

# Collaborative Food Safety Forum (CFSF)

## Role of Testing in FDA's Hazard Analysis and Risk-Based Preventive Controls Rule: Workshop Summary

March 22, 2013  
Washington, D.C.

### Background

The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF) are co-sponsors of the [Collaborative Food Safety Forum](#) (CFSF or Forum). Invited representatives from federal and state agencies, industry, consumer advocacy groups, and academia attended a workshop on March 22, 2013 to discuss how testing could be integrated in the U.S. Food and Drug Administration's Preventive Controls regulations implementing the FDA Food Safety Modernization Act (FSMA).

The proposed goals of the workshop were the following:

- Learn about testing programs currently being used by the food industry;
- Identify the principles that underlie and guide the use of testing as a verification tool in a preventive food safety system (including testing of finished product, environment samples and raw materials); and
- Provide ideas that address some of the main questions posed in FDA's proposed hazard analysis and risk-based preventive controls rule concerning the use of testing as a verification tool.

The proposed outcomes of the workshop were the following:

- A document (or documents) summarizing the deliberations—particularly highlighting ideas on how to structure a testing program that will function as a verification tool—in relation to the new proposed rule on hazard analysis and risk-based preventive controls.

This workshop opened with a welcome and remarks from Sandra Eskin (Pew) and Mike Taylor (FDA), followed by a review of the workshop's goals, outcomes, and agenda by Abby Dilley (RESOLVE).

The FDA's 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.

### **Presentation—Overview of FDA Proposed Preventive Controls Rule**

Jenny Scott, FDA, presented background on FDA's current thinking on testing, which is contained in the preamble and appendix of the proposed rule. The questions FDA poses in the proposed rule are to help determine a risk- and science-based approach to testing. Ms. Scott reviewed considerations for raw material/ingredients, finished product, and environmental testing, including questions of when and how testing should occur, frequency and sample size, and specificity of the rules. A brief presentation on the sprouts section of the Produce Standards Rule contained many elements for the meeting discussion and provided a model protocol that, while unique to this particular product, could offer insights for testing other food products. The sprouts testing protocol includes testing requirements, proposed actions when there is a positive result, and a written sampling plan requirement.

Jenny Scott's slides can be found [here](#).

### **Presentations—Industry Examples of Testing Programs**

The following industry representatives gave brief presentations on how testing is integrated into their firm's food safety program:

- [Will Daniels, Earthbound Farm Organic](#)
- [Frank Yiannis, Walmart](#)
- [Mike Robach, Cargill](#)
- Donna Garren, American Frozen Food Institute
- [Scott Brooks, Yum! Brands](#)

Will Daniels described Earthbound's extensive field input testing, facility environment, field tissue, and raw and finished goods tissue testing. In addition to detailing sampling plans and procedures, Mr. Daniels explained several customer requirements, such as Costco's test and hold provision. Earthbound employs a "test and hold" requirement. For fresh produce and perishable products, the time for confirming negative results shortens the shelf-life, adding pressure to Earthbound and its customers. New technology that is beginning to be used will deliver quicker results and relieve some of this burden.

Frank Yiannis explained Walmart's food safety program, specifically focusing on their approach to ground beef. This program was launched as a proactive response to concern about beef safety that occurred about five years ago. Even though Walmart had received certificates of analysis that showed no positive tests for pathogens, they wanted to establish scientific control validation. Walmart's beef safety requirements include facility

food safety certification by the Global Food Safety Initiative (GFSI), testing (raw material and/or finished ground beef), and process control validation.

Mike Robach drew on Cargill's program to propose how to decide when testing is useful. Emphasizing that a testing regime should be based on a hazard analysis and risk assessment, Mr. Robach provided criteria and examples for when finished product testing is helpful and when it is inappropriate. Participants were also interested in Cargill's environmental monitoring decision tree, which determines which environmental monitoring, if any, is required, and when additional testing or other actions might be merited.

Donna Garren presented the perspective of the American Frozen Food Institute's small and mid-sized companies, predominantly from the Pacific Northwest, California, and the Midwest. This constituency is both supportive of testing as a key component to a food safety program and concerned about the costs of implementing testing requirements. Dr. Garren reiterated that a testing regime must be individualized to the commodity, facility, and process. Smaller producers will need technical assistance to develop testing programs.

Scott Brooks provided an overview of Yum! Brand's testing program. He stated that their overall approach is "trust, but verify." The company specifies minimum testing requirements for most products or ingredients depending on product risk. A higher risk profile and lower confidence in process controls equates to more frequent testing. Dr. Brooks covered the cost-benefit and challenges of their testing program, which includes a test-and-hold requirement. For example, products with limited control steps, such as fresh-cut produce, require increased testing and larger sampling, which is more costly.

### **Constructing a Testing Program**

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.

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 the industry.

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.

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 in order to construct an effective testing program, a facility needs to determine the risk of the product(s) produced. All agreed that the rule should align with hazard analysis and critical control point, or HACCP, principles regarding testing. 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's) 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, including the following:

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

Many participants suggested 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. Additionally, several participants expressed the need to move testing toward quantitative, rather than qualitative, outcomes.

Meeting participants discussed specifics of three types of testing—environmental, raw material, and final product—and concluded with a discussion of trend analysis.

### **Environmental Monitoring**

Participants discussed the need for a protocol to verify environmental controls by testing, including sample methods, target organisms, and specified frequency. Participants suggested that an analysis 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 or 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, or may indicate seasonal impacts. Positive results should trigger additional action, such as increased testing and corrective action around the location of the positive results to identify if there is a larger 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 food-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 organisms. 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, 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 pathogenic 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, particularly high-risk populations such as young children or the elderly
- There is no validated “kill” step as part of the processing/production of the ingredient
- Supplier verification information is inadequate

Several participants noted that the foreign supplier verification program that is required under FSMA will likely include raw material testing

### 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 safe food.

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. Some participants did not want finished product testing to provide a false sense of security and deter innovation, but it is also viewed as an extra step of due diligence. 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 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 a “hazards and control guide,” such as the one developed for Seafood HACCP, can be useful in outlining testing regimes for target organisms.

## Trends

Many meeting 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.

Providing anonymity for industry data and standardizing testing and data are fundamental to inter-company comparison. One participant noted that VoluntaryNet is gathering data that will hopefully show trends and illuminate riskier commodities and regions.

Additionally, participants noted that both prevalence data and test results of pathogens in foods and ingredients are highly useful, and testing methods that cover multiple organisms would be useful.

### **Capacity Building**

Training staff from all sectors will be critical for implementing and regulating FSMA preventive controls and testing regimes. Small food producers are in need of training and technical support. Programs at land grant universities that provide this type of support should be bolstered. Another participant noted that those assessing hazards and risk and writing food safety plans may need training as well. The number of FDA subject matter experts should be increased and their breadth of sector expertise should be enlarged in order to manage the individuality of food safety plans.

### **Outcomes and Next Steps**

The outcomes from this CFSF session included two documents: 1) Key Themes of the deliberations; and 2) a full summary, including the presentations provided during the meeting (this document). As mentioned in the meeting goals, the purpose of this discussion was to share information, have discussion around questions raised in the Preventive Controls Proposed Rule, and to help inform comments that individuals and organizations will submit to the docket. Participants that submit comments to the docket may draw on information or insights from the meeting deliberations. Participants agreed, however, that if references are made to the conversations or the summary, comments will not be attributed to individuals, unless those individuals are asked for and confirm consent, and that individual or organizational comments are not represented as supported by the meeting participants.