”

GMA Recommends

- FDA should establish regulations that reflect the statutory language of “product testing,” which may include ingredient, or finished product testing, rather than taking a narrower, prescriptive approach that focuses only on finished product testing.

29 Id.
2. **Product Testing Requirements**

**Reference**
- “There are shortcomings for microbiological testing of food for process control purposes.” ³³²
- “The utility of finished product testing for verification depends on many factors that industry currently considers in determining whether finished product testing is an appropriate approach to reducing the risk that contaminated food would reach the consumer and cause foodborne illness.”³³³

**GMA Feedback**
GMA strongly agrees with the above statements by FDA. As FDA has primarily discussed microbiological testing, GMA assumes “testing” in the proposed rule appendix means microbiological testing. Our responses are based on this assumption and tailored accordingly.

Finished product testing is sometimes used in addition to environmental monitoring to provide additional information about the hygienic status of the production line, the effectiveness of process controls, or the performance of an ingredient supplier. Product testing can be applied to verify the status of a production lot when other verification information indicates a potential loss of control.

However, due to the statistical limitations of sampling plans, reliance on finished product testing in the absence of information from other process monitoring and verification activities is insufficient for routine use in lot acceptance. Environmental and sanitation controls are more effectively verified with environmental monitoring programs. Ingredients are more effectively verified through supplier verification procedures, which may include ingredient testing. Process controls are more effectively managed through monitoring and verification of the operation. It is more effective and meaningful for companies to focus on prevention of contamination by creating a robust food safety plan with validated safeguards built in early in the process than to rely on finished product testing.

GMA agrees that finished product testing can be a valuable verification tool. GMA also agrees with FDA that implementation of finished product testing should be based on relevance to a particular facility, food type, and on information from other verification activities. This will depend on a number of factors specific to the product and process, such as likelihood that relevant pathogens are present in the environment, exposure of product after processing, robustness of process controls, and impact of product formulation on pathogen survival or growth. There are many examples of food commodities where finished product testing would have little or no impact on public health. These would include foods with intrinsic characteristics that inactivate pathogenic microorganisms, aseptically packaged foods, and products that receive a lethal process in final packaging such as canned foods, in-pack pasteurized products, or hot-filled products. Finished product testing is of little value in products that are formulated to prevent microbial growth of pathogens that cause illness at high levels.

When testing is used, it functions as a verification step to verify whether the control(s) being used are working effectively. As such, testing constitutes a “check on the system,” but it is not the core of the underlying system itself.

Due to statistical, sampling, and analytical limitations it is not feasible to test a sufficient number of samples to verify with certainty that pathogens are not present in the product lot (ICMSF 2002; NRC 1985). Finished product testing is retrospective and does not allow modifications or corrections of process or environmental control during the production of the affected lot, or even subsequent lots manufactured before the test results are received. As such, lot-by-lot testing of finished products is insufficient to ensure the absence of foodborne pathogens. In many circumstances, other verification procedures are more effective at evaluating the implementation of product and environmental controls. Furthermore, negative finished product test results can provide a false-sense of security in the absence of other information about the functioning of control measures or hygienic status of the environment.

GMA agrees with a number of points included in the Appendix about finished product testing, including:

1) finished product testing would not be generally conducted on a product if pathogens would die-off in a relatively short period of time, and
2) the frequency of finished product verification would depend on all the preventive control measures applied in the facility.

GMA also agrees with the example provided by the Agency that testing can be used to bracket a problem:

A third benefit to ongoing verification testing is the accumulation of data that can help bracket any problem that occurs. For products in which there are large production runs without intervening sanitation cycles, this may provide data that can be used in conjunction with other information to limit the scope of a recall.

Verification information, including environmental and finished product testing may be used with production information to determine the time and scope of a contamination event. For example, wet cleaning breaks are not feasible in much of the chocolate manufacturing process, as the use of water is avoided to control Salmonella in the environment and processing equipment. Ongoing Salmonella analyses that confirm the absence of Salmonella in storage tanks and other points in the process and manufacturing environment in conjunction with finished product testing could be used to substantiate the control of chocolate manufacturing processes. Verification testing of samples collected representing different times during manufacturing also could identify pathogen ingress points into the process (chronologically and location) should a positive result occur. Coupled with Salmonella mitigation activities (e.g., scheduled breaks in the rework stream, validation of limited wet cleaning protocols (e.g., belts), ingredient screening, and validation of cocoa bean roasting), a strong evidence-based case can then be made that Salmonella control programs are in place and effective. In many cases it is most appropriate to conduct such product testing for Salmonella as part of an investigation of an issue rather than as

34 78 Fed. Reg 3818.
part of routine testing when other verification information indicates that the production line is under control.

In the appendix to the proposed rule, FDA provided several examples of situations where finished product testing may be applied. GMA believes that in each of these examples it would be more appropriate to test the ingredients:

- “If the ingredient is associated with a hazard and the processes used by the supplier and the receiving facility will not significantly minimize it, or if a facility is using a new supplier, the frequency of finished product verification testing increases.”  
- “Verification testing also would be more frequent if an ingredient that has potential to be contaminated with a pathogen is added to a food that was previously treated to significantly minimize a hazard (e.g., adding seasonings to chips or crackers after frying or baking) than if all ingredients are added before the treatment.”  
- “For example, the frequency or finished product verification testing generally could be lower for a food that is subject to supplier controls that include audits and certificates of analysis (COAs).”

In the preamble, FDA provided the following examples as situations where the Agency believes that finished product testing is particularly useful as a verification activity:

i. No process controls are present that will significantly minimized the hazards
   a. RTE cut raw vegetables intended to be used in RTE foods (Salmonella spp. or Listeria monocytogenes)
   b. Nutritional Bars with dry mix ingredients with no lethality steps
   c. Mixtures of shell nuts in which the mixture may be contaminated with Salmonella
ii. Ingredients added post process
   a. Chips, nuts and Cereal with seasonings added after the lethality step.
iii. Handling of products or exposure of a product to the environment after the process control step
   a. Manufacture of nut butter from roasted nuts when Salmonella from the environment is a concern
   b. Addition of herbs and vegetables to a product like cream cheese or cottage cheese – L. monocytogenes is a concern
   c. Manual assembly of sandwiches – S. aureus; L. monocytogenes and enteric pathogens such as Salmonella are concern.

GMA disagrees with the Agency and contends that for each of these cases, ingredient testing and environmental testing are generally more useful than product testing as they verify the specific controls that could lead to the presence of the hazard in the finished product. GMA believes that testing resources should be focused at the most appropriate point in the process, which in many

38 Id.
instances will be either environmental monitoring or ingredient testing. For example, in the case of examples i.b., i.c. and ii. listed above, it is likely that any ingredient contamination would be at a low level (e.g., at or below a detection level of 3-6 cells per 375g). Coupled with the usage rate, the probability of detecting the contaminant in the finished product would be lower than for the ingredient. In comparison to testing finished product after the fact, in these examples testing the incoming material would be more practical and have a better chance of detecting a problem and, more importantly, would be able to identify the problem before the ingredient is used on the line.

Where a hazard analysis has identified that there are no process controls that will significantly minimize the hazard at the ingredient supplier or at the receiving facility, a reliance on finished product or ingredient testing is not a sufficient replacement for validated process and operational controls.

GMA Recommends

- The Agency should not mandate finished product testing and instead, FDA should provide for use of finished product testing as a useful verification tool when determined to be appropriate and necessary based upon product risk and verification of the hygienic status of the line.
- FDA should not indicate that finished product ingredient testing is a sufficient replacement for validated process and operational controls where the hazard analysis has identified that there are no process controls that will significantly minimize the hazard at the ingredient supplier’s facility or at the receiving facility.

A discussion of product testing in response to the FDA request for comment is included in Section 3.

F. Metrics for Microbiological Risk Management

Reference

“The proposed rule that is the subject of this document would not establish criteria or metrics for verifying that preventive controls in food safety plans achieve a specified level of public health control in this proposed rule. However, FDA will give consideration to appropriate microbiological risk management metrics in the future.”

GMA Feedback

GMA acknowledges the application of food safety metrics, such those outlined by the Codex Alimentarius Commission in Annex II of Principles and Guidance for the Conduct of Microbiological Risk Management (Codex Alimentarius Commission 2007b), particularly in international standards and guidelines. GMA agrees with FDA that specific verification criteria and metrics should not be part of the final rule. The inclusion of relevant metrics would be impractical given the wide range of products and processes covered by the rule. However, the development of performance objectives for some foodborne hazards by FDA, in particular

allergen thresholds, could assist manufacturers in the design of products and processes and the design and implementation of validation and verification activities. The development of “safe harbor” product and process criteria for specific products in guidance documents will be particularly useful for small companies that do not have sufficient resources to conduct formal validation studies to determine formulation and processing conditions necessary to ensure the control of identified hazards.

GMA Recommends

- The Agency should work with industry and academic experts to develop performance objectives where necessary and appropriate to clarify contaminant levels necessary for food safety, and to establish “safe harbor” product and process criteria in guidance to assist manufacturers that do not have sufficient time and resources to validate specific product and process parameters.

RESPONSES TO REQUESTS FOR COMMENTS

In the preamble to the proposed rule FDA has made several requests for comments related to the inclusion and scope of testing requirements in the final rule. What follows is GMA feedback and recommendations related to the specific comment requests.

A. Product Testing (Proposed Rule Section XII.J.2)

Comment Request

- “FDA requests comments on when and how product testing is an appropriate means of implementing the statutory directives set out above.”
- “Should a product testing program be limited to finished product testing or include ingredient testing?”

GMA Feedback

GMA agrees with FDA that “the utility of finished product testing for verification, depends on many factors that industry currently considers in determining whether finish product testing is an appropriate approach to reducing the risk that contaminated food would reach the consumer and cause foodborne illness.” There are a variety of factors to consider in determining whether finished product testing is a necessary and appropriate verification procedure (see Section 2 comments). Of all verification testing programs, finished product testing is the least likely to detect potential food safety issues and specific control measure failures. In most cases, verification procedures targeted to the specific control measure are more appropriate in routine

---

operations. Where implemented, microbial finished product testing may include indicator organisms and/or specific pathogens of concern. Examples of verification programs appropriate for various products are included in Section 2 (Table 1).

Routine finished product testing is not of value for allergens or chemical contaminants. While such testing may be part of an investigation, testing to determine root cause is often more effective when focused on potential areas of failure, such as equipment or ingredients. Metal detectors or x-ray machines are means to evaluate finished products for foreign material; however verification of the control of these hazards may be more appropriately focused on verification of supplier controls or operating conditions and employee practices that could lead to the generation of foreign material.

GMA believes that product testing programs may include ingredient testing, particularly where the receiving manufacturer does not have a validated control measure in-house. Such programs are most often applied for microorganisms, but may be applied for foreign objects or chemical contaminants, where appropriate. Generally ingredient testing is preferred over finished product testing, as it is focused on verifying supplier controls and is focused on incoming material (or material before leaving the supplier) before it is used in production by the receiving facility.

GMA Recommends
- A product testing program can be used as a verification tool, when appropriate, based on risk, and not as a preventive control
- Product testing should not be limited to finished product testing. Ingredient or in-process testing may play an important role in verification programs for some products and materials and is more effective at verifying supplier controls than finished product testing.
- FDA should not establish mandatory requirements for finished product or ingredient testing. Such testing is not relevant for some products and processes and there are a number of factors to be considered determining the necessity, design, and application of such programs. It will be difficult and impractical for the Agency to account for all scenarios in the final rule. GMA supports the use of guidance to provide specific, clarifying details that are not included in the regulation.

Comment Request
- “What is the appropriate level of specificity for a product testing program? For example, should we simply require that the owner, operator or agent in charge conduct, as appropriate to the facility and the food, finished product testing, when appropriate based upon risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur. This would provide flexibility to account for the wide diversity of food and food manufacturing, processing, packing and holding systems subject to this rule and be consistent with the discussions within the proposed rule?"  

GMA Feedback
GMA agrees that flexibility is essential as there is considerable variability in products and processes. The design of any testing program will vary based upon the product, process, environmental controls, and relevant hazards. Therefore GMA advises the Agency against proposing specific requirements for testing programs in the rule as:

- It will not be possible to cover all scenarios, and
- Prescriptive programs may limit suitable adaptation and implementation of programs by facilities to properly address food safety concerns.

GMA agrees that the draft language in the OMB Redline document is appropriate with minor modification (see Section 4).

GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate as it does not appear in the statute. Please see GMA comments on § 117.135(c)(1) in our document submission on the proposed rule Parts A, C and D.

GMA Recommends
- FDA should refer to existing industry guidance on testing programs and develop any necessary additional guidance with the input of qualified stakeholders such as GMA. Guidance could address the design and implementation of testing programs including, where appropriate and necessary, finished product and ingredient testing.

Comment Request
“FDA also requests comments on whether more detail would be appropriate, by, for example:

- Specifying particular hazards, situations or product types for which finished product testing would be required;
- Specifying the frequency of testing and, if so, whether this frequency should depend upon the type of product;
- Identifying appropriate sampling plans for finished product testing;
- Requiring periodic testing for trend analysis and statistical process control; and
- Requiring written procedures for conducting finished product testing and, if so, also require that procedures for finished product testing be scientifically valid and include the procedures for sampling and the sampling frequency.”

GMA Feedback
In order to allow flexibility and account for the diversity of food manufacturing systems, FDA should avoid including specific requirements for product testing (finished product or otherwise) in the regulation. FDA should not specify particular hazards, situations, or product types for which finished product testing would be required; the frequency of and need for testing should depend upon the type of product.

\textsuperscript{44} Id.
Furthermore, GMA believes that FDA should not identify appropriate sampling plans for finished product testing in the proposed rule. Sampling plans differ based upon the nature of the hazard, whether the product allows growth during storage, product distribution, and how the product is manufactured and used. Sampling plans are also adapted based upon facility history. It would not be feasible or helpful to provide sampling plans for all of these scenarios in regulation. Prescribing a specific plan could encourage some manufacturers to perform the minimum dictated by the regulation, even if it may not be the optimum approach for verification. Prescribed sampling plans could also give the impression that any product that “meets the requirement” of the sampling plan is safe to eat even where there are preventive control failures that would warrant a more detailed investigation or where the hazard could be present at a level and/or distribution that could not be detected by statistical sampling. The Agency may establish sampling plans for specific significant contaminants as part of the requirements of Section 104 “Performance Standards” or could develop guidance to indicate how statistical sampling plans are developed and function in verification activities throughout the food chain.

GMA does not agree that periodic testing for the specific purpose of trend analysis or statistical process control should be required. The concept of trend analysis has not been well defined and it would be difficult to mandate specific circumstances due to the variability of application. Trend analysis could be as simple as mapping positive findings or could require complicated statistical analysis, a resource not available to many facilities. Recommendations for procedures for collecting samples for the purpose of trend analysis, as well as the analysis itself, would be better placed in guidance, which can be adapted as needed.

**GMA Recommends**

- GMA agrees that the following items would be reasonable to include in the regulation, so long as facilities have the flexibility to apply them as appropriate and necessary:
  - Requiring written procedures for conducting finished product testing and,
  - Requiring methods used for finished product testing to be scientifically valid and procedures for sampling and the sampling frequency be “technically sound.”
    - Please see Section 2 for further discussion of the concept of technically sound.
- Specific requirements or recommendations on the design of testing programs should not be included in the final rule, rather these recommendations should be provided in the preamble and guidance documents developed with industry and other stakeholders:
  - FDA guidance should recommend a risk-based approach to the establishment and implementation of sampling programs.
  - Guidance documents should provide support to industry about how to assess risks associated with products, processes, and materials and how to identify relevant sampling sites, sampling types, and frequency. Guidance documents should provide examples of various scenarios, including sampling locations and sampling frequencies.
  - GMA supports the role of guidance documents to enhance understanding of and compliance with the regulatory framework. GMA is concerned, however, that guidance documents may be applied by FDA investigators as having the binding force of regulations. GMA supports the promulgation of properly developed and vetted guidance.

- The Agency should reiterate and emphasize the following statement from the proposed rule preamble in the final rule preamble: “Guidances do not establish legally enforceable rights or responsibilities and to not legally bind the public or the FDA (§ 10.115(d)(1)). Accordingly, regulated industry is not required to employ the approaches contained in a guidance and instead may choose to use an alternative approach, provided that the alternative approach complies with the relevant statutes and regulations (§ 10.115(d)(2)).”

This point is of particular concern to industry to ensure that FDA investigators do not interpret details and examples included in guidance as though they are binding regulatory requirements.

Comment Request

- “FDA also requests comments on the impact of product testing requirements on small businesses and on whether any product testing requirements should differ based upon the size of operation.”

GMA Feedback

GMA contends that the relevance of product testing depends upon the nature of the product, process, ingredients, and associated controls. Significant outbreaks of foodborne illness and large product recalls have been associated with companies of all sizes, including smaller companies. Several of the outbreaks cited by FDA in the preamble to the proposed rule originated in small to mid-size manufacturers. Smaller facilities may have a smaller processing area or fewer production lines, resulting in a smaller number of relevant sampling sites for environmental monitoring; however, the size of a facility does not by itself impact the risk, control of potential hazards, or the relevance of product testing. There should not be different requirements based upon facility size. Where smaller companies lack internal technical resources with the expertise in the design of testing programs, they can use appropriate guidance as the basis for their programs or solicit the support of trade associations or external qualified individuals.

GMA Recommends

Requirements should be standard regardless of company size. Where necessary, relevant guidance can be specifically developed for and targeted at smaller companies to address unique challenges such companies may have in implementing the regulation, consistent to the current FSIS approach (USDA FSIS 2008).

B. Environmental Monitoring (Proposed Rule Section XII.J.3)

Comment Request

- “FDA requested comment on when and how environmental testing is an appropriate means of implementing the statutory directives set out above.”
- “If they are included, what is the appropriate level of specificity? For example, should we simply require the performance of environmental monitoring, for an appropriate microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur?”

GMA Feedback

Environmental monitoring can be an important verification procedure for sanitation and environmental control measures to prevent post-process contamination of RTE foods when environmental pathogens have been determined to be a hazard that needs to be controlled. Such control measures include hygienic design principles, physical separation of raw ingredients from RTE areas, implementation of appropriate cleaning and sanitation programs, employee hygiene (e.g., hand washing, appropriate garb), and pest control. However, a blanket requirement for environmental testing in all facilities is not appropriate. This is because an environmental monitoring program is not relevant in food manufacturing facilities where post-processing contamination of RTE foods is not a relevant hazard. Examples of these types of facilities may include operations utilizing a hot fill or aseptic processing.

The intent of environmental monitoring is to identify gaps in environmental controls before they impact product safety. A well-designed and executed program will focus on finding and addressing gaps in environmental controls, allowing an investigation and corrective actions to be made to address issues before they could potentially lead to product contamination. The finding of a pathogen or indicator in the environment does not necessarily mean the process or processing environment is out of control or that the product is contaminated.

GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate as it does not appear in the statute. Please see GMA comments on § 117.135(c)(1) in our document submission on the proposed rule Parts A, C and D

GMA Recommends

- FDA should not propose specific requirements for environmental monitoring programs in the final rule as it will not be possible to cover all scenarios. Prescriptive programs may limit flexibility and adaptation of risk-based programs implemented by factories.
- FDA should recognize that effective environmental monitoring programs are designed to find and address likely issues. The Agency should regard programs that find issues, which are subsequently addressed, to be successfully implemented. Agency inspectors should not penalize facilities for finding potential problems through verification testing if appropriate corrective actions are taken.

• FDA should refer to existing industry guidance on testing programs. FDA should develop additional guidance, with the input of stakeholders such as GMA, on the design and implementation of testing programs, including guidance that explains when it is appropriate and necessary to engage in finished product and ingredient testing.

Comment Request
• “Specifying the environmental pathogen or the indicator organism for which the samples must be tested”

GMA Feedback
When developing facility-specific environmental monitoring programs, the environmental pathogen, pathogen indicator organism, or hygiene indicator organism(s) tested for at each sampling location should be determined based on risk and the preventive control being verified. Therefore, FDA should not specify the environmental pathogen or the indicator organism for which the samples must be tested. Additionally, pathogens may emerge in the future that will need to be addressed, or technology may be developed that will ensure the absence of a pathogen of concern so that it is no longer relevant for a particular product and process. A regulation that codifies the specific organisms that must be addressed could limit the Agency’s authority for enforcing testing requirements in the future if science supports testing for different organisms.

GMA Recommends
• GMA’s proposed regulatory language will provide more flexibility: “hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.” (See comments on § 117.135 in our document submission on the proposed rule Parts A, C and D.)
• The Agency should not specify the environmental pathogens or indicator organism for which samples must be collected and tested; selection of test organisms should be determined by the facility based on its hazard analysis.
• The Agency should acknowledge existing guidance and work with the food industry and other qualified stakeholders to develop guidance, which could include product and process specific examples to assist food producers in the design and execution of monitoring programs.

Comment Request
• “Specifying the corrective actions that should be taken if environmental testing identifies the presence of an environmental pathogen, such as:
  o Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;

Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
- Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated; and
- Conducting finished product testing.”

**GMA Feedback**

GMA agrees that a facility should have a documented corrective action program but does not agree that FDA should prescribe specific corrective actions. Appropriate corrective actions will depend on knowledge of the affected area, mitigation strategies, and the product being manufactured. Such facility-specific factors will determine what corrective actions are needed.

The manufacturer will identify actions to be taken following an adverse finding and other corrective action procedures that are appropriate to address the contamination source, identify the root cause, and ensure that finished product and product contact surfaces are not affected. These procedures are defined in the facility’s food safety plan. Evidence of corrective action efficacy should be recorded. The Agency should expect that the corrections and corrective actions outlined are sufficient to address the risk.

**GMA Recommends**

- GMA has included recommendations on regulatory language on corrective actions in Section 4.

---

**Comment Request**

- “Specifying the locations within the facility at which samples must be collected;”

**GMA Feedback**

GMA does not agree that FDA should specify “locations within the facility at which samples must be collected.” ICMSF (2002) notes that environmental sampling plans are not statistically designed and are based on experience and knowledge of the sites most likely to detect a failure in good hygiene practices. Selection of sampling locations requires an in-depth knowledge of the product and process, including plant hygienic zoning, traffic flow, ingredient storage, personnel practices, and related environmental controls. This experience and knowledge is best exercised by a qualified individual with familiarity within the specific facility. Site selection should be justified based on risk and not specified by the Agency. One problem with mandating specific sampling locations is that some facilities may test only these locations. Another problem is that specific sites may have greater significance in some processing areas than others (e.g., a drain in raw vs. RTE production area).

**GMA Recommends**

- FDA should not specify the sampling locations within the facility in the final rule. The Agency should work with industry and other qualified stakeholders to develop guidelines, similar to the Almond Board of California Environmental Monitoring Guideline (ABC

---

51 Id.
2011), which could include product and process-specific examples, to assist food producers in the design and execution of monitoring programs.

Comment Request

- "Specifying the frequency of collection of environmental samples (e.g., weekly or monthly depending on risk). For example, should the frequency of collection:
  - Be greatest for foods that are likely to be consumed as RTE or consumed after a minimal treatment that may not adequately reduce the environmental pathogen?
  - Be greater for an environmental pathogen that is frequently introduced into a facility (e.g., *Listeria monocytogenes* which is ubiquitous in the environment and can be continually introduced into a facility from many routes, including ingredients, people and objects (Ref. 144)) than for an environmental pathogen that is less frequently introduced?
  - Be greater for refrigerated or frozen RTE food products that support growth of *Listeria monocytogenes* than for those that do not? Be greater if there is greater risk of a negative impact on public health (e.g., the product is specifically intended for a sensitive population such as infants) than if there is a lesser risk of a negative impact on public health?
  - Be greater if there is a greater risk of a negative impact on public health (e.g. the product is specifically intended for a sensitive population such as infants) than if there is a lesser risk of a negative impact on public health?
  - Be greater for products that undergo significant handling and exposure to the environment than for products that undergo limited or no handling or have little exposure to the environment?
  - Increase as a result of finding the environmental pathogen or an indicator of the environmental pathogen or as a result of situations that pose an increased risk of contamination, e.g., construction? (Ref. 52) (Ref. 185) (Ref. 184) (Ref. 187)."

GMA Feedback

Environmental sampling frequencies are established and justified based on the preventive controls to be verified for the particular facility and risk. Facilities should perform a risk assessment to determine appropriate organisms, baseline, zoning studies, need, and frequency. GMA agrees that some of the scenarios listed would influence the design and implementation of environmental monitoring programs, including the frequency of environmental sampling and number of samples collected. However, numerous other factors such as hygienic design, zoning, sanitation, other prerequisite programs, and facility history are also factors considered in program design. ICMSF emphasizes the importance of knowledge of the operation and its variability when determining the number of samples and sampling frequency (ICMSF 2002). It is not feasible for the Agency to prescribe details of a monitoring program, such as the frequency and/or number of samples to be taken, to address effective sampling programs in all scenarios. The establishment of prescribed frequencies could also

---

discourage some processors from employing a more aggressive plan when appropriate, as they may limit their program to the one prescribed.

FDA references refrigerated and frozen RTE foods that may support the growth of *Listeria monocytogenes*. GMA notes that there is no risk of *Listeria monocytogenes* outgrowth in frozen products due to the low temperature of commercial storage and distribution and frozen storage by the consumer (FDA 2011). The minimum growth temperature for *L. monocytogenes* is 0.4°C, well above standard temperatures used in frozen storage at the producer, retailer, and consumer. There may be a potential for *L. monocytogenes* to grow if it is present in frozen products that are slackened and stored chilled for a length of time longer than the lag phase after which the organism may begin to grow.

GMA contends that increased testing is not sufficient to ensure the safety of foods that are likely to be consumed “after a minimal treatment that may not adequately reduce the environmental pathogen.” Adequate control measures are needed either at the supplier site or the receiving facility to ensure that the hazard is significantly minimized or prevented. If the control applied is at the supplier level, then ingredient testing by the supplier or receiving facility should be adequate to verify supplier controls.

**GMA Recommends**

- While environmental monitoring often is a valuable verification tool, the Agency should not specify the frequency and/or number of samples to be taken, as they may not be appropriate in all scenarios. The Agency could, if necessary, provide a list of factors to consider when establishing sampling frequency, but should not prescribe relative frequencies; however, such information is contained in existing guidance. The Agency should recognize existing guidance and work with industry and academic experts to provide any necessary additional guidance.

---

**Comment Request**

- “Requiring written procedures for conducting environmental testing and, if so, also requiring that procedures for environmental testing be scientifically valid and include the procedures for sampling and the sampling frequency.”

**GMA Feedback**

GMA believes that it would be reasonable for the Agency to require written procedures for conducting environmental testing as part of the Food Safety Plan, including procedures for sampling and sampling frequency. GMA understands that “the procedures for sampling and the sampling frequency” is in reference to the procedures that the facility would establish (i.e., that the sampling procedures and sampling frequency would not be mandated by the Agency). GMA suggests that the term “technically sound” be used rather than “scientifically valid” as discussed in Section 2. As noted previously, ICMSF (2002) asserts that environmental sampling plans are

---

54 Id.
not statistically designed and are based on experience and knowledge of the sites most likely to detect a failure in good hygiene practices.

**GMA Recommends**
- The final rule should require procedures for sampling and testing of environmental samples to be written and technically sound, but not be prescriptive in nature.

**Comment Request**
- “Requiring data analysis to detect trends.”

**GMA Feedback**
Trend analysis of environmental monitoring data can be a valuable tool in identifying sources of contamination or trends towards loss of control. Trend analysis can be a specific review of data against established baselines (e.g., for levels of hygiene indicators), or an evaluation of patterns associated with the presence of pathogens in the environment to assist in root cause analysis. Trend analysis is usually beneficial to evaluate problems before a product or production line is out of control; however, trend analysis may not be possible for some types of analyses (e.g., presence or absence data for a specific pathogen).

**GMA Recommends**
- FDA should not require trend analysis for environmental testing in the final rule.
- FDA should indicate that trend analysis can be an important component of verification where such analysis can indicate trends towards loss of control or provide value in root cause analysis and provide details in guidance of how to effectively use trend analysis.

**Comment Request**
“In addition, with respect to environmental testing for *L. monocytogenes*, FDA requests comment on whether it would be appropriate to distinguish between environmental testing for RTE foods depending on whether the food supports the growth of *L. monocytogenes*."

**GMA Feedback**
The necessity and stringency of environmental monitoring programs are determined based upon the risk of the pathogen in the product and processing environment. Determining whether the product supports the growth of *L. monocytogenes* is part of the hazard assessment. Therefore, when implementing an environmental testing program, GMA supports distinguishing between RTE foods that support the growth of *L. monocytogenes* and those foods that do not. In many cases there is a higher risk associated with RTE foods that support the growth of *L. monocyto...
monocytogenes. However, other factors, such as possibility of exposure to the plant environment, must also factor into the equation. It may not be possible to broadly group food categories as supporting versus not supporting the growth of *L. monocytogenes*. Formulation and other factors may affect the ability of a food product to support the growth of *L. monocytogenes*, so that categorizing risk by product categories may not be applicable. For example, deli meats and hot-dogs have traditionally been associated with *L. monocytogenes*, but recent data (CDC Vital Signs June 2013) shows a reduction in *L. monocytogenes* risk associated with these products, which could be in part due to anti-listerials included in product formulation. Therefore, the determination of whether a food can support the growth of *L. monocytogenes* would need to be determined via means such as formulation or challenge testing, rather than by product category.

**GMA Recommends**

- In guidance, FDA should distinguish between RTE foods that support the growth of *L. monocytogenes* versus those that do not, but should not broadly group foods into categories.

---

**Comment Request**

- “We also request comment on whether there are appropriate indicator organisms for any environmental pathogen other than *Listeria monocytogenes*.”

**GMA Feedback**

GMA is not aware of pathogen index organisms for environmental pathogens other than *L. monocytogenes*. However, GMA asserts that useful process information can be ascertained through the use of indicator organisms such as *Enterobacteriaceae*, as discussed in Section 2. GMA also notes that appropriate indicator organisms for pathogens other than *L. monocytogenes* may be discovered in the future. Codifying an absolute requirement about indicator organisms in the regulation could constrain facilities from using indicator organisms in the future if scientific support is developed to justify their use. Statements about appropriate indicator organisms are better suited for guidance.

**GMA Recommends**

GMA recommends that the FDA explain through guidance that the facility expert is responsible for determining which test organism(s) are most suitable for their environmental testing. Specific index and indicator organisms and requirements should not be included in the rule.

---

**Comment Request**

- “We further request comment on whether there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.”

---


GMA Feedback
GMA agrees that “there is benefit in conducting routine environmental monitoring for other organisms in addition to, or instead of, the environmental pathogen of concern.” Routine environmental testing for pathogen index organisms or other indicators is useful in that it provides a broader picture of the facility’s hygienic status since more microorganisms are included in these groups. In many cases, these results are actionable before evidence of pathogen presence could be gathered. Trending of results from indicator monitoring can be useful since it is more likely that the data is quantitative.

GMA Recommends
- FDA should indicate in the final rule or the preamble that index and indicator organisms can be part of an effective monitoring program.
- FDA should indicate that design and implementation of environmental monitoring programs will be facility specific and flexibility is needed to determine how such programs should be applied, including the index and indicator organisms used.

C. Testing in Supplier Verification (Proposed Rule Section XII.J.4)

Comment Request
- “FDA requests comments on when and how supplier approval and verification is an appropriate means of implementing the statutory objectives [set out above].”
- “Provide more flexibility with respect to hazards for which there is not a reasonable probability that exposure to the hazard will result in serious health consequences or death to humans – e.g., . . . periodic or lot-by-lot sampling and testing of the raw material or ingredient and periodic review of the supplier’s food safety records”\(^{59}\)

GMA Feedback
Separately from this document, GMA is providing comprehensive comments on the Agency’s request for information on supplier approval and verification. Here, comments focus on the testing-related issues involved with supplier verification.

GMA agrees that testing, microbial and otherwise, may be an appropriate supplier verification activity, but flexibility is needed so that each facility can tailor its program to its own products and suppliers.

The implementation of ingredient testing as part of a supplier verification program depends upon the nature of the material/ingredient, the processing applied to the ingredient by the end-user or processor, the distribution and final use of the finished product, and the history of supplier performance.

Verification testing may be useful for ingredients situations that include the following:
- To verify the conformance of a new or existing ingredient to agreed-upon specifications;

\(^{59}\)78 Fed. Reg. 3766.
• As periodic verification of Certificates of Analysis provided by the supplier;
• When a new supplier is used, or if the history of supplier performance suggests that verification should be conducted; and
• When new information about hazards associated with the ingredient comes to light.

When ingredient testing is appropriate, verification testing often is most effectively conducted by the facility manufacturing the material. Testing at the supplier site permits proper isolation, testing and confirmation of results prior to shipping. The results may be captured on a COA and sent to the receiving location with or prior to receipt of the material. The COA typically includes the test results for the production lot to be received based upon specifications relevant to the pertinent food safety hazards. A COA will also include the product description, lot evaluated, sample size, testing method, date, name of the analyst, signature of the reviewer, and receiving location information. The receiving facility may conduct testing upon receipt to verify the supplier COA at a frequency based upon the risk of the material, its intended use, material history, shelf life, supplier performance, or other factors.

GMA Recommends
• FDA should acknowledge in the final rule or preamble that flexibility is needed in the design and implementation of ingredient testing programs so that the manufacturing site can tailor a program appropriate to the ingredient, product, process, and supplier history.
• FDA should not require that ingredient testing be conducted by the receiving facility, instead, encourage testing by the manufacturer of the material as a provision of a COA.

RESPONSES TO OMB REDLINE (DRAFT CODIFIED LANGUAGE)

Responses to Draft Codified Language Provided in OMB Redline:
Draft §§ 110.145(c), 110.150(d)(3) and[(4)]

GMA has reviewed the OMB redline document and offers the following comments on the draft codified language from the redline that was not included with the proposed rule. Although GMA is providing comments on this draft codified language, GMA strongly encourages FDA to publish proposed language for public comment before issuing a final rule. Below, the language from the OMB Redline is shown in italics.

§ 110.145 Corrective Actions.
(c) Corrective actions for environmental monitoring. If environmental monitoring in accordance with § 110.150(d)(4) identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility must take corrective actions that include:
(1) Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
(2) Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
(3) Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated;
(4) Conducting finished product testing when appropriate; and
(5) Performing any other corrective actions necessary to prevent reoccurrence of the contamination.

GMA Feedback
GMA agrees that it is important to take corrective action in response to the detection of a pathogen or hygienic indicator organism in the production environment. However, GMA contends that the requirements suggested here lack the flexibility required for manufacturers to implement corrective actions as appropriate. The actions itemized in points (1) through (4) above would be appropriate in some, but not all, circumstances. GMA contends that the corrective action undertaken should be consummate with risk.

GMA notes that while a root cause analysis is conducted after finding an adverse result, such analysis in many cases cannot identify a definitive source of the problem because sampling is a retroactive indicator. Potential root causes may be identified, which will be addressed, or the data point may be evaluated in the context of overall trends in the facility.

GMA Recommends
- FDA should modify the corrective action requirement to allow implementation of corrective actions appropriate to the situation, including omitting the four sentences in strikethrough as shown below.

(c) Corrective actions for environmental monitoring. If environmental monitoring in accordance with § 110.150(d)(4) identifies the presence of an environmental pathogen or appropriate indicator organism, the owner, operator, or agent in charge of a facility must take corrective actions that include:
(1) Conducting microbial sampling and testing of surrounding surfaces and areas to determine the extent of the contamination and the potential source of the contamination;
(2) Cleaning and sanitizing the contaminated surfaces and surrounding areas to eliminate the test organism;
(3) Conducting additional microbial sampling and testing to determine whether the contamination has been eliminated;
(4) Conducting finished product testing when appropriate; and
(5) Performing any other corrective actions to prevent reoccurrence of the contamination.

§ 110.150 Verification
(d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, by conducting activities that include the following, as appropriate to the facility and the food:…
(3) Performance of finished product testing, when appropriate based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that are reasonably likely to occur

GMA Feedback
GMA agrees that finished product testing can be a useful food safety tool, for example as periodic verification of the overall food safety system, and also agrees with FDA’s suggestions that it should be implemented as appropriate based on risk. A blanket requirement should not be made to conduct finished product testing for all foods or all RTE foods. Finished product testing would not be appropriate as a verification activity for products in which pathogens rapidly die-off (e.g., acidified sauces), or which receive a validated kill-step and are not exposed to the environment (including finished products that are pasteurized in pack, hot filled, or commercially sterilized). Appropriate verification activities for these products might include records review and verification of preventative controls.

GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate as it does not appear in the statute. Please see GMA comments on § 117.135(c)(1) in our document submission on the proposed rule Parts A, C and D.

GMA Recommends
- The term “when appropriate” is critical to the success of this measure and GMA suggests a slight modification to the language:

(3) Performance of finished product testing, when appropriate and necessary based on risk, to assess whether the preventive controls significantly minimize or prevent the hazards that must be addressed in the food safety plan, are reasonably likely to occur.

§ 110.150 Verification.
(d)(4) Performance of environmental monitoring, for a microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur, by collecting environmental samples at locations within the facility at a frequency of not less than monthly, testing the samples to assess whether the preventive controls significantly minimize or prevent the potential for an environmental pathogen to contaminate food;

GMA Feedback
As outlined in this document, GMA agrees that environmental monitoring is an important tool, but it may not be applicable or necessary in all facilities. Therefore, implementation should be based upon a facility and product specific risk assessment. Frequency of sampling and testing will also depend on these factors.

GMA contends that the term “reasonably likely to occur” (RLTO) is not appropriate as it does not appear in the statute. Please see GMA comments on § 117.135(c)(1) in our document submission on the proposed rule Parts A, C and D.
GMA Recommends

- GMA recommends modifying this requirement to read:

(4) Performance of environmental monitoring, for a microorganism of public health significance or for an appropriate indicator organism, if contamination of food with an environmental pathogen is a hazard reasonably likely to occur, as appropriate and necessary, by collecting environmental samples at locations within the facility at a sufficient frequency of not less than monthly, testing the samples to assess whether the preventive controls significantly minimize or prevent the potential for an environmental pathogen to contaminate food.

§ 110.150 Verification.
(d)(5) Review of the following records within the specified timeframes, by a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions: …
(ii) Records of […], finished product testing, environmental monitoring, within a reasonable time after the records are made

GMA Feedback
GMA agrees that this requirement is reasonable. As noted by the Agency, the frequency of these record reviews will be variable and will depend, in part, on the frequency with which those activities occur, which will be established in the food safety plan. As noted by the Agency, environmental monitoring may be conducted monthly in some facilities and weekly in others. GMA agrees that it would be reasonable to review the results of the tests in a timely manner, but we contend that it may not be feasible to review results on the day that they are received (for example, if they are received via email on Saturday evening they may not be reviewed until Monday morning).

GMA Recommends
- FDA should not specify timeframes for these activities.

(ii) Records of […], finished product testing, environmental monitoring, within a reasonable time after the records are made

§ 110.150 Verification.
(e)(1) Written procedures for verification activities. The owner, operator, or agent in charge of a facility must establish and implement written procedures for
(i) Conducting finished product testing. Procedures for finished product testing must be scientifically valid and must include the procedures for sampling and the sampling frequency; and
(ii) Conducting environmental monitoring. Procedures for environmental monitoring must:
(A) Be scientifically valid
GMA Feedback
For environmental sampling, GMA suggests that the term “technically sound” be used rather than “scientifically valid.” ICMSF (2002) notes that environmental sampling plans are not statistically designed and are based on experience and knowledge of the sites most likely to detect a failure in good hygiene practices. Therefore, it may be difficult for a facility to provide scientific evidence, such as journal articles, to justify choice of sampling locations or the number of samples collected.

GMA Recommends
- FDA should clarify the language of the final rule to substitute “technically sound” with “scientifically valid.”

(A) Be scientifically valid technologically sound;

§ 110.150 Verification.
(e)(1)(ii)(B) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be sufficient to determine whether preventive controls are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces within the manufacturing, processing, packing and holding environment; and

GMA Feedback
GMA notes that most of the sampling sites in an environmental monitoring plan are predetermined based upon the identified risks and relevant environmental and sanitation controls, but some will be based on in-plant observations. GMA strongly objects to the potential requirement that testing “must include appropriate food-contact surfaces,” as the application of PCS testing will depend on the facility, product, and risk (see previous discussion in Section 2).

GMA Recommends
- The final rule should provide for testing of food contact surfaces only when it is relevant for the circumstances:

(B) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be sufficient to determine whether preventive controls are effective and may include appropriate food-contact surfaces, must include appropriate food-contact surfaces and non-food-contact surfaces of equipment, and/or other surfaces within the manufacturing, processing, packing and holding environment; and

§ 110.150 Verification.
(e)(1)(ii)(C) Identify the test microorganism(s);
GMA Feedback
GMA agrees that this requirement would be acceptable.

GMA Recommends
• No changes.

§ 110.150 Verification.
(e)(2) Written procedures must identify or include the analytical methods used to test finished product or environmental samples.

GMA Feedback
GMA agrees written procedures are needed for analytical methods and sampling procedures; however, the method used may vary based upon the situation or purpose (e.g., testing for investigation, or testing to verify conformance to domestic or foreign regulatory requirements). As a result, it may not be practical for facilities to define specific analytical methods in written testing procedures. Testing records should include the method that was used in the analysis.

GMA Recommends
(2) Written procedures must identify or include the analytical methods used to test finished product or environmental samples.

§ 110.175 Records required for subpart C.
(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records: …
(4) Records that document verification, including, as applicable, those related to: …
(iii) Corrective actions, including corrective actions for environmental monitoring,
(vi) Finished product testing,
(vii) Environmental monitoring,

GMA Feedback and Recommendations:
GMA agrees that the identified records are necessary. Records are addressed in separate comments GMA is filing to this docket.

117.3 Definitions.
Environmental pathogen means a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment.
GMA Feedback
Environmental pathogens should be limited to those, such as *Salmonella* and *Listeria monocytogenes*, that have been demonstrated to cause foodborne illness via food contaminated from the production environment

GMA Recommends
*Environmental pathogen* means a microorganism that is foodborne pathogen of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment for which their presence or harborage in the food processing environment may result in product contamination at levels that may result in foodborne illness when the product is consumed.
REFERENCES


