

COLLABORATIVE FOOD SAFETY FORUM Role of Testing in FDA's Hazard Analysis and Risk-Based Preventive Controls Rule

Key Themes

The goals of the March 22nd Collaborative Food Safety Forum Workshop were to 1) learn about testing programs currently being used by the food industry, and 2) identify the principles that underlie and guide the use of testing as a verification tool in a risk-based, preventive-controls food safety system (including testing of raw materials and ingredients, environmental monitoring, and finished product testing).

Constructing a Testing Program

The U.S. Food and Drug Administration's (FDA) proposed Preventive Controls rule requires facilities to develop a food safety plan that contains the following components:

- Hazard analysis
- Identified preventive controls
- Monitoring procedures
- Corrective action procedures
- Verification procedures
- Recall plan

Testing is one method for verifying the effectiveness of the food safety plan; however, FDA did not require or expressly identify it as a verification method in the proposed rule. It was noted that in FSMA, testing is mentioned as a verification tool. Meeting participants identified concepts for the use of testing as a verification tool in a preventive controls system. The group agreed that testing—whether environmental, raw ingredient, or finished product—can be used to evaluate the effectiveness of process controls that eliminate or minimize microbial and other hazards in food, as well as to determine residual risk.

Many of the meeting participants agreed that the preventive-controls regulations should balance the challenge of providing clarity for testing requirements with flexibility for tailoring requirements to particular facilities, processes, products, and hazards. The FDA should detail the issues that a facility must consider to determine when and what type of testing is appropriate. Additionally, many participants encouraged the use of decision trees in deciding where and when to employ testing as a verification procedure. Some participants indicated that there may be instances (pathogen/food combinations) when FDA should require testing as a verification method, such as with sprouts as detailed in the proposed rule and discussed during the meeting. While it was noted that sprouts are a unique commodity in terms of how they are grown, the fact that they are considered a high risk product indicates one scenario where detailed testing requirements are appropriate.

They also agreed that FDA should address testing in an Interim Final Rule, rather than issue a supplemental rulemaking proposal. This approach would not delay implementation and would also provide opportunity to comment. Moreover, it would be useful for FDA to issue a detailed guidance document for industry.

Participants noted that testing can be a tool for both validation and verification, and that clarity about these different references is important. Validation and verification are defined by the *Codex Alimentarius* as follows:

- Validation – obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified level.
- Verification – the application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control is or has been operating as intended.

Many participants agreed that the Final Rule should encourage continuous improvement, including innovative approaches to reducing risk, and that testing should be used as an incentive to reduce risk. By incorporating these strategies for continuous improvement, participants hope the Preventive Controls rule will encourage critical thinking for reducing risk. Accompanying this goal should be capacity building, training, and support, particularly for small food producers. For example, outreach and extension programs at land grant universities that provide this type of support should be bolstered.

Many participants agreed that in order to construct an effective testing program, a facility needs to determine the risk of the product(s) produced. The testing program should clearly and directly address the hazards identified in the hazard analysis. The food safety plan should describe the target organisms, test methods and frequency, point of sampling (environmental, ingredients, finished product), and corrective actions when positives are found. Many participants mentioned the International Commission on Microbiological Specifications for Food's (ICMSF) book *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance* as a useful resource in designing testing programs. Additionally, some participants suggested that certain products do not need to be tested, such as:

- Raw ingredients subject to further processing that include a verified “kill” step
- Ingredients that inherently have strong antimicrobial activity (e.g. citric acid)

Environmental Monitoring

Participants discussed the need for a protocol to verify environmental controls by testing, including sample methods, target organisms, and specified frequency. Several participants suggested that an analysis be conducted to determine if and what environmental monitoring is needed, including the following considerations for facilities and processes:

- Handling or processing products with a history of contamination
- Handling or processing steps that could introduce recontamination
- Producing Ready to Eat (RTE) products

- Potential for colonizing and/or promoting growth of a pathogen once it enters the facility, or in the product

Positive results from environmental monitoring are a signal that there is a problem related to the facility, such as its design or construction effects, or may indicate seasonal impacts. Positive results should trigger additional action, such as increased testing and corrective action around the location of the positive result to identify if there is a bigger problem. The action taken could depend on the zone in which the positive is located. For example, a positive result in a drain would trigger additional testing of product contact surfaces; a positive result from a product contact surface would trigger not only product testing, but also identification of the source of contamination.

Many participants recommended that environmental testing should, when possible, target specific pathogens over indicator microbes. Indicator species, such as *Listeria* spp. can serve an important function, but should only be used if specific surrogates have been identified and substantiated for specific pathogens, and with recognition that even validated surrogates may not be useful when present at very low levels of contamination. Generally, indicator species identify conditions fostering the potential presence of pathogens more than the confirmed presence of a specific pathogen, and do not necessarily indicate that food is contaminated.

Some participants suggested that if a plant is “wet” and produces RTE products that can permit or facilitate *L. monocytogenes* growth, then the plant should test for *Listeria monocytogenes*. If the plant produces RTE products in a “dry” environment, then it should, at a minimum, test for *Salmonella* spp.

Raw Material Testing

Raw material testing is particularly important when the following conditions are present:

- The ingredient will be included in a RTE product, especially when no pathogen inactivation treatment is applied to the product after the ingredient is added
- The ingredient has a history of pathogen contamination or re-contamination
- The ingredient is high risk, i.e., it is likely to contain a contaminant that can make people very ill if consumed or used in foods for high-risk populations such as infants or the elderly
- There is no validated “kill” step as part of the processing/production of the ingredient
- Supplier verification information is inadequate

Finished Product Testing

Participants had differing views regarding the value of finished product testing, but did concur that finished product testing is most useful to detect failures of process controls and residual risk. Additionally, it is helpful in identifying “bad actors,” those operations unable or unwilling to produce food safely.

Finished product testing captures the most information on the total product. Acknowledging that finished product testing is appropriate for some but not all products, the most animated meeting discussion focused on when and where finished product testing may be appropriate. Many participants agreed that, generally, there should be a direct relationship between the risk associated with a product and the frequency of finished product testing. A finished product's risk depends on the following:

- The overall robustness of environmental and ingredient testing programs and controls, as described in the above sections.
- The risk of pathogen growth over the product's shelf life. For example, if the product, post packaging, has a likelihood of bacterial growth under temperature abuse conditions.
- The history of the product as being associated with numerous foodborne illness outbreaks.
- The results of trend analysis within a facility of presence of microbial pathogens or other hazards.
- The results of statistical process control or lot sample, e.g., evidence of an ingredient "hot spot" or process failure.

Some meeting participants believe that FDA should require finished product testing for products it defines as "high risk." Moreover, the group agreed that Hazards and Controls Guides, such as the one developed for Seafood HACCP, can be useful in defining testing regimes for target organisms.

Trend Analysis

Many participants thought it was critical to use results of testing programs to conduct trend analysis to identify patterns and, with this information, refine food safety processes and controls and testing programs. A written trend analysis plan that includes corrective actions corresponding to positive results is essential for continuous improvement.

Data analysis should allow for clarity, flexibility and continuous improvement. Intra-company analysis is important for internal improvement—evaluating whether a specific plant's and/or the entire firm's approach to preventive controls is improving food safety. More difficult, but still important, is inter-company comparison for benchmarking and innovation purposes. These comparisons can only be accomplished if the target organism, test methods and frequency is fully described or if government conducts tests according to the same protocols as the industry in the context of oversight. Additionally, participants noted that both prevalence data and quantitative results of pathogens in foods and ingredients are highly useful, and testing methods that cover multiple organisms would be useful.