The United Fresh Produce Association appreciates the opportunity to comment on the proposed regulation *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (“Produce Safety rule”).

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

United Fresh has long been the leader in continual enhancement of produce safety, bringing together food safety experts from across the industry to share understanding and drive process improvement, publish educational materials and best practice documents for multiple commodities and practices, and provide sound scientific input on potential policy actions by local, state, federal and international regulatory bodies.

United Fresh was a strong advocate for the Food Safety Modernization Act (FSMA) during its development. At its Board of Directors meeting January 20, 2007, United Fresh unanimously adopted the following guiding legislative principles for a food safety regulatory framework for produce:

- Produce safety standards must be consistent and applicable to all produce grown anywhere in the United States, or imported into the country.
- Produce safety standards must be mandatory, with sufficient federal oversight, in order to be most credible to consumers.
- Produce safety standards must allow for risk-based, commodity-specific food safety practices based on the best available science.

With the historic enhancement of FSMA, United Fresh believes this legislation provides adequate instruction to FDA for the development of practical, enforceable requirements consistent with the guiding principles above, with one exception regarding exemption of certain small farms and facilities.

In preparing our comments on this proposed rule, we have implemented a widespread and intensive discussion with member companies with expertise in diverse commodities and multiple growing regions throughout the United States and foreign countries. We organized diverse working groups of members that met together many times to review the proposed rule line-by-line and its implications for protecting public health without unnecessary impact
on the industry’s ability to deliver today’s vast array of affordable fresh produce choices to consumers. We participated in numerous FDA public meetings, and traveled widely throughout the industry listening to member input on the rule. Our comments here are a synthesis of that effort.

As FDA recognizes, the fresh fruit and vegetable industry is not one monolithic industry, but rather a collection of hundreds of smaller industries that grow, pack and distribute different commodities. As such, our comments can only address those broad issues that we have heard are of concern to the majority in our industry. We also encourage FDA to seriously consider the numerous comments you will receive on the rule from specific commodity groups and regional associations that address the more narrow, but equally critical, issues affecting their constituents.

We commend FDA for its first attempt to implement Congressional intent with this proposed rule, the first in U.S. history to regulate on-farm food safety practices for fruit and vegetable production.

However, we believe that FDA’s proposed rule has failed to follow the legislative intent of FSMA to provide for a true risk-based approach that recognizes the diversity of the fruit and vegetable industry. FSMA was clear in directing FDA to take into account differences in risk profile among commodities and practices:

“(a)(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based on known risks which may include a history and severity of foodborne illness outbreaks.”

While FDA has shown a willingness to recognize different risk profiles by proposing exemptions for thermally processed fruits and vegetables and certain commodities rarely consumed raw, FDA has failed to take into account differences in risks and practices for various commodities that are substantive. For those commodities not exempted, FDA has proposed a one-size-fits-all approach that fails to focus both government and industry resources on maximizing the rule’s potential benefit on public health.

In the co-published Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce, FDA lists only 17 commodities linked to foodborne outbreaks between 1996 and 2010 (Table 4). While we agree with FDA’s conclusion that “Using crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination”, there are hundreds of fresh produce commodities that have never been linked to a foodborne outbreak and FDA should not conclude that commodity characteristics do not play a role in potential risk. In the same document, FDA identifies two “commodity effects” (adhesion and infiltration) as factors affecting the likelihood of contamination (Table 7). Yet there is no provision for such differences in commodity effects in the proposed rule.

Also from that table, FDA emphasizes that the stated risks are relative only to others within a row (“Relative likelihood is read only left and right (across columns within individual rows); no implied comparison is made within columns (up and down)”). This restriction in conclusion also applies to commodities; i.e., the relative risk of, for example, using surface water unprotected from runoff is not necessarily the same across commodities.

Although the present state of scientific research may not provide definitive factors that reduce a commodity’s inherent risk of contamination, pathogen survival, and ultimately risk to public health, this does not mean such differences in risk do not exist, as demonstrated
by outbreak history. Requiring the one-size-fits-all approach and metrics proposed by FDA in the rule would preclude future research from identifying such factors, and allowing for modified requirements.

By applying the same requirements to all commodities despite significant variation in risk profile across the vast diversity of fruits and vegetables, the Agency unnecessarily adds huge economic burdens on producers with little to no impact on risk reduction. In fact, the likely unintended effect of the proposed rule in its current form would be counter-productive to public health by raising the costs of healthy fruits and vegetables and pushing growers out of business. We propose in our subsequent comments the means for FDA to rectify this matter by addressing current knowledge in accompanying Guidance rather than the rule.

**General Comments**

1. **Exemptions Based on Company Size**
   United Fresh opposes the concept that producers of any size should be “exempt” from the basic rule. FSMA was intended to provide public assurance that FDA has provided for appropriate regulatory oversight of ALL fruits and vegetables. Within the limits of the law, we strongly advocate that all producers of fruits and vegetables for sale to the public be covered, without regard to size.

   We recognize that a late amendment to FSMA required FDA to provide qualified exemptions for certain small/very small operations that sell a majority of their food products direct to consumers (i.e., the “Tester Amendment”). FDA went beyond the Tester Amendment when it proposed exempting all operations with annual food sales of less than $25,000. We believe that such exemptions are contrary to protection of public health. Pathogens do not discriminate on the basis of the size of an operation, and very small operations are often the least likely to have the food safety resources on site to evaluate and control hazards reasonably likely to occur.

   We further disagree with FDA’s conclusion that “imposing the proposed requirements on these businesses is not warranted because it would have little measurable public health impact”. An illness caused by unsanitary practice on a small farm is just as serious as that of any other farm. We also strongly dispute any implication that small farms cannot comply with appropriate food safety practices.

   Since 2009, United Fresh has served as Secretariat for the Produce GAPs Harmonization Initiative, an all-industry effort to harmonize on-farm food safety audit standards in a risk-based approach. These standards are consistent with FDA’s 1998 *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* and the basic requirements of this proposed rule. In 2010, the “Harmonized Standards” were piloted at a number of farm operations, several meeting the criteria of exempted operations above. In all cases, the operations declared the standards “achievable” and did not consider them beyond their abilities because of size.

   Since then, the Harmonized Standards have been used by a number of audit organizations, including USDA AMS, in assessing food safety practices on hundreds of operations, including very small farms. In no case have the audit organizations declared farms too small to comply with these standards. The USDA-funded On-Farm Food Safety Project ([http://onfarmfoodsafety.org](http://onfarmfoodsafety.org)) was designed to help very small operations develop and implement food safety plans based on the Harmonized Standards. The organizers of that project report hundreds of auditable food safety plans have been developed.
In short, there is adequate evidence that very small farms are able to implement adequate food safety practices and should not be exempt from the basic requirements of this proposed rule. Consumers who buy direct from such operations, whether at the farm, at farmers markets, or from retail and restaurant operations that buy "local", are entitled to the same level of food safety protection as consumers who buy from conventional sources. Instead, United Fresh believes that public health and confidence in the safety of fresh produce would be better served if FDA, USDA and State Departments of Agriculture would provide sufficient guidance and support to enable these operations to comply with these requirements.

The small farm exemption proposed also has significant unintended consequences in relation to imported foods. Foreign farms that export foods to the United States from around the world are often very small, well within the exclusion limit of $25,000 annual food sales. Produce from these farms is aggregated for export to the United States, but the farms themselves would be exempt from these regulations in order to comply with global trading standards requiring equal treatment of domestic and foreign suppliers. Please reference comments from the US Apple Association detailing the likelihood of thousands of apple producers exporting product from China that would be exempt under this rule.

2. Exemptions Based on Processing/Consumer Cooking

We are also uncomfortable with the concept of any fruits and vegetables being wholly exempt from the rule, under the same philosophy that the public expects FDA has provided for appropriate regulatory oversight of ALL fruits and vegetables. Rather, we propose an approach similar to 21 CFR part 123, the Seafood HACCP rule, which provides for regulatory oversight of the diversity of all seafood, coupled with companion Guidance that addresses specific variability appropriate to different products. This approach would provide for the comprehensive regulatory oversight of all commodities that both FDA and industry desire, with the ability to target appropriate specific practices and metrics to individual commodities or commodity groupings as contemporaneous science and experience mandates. In fact, this approach to combine broad regulatory oversight with specific guidance that can better differentiate risk management needs among different commodities is the approach that United Fresh recommends FDA take overall. We will discuss this in more depth later in these comments.

Within the context of Guidance, United Fresh would support modified requirements for fruits and vegetables intended to be thermally processed foods, or with another validated kill step sufficient to eliminate pathogens reasonably likely to occur. Such modified requirements should only be allowed if producers and processors can provide assurance that fruits and vegetables not grown according to standards in the rule cannot enter the fresh produce supply chain. This could require specific processing contracts that provide for control of raw products, and significant penalties to any person who diverts fruits and vegetables grown for processing into the fresh market.

Similarly, an “exhaustive” list of fresh fruits and vegetables being exempted because they are "rarely consumed raw" is not acceptable in the rule, but may be addressed appropriately in Guidance. While we agree that produce that is cooked by the consumer can achieve the same level of public health protection as any validated kill step, dietary practices and eating norms change. FDA is well aware of its mistake proposing that kale could be exempt as rarely consumed raw, when today it is the fastest growing vegetable in the United States often eaten raw in salads and in “healthy” beverages. Given that such a list in the regulation would be onerous for the Agency to amend, we believe such a list should be addressed as part of Guidance, allowing fresh fruits and vegetables to be added or deleted from the list as warranted by future information, without the necessity of rulemaking procedures. Further, consistent with our recommendations in the paragraph above, we
believe that such a list be accompanied by a caution to handlers of such commodities that an exemption from the requirements of growing practices would be invalidated if the produce is marketed for fresh consumption.

3. **Basic Structure of the Rule**
The proposed regulation appropriately identifies those major risk factors that all producers should evaluate in their operations; i.e.:
- Assurance of Worker Health and Hygiene;
- Prevention of Animal Intrusion and Exclusion of Potentially Contaminated Product;
- Use of Soil Amendments;
- Cleanliness of Equipment and Food Contact Surfaces; and
- Uses of Agricultural Water

We support the identification of these risk factors in the rule, including general provisions that they be adequately controlled to minimize the risk of becoming sources of produce contamination. Requirements worded such as in Subpart I, to "monitor...for evidence of animal intrusion" and "evaluate whether the covered produce can be harvested", allow for regional and commodity diversity and provide sufficient flexibility to be applicable to any operation.

On the other hand, we believe that quantitative metrics, such as in § 112.44, § 112.45, § 112.55 and § 112.56, are too prescriptive and inflexible to be included in the text of the regulation. We agree with FDA's intent to provide "safe harbor" standards for agricultural water and animal-based soil amendments, but the current status of produce food safety research is inadequate to establish these numbers as necessary criteria for all commodities and regions and all situations. While we appreciate, and agree with, FDA's conclusion not to create a list of "high risk" commodities warranting special control, we disagree with FDA’s conclusion that all non-exempt commodities must control identified risk factors to the same degree. As noted below, FDA has not provided a quantitative risk assessment to justify, for example, that public health protection requires weekly testing of surface water subject to runoff and used for direct application to covered produce, regardless of commodity grown. By focusing exclusively on agricultural practices, FDA has ignored commodity factors that may affect risk. Science has not yet revealed why commodities such as citrus, onions and grapes have not been linked to foodborne outbreaks. We can envision future research that is regionally or commodity focused revealing very different standards for test organisms or minimum standards, perhaps revealing an equivalent level of public health protection with no testing at all, similar to FDA’s conclusion regarding water and soil amendments not reasonably likely to contact covered produce.

Indeed, FDA admits to providing only a qualitative assessment of these risks, and has provided almost no scientific support for these quantitative requirements. The only support provided was reference 42, *Quantitative Risk Assessment to Support the Proposed Produce Rule*, which provided a scientific rationale for agricultural water standards for one commodity, based admittedly on incomplete data. That FDA asks in the preamble for “any data or factual information that may help the agency to conduct...a thorough and robust quantitative assessment" underscores that establishing such standards in the text of the regulation is premature. Instead, United Fresh believes the Congressional intent of “risk based standards” would be better met if FDA relegated such standards to companion Guidance, which can be informed and updated periodically, and can consider regional and commodity differences with an open and transparent assessment of current science.

We strongly urge FDA to re-evaluate its approach in the proposed rule, which clearly adopts a Precautionary Principle approach to regulate any and all theoretically potential hazards, no matter whether they have ever been shown to occur nor be reasonably likely to occur under current farming and distribution practices with different commodities. Ironically, while FDA
has often counseled that its European counterparts should follow a more science-based rather than precautionary principle regulatory approach on other issues, FDA’s approach in the case of the proposed produce rule is far more restrictive than the European regulatory approach to assure safe fruit and vegetable production.

Due to these significant issues, United Fresh formally requests that FDA issue a revised proposed produce rule for public comment before issuing a final rule. Significantly, we join in this request from the National Association of State Departments of Agriculture, the group representing many of the actual regulators that will be overseeing work with growers to implement the new law. With the most profound regulatory overhaul of food safety rules in some 70 years, it would not serve the integrity of the rulemaking process nor, indeed, the important policy objectives embodied in FSMA, to move to a final rule without affording stakeholders the opportunity to review and comment on modifications to this proposed rule.

Notwithstanding our comments calling for a fundamental new structure of the rule combined with FDA Guidance, we will comment below on other aspects of the current proposal.

4. **Alternative Methods**

As proposed, § 112.12 of the rule is inequitable in restricting the use of “alternative” methods to only the requirements in § 112.44(c) for testing water, § 112.54(c)(1) and (c)(2) for composting treatment processes, § 112.56(a)(1)(i) for minimum application interval for an untreated biological soil amendment of animal origin, and § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process. We propose that the same option of allowing alternative methods should be applicable to all required parameters of the rule. Further, we recommend that FDA specifically state that individual producers should be able to rely upon scientifically credible research and publications of commodity boards and trade associations that provide for such alternative measures.

5. **Variances**

Similarly, we believe that Subpart P of the rule, specifically § 112.171, is inadequate in restricting the ability to petition for a “variance” to state and foreign governments. Unlike “alternatives”, FDA proposes that “variances” can be submitted for any requirement in the rule. We propose that commodity boards and trade associations also be recognized as having standing to request a variance to the rule. Food safety risks and practices are rarely restricted to political boundaries. Commodity boards and trade associations are more likely to encompass the affected industry and are in a better position to consider and represent the risks and practices of the covered commodity. Petitions originating from the industry are no less credible, and require no less scientific support, than petitions originating from governments. Indeed, there is nothing in 21 CFR 10.30 that restricts submission of a citizen petition to state or foreign governments.

6. **Agricultural Water Metrics**

We agree with FDA’s conclusion that agricultural water that does not come in contact with the harvestable portion of the crop does not constitute a public health risk, and does not warrant any food safety standards, let alone mandatory testing at any frequency.

However, the proposed rule requires operations that use untreated water or water not from a municipal source for direct product contact pre-harvest to perform testing for generic *E. coli* at a frequency determined by the nature of the source. While this proposed standard may provide a “safe harbor” for operations that can meet it, the proposed rule sets an inappropriate level for the maximum number of generic *E. coli* before taking corrective action. In addition, the rule does not allow for alternatives to the test organism or the
frequency of testing. We strongly urge FDA to revise its agricultural water metrics in the rule for the following reasons:

- **Required testing for generic *E. coli***. The requirement to test for generic *E. coli* that FDA has proposed was established by the Environmental Protection Agency as an indicator of fecal contamination in recreational waters, not as an indication of the potential for foodborne pathogens. Published research in the past decade demonstrates that there is not a reliable correlation between generic *E. coli* presence or levels in agricultural water with human pathogen presence. While science has not yet identified a definitive indicator of the safety of agricultural water, we recommend that FDA allow for such a discovery in the future, and not limit the indicator of water safety to testing for *E. coli*.

- **Required maximum levels of generic *E. coli***. Again, using the EPA recreational water standard for fecal contamination of 235 CFUs generic *E. coli* per 100 mL is an inappropriate measure. FDA has provided no scientific rationale or justification for this testing beyond a single commodity and only on a single region’s data. We believe that current science is inadequate to justify a fixed test organism, number or testing requirement. At a minimum, FDA should recognize the global standard of 1,000 CFU/100 mL set by CODEX as appropriate for irrigation water. We urge that quantitative metrics like this would be more appropriately contained in companion FDA Guidance.

- **Required frequency of testing**. FDA proposes a weekly (every 7 days) testing of water sources that are open and susceptible to runoff. Some open water sources (e.g., lakes, ponds and reservoirs) have sufficient microbiological stability to make such a testing frequency unnecessary, regardless of being open to runoff, which can be demonstrated by a history of testing. In other sources (e.g., rivers and canals), the microbiological profile changes so rapidly that even weekly testing is meaningless; the water that is tested has moved downstream within minutes or hours and is no longer representative of the water being used later that same day. In this situation, there is no practical frequency to testing that is meaningful.

FDA also proposes that such testing must be “at the beginning of each growing season”. Research has revealed that human pathogens do not survive well on fresh produce in the field, and contaminations that occur early in a growing season may not survive to harvesting. FDA recognizes this in the *Quantitative Risk Assessment to Support the Proposed Produce Rule* (reference 42 in the proposed rule). In fact, emerging science appears to show significant and rapid degradation of pathogens in certain growing environments that would suggest only contaminations that occur near the time of harvest to be of significant public health concern. While science has not yet determined a definitive model for pathogen degradation, by fixing these proposed standards in the rule, FDA allows no modification based on future research or innovation.

We recognize that rulemaking is a complicated process, but also suggest that making any revisions to a finalized rule is even more problematic. FDA neither protects public health nor provides for use of emerging scientific information by inserting all of the water metrics discussed here in the final rule. Alternatively, we propose that FDA require in the rule a strong requirement that “All agricultural water must be safe and of adequate sanitary quality for its intended use” (§ 112.41), but relegate all quantitative standards and testing requirements, including any “safe harbor” standard, to companion Guidance.
7. Defining Regulatory Coverage by Farm Purposes
In both the Produce Safety and the Preventive Controls rules, FDA has proposed an untenable differentiation in standards and practices based on whether a facility is defined as a “farm.” While we recognize FDA’s intent to define “farms” for regulation under the Produce Rule, and “facilities” as operations that are required to register with FDA, as defined and described in 21 CFR part 1, subpart H, (and thus subject to the Preventive Controls Rule), we believe this to be an artificial restriction, creating more cost and confusion without enhancing public health in any way. Furthering muddying these false differences is FDA’s proposed new category of “mixed-type” facilities, which is not based on risk nor an understanding of actual operations in the produce industry.

United Fresh proposes that public health would best served by regulating facilities handling intact fresh produce under the Produce Rule, rather than the Preventive Controls Rule, as they represent a specific “farm purpose” in packing or holding raw agricultural commodities. There is a critical difference in the risk profile of food processing facilities versus packing/holding facilities for intact raw fruits and vegetables. Again, a one-size-fits-all approach that lumps produce packing sheds, warehouses and coolers together with food processing plants does not increase public health and is likely counterproductive. We will address this distinction further in comments on the Preventive Controls Rule. In order, however, to ensure that each docket for FSMA’s interlocking rulemakings are complete and that FDA can evaluate how the industry can be effectively and efficiently operate under the new FSMA rules, submitted to this docket as part of these comments is a copy of United Fresh’s comments on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. Docket No. FDA–2011–N–0920; RIN 0910–AG36.

8. Defining Regulatory Coverage by Farm Ownership
FDA has also proposed a convoluted scheme to regulate farms and facilities based on farm ownership and geography, both of which have nothing to do with safety standards and practices. We strongly recommend that all operations that serve the primary “farm purpose” of growing, packing, cooling and holding intact produce fall under the same standards, regardless of ownership of the facilities or ownership of the fruits and vegetables that are being packed or held. Numerous packing and holding facilities aggregate fruits and vegetables from more than one grower, independent of who might actually own the farm or the facility. In the fresh produce industry, actual ownership of a farm, packing operation or the produce itself might be the farm land owner, a grower leasing the land, an agricultural company managing production, or a buyer who has contracted with the produce being grown. Regardless, if all fruits and vegetables are required to comply with the Produce Safety Rule, as appropriate to the commodity, then ownership of the fruit or vegetable during growing is irrelevant to the risks incurred during packing and holding.

United Fresh is aware of some analysis that the proposed system is mandated by the existing facility registration requirements, 21 CFR Part 1 Subpart H. If that is the case, United Fresh strongly urges the agency to reconsider and redefine the “farm” definition to include any operation engaged in the primary farm purpose of growing, packing, cooling and holding intact produce under the Produce Safety Rule regardless of source. In this way, the simple act of aggregating produce from other operations – under the Produce Safety Rule – will not result in some operations moving back and forth between coverage by the Produce Safety rule and the Preventive Controls rule depending on sourcing of intact raw agricultural commodities – commodities that would all have to be grown and harvested under the Produce Safety rule in any event. If the agency declines to take this course, we respectfully request that it provide a full explanation of the legal, regulatory, scientific, and policy bases for doing so, beyond the singular fact that the facility registration requirements put in place pursuant to the Bioterrorism Act predate FSMA.
9. Supporting Comments
In addition to our concerns, we commend FDA on the regulatory approach taken for a number of proposed requirements. Specifically:

- FDA recognized that food safety resources should be allocated where public health is best served, by limiting the hazards covered in the rule to microbiological, not chemical or physical. There are already sufficient regulatory controls on the use of agricultural chemicals in the U.S. to make illnesses due to lack of control not reasonably likely to occur, as evidenced by FDA’s own historical data. Food allergens are rarely included in the growing and handling of intact fresh produce, except when the produce itself is a food allergen (i.e., tree nuts and peanuts). And most operations have already implemented sufficient controls to minimize the likelihood of physical hazards reaching consumers; e.g., washing, visual sorting, and mechanical separation devices such as gaps in rollers that do not need control to remove potentially harmful objects from produce. The rarity of injuries from physical hazards in fresh produce demonstrates the low risk. Therefore, we agree with FDA that regulatory requirements in this regulation should be limited to control of human pathogens.

- FDA recognized that certain risks, e.g., animal intrusion, can be minimized but not eliminated. Most produce is grown outdoors and, short of draconian measures, animal intrusion cannot be prevented. While fences, ditches and berms may dissuade larger animals from entering fields, little can be done to prevent smaller animals that may carry contamination, such as rodents, reptiles, amphibians and birds. We agree with FDA’s proposed approach that operations monitor growing fields for signs of significant animal intrusion and evaluate whether the level and degree of intrusion warrants corrective actions, such as not harvesting affected produce.

- In the companion Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce, FDA recognized that certain agricultural practices inherently represent less risk, e.g., application of agricultural water, and application of biological soil amendments of animal origin, in a manner that does not directly contact covered produce. FDA has appropriately responded to this qualitative assessment by avoiding unnecessary standards for those practices identified as lower risk. (However, a similar approach needs to be taken throughout the rule, with specific management practices in specific circumstances included in Guidance rather than the rule.)

- FDA proposes to require only those documents and records necessary to demonstrate compliance with the regulation; i.e., primarily records of required monitoring activities and corrective actions. For example, requirements for a written hazard analysis or food safety plan, such as proposed in the Preventive Controls for Food rule, would be unnecessarily burdensome, particularly to small operations, without significant public health benefit. FDA has already performed a hazard analysis for most operations by identifying in this proposed rule the hazards reasonably likely to occur during growing, harvesting and post-harvest handling. FDA has already communicated that future guidance will include control measures that operations can use to minimize the likelihood of those hazards affecting produce, and monitoring and corrective action records will demonstrate an operation’s level of understanding and compliance with those measures. We agree with FDA’s proposed requirement that any alternatives to final requirements used by an operation be provided to FDA officials upon request. Therefore, FDA should not need additional routine documentation beyond monitoring and corrective action records in order to evaluate an operation’s level of compliance to requirements.

- FDA does not propose that alternatives be pre-approved by FDA. FDA and the food industry learned that pre-approval of food safety plans can be a long, arduous task,
subject to unnecessary delays and bureaucracy, as evidenced by delays in preapprovals to comply with the Low Acid Canned Food and Acidified Food regulations (21 CFR parts 113 and 114). However, FDA should provide, perhaps in Guidance, a mechanism by which operations can have their alternatives reviewed if they so choose, e.g., by recognition of private sector experts in the same way that Process Authorities are recognized as able to evaluate thermal, aseptic and acidified food processes for certain regulated foods.

• And, finally, FDA recognized that sporadic contamination of fresh produce cannot be detected reliably by product testing, and did not include any requirements for product testing for commodities other than sprouts. Even under the most rigorous application of Good Agricultural Practices, fresh produce remains fresh and vulnerable to sporadic contamination from the environment. If produce is grown and harvested in compliance with this proposed Produce Safety regulation but is, in fact, contaminated with a pathogen, experience has demonstrated that the contamination is most likely to be sporadic (not uniform) and at a low frequency (i.e., less than 1%; data from several leafy greens companies operating under LGMA metrics put the frequency close to 0.2%). Indeed, experience with field testing has demonstrated that, generally, a “positive” test result cannot be repeated, even if the original sample site is GPS identified. Experience has also demonstrated that a positive test result from one part of a plant (e.g., the interior of a head of Romaine lettuce) usually cannot be replicated on other parts of the same plant. In this situation, testing results on any given piece of produce will not be representative of the “lot”, only of that piece of produce. This weakness continues through to testing of finished product coming from a packinghouse. Most statistical sampling protocols are based on an assumption of uniform contamination. Even under this false assumption, the number of samples necessary to detect, with a reasonable statistical confidence, contamination at a frequency less than 1% is impractical (ICMSF, volumes 2 or 7). Therefore, any “negative” test result is essentially meaningless. Even using the ICMSF class 15 sampling protocol for lots with uniform contamination (i.e., 60 samples), a negative test result for all samples only supports that any contamination is present at less than 5%. Consequently, even if test results are negative, companies are not protected from allegations of contamination and foodborne illness. A positive test result only means that the tested piece of produce was contaminated. It provides no depth of analysis with which to determine if this was the one contaminated piece in the lot, or one of many. Root causes of contamination are rarely discoverable, so a positive test result rarely leads to improvements in food safety procedures. Further, as test procedures become more sensitive, there is no measure with which to determine whether the detected pathogen actually presents a public health hazard. If the 0.2% frequency of detectable contamination in leafy greens cited above is accurate, and the industry sells 1 Billion servings of bagged salads per year in the U.S., we should expect daily multi-state outbreaks, which clearly is not the case. Therefore, there are likely unidentified factors reducing the expected public health impact of detected pathogens on fresh produce. Finally, the potential consequence of a testing program is over-reliance on the results. Anecdotal reports of operations that ignore violations in GAPs and safe handling practices because “the test results were negative” illustrate the potential food safety consequences. Therefore, reliance on controls that limit the introduction of hazards, limit the growth of pathogens, and/or serve to reduce the levels of hazards are preferred to finished product testing. More on this subject can be found in the Microbiological Testing of Fresh Produce White Paper published by the United Fresh Produce Association Food Safety & Technology Council, which is Attachment A to these comments. www.unitedfresh.org/assets/food_safety/MicroWhite%20Paper-%20Final.pdf.
Reassessment of the Preliminary Regulatory Impact Analysis (PRIA) on Produce Safety Rule

On January 16, 2013, the FDA released the Preliminary Regulatory Impact Analysis on the Produce Safety Rule. This analysis is required under Executive Order 13563 and 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Since its release, the fresh produce industry has closely examined this analysis and assumptions FDA used in the PRIA. Further, United Fresh and allied partner organizations commissioned an independent economic study of FDA’s PRIA by Informa Economics to gauge the relative accuracy this analysis contains to current produce industry food safety practices. The complete report is Attachment B to these comments. The industry study found several areas that call into question the overall economic cost estimates FDA has concluded in the PRIA. In particular this report identified two fundamental flaws:

- **FDA’s cost estimates do not adequately differentiate cost differences across crops or across production regions.** Due to the diversity of fruit and vegetable production in the U.S., the assumptions for compliance with the rule that are based on a particular crop or on the growing practices used in a particular region are often not representative of the average cost of compliance across the U.S. This analysis suggests that there are certain crops and regions of the country that are not thoroughly addressed in FDA’s cost analysis. For some provisions, the costs will vary substantially across the crops or growing conditions in a particular region. For example, the costs of complying with monitoring provisions may vary substantially for leafy greens when compared to tree crops.

- **FDA’s cost estimates are in some instances in disagreement with current average costs experienced by the produce industry.** Examples include:
  - Outdated wage rates and inconsistent application of wage rates throughout the report, and
  - A lack of cost estimates for replacing tools and equipment that were not able to be brought into compliance with FDA’s proposed rule.

Based on these concerns, it is clear additional research on the validity of the assumed costs presented is needed to understand the true economic impact on fruit and vegetable production. By underestimating the true costs of regulatory compliance, FDA not only underestimates the burden on growers, but also the inflationary price impact on fruits and vegetables and the commensurate negative effect on public health through reduced consumption.

The following chart highlights the potential increased cost using more accurate and current data on key areas under the proposed rule.
<table>
<thead>
<tr>
<th>Cost Description</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Reason for Alternative Assumption</th>
<th>FDA Estimated Cost</th>
<th>Alternative Estimated Cost</th>
<th>Increase above FDA Estimated Cost</th>
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<tbody>
<tr>
<td><strong>Labor Costs</strong></td>
<td>Labor rate of $14/hour for farm workers, $30.26/hour for farm managers, and $40.47/hour for farm operators.</td>
<td>Labor rates of $14.42/hour for farm workers, $33.47/hour for farm managers, and $50.18/hour for farm operators.</td>
<td>Updating outdated wage rates from 2000 to wage rates from 2012.</td>
<td>$66.0 million</td>
<td>$69.0 million</td>
<td>$3.1 million</td>
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<tr>
<td><strong>Water Testing and Sampling</strong></td>
<td>Average cost of water sampling of $87.30.</td>
<td>Average cost of water sampling of $120.05.</td>
<td>Higher expected cost of analysis and weighting is based on farm size. This impacted the cost of testing irrigation water and water or ice used for specified operations.</td>
<td>$10.8 million</td>
<td>$20.5 million</td>
<td>$9.7 million</td>
</tr>
<tr>
<td><strong>Irrigation Cost and Frequency</strong></td>
<td>Of the 7,146 covered farms that would test irrigation water more than once, half would test weekly and half would test monthly.</td>
<td>Of the 7,146 covered farms that would test irrigation water more than once, all would test weekly.</td>
<td>A higher expected frequency of irrigation use results in a more frequent expectation of testing.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inspection of Agricultural Irrigation Water Sources and Distribution Systems</strong></td>
<td>Large farms have 1 irrigation water distribution system to inspect.</td>
<td>Large farms have 2 irrigation water distribution systems to inspect.</td>
<td>Large farms have more irrigation facilities to inspect and thus the hours required to do inspections should be higher.</td>
<td>$17.5 million</td>
<td>$18.5 million</td>
<td>$920,539</td>
</tr>
<tr>
<td>Cost Description</td>
<td>FDA Assumption</td>
<td>Alternative Assumption</td>
<td>Reason for Alternative Assumption</td>
<td>FDA Estimated Cost</td>
<td>Alternative Estimated Cost</td>
<td>Increase above FDA Estimated Cost</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
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<td>----------------------------------</td>
</tr>
<tr>
<td>Recordkeeping for Agricultural Water Testing</td>
<td>Farm workers are responsible for keeping all relevant records.</td>
<td>Farm owners or farm managers would be responsible for recordkeeping.</td>
<td>Failure to keep appropriate records could be a significant liability for the farm, and interviews indicate it is likely that a farm owner or manager would take that responsibility.</td>
<td>$7.2 million</td>
<td>$24.4 million</td>
<td>$17.26 million</td>
</tr>
<tr>
<td>Recordkeeping for Equipment, Tools, Sanitation, and Maintenance</td>
<td>It takes 8 hours per very small farm and 25 hours per small or large farm to keep records. 29,766 farms must begin keeping records. Farm workers are responsible for keeping all relevant records.</td>
<td>Record keeping hours and the number of farms that need to keep records are expected to be 50% more than FDA’s estimates. Farm owners or farm managers would be responsible for recordkeeping.</td>
<td>Changes in hours of labor required, number of farms affected, and person responsible for recordkeeping were all indicated by interviews with industry associations.</td>
<td>Recordkeeping for cleaning worker tools: $5.6 million; Recordkeeping for cleaning machinery: $5.4 million</td>
<td>Recordkeeping for cleaning worker tools: $39.9 million; Recordkeeping for cleaning machinery: $37.6 million</td>
<td>$66.4 million</td>
</tr>
<tr>
<td>Preventing Contamination from Trash or Litter</td>
<td>It takes 2 seconds per acre average to comply with rule.</td>
<td>It takes 5 minutes per acre to comply with the rule for tree crops.</td>
<td>FDA’s estimated cost per acre is based on an expected minimum time to comply, but is not applicable to all crops.</td>
<td>$14.9 million for compliance for the entire industry</td>
<td>$19.3 million for compliance for California citrus industry only.</td>
<td>$4.4 million higher for a single state’s citrus industry than FDA’s national total for all crops.</td>
</tr>
</tbody>
</table>
Additional Specific Comments

A. § 112.3, definition of Direct water application method: “means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.” We agree with this definition, and encourage FDA to provide clarifying examples of application methods that are not direct, such as drip and furrow irrigation where any pathogen contamination is reasonably likely to be filtered by the soil before contacting the produce, including root crops like radishes, carrots and onions.

B. § 112.3, definition of Farm: “Farm includes: (i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership” In many fresh produce operations, “ownership” can be a complex situation. For example, the land may be “owned” by one person, who leases it to a grower, who grows the produce under contract to a buyer (i.e., the buyer “owns” the produce, even while in the ground). In such a scenario, which owner describes the farm? We provide this, and other examples of potential confusion and lack of clarity, as support for our Comment 8, above.

C. § 112.3, definition of Produce: “…vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food…” While FDA has provided examples of fresh produce covered by this rule, we believe this definition creates ambiguity whether edible parts, such as sunflower seeds and edible flowers, are within the intended scope of this rule. While not widely consumed in the U.S. today, dietary preferences can change, as noted above, and we see no reason to completely exempt such produce from this rule.

D. § 112.12(b): “You may establish and use an alternative to any of the requirements listed in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part…” FDA has not provided information, criteria or rationale with which operations can determine if an alternative provides the same level of public health protection, or even how FDA has determined the level of public health protection afforded by the requirements in this proposed rule. We respectfully request that FDA provide such information.

E. § 112.21(b): “All personnel...who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, must have the training, in combination with education or experience to perform the person’s assigned duties...” We agree with the provision for adequate training, but disagree with an additional requirement for “education or experience”. First, what level of education would be required for such duties, and who decides if an individual’s education was sufficient? Second, a requirement for “experience” would, by definition, preclude inexperienced workers from seeking such employment, although training could provide the knowledge with which to perform the tasks appropriately. However, we recognize that “education and experience” can replace the need for specific training. We recommend revising this requirement to read “…must have the training, education or experience to perform the person’s assigned duties…”

F. § 112.22(3)(c): “At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.” We recommend that FDA include a provision allowing personnel to be “otherwise
qualified through job experience”, in the same manner as allowed in 21 CFR parts 120 and 123 and in the proposed Preventive Controls for Food rule.

G. § 112.30(b): “You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.” While this is reasonable for personnel trained by the operation or during the operation’s employ, it is not reasonable for operations to be required to keep training records for personnel who received training at another operation or for contract workers (e.g., harvest crew, sanitation crew). We recommend that FDA revise this requirement to records of trainings performed or paid for by the operation, supplemented by additional records providing a rationale for personnel who did not receive such training at or by the operation.

H. § 112.42(a): “At the beginning of a growing season, you must inspect the entire agricultural water system under your control...” While “At the beginning of a growing season” may be reasonable for seasonal, single crop operations, it becomes confusing for year-round operations and for multiple crop operations whose “growing season” begins at different times of the year.” We recommend FDA clarify this requirement to read “At the beginning of a growing season or at least annually...” We further recommend that FDA clarify that this provision only applies to water systems used for covered produce; i.e., does not apply to water systems used exclusively for fields intended to be plowed under for soil management or for young orchards not intended to be harvested in the current growing season.

I. § 112.52(a): “You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to...water distribution systems.” As written, this provision forbids drip fertigation with biological soil amendments of animal origin, even if the material is not reasonably likely to contact covered produce. We recommend that FDA clarify this requirement to read “...such that it does not become a potential source of contamination to...water distribution systems, if such contamination may reasonably be likely to result in contamination of covered produce.” We further recommend that FDA provide clarifying examples in companion Guidance.

J. § 112.55: “The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.” FDA has provided no scientific rationale or justification for this testing and we believe that current science is inadequate to justify a fixed test organism, number or testing requirement. We recommend that quantitative metrics like this be relegated to companion FDA Guidance.

K. § 112.123(d)(2): “You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.” Non-food-contact surfaces are, by definition, not expected to come into contact with produce, and are rarely designed to be cleaned to the same level as food contact surfaces; for example, wooden trailers, tractors and vehicles. FDA’s intent in this requirement is not clear, nor how operations are expected to implement this requirement (what level of “clean” will be sufficient)?. Therefore, we recommend either provide clarifying examples, here or in companion Guidance, or deleting this requirement.

L. § 112.129(b)(2): “Be directly accessible for servicing, be serviced and cleaned on a schedule sufficient to ensure suitability of use...” It is not necessary for toilet facilities to be cleaned “on a schedule”, only that they be “...serviced and cleaned at a frequency sufficient to ensure suitability of use...”
M. § 112.130(d): “You may not use hand antiseptic/sanitizer or wipes as a substitute for soap and water.” While this may be true for current technology, this requirement prohibits the use of future innovation. We recommend revising this requirement to read “…as a substitute for soap and water unless validated by the manufacturer as effective for that purpose.”

N. § 112.165(c): “Electronic records, in compliance with part 11 of this chapter.” This simple requirement can create a significant burden on the fresh produce industry. While large operations may maintain records electronically and have invested in part 11-compliant software, the majority of farm operations, if they use electronic records, will maintain them on open software (e.g., Excel). According to part 11, “Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.” Few growers will have the computer training to implement this requirement themselves and will need to invest in expensive computer software or programming consultants to adapt existing systems to part 11-compliance, or revert to paper for required records. We recommend that FDA delete this requirement from the regulation without disallowing electronic records and provide, in Guidance, how operations should (not shall) protect electronic records from intentional or unintentional falsification. Doing so in no way relieves an operation from its responsibility to maintain accurate records.

O. § 112.162(a): “Offsite storage of records is permitted after 6 months following the date the record was made if such records can be retrieved and provided onsite within 24 hours of request for official review.” Operations, such as those that move seasonally or those that operate multiple growing sites, may retain their records at an offsite location routinely. We believe the “6 months” provision is unnecessarily burdensome and we recommend that FDA revise this requirement to read, “Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.”

The members of United Fresh hope that FDA finds value in these considered comments, and we stand ready to clarify or assist FDA in these recommended changes to the proposed rule.

Respectfully submitted,

David Gombas, Ph.D.
Senior Vice President
Food Safety and Technology
Microbiological Testing of Fresh Produce  
April 21, 2010

A White Paper on Considerations in Developing and Using Microbiological Sampling and Testing Procedures if Used as Part of a Food Safety Program for Fresh Fruit and Vegetable Products

OBJECTIVE

The purpose of this white paper is to briefly identify where a microbiological testing program may be useful and considerations to take for designing and implementing a program.

It is not the intention of this paper to establish specific microbiological testing recommendations or requirements for any fruit or vegetable product or commodity.

This paper was developed based on the best available current knowledge, and implications may change as more data are collected regarding the microbiology of fresh fruit and vegetable products.

INTRODUCTION

Food safety is an integral part of the production of all foods and the shared responsibility of all segments of the supply chain. In recent times there has been increased awareness for the need to evaluate the food safety practices in the production of agricultural products. Consumer demands for fresh and convenient forms of produce have led to the development of “Field to Fork” food safety practices in the fresh produce industry. The use of a microbiological testing program is one tool that may be used in the development and verification of a food safety program.

For purposes of this white paper, the term “produce” is synonymous with “fruits and vegetables”.

BACKGROUND

Microbiological testing is not a guarantee of product safety. It is one component of an overall food safety system. Before microbiological testing is initiated, prerequisite programs must be in place. These should include programs that are appropriate to the specific operation, such as: Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Sanitation Practices, Hazard Analysis Critical Control Point (HACCP), Traceability and Recall Management.

When sampling plans and methodology are properly designed and performed, microbiological testing can provide important information about an environment, a process, and even a specific product lot. However, when not properly designed and performed,
testing can provide inaccurate information that can easily be taken out of context and create unwarranted concerns or false reassurances about the safety of the product.

Proper testing design depends on a number of pre-sample factors, including:

- The intended purpose of the test
- The intended target organism that is being tested for
- Where the sample is in the supply chain
- The commodity under consideration, knowledge of the growing, harvesting, and processing control strategies;
- The region where the product is grown;
- The intended use of the product.
- The level of “stringency” required and level of “confidence” required to demonstrate that level of stringency is being achieved.

The design of microbiological testing programs is a complex process and microbiological testing is not a standalone program.

ASSESSING THE NEED TO TEST

Risk can easily be defined: it is the possibility that an undesirable outcome will occur. However, the quantification of risk in order to develop sound risk management programs is a much more daunting task. Developing a thorough understanding of the probabilities of all alternative outcomes throughout the process is the essential first step in determining the need to test. From a microbial food safety standpoint, this means identifying all the possible sources/points that pathogens may contribute to one of the two final, alternative outcomes: pathogen detected or not detected.

However, it is important to realize that microbiological testing can never determine whether a food is pathogen-free, unless 100% of the food is tested (and then there is nothing left to sell or eat). The most one can achieve with microbiological testing is “pathogen not detected” and understand the levels of sensitivity and confidence provided by the sampling plans and testing methodologies used. International organizations recommend testing only when there is good evidence that there is a microbiological problem and that testing will help to control the problem (Codex and ICMSF). Any misunderstanding in what is achievable by microbiological testing, and the limitations of such testing, will tend to waste resources, product and potentially create a worse food safety situation than if no testing was performed.

Why test?

Any testing program should be science-based and objective driven. Prior to implementation one should know why the testing is being performed, the basic assumptions underlying the test, the relative certainty of detecting an issue, and potential results. This will allow one to identify the type of samples to be collected, the sampling plan to be used, the specific test to be performed, and actions to be taken prior to and after the test results are obtained.

Typical reasons for testing in the fresh produce industry are:

1) Meeting product specifications (inputs and finished product)
2) Baseline development and identification of risk factors,
3) Process capability/validation,
4) Process verification,
5) Investigative testing and remedial activity verification, and
6) Verifying that regulatory guidelines have been met.

(1) Product specifications.

The most common reason for microbiological testing in the fresh produce industry today is to comply with a product specification. Inherent in any product specification are assumptions that the sampling and test methods will provide a standard deviation and level of confidence in test results such that the user of the result will “know” that their specification was or was not met. In reality, specifications are rarely set by statisticians, and users wrongly assume that the number they’ve selected is an absolute limit. Consequently, test and method developers must take these expectations into consideration when establishing sampling plans and interpretations of the results.

So, in a practical sense, specifications should identify:

- The product to be tested
- The frequency of testing (e.g., every fifth lot shipped to Customer)
- The sample size and how the sample is to be collected (e.g., a 125 g composite of five 25 g samples collected from the beginning, middle and end of the production run)
- The target organism
- Test method
- Acceptance criteria (examples: “not to exceed 10^6 cfu/g aerobic plate count”, “not to exceed 1000 cfu/g yeast and mold”, or “no detectable Salmonella or E. coli O157:H7 in 25 g”)
- Actions to be taken in the event that the acceptance criteria are exceeded.

Best practices dictate that any lots tested for pathogens are maintained in the supplier’s control until cleared by the test results.

(2) Baseline determination and identification of risk factors.

Prior to using microbiological testing to assess quality, safety or process verification, it is important to understand what’s statistically “normal”. Microbiological testing can be useful to understand the range of microbial populations that can be observed and how they may change by specific type of produce, growing and handling practices, season, weather, geography, environmental controls and other effectors that may not be as obvious. Baseline assessment should take place over a timeframe sufficient to capture the variability of interest, e.g., hourly, daily or seasonally.

Key elements of a baseline assessment are:

- Standardization of test methodology to enable comparing and compiling of data;
- Establishing the frequency, number of tests and/or period of time required to have confidence in the accuracy of the baseline;
- Managing such data through “control charting” (a graphic representation of the data) and/or in a database; and
- Analyzing for trends and patterns

(3) Process capability/validation.
Microbiological testing can be used to “validate” the process’ capability to reduce a particular or overall microbial population, or at least to ensure that the process does not allow microorganisms to grow or spread throughout a lot. Validations most often begin with whatever background microflora that comes with the test lot. It is important to have an accurate assessment of the variability (levels and type) of this target microflora in the starting material. Samples are collected at points in the process, to assess the impact of individual steps. Properly performed, a validation study may conclude that “under the conditions of this study, this process is consistently capable of producing product with an acceptable level of microbial quality.”

The benefits of a validated process are:

1) The operator understands the factors that are critical to control to produce reliable results
2) The operator understands the limits at which those factors must be maintained, and
3) Routine monitoring of the microbiological quality of individual lots can be greatly reduced.

(4) Process verification.

Process verification utilizes microbiological testing to “verify” (i.e., confirm) that the “process” performed as anticipated. Process verification differs from validation in that validation utilizes an initial, fixed, predetermined number of repetitions and tests, while verification involves periodic, ongoing testing. Process verification is intended to demonstrate your validated process is functioning as designed, i.e., one is not getting statistically significantly different results than those observed during the validation trials.

(5) Investigative testing and remedial action verification.

Microbiological testing can be a very effective tool to investigate sources and causes of an unexpected microbiological result. For example, if a process verification test indicates a much higher aerobic plate count than expected, or if an undesirable and unexpected microorganism is detected in a finished product, targeted microbiological testing can be used to:

a. investigate the source of the unexpected microorganisms
b. verify that remedial action was successful in eliminating the source.

(6) Verifying that regulatory guidelines have been met.

Microbiological testing can be used to demonstrate compliance to published regulatory guidelines or requirements.

A. Why Not to Test

1) Used as a substitute for sound process controls
2) Repeat testing to negate an unwanted or undesired result
3) “Prove” that a contaminated product is “safe”
(1) Process Control

Microbiological testing is not a substitute for a sound process. Process control, if achievable, will always be more effective and reliable than microbiological testing in assuring microbiological quality and safety.

(2) Unwanted/Undesired Results

An unacceptable microbiological result is always valid unless there is a sound reason (i.e. lab error) that the result may be false. Produce grown outdoors is subject to random environmental factors. This results in the microorganisms present to be non-uniform in distribution. Multiple testing of the same lot can provide very different results. Retesting and getting a “negative” result after getting a “positive” result does not negate the positive result.

(3) Contaminated Product

If a produce product becomes contaminated with a pathogen of public health significance, it is considered adulterated. Unless an acceptable, effective reprocessing method can be employed to eliminate the contaminant, the product cannot be “tested” into safety. The FDA does not currently recognize any reprocessing method, other than diversion to a cooked or otherwise pasteurized product, as an acceptable method to “clear” an adulterated fresh produce product.

B. What to test

In selecting what should be sampled and tested, first understand the objective of the test as noted in section A. Second, select samples or sampling points most likely to achieve that objective.

Items to consider when determining what to test are:

- What is the target microorganism of interest and where may it be observed?
- The expected prevalence of the microorganism in the product, process or environment: Is it commonly found or rarely found?
- The expected distribution of the microorganism in the product, process or environment: Is it uniformly distributed or a sporadic event?
- Are there practices (or failure to follow them), conditions, or events with a history of leading to contamination events? For example: Product flow fails to follow a raw to process pattern, which causes a mingling of raw product and processed product and potential cross contamination of the finished product

Where answers to these questions may indicate a need for testing, an evaluation must be done to determine the appropriate step in the process where testing may provide information that is most useful.

The following are examples of what could be subject to testing and the rationale for testing:

- Water: Generic E. coli, which may be present in irrigation canal water if fecal contamination has occurred, in levels and distributions depending on the source of the E. coli and, if present in high numbers, may indicate a fecal contamination which indicates the potential presence of human pathogens.
• Compost: Thermotolerant coliforms, which are expected to be present in raw manure in a generally uniform distribution and, if present in composted manure, may indicate incomplete composting.

• Environmental Testing: *Listeria spp.* are not expected to be present in the produce processing area. If present, *Listeria spp.* are expected to be distributed sporadically and, if detected, may indicate harborage of *Listeria monocytogenes*.

**When to test**

As with all aspects of microbiological testing, when to sample, the frequency of sampling/testing and the size/number of samples to analyze, should be objective driven. The timing or frequency of sampling and testing affect the likelihood of achieving the objectives of the testing.

**QUESTIONS TO ANSWER TO DETERMINE WHEN TO SAMPLE AND TEST**

1. What information do we want the test to give us?
2. Where are those test organisms most likely to be found?
3. Do we have any information or evidence of contamination or potential contamination?
4. When is contamination most likely to occur?
5. What is the expected prevalence of the target organism?
6. What is the expected distribution of the test organism?
7. What are the expected levels of the organism, if present?
8. Do we have sampling plans and testing methodologies available that can reliably detect the test organism at the expected distribution and levels, if present?
9. Will the test results be available in time to take action, if needed?

When testing finished product, the best time to sample the product would be after the last potential source of contamination, as defined by a hazard assessment. In the absence of a hazard assessment, then sampling might be performed as soon after completion of the process as feasible; e.g., after packaging or from shipping containers.

**Limitations of testing.**

Just as one should know why the testing is being performed, it is important to know that the reasons for testing are valid and that testing is an effective tool towards achieving the objective.

• **Microbiological testing is not a substitute for a reliable and validated process.** Ongoing, validated process control, if achievable, will be more effective and reliable than microbiological testing in assuring microbiological safety.

  o **Example** – real time monitoring and verification of antimicrobial levels in flume water provides actionable information for immediate process control, as opposed to microbiological testing which provides information after the fact and too late to take effective action.

• **Testing cannot assure the absence of pathogens.** There is a natural tendency to believe that a negative test result means the product is safe, even if a process goes out of control and there is reason to believe that the product may be contaminated. Before relying solely on a negative test result to affirm the safety of a material, remember there is truth to the adage, "absence of evidence is not evidence of
absence.” The effectiveness of microbiological testing to detect lots that are contaminated decreases when the defect rate (e.g., the percentage of contamination in a single produce item or lot of items) falls below approximately 5%

- **Product reconditioning.** FDA does not recognize any process (other than diversion to a product that is cooked or will otherwise receive pasteurizing treatment) for reconditioning fresh produce that may have been adulterated with pathogens.

**MICROBIOLOGY**

**C. Which microorganisms to test for**

Many different kinds of microorganisms can be found on fresh produce, and most have little to no effect on humans, even if consumed in large numbers. Only a relative few have the ability to cause human illness. Fresh and fresh-cut produce are not sterile products. The microorganisms present fluctuate greatly depending on the type and variety of produce, the season and weather, the growing conditions and locations, as well as the health and condition of the produce.

**Aerobic Plate Count**

- Aerobic plate count (APC), also known as Total Plate Count (TPC) is used as an indicator of the number of bacteria in a food product. APC only measures those microorganisms capable of growing at 30-37°C in the presence of oxygen.
- Aerobic plate counts are typically incubated at 35±1°C for 48±3 hours, but other temperatures (e.g. 25°C) may be used.
- It is not unusual for Aerobic Plate Counts on produce to range from thousands to millions (10³ to 10⁷/g) depending on the commodity. Many of these organisms cannot grow at the low temperatures used for storing fresh and fresh-cut produce, and fewer can grow in an oxygen-depleted atmosphere. Further, many of the organisms that can grow at low temperatures cannot grow at the higher temperature used for the APC test.
- It is important to remember that microorganisms detected by APC are usually not pathogens, APC results do not correlate well with the potential for pathogen contamination, and are not useful predictors of product safety.

- When to measure:
  1. Trend analysis of finished product microbial ecology
  2. Environmental indicator of sanitation processes
  3. Indicator of process control
  4. Have a reason to suspect that the microbiological quality of the product may be unacceptable.

- When not to measure:
  1. Indicator of safety
  2. Indicator of the presence or absence of pathogens
  3. Routine indicator of initial quality
  4. When baseline studies demonstrate that product or environmental conditions normally have a wide variability in microbial populations

**Psychrotrophs**
• Psychrotrophs are microorganisms capable of growing at refrigeration temperatures. They may or may not be able to grow at higher temperatures. The microorganisms capable of spoiling fresh produce under refrigerated conditions are psychrotrophs.

• Incubation parameter for psychrotroph growth is 7°C± 1°C for 4-10 days.

• Total Psychrotrophic Counts have been used by some as an indicator of microbial quality. Total Psychrotrophic Count is not generally considered a good indicator of potential pathogen contamination.

• When to measure:
  1. Profiling spoilage processes of refrigerated products

• When not to measure:
  1. Indicator of safety
  2. Indicator of the presence or absence of pathogens
  3. Indicator of initial quality
  4. When rapid results are necessary, because the test takes 4-10 days

**Yeast/Mold**

• A variety of yeast and molds are commonly found on fresh produce, usually at far lower numbers than bacteria. Yeast and molds tend to have the most effect on fruit quality, because of the higher sugar content and lower pH of many fruits.

• Yeasts and molds are typically grown at 20-25°C for 3-5 days. These organisms tend to grow more slowly than the bacteria detected by APC; slow enough that detection usually requires a test that inhibits the growth of bacteria.

• They are not important spoilage factors in fresh-cut vegetables because their growth is generally far slower than the enzymatic or psychrotrophic bacterial spoilage of the fresh-cut produce.

• It is highly unlikely that the yeast and molds typically found on fresh produce will cause illness, and they are not good indicators of potential pathogen contamination.

• When to Measure:
  1. Indicator of quality for fruit products
  2. Indicator of air quality in coolers and fruit packing facilities

• When not to measure:
  1. Indicator of safety
  2. Indicator of the presence or absence of pathogens
  3. When rapid results are necessary, because the test takes 3-5 days

**Coliforms**

• “Coliforms” includes a wide array of bacterial genera, and were so named because they were originally thought to grow only in an animal’s or human’s colon. It is now known that coliforms grow in a wide variety of environments.

• Incubation for coliforms occurs at 35±1°C for 24-48 hours.

• Because some coliforms are part of the natural flora of produce, they are not an accurate indicator of fecal contamination for these products. Consequently, coliform testing has limited value in fresh produce.

• When to measure:
  1. Indicator of potable water quality
• When not to measure:
  1. Indicator of safety of fresh produce
  2. Indicator of the presence or absence of pathogens in fresh produce
  3. Indicator of initial quality

Thermotolerant or “fecal” coliforms

• “Fecal coliforms” are coliforms that are able to grow at higher incubation temperatures
• Incubation for fecal coliforms is typically 44.5 - 45.5ºC for 24-48 hours.
• There has been a movement to rename this group “thermotolerant coliforms” because not all so-called fecal coliforms are of fecal origin. Because of this, care must be taken in interpreting the significance of fecal coliform results. For example, it may be very appropriate to verify the adequacy of a manure compost operation using thermotolerant coliforms to ensure that their numbers are reduced; however, testing fresh produce for this group of organisms may have questionable value since they can be part of the normal flora of the plants.
• Detecting thermotolerant coliforms does not necessarily indicate the presence of either fecal matter or pathogens.

When to measure:
  1. Indicator of proper compost treatment.

When not to measure:
  1. Indicator of safety of fresh produce
  2. Indicator of the presence or absence of pathogens in fresh produce
  3. Indicator of initial quality

Generic E. coli

• Generic E. coli are non-pathogenic. These organisms are ubiquitous to most animal, including human, digestive systems and are beneficial to digestive health.
• The minimum growth temperature for generic E. coli is about 7°C/45ºF, so it is unlikely to become established or grow in a fresh-cut processing environment when the environmental temperature is maintained at <4ºC/40ºF.
• Testing for generic E. coli using traditional most probable number (MPN) and direct plating methods typically take 48 hours at 35±1º C for results. Recent advances in microbiological testing have been able to reduce this time in some cases to a shorter period (e.g. 24 hrs for Colilert® water testing).
• Generic E. coli has long been used as an indicator of fecal contamination in water treatment because it is present in almost all fecal samples.
• Generic E. coli is generally considered a better indicator of the potential for fecal contact than APC or coliforms, but does not necessarily indicate the presence of pathogens.
• The levels of E. coli do not necessarily correspond to the initial level of fecal contamination in food products that support its growth, but may be indicative of conditions (e.g., temperature abuse) that could support the growth of mesophilic pathogenic bacteria.
• When to measure:
  1. Indicator of water quality
  2. Indicator of proper compost treatment
When not to measure:
1. Indicator of shelf life
2. Indicator of initial quality

Pathogen Testing

- A pathogen is any agent (bacteria, virus, etc.) that may cause human or animal illness or disease.
- Technology has advanced to permit direct testing for many pathogens in a relatively rapid manner.
- It is recommended that the selection of pathogen tests be “risk based”. That is, testing should be designed for pathogens that may be present based on historical or lot specific evidence. For example, the human pathogens *Staphylococcus aureus* and *Clostridium perfringens* are responsible for many foodborne illnesses every year, but neither has been identified as a pathogen of concern for fresh produce, so routine testing of fresh produce for either is unlikely to provide value.
- Considerations when testing for pathogens in fresh and fresh cut produce:
  - If present, the pathogens will usually be at such a low level, and so heterogeneously distributed, as to make it a “needle in a haystack” chance of detecting them by anything less than extensive product sampling.
  - A negative result does not necessarily mean that the product lot was pathogen-free. Properly designed, sampling, and testing for pathogens may be able to detect “gross contamination” (i.e., high frequency contamination events in the same field or produce lot at pathogen levels higher than normal), but is often unreliable in detecting the low levels of contamination that have typically been found when pathogens are detected in produce grown under GAPs (Good Agricultural Practices).
  - Since most test results will be negative, little data that can direct continuous improvement efforts are generated through pathogen testing.
  - Whenever testing for a pathogen, it is important to hold that product lot until cleared by the test results.

When to test:
1. When there is reason to suspect contamination with pathogens or fecal contact, either directly (e.g., animals) or indirectly (e.g., contaminated water or improperly treated compost).
2. When there are significant numbers of generic *E. coli* in water that have contacted the edible portion of the plant.
3. When there is evidence that prerequisite programs have not been properly or adequately followed.
4. When there is evidence that a food safety process is out of control.

When not to test:
1. When there is no reason to suspect contamination

Environmental Testing
Environmental monitoring programs are a commonly used tool to assess microbial contamination and to track sanitation effectiveness in a processing facility.

Aerobic Plate Counts or coliforms are used by some to measure the effectiveness of environmental sanitation, as virtually all non-sporeforming bacteria are expected to be eliminated by an effective sanitation program. However, microbiological testing has largely been replaced by ATP testing procedures, which provide real-time results of sanitation effectiveness. While ATP tests do not reliably correlate with microbial levels, experience has demonstrated the superiority of ATP tests as a sanitation monitoring tool.

Environmental monitoring for pathogens like *E. coli* O157:H7, *Salmonella* or *Shigella* is rarely done in fresh-cut operations because the typical environmental temperature in a fresh-cut operation is less than 40ºF, generally below the minimum growth temperature for most human pathogens, including the three mentioned, so such pathogens are not reasonably likely to be able to become established.

In fresh cut operations, environmental testing is often performed to detect the presence of *Listeria* which is able to grow at temperatures less than 40ºF. While, *Listeria* may be present on produce in the field, experience has demonstrated that, when it occurs, it is predominantly an environmental contaminant of processing facilities with cold and/or wet environments. Consequently, fresh-cut processors, like most ready-to-eat product processors, use environmental testing for *Listeria* spp. as an indicator to detect potential harborage of the pathogenic species *Listeria monocytogenes*.

Although *Listeria monocytogenes* is a potentially dangerous human pathogen, with a high mortality rate, fresh and commercially prepared fresh-cut produce has not been associated with a listeriosis outbreak in the U.S. since the early 1980’s, when listeriosis was first recognized as a foodborne human disease. Consequently, fresh and commercially-prepared fresh-cut produce are not considered high risk for *L. monocytogenes* exposure. However, a prudent fresh-cut processor will maintain an environmental monitoring program in the processing area for *Listeria* spp.

Monitoring for *Listeria* spp. in a raw material area is rarely useful, because transient positives of the organism are expected from field sources. However, with proper trimming, washing and other interventions, low levels of these transient pathogens are not expected to persist through the fresh-cut process.

Any microbiological monitoring is not usually advised in areas where fresh produce is not exposed, e.g., after packaging, as the risk of contamination from the environment is not reasonably likely to occur.

A single positive result for *Listeria* spp. in a non-food contact environmental sample of a processing area would not necessarily be a cause for concern because *Listeria* positives are often transient and non-repeating. However, a repetitive positive would be cause for investigation of the environment for potential harborage points, sanitation practices, and GMPs.

Product testing for *L. monocytogenes* is not often recommended, for the same reasons as noted above for pathogen testing, unless there was reason to believe that the risk of *L. monocytogenes* presence was higher than normal.

When to test:
1. As part of a routine environmental monitoring program of fresh-cut processing areas for *Listeria*.
2. If contamination is suspected.

When not to test:
1. For environmental monitoring of areas where conditions are not typically favorable for the harborage of *Listeria*.
2. When ATP testing can be used to provide real-time results.
3. When the target organism is not reasonably likely to colonize the environment.
4. In raw product areas where transient *Listeria* positives from the field are expected.
5. In areas where finished product is not exposed to a risk of environmental contamination (e.g., fresh-cut salads after packaging).

D. Test methods to use

The selection of test method is often dictated by the conditions of the test, such as the target organism, the material or surface to be tested, whether testing for presence/absence or for quantitative levels, and how soon the results are needed.

Standardization of test methods enables comparing and compiling data with others who may be conducting similar tests in different regions. This allows the management of such data in a database that brings more value than the individual test results by facilitating trend analysis, pattern identification, and input for risk analysis. For example, when evaluating the microbiological quality of a common water supply, pooling data for that water supply from a number of sources would accumulate data to establish a baseline of expected results, and more quickly to potentially identify a possible source of contamination. This type of testing has a great potential to identify and prioritize risks, and subsequently control strategies to reduce risks that warrant control.

**Validated Methods**

Ideally, the test method used has been validated for the target organism and for the material being tested to ensure accuracy, precision, and reproducibility.

Important points to consider in the selection of a method:

- It has been validated for the material of interest.
- It has been validated against an internationally recognized official method such as AOAC International or Bacteriological Analytical Method (BAM).
- It has been validated through an independent validation study (internal or third party)

The importance of selecting a properly validated method cannot be overstated. Historically there was little interest in testing fresh produce therefore many available testing methods have not been specifically validated for fresh produce applications. This is particularly true for more recently developed, rapid methods.

**Types of Test Methods**

While there are wide ranges of technologies for the detection of microorganisms, the three most common commercially available types are: cultural, immunoassay, and PCR.

- Cultural Methods
  - Cultural methods are typically tests that allow the target organism, if present, to grow to levels that can be seen or otherwise detected.
  - Historically, cultural methods have been the tests of choice for fresh produce. However, because of recent developments in the methods and validation studies, immunoassay and PCR methods are becoming more accepted.
  - Cultural methods can show the presence/absence of an organism (qualitative) or can provide information on the number of organisms present through plate counts or Most Probable Number/MPN (quantitative).
Produce plating methods can produce a live, isolated sample that can be further tested to verify the results. MPN methods require additional handling to produce a live, isolated sample for further testing. Plating methods are relatively insensitive, with a minimum level of detection of about 10-100 cfu/gm (colony forming units per gram of test material), unless paired with a cultural pre-enrichment. MPN methods can be more sensitive, with a minimum level of detection of about 1 cfu/g.

- Time to obtain results can range from 12 hours to more than a week.

- **Imunoassay:**
  - One common, commercially available type is ELISA (Enzyme-Linked Immuno Sorbent Assay, i.e. “dip stick” or “pregnancy test” type method or 96-well methods).
  - Uses antibodies to detect specific proteins that are expected to be unique the target microorganism.
  - Methods are typically presence/absence tests but some can be quantitative.
  - Immunoassay methods are only sensitive if paired with a cultural enrichment.
  - Results are usually obtained in 24-48 hrs, including time for cultural pre-enrichment.
  - Additional cultural handling is required to produce a live, isolated sample for further testing.
  - Have been known to be susceptible to false negative and false positive results with various produce matrices.

- **PCR (Polymerase Chain Reaction) Methods:**
  - This type of test recognizes pieces of DNA or RNA that are expected to be unique to the target microorganism.
  - PCR methods are typically presence/absence tests but some can be quantitative.
  - PCR tests can be rapid and sensitive methods, particularly if paired with a cultural pre-enrichment.
  - Results are usually obtained in 24-48 hours, including time for cultural pre-enrichment, although results can be obtained in less than a day if pre-enrichment is not used.
  - Additional cultural handling is required to produce a live, isolated sample for further testing.
  - Validated PCR tests rarely cross-react with other non-target microorganisms.

**Confirmation Testing**

During initial screening of a food product for a pathogen, most microbiological tests, particularly presence/absence tests, are designed to provide either a “negative” result, where no further testing is required, or a “presumptive positive” result, which requires further testing. A presumptive positive result is NOT a positive result until confirmation testing is performed.

Many test kits that are designed to detect the presence of one specific target organism (such as *Salmonella*) can also detect organisms that are similar to, but not, the target organism. This situation yields a “false positive” or “presumptive positive” result.

A false positive is when the test, taken to completion, yields a result that the target organism is present, when it really is not. A key aspect of the method validation process is to determine the frequency and causes of false positive results, so that users of the test can be aware and take steps to detect false positive results.
A presumptive positive, on the other hand, is when the test detects an organism that might be the target and cannot quickly yield a result that the target organism is not present. Many tests are designed with a screening feature, that can indicate that no organism matching the target organism is present, quickly clearing the tested material. When a presumptive positive result occurs, the test must be taken to completion to “confirm” whether the detected organism is the target organism or only an organism that behaves similarly in the test. It is important to understand that a presumptive positive that is confirmed as “negative” is not a false positive; a presumptive positive is only a preliminary indication that the target organism may be present.

There may be occasions that justify using a second validated test to further confirm the results of the first test, such as when a test result is unexpected. However, it is important that such confirmation testing be performed only with the original sample or enrichments from the original sample. Testing a different sample, even if it is a "split sample" of the original, cannot be used to negate a positive finding in the first sample.

II. DEVELOPING A TESTING PROGRAM

Determining the quantity of samples

Selecting an appropriate number of samples to test, and understanding the level of confidence in the result that those samples represent, is one of the biggest weaknesses in microbiological testing of fresh produce today. Too frequently, a testing protocol or customer specification will state the maximum acceptable number (e.g., <1000 coliform/g, or none detected in 25 g) and either provide no number or some low number of samples to test, expecting that any sample tested will provide 100% confidence in the result. The International Commission on Microbiological Specifications for Foods (ICMSF, volume 7) examined the statistical confidence of test results on the basis of samples tested, and reported that the probability that a test result will give a false sense of security depends on what level of contamination is present, what percent of the lot is actually contaminated at that level, and how many samples are tested.

Table 1, adapted from ICMSF volume 7, Table 7-1, shows the probability of accepting a contaminated lot (i.e., getting an acceptable test result on a lot that is actually contaminated) on the basis of contamination rate and the number of samples tested.

<table>
<thead>
<tr>
<th>Composition of lot</th>
<th>% probability of accepting a defective lot at the number of sample units tested from that lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>% acceptable</td>
<td>% defective</td>
</tr>
<tr>
<td>98</td>
<td>2</td>
</tr>
<tr>
<td>95</td>
<td>5</td>
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<td>90</td>
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<td>20</td>
<td>80</td>
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<tr>
<td>10</td>
<td>90</td>
</tr>
</tbody>
</table>
Table 1. *< means less than a 0.5% probability

From the table, one can see, for example, that if a test result is based on 3 samples tested, there is less than a 0.5% chance of missing the contamination if the lot is 90% contaminated, but a 94% chance of missing the contamination if the lot is 2% defective (2 of every 100 leaves or fruit or other unit). At contamination rates less than 2%, one is virtually guaranteed to miss the contamination if testing only 3 samples. The table also shows that if one is trying to detect lots that are 2% contaminated, testing 100 samples would still leave you with a 13% chance of missing the contamination (collecting 100 samples and compositing them may or may not improve the chances of detecting contamination, depending on the test and whether it has been validated for compositing). While increasing the number of samples to be tested would seem an obvious solution, the table shows that one would have to test an impractical number of samples to detect low levels of contamination with any reasonable level of confidence. Taken to the extreme, the only way to achieve near 0% chance of missing a lot contaminated at very low levels would be to test everything. So, if one wants to determine if a lot is contaminated based on, for example, 5 samples, one can either accept good confidence of detecting gross contamination (1% chance of missing a lot contaminated at 60%) or poor confidence of detecting low level contamination (90% chance of missing a lot contaminated at 2%).

Ensuring proper sample collection

The accuracy of a test is as dependent on proper sampling technique as on the test itself. Ideally, sample-handling procedures are defined for the specific test method, and all training on sample collection recorded. The following can be used as general guidelines:

- **Training in sample collection** – The sample collector must be trained on how the sample is to be collected, including where and when in the process, how much sample, and specific methods and techniques for collecting the sample.

- **Aseptic technique** – The sample collector must be trained in aseptic sampling procedures. This minimizes the potential for contamination from other sources, including the individual collecting the sample, and from causing a false positive reaction. When aseptic sampling is not practical, such as sampling water at the end of irrigation line, the use of sterile containers and sanitized gloves or handling utensils and careful handling procedures will help minimize the potential for sample contamination.

- **Traceability** – It is essential that all samples, regardless of number, be clearly and accurately identified. At a minimum, a sample should have the following identification information: sampling date and time, sample location or other relative identification, and the person performing the sampling. Depending on the product, additional information such a lot code and sample ID number may be required.

- **Temperature control** – Unless specified otherwise by the test method, fresh produce, water and environmental samples should be chilled (32°-40°F) as soon after collecting the sample as practical and kept cold, without freezing, until tested. A time/temperature recorder, or other device to verify proper temperature control, is recommended if the samples are shipped or held for more than a few hours before testing.

- **Time Dependency** – Even at low temperatures, microorganisms in the sample may grow or die if held for too long before testing, potentially causing erroneous results. Samples should be tested as soon after collection as practical, but should be within
24 or 48 hrs, depending on the test, with < 30 hrs (1 day) highly recommended, especially for environmental swab samples.

- **Sample Handling** – Even when all sampling procedures and techniques are followed, the result will only be as good as the final sample handling. Samples must be handled in an aseptic manner with sterile supplies. Only sterile bags and dilution bottles are to be used. All media need to be properly sterilized before use and when possible, use pre-made media. Work areas must be sanitized and supplies such as pipettes, used in an aseptic manner.

- **Negative Control** – Negative controls should be included as part of sample collection to ensure that proper technique was employed and cross contamination was avoided. The negative control samples should be handled in a manner identical to that of all other samples within the lot. Collection data, storage and handling should be identical to that of true samples to be tested.

**Selecting a Sample Site**

The selection of a sample site must reflect the intended goal of the testing program. This may include the product itself, product-contact environmental, non-product contact environmental, field or water samples.

Some examples of sample site selection follow:

- **Example 1**: Raw agricultural commodity testing prior to harvest:

  If it is a general field-testing program, samples must be taken from areas that clearly represent the field. On the other hand, if there is a need to identify the possible effect of a localized contamination, such as animal intrusion in a field, then sampling should be restricted to only the affected areas.

- **Example 2**: Measuring the effectiveness of antimicrobial treatments in process wash water at various concentrations:

  If the goal is to validate the effectiveness of an antimicrobial treatment in process wash water, samples taken at the point of the flume where antimicrobial is added may provide misleading results. Sampling should be conducted near the end of the flume in addition to the beginning to clearly identify the treatment’s efficacy.

- **Example 3**: Process verification of sanitation effectiveness.

  Testing can be used for process verification; i.e., was this run of the process as effective as expected? In order to measure how effective sanitation is in a processing environment, product-contact and non-product contact surfaces may be selected as sampling sites.

When identifying sample sites, one must consider:

- Does the site reflect the product in its “intended use” state?
- Can a representative sample be obtained at the site with reasonable control of preventing contamination?
- Is there a more representative site?

**Actions based on results**
Prior to implementing any testing program, identification of what the results will mean and any subsequent actions that will need to be taken must be clearly identified. Unless there is a reason to suspect the result was not accurate (e.g. lab error identified by not following a written laboratory protocol), all results must be considered valid and actionable. One must remember that microorganisms may not be uniformly distributed in samples.

Examples:

a. APC in a fresh diced onion sample can have an initial count of 95,000 cfu/g, but when ten samples are analyzed, this 95,000 cfu/g sample is found to range from 75,000 cfu/g to 200,000 cfu/g. All results would be valid.

b. A sample of spinach may have a generic *E. coli* count of 20 cfu/g. But when nine additional samples are tested, all are observed to be <10 cfu/g. Finally, the product is tested using an MPN method and a result of <2.2 MPN/g is observed. The 20 cfu/g is still a valid result. None of the <10/g results rule out the initial result. Looking closer, the average of the 20 cfu/g and the nine <10/ cfu/g is 2 cfu/g, which is also consistent with the MPN reading of <2.2 MPN/g. The 20 cfu/g remains a valid result.

Knowing there is a possibility that an unexpected or undesired result may (and will) occur, a clearly defined course of action must be in place. This may include an applicable pasteurization or sterilization treatment, or destruction of the product.

In all cases, including regulatory sampling, it is highly recommended that product subject to pathogen testing should remain on “hold” status, within company custody and control, until the results of all testing are complete and all results are negative for the product. If there are multiple samples taken of a lot, and one sample is found positive, none of the negative results negates the positive result. The lot is positive for the pathogen and the appropriate predetermined action must be implemented.

**SUMMARY**

Microbiological testing during the processing of fresh produce is a tool that may be of value in verifying the integrity of the product as it passes though each segment of the supply chain. However, if testing is used, it would be but one component in the development of any “Field to Fork” food safety program that includes programs such as Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), HACCP, Traceability and Recall Management.

A proper testing program must have clearly defined the intended purpose of the test, the organism of concern, logical and defined sampling locations in the supply chain, the use of appropriate and validated methods, and defined actions based on the potential results.

If not properly designed and implemented, microbiological testing can provide unreliable information that can easily be taken out of context and create unwarranted concerns or false assurances about the safety of the product.

Though microbiological testing cannot assure the absence of pathogens, microbiological testing can provide important information about an environment, a process, and even a specific product lot, when sampling plans and methodology are properly designed and performed.
RESOURCES

The following resources may provide additional information and assistance in the development of a microbiological sampling and testing program for fresh product applications. Note: These resources are not all inclusive.


Official Methods of Analysis of AOAC International (2007) 18th Ed., AOAC INTERNATIONAL, Gaithersburg, MD


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April 21, 2010
Economic Impact of FDA’s FSMA Produce Safety Rule

informa economics

Prepared for:

United Fresh
PRODUCE ASSOCIATION

August 2013
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Disclaimer

This report was produced for the United Fresh Produce Association (“UFPA”). Informa Economics, Inc. (“Informa”) has used the best and most accurate information available to complete this study. Informa is not in the business of soliciting or recommending specific investments. The reader of this report should consider the market risks inherent in any financial investment opportunity. Furthermore, while Informa has extended its best professional efforts in completing this analysis, the liability of Informa to the extent permitted by law, is limited to the professional fees received in connection with this project.

Acronyms

BLS  Bureau of Labor Statistics
CASS  California Agricultural Statistics Service
CDFA  California Department of Food and Agriculture
FDA  Food and Drug Administration
FSMA  Food Safety Modernization Act
NASS  National Agricultural Statistics Service
USDA  United States Department of Agriculture
I. EXECUTIVE SUMMARY

Informa Economics (“Informa”) reviewed three key areas of the Food and Drug Administration’s (FDA’s) economic cost analysis of the proposed Produce Safety Rule issued under the authority of the Food Safety Modernization Act (FSMA):

- Agricultural Water (excluding sprouts)
- Domestic and Wild Animals
- Equipment, Tools, Buildings, and Sanitation (excluding sprouts)

Informa found several areas of the overall economic cost estimate\(^1\) to be in question. When errors or omissions were identified, these primarily were due to the following reasons:

- **FDA’s cost estimates does not adequately differentiate cost differences across crops or across production regions.**
  Due to the diversity of fruit and vegetable production in the U.S., the assumptions for compliance with the rule that are based on a particular crop or on the growing practices used in a particular region are often not representative of the average cost of compliance across the U.S. Informa’s analysis suggests that there are certain crops and regions of the country that are not thoroughly compared in FDA’s cost analysis. For some provisions, the costs will vary substantially across the crops or growing conditions in a particular region. For example, the costs of complying with monitoring provisions may vary substantially for leafy greens when compared to tree crops.

- **FDA’s cost estimates are in some instances in disagreement with current average costs experienced by the produce industry.** Examples include:
  - Outdated wage rates and inconsistent application of wage rates throughout the report, and
  - A lack of cost estimates for replacing tools and equipment that was not able to be brought into compliance with FDA’s proposed rule.

Of the three sections examined, Informa was able to quantify significantly underestimated costs for both agricultural water and for equipment, tools, sanitation, and maintenance, and still has concerns about the costs described in the domesticated and wild animal section of the proposed rule.

Additional research by the FDA on the validity of the assumed costs is needed in ensuring that fruit and vegetable growers do not face an undue burden to comply with the proposed rule. This report provides alternative assumptions and

\(^1\) Informa did not examine the FDA approach or valuation estimates regarding the economic benefits of the proposed Produce Safety Rule.
updated cost estimates for certain portions of the proposed rule. Exhibit 1 highlights major examples of higher costs of the proposed rule than those estimated in FDA’s analysis.

### Exhibit 1: Summary of Revised Costs of FSMA Produce Safety Rule Provisions

<table>
<thead>
<tr>
<th>Cost Description</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Reason for Alternative Assumption</th>
<th>FDA Estimated Cost</th>
<th>Alternative Estimated Cost</th>
<th>Increase above FDA Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor Costs</td>
<td>Labor rate of $14/hour for farm workers, $30.26/hour for farm managers, and $40.47/hour for farm operators.</td>
<td>Labor rates of $14.42/hour for farm workers, $33.47/hour for farm managers, and $50.18/hour for farm operators.</td>
<td>Updating outdated wage rates from 2000 to wage rates from 2012.</td>
<td>$66.0 million</td>
<td>$69.0 million</td>
<td>$3.1 million</td>
</tr>
<tr>
<td>Water Testing and Sampling</td>
<td>Average cost of water sampling of $87.30.</td>
<td>Average cost of water sampling of $120.05.</td>
<td>Higher expected cost of analysis and weighting is based on farm size. This impacted the cost of testing irrigation water and water or ice used for specified operations.</td>
<td>$10.8 million</td>
<td>$20.5 million</td>
<td>$9.7 million</td>
</tr>
<tr>
<td>Irrigation Cost and Frequency</td>
<td>Of the 7,146 covered farms that would test irrigation water more than once, half would test weekly and half would test monthly.</td>
<td>Of the 7,146 covered farms that would test irrigation water more than once, all would test weekly.</td>
<td>A higher expected frequency of irrigation use results in a more frequent expectation of testing.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspection of Agricultural Irrigation Water Sources and Distribution Systems</td>
<td>Large farms have 1 irrigation water distribution system to inspect.</td>
<td>Large farms have 2 irrigation water distribution systems to inspect.</td>
<td>Large farms have more irrigation facilities to inspect and thus the hours required to do inspections should be higher.</td>
<td>$17.5 million</td>
<td>$18.5 million</td>
<td>$920,539</td>
</tr>
</tbody>
</table>
## Economic Impact of FDA’s FSMA Produce Safety Rule

<table>
<thead>
<tr>
<th>Cost Description</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Reason for Alternative Assumption</th>
<th>FDA Estimated Cost</th>
<th>Alternative Estimated Cost</th>
<th>Increase above FDA Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recordkeeping for Agricultural Water Testing</strong></td>
<td>Farm workers are responsible for keeping all relevant records.</td>
<td>Farm owners or farm managers would be responsible for recordkeeping.</td>
<td>Failure to keep appropriate records could be a significant liability for the farm, and interviews indicate it is likely that a farm owner or manager would take that responsibility.</td>
<td>$7.2 million</td>
<td>$24.4 million</td>
<td>$17.26 million</td>
</tr>
<tr>
<td><strong>Recordkeeping for Equipment, Tools, Sanitation, and Maintenance</strong></td>
<td>It takes 8 hours per very small farm and 25 hours per small or large farm to keep records. 29,766 farms must begin keeping records. Farm workers are responsible for keeping all relevant records.</td>
<td>Record keeping hours and the number of farms that need to keep records are expected to be 50% more than FDA’s estimates. Farm owners or farm managers would be responsible for recordkeeping.</td>
<td>Changes in hours of labor required, number of farms affected, and person responsible for recordkeeping were all indicated by interviews with industry associations.</td>
<td>Recordkeeping for cleaning worker tools: $5.6 million; Recordkeeping for cleaning machinery: $5.4 million</td>
<td>Recordkeeping for cleaning worker tools: $39.9 million; Recordkeeping for cleaning machinery: $37.6 million</td>
<td>$66.4 million</td>
</tr>
<tr>
<td><strong>Preventing Contamination from Trash or Litter</strong></td>
<td>It takes 2 seconds per acre average to comply with rule.</td>
<td>It takes 5 minutes per acre to comply with the rule for tree crops.</td>
<td>FDA’s estimated cost per acre is based on an expected minimum time to comply, but is not applicable to all crops.</td>
<td>$14.9 million for compliance for the entire industry</td>
<td>$19.3 million for compliance for California citrus industry only.</td>
<td>$4.4 million higher for a single state’s citrus industry than FDA’s national total for all crops.</td>
</tr>
</tbody>
</table>

Note: Assumptions have been simplified or abbreviated for inclusion in this table. Additional detail is available in the full report. Figures may not add due to rounding. Source: FDA and Informa

The results present in Exhibit 1 suggest that additional research on the costs of the Produce Safety Rule is needed to ensure that crop producers are not unduly harmed by the rule and that the expected benefits are achieved.
Informa's analytical focus was on three sections of the proposed Produce Safety Rule. Informa did not attempt to validate every assumption made by FDA. Instead, the focus was on those aspects that industry, via interviews with regional and crop industry representatives, indicated as being potentially underestimated or on assumptions that had the potential to have significant cost implications. If an assumption was not included in the analysis presented, it was due to lack of verifiable information to develop alternative assumptions or because available information was conflicting or not broadly focused to provide an accurate or defendable estimate. Informa expects that further analysis and primary research would bring more clarity of the costs presented in FDA's economic impact analysis into question. However, Informa's analysis found sufficient inconsistencies and inaccuracies in FDA's economic cost analysis that question FDA's overall cost estimates and suggest a more detailed and crop-specific review is necessary.

Based on the findings of this report, Informa recommends that FDA's costs estimates of the economic cost analysis be further reviewed before the proposed Produce Safety Rule is finalized to include:

- Additional quantitative analysis that reflects updated or more accurate estimates of the costs associated with specific requirements, and
- Cost estimates for a wider set of products and regions; that is, as opposed to generalizing estimates from one or a few products/regions to all products and regions.
II. INTRODUCTION

A. Background on Proposed Produce Safety Rule

The FDA Food Safety Modernization Act, or FSMA, was passed by the 111th Congress in December 2010 and signed into law in January 2011. The legislation focuses primarily on the foods regulated by the Food and Drug Administration (FDA) and extended a new structure and new authority to the FDA. The law specifies a need for increased inspections at food facilities, increased record-keeping requirements, and extended on-farm oversight. Other extensions include more oversight of food processing, manufacturing, and shipping facilities; increased scrutiny of food imports, and establishment of “performance standards” for the most significant food contaminants.

In order to implement FSMA, FDA has issued the FSMA Proposed Rule for Produce: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, or the “Produce Safety Rule.” The proposed standards focus on the commonly identified routes of microbial contamination of produce, including agricultural water; equipment, tools, and buildings; and domestic and wild animals. The proposed rule applies to farms that grow, harvest, or pack most fruits and vegetables. There are exceptions for certain produce items that are rarely consumed raw, items with a kill-step involved in processing, and for farms of a certain size or meeting other criteria. FDA’s estimated cost and benefit for three selected sections of the proposed Produce Safety Rule are given in Exhibit 2.

Exhibit 2: FDA’s Estimated Costs for Selected Portions of the Produce Safety Rule

<table>
<thead>
<tr>
<th>Section of Produce Safety Rule</th>
<th>FDA’s Estimated Cost</th>
<th>FDA’s Estimated Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very Small Farms</td>
<td>Small Farms</td>
</tr>
<tr>
<td>Agricultural Water</td>
<td>$32.6</td>
<td>$8.0</td>
</tr>
<tr>
<td>Domestic and Wild Animals</td>
<td>$10.3</td>
<td>$6.0</td>
</tr>
<tr>
<td>Equipment, Tools, Buildings, and Sanitation</td>
<td>$15.7</td>
<td>$10.6</td>
</tr>
<tr>
<td>Total Cost for These 3 Sections of Produce Safety Rule</td>
<td>$58.7</td>
<td>$24.5</td>
</tr>
</tbody>
</table>

Note: Agricultural Water costs include agricultural water recordkeeping costs. Equipment, Tools, Buildings, and Sanitation costs include recordkeeping costs to clean/sanitize tools and to clean machinery.

Source: FDA.
B. Objective and Approach

FDA released a Preliminary Regulatory Impact Analysis along with the proposed Produce Safety Rule. Informa reviewed the FDA’s analysis of the costs of three components of the proposed rule and developed its own conclusions on those costs. The three areas are:

- Agricultural Water (excluding sprouts)
- Domestic and Wild Animals
- Equipment, Tools, Buildings, and Sanitation (excluding sprouts)

Informa examined the cost of the proposed rule in each of these areas, including an analysis of which costs are most critical and what additional costs should be considered. Specific examples are provided to illustrate FDA’s underestimation of the costs of the proposed Produce Safety Rule, and specific references to the assumptions used in FDA’s impact analysis are provided.

- FDA’s impact analysis contains hundreds of assumptions necessary to calculate the costs of the proposed rule.
  - While these were generalized for all produce crops, they impact each of dozens of produce crops differently.
  - Some crops will face higher or lower costs of compliance than the average estimated by FDA.

- As such, it was not possible for Informa to examine every assumption for every crop made by FDA in its analysis of the costs of the proposed Produce Safety Rule.

- Instead, Informa focused its analysis on the assumptions that were most likely to significantly impact the expected costs of the proposed rule.
  - Informa also utilized information on particular crops to assess whether a particular cost would have a more significant impact on certain crops, and looked for instances where flexibility in the rule might benefit producers.
III. COSTS OF PROPOSED PRODUCE SAFETY RULE

As with any new regulation, the parties regulated by the Produce Safety Rule will be faced with additional costs in order to ensure compliance. While the U.S. produce industry has several programs in place to address produce safety, and further, many farms carry out the practices that are recommended by FDA as a part of their own good agricultural practices programs, there are many provisions of the Produce Safety Rule that will require substantial investment, labor, and recordkeeping. As written, the rule does not address the differences in production practices or (non-kill step) packing and processing of different types of produce destined for raw human consumption. If these issues are not addressed in the final rule or in guidance documents to the industry related to the rule, then there will be significant costs to produce growers without a guarantee of an improvement in food safety.

A. General Assumptions

There are a few key assumptions used by FDA that are essential to understanding the economic impact analysis FDA conducted.

FDA’s analysis is based on the size of farms impacted, with the assumption that there are efficiencies of scale and other reasons that costs would vary from very small farms to large farms. FDA’s definitions of the three farm sizes used in its economic impact analysis are:

- **Very Small Farm**: Farm with production of $250,000 or less in total monetary value of food per year.
- **Small Farm**: Farm with production of more than $250,000 and no more than $500,000 in total monetary value of food per year.
- **Large Farm**: Farm with production of more than $500,000 in total monetary value of food per year.

FDA bases its cost analysis on potential differences in the costs of complying with the proposed rule for farms of these three sizes. It is important to understand the different farm size categories used by FDA when it, for example, refers to differences in the number of employees, hours required to complete a task, number of pieces of equipment, or other assumptions used.
1. Labor Cost Assumptions

(a) FDA and Alternative Assumptions
The FDA economic impact analysis of the costs of several provisions of the Produce Safety Rule rely on assumptions of the amount of time that a practice will take to implement or improve in order for a producer to be in compliance with the proposed Produce Safety Rule. The FDA analysis references the U.S. Bureau of Labor Statistics occupational employment and wage estimates from 2000. A review of more recent data from the same source, available from May 2012, indicates that average wages for farm workers, managers, and operators, have risen since the 2000 estimates used by FDA’s analysis. This suggests that costs for labor to implement the produce safety rule are higher than those estimated by the FDA. Further detail is provided in Exhibit 3.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Farm Worker</td>
<td>$/ hour</td>
<td>14.00</td>
<td>14.42</td>
</tr>
<tr>
<td>Farm Manager</td>
<td>$/ hour</td>
<td>30.26</td>
<td>33.47</td>
</tr>
<tr>
<td>Farm Operator</td>
<td>$/ hour</td>
<td>47.40</td>
<td>50.18</td>
</tr>
<tr>
<td>Biological Technician</td>
<td>$/ hour</td>
<td>30.11</td>
<td>30.72</td>
</tr>
</tbody>
</table>


Note: Overhead and benefits are calculated by FDA as an additional 50% added to the average hourly wage reported by the Bureau of Labor Statistics for each farm occupation. Informa matched this calculation in its alternative assumption.
(b) Cost Implications
In regard to the labor costs of implementing the Produce Safety Rule, it is a more accurate reflection of the cost to use the more recent Bureau of Labor Statistics’ estimates of the cost of labor. The differences in Informa’s assumptions for the price of labor reflect a 3% hourly increase for farm workers, a 10.6% increase for farm managers, and a 5.9% increase for farm operators above FDA’s assumptions.  

The size of the additional labor costs reflects the expected time required to implement each of the water testing and equipment, tools, building, and sanitation practices listed by the FDA, as an example of the increased costs (Exhibit 4). Applying these additional labor costs to the other components of the rule would show an even further increase in costs.

| **Exhibit 4: Labor Cost Comparison for Water Testing and for Equipment, Tools, Building, and Sanitation** |
|-----------------------------------------------|-----------------|-----------------|-------------------|
| Total Labor Costs for Testing Water Subject to the Proposed 0 Detectable *E*. *coli* Proposal | $1,428,257 | $1,433,577 | $5,320 |
| Total Labor Costs for Agricultural Water Recordkeeping | $7,174,586 | $7,387,262 | $212,676 |
| Total Labor Costs to Clean/Sanitize Tools | $7,706,010 | $8,163,619 | $457,609 |
| Total Labor Costs to Clean Machinery | $16,161,082 | $16,644,910 | $483,828 |
| Total Labor Costs of Pest Control | $1,982,590 | $2,041,661 | $58,071 |
| Total Labor Costs of Cleaning Toilets and Hand-Washing Units | $1,820,945 | $1,888,546 | $67,601 |
| Total Labor Costs to Prevent Contamination from Sewage after Significant Event | $26,224 | $27,517 | $1,293 |
| Total Labor Costs of Preventing Contamination from Trash, Litter, or Waste | $14,900,000 | $16,355,145 | $1,455,145 |
| Total Labor Costs of Recordkeeping for Cleaning Worker Tools | $5,690,776 | $5,859,885 | $169,109 |
| Total Labor Costs of Recordkeeping for Cleaning Machinery | $5,361,769 | $5,520,887 | $159,118 |
| Total Labor Cost For Agricultural Water Testing and Tools, Equipment, Buildings, and Sanitation | $65,961,382 | $69,045,970 | $3,084,588 |

Note: Assumes same labor hours as the original FDA cost analysis, but uses the labor rate assumptions given in Exhibit 3. Source: FDA and Informa Economics.

Informa also anticipates differences in the number of hours required to complete certain tasks and differences in the person responsible for a task. For example, Informa does not expect that all of the hours for recordkeeping will be completed by farm workers, but that those tasks may be completed by farm owners or farm managers. Additional details on these differences in assumptions on labor is included in the analysis for each respective section.

2 FDA does not use the same wage rate throughout the report. These percentage increases are based on the wages listed in Exhibit 3.
B. Agricultural Water

Agricultural water testing is divided into six different cost centers that cover the water testing needs for growing, harvesting, and packing of fresh produce. Each cost category was analyzed by Informa and, when necessary, alternative assumptions were provided for comparison with FDA’s estimated cost.

Informa has updated assumptions associated with the three cost categories presented below:

- Inspection and maintenance of agricultural water resources,
- Water sampling and testing surface water used for direct application irrigation water,\(^3\)
- Water sampling and testing for farms that use water or ice in direct contact with covered produce or food contact surfaces, for harvest, packing, and holding operations, water for hand-washing during and after harvest, water for treated agricultural teas, and water for sprouting operations.

Through industry interviews, assumptions regarding the testing costs, tests needed per farm, and adoption rates of specific practices were found to be inaccurate in FDA’s original report. Other issues, such as days of irrigation and technology preference were found to be questionable, but additional analysis is needed to either confirm FDA’s findings or provide a well-researched alternative. As such, all other assumptions were left unchanged.

FDA found that there would be reduced expenditures by farms if water was tested on-farm for operations that had the appropriate onsite laboratory capabilities. The report uses a “weighted average cost” in which it is assumed that half of the farms that need to test water will have onsite capabilities and that the other half will use a third-party laboratory. Initial interviews suggest that only a small portion of large farming operations will have in-house water testing capabilities. The table in Exhibit 5 presents the original water collection and sampling costs from the FDA report (Table 43 in the FDA report).

\(^3\) Other than for sprouts.
Although the table suggests that there was a weighted average, equal weights were used making the calculation a simple average of the laboratory and in-house estimates. Interviews suggested that the laboratory analysis is more expensive than $12. Also, the FDA report suggests that the in-house analysis and the laboratory analysis use the same analysis cost. An alternative cost scenario is presented in Exhibit 6, which uses a weighted average based on farm size and the higher analysis cost. The analysis cost of $50 is composed of $45 for analysis (up from $12), and $5 for supplies (no change) was taken from a letter Informa received by request from BioSafe Systems. 

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4 BioSafe Systems is a national provider of sanitization for food production use and provides a laboratory service for testing water quality. The company, which is based out of East Hartford, Connecticut, analyzed the Food Safety Modernization Act and provided specific cost estimates in the form of a letter to Informa.
The water collection and sampling costs were a key element used to drive the cost of water sampling and testing for farms that use water or ice in direct contact with covered produce or food contact surfaces. The alternative costs for the 0 detectable E. Coli Standard in Exhibit 7 was used by FDA to determine the cost per farm, in which water or ice comes into direct contact with covered produce or food contact surfaces. In the table, Informa uses the same number of farms and municipal water use assumptions as the FDA. Municipal water use is an important assumption because it assumes that municipal water is already treated, sparing the farmer from additional costs. The difference of $48 per farm is shown in Exhibit 7 and is an important cost consideration, which is used in the overall cost estimates for this part of the rule (see Exhibit 8).
### Exhibit 7: Alternative Costs of the Sampling and Testing Requirements for the 0 detectable E. Coli Standard

<table>
<thead>
<tr>
<th>Number of farms</th>
<th>Percent municipal water</th>
<th>Costs</th>
<th>Number of farms</th>
<th>Percent municipal water</th>
<th>Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost per sample</td>
<td>$87.30</td>
<td></td>
<td>$120.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Produce farms that use surface water sources for post-harvest uses that would treat their water directly rather than incur any sampling and testing costs</td>
<td>21,463</td>
<td>0</td>
<td>21,463</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Produce farms that use groundwater sources for hand-washing purposes during and after harvest and would test 2 times during the production season</td>
<td>19,033</td>
<td>26%</td>
<td>$2,455,106</td>
<td>19,033</td>
<td>26%</td>
</tr>
<tr>
<td>25 percent of produce farms that use groundwater sources for post-harvest uses that would sample and test 1 time and then opt to treat</td>
<td>1,087</td>
<td>26%</td>
<td>$70,087</td>
<td>1,087</td>
<td>26%</td>
</tr>
<tr>
<td>50 percent of produce farms that use groundwater sources during and after harvest that would sample and test 2 times</td>
<td>2,173</td>
<td>26%</td>
<td>$280,348</td>
<td>2,173</td>
<td>26%</td>
</tr>
<tr>
<td>25 percent of produce farms that use groundwater sources during and after harvest that would sample and test 1 time and then switch wells and sample 2 more times (for a total of 3 times)</td>
<td>1,087</td>
<td>26%</td>
<td>$210,261</td>
<td>1,087</td>
<td>26%</td>
</tr>
<tr>
<td>50 percent of sprouts producers who use groundwater that would sample and test 1 time</td>
<td>142</td>
<td>74%</td>
<td>$3,223</td>
<td>142</td>
<td>74%</td>
</tr>
<tr>
<td>50 percent of sprouts producers who use groundwater that would sample and test quarterly</td>
<td>142</td>
<td>74%</td>
<td>$12,903</td>
<td>142</td>
<td>74%</td>
</tr>
<tr>
<td>Total Testing Costs Gross of Current Rates of Practice</td>
<td>23,664</td>
<td>$3,031,928</td>
<td>23,664</td>
<td>$4,176,049</td>
<td></td>
</tr>
<tr>
<td>Cost per farm that would sample and test their water</td>
<td>$128</td>
<td>$176</td>
<td>$48</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes: It should be noted that one of the FDA’s cost estimates has been changed and is highlighted in the table. The original estimate shown by FDA was $6,451, but this would be inconsistent with the other calculations in the table. The change is not material in that it is too small to change the final $128 per farm cost estimate.

Source: Informa and FDA
The difference between Informa’s alternative estimate and the FDA assumptions was $1,074,811. The difference represents a 36% increase. The main difference is ultimately driven by the sampling and testing requirement costs presented earlier in Exhibit 6. Informa’s process for examining FDA’s estimates also meant relying on many FDA assumptions. More detailed information about the percent of farms that use municipal water and how those farms would choose to test and treat their water could further increase the cost estimate.

Exhibit 8: Alternative Costs for Produce Farms that Use Water or Ice for Specified Operations

<table>
<thead>
<tr>
<th></th>
<th>FDA Assumption</th>
<th>Informa Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very Small</td>
<td>Small</td>
<td>Large</td>
</tr>
<tr>
<td>Cost per Farm</td>
<td>$128</td>
<td>$128</td>
<td>$128</td>
</tr>
<tr>
<td>Number of covered</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>produce farms that</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>use water or ice in</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>direct contact with</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>produce for harvest,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>packing and holding</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>operations, water for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hand-washing during</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and after harvest,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>water or ice for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>direct contact with</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>food-contact surfaces,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>water for treated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>agricultural teas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and sprout producers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>that would test their</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost per Year</td>
<td>$2,033,970</td>
<td>$354,262</td>
<td>$646,924</td>
</tr>
<tr>
<td>Rate of Current</td>
<td>1.30%</td>
<td>0.06%</td>
<td>3.78%</td>
</tr>
<tr>
<td>Practice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Costs</td>
<td>$2,007,560</td>
<td>$354,042</td>
<td>$622,462</td>
</tr>
<tr>
<td>Total Costs of the</td>
<td>$2,984,064</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requirement</td>
<td></td>
<td>$4,058,875</td>
<td></td>
</tr>
</tbody>
</table>

Source: Informa and FDA

The FDA cost analysis assumes farmers will adopt differing strategies in terms of testing and treating. The approach FDA used to build up the cost of testing and treating irrigation water included several categories, with two of them being farmers who would test monthly and farmers who would test weekly. Interviews suggest that water is applied more frequently than on a monthly basis. As a result an alternative cost scenario is used that increases the monthly adoption rate to a weekly rate. The estimates were then applied to the farm size categories and rates of current practice in Exhibit 10 to estimate the expected realized costs. Exhibit 10 includes FDA’s estimate as well as Informa’s alternative estimate. Informa estimates that the cost of testing and sampling requirements will be more than double the original FDA estimate or an additional $8,648,084.
### Exhibit 9: Irrigation Cost and Frequency Assumptions with Alternative Cost Scenario

<table>
<thead>
<tr>
<th>Units Costs</th>
<th>FDA Assumption</th>
<th>Informa Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of covered produce farms that apply surface water directly to their produce during growing</td>
<td>7,435</td>
<td>7,435</td>
<td>0</td>
</tr>
<tr>
<td>Cost per sample</td>
<td>$87.30</td>
<td>$120</td>
<td></td>
</tr>
<tr>
<td>Number of weeks per year when covered produce is present</td>
<td>19.5</td>
<td>19.5</td>
<td></td>
</tr>
<tr>
<td>Produce farms that would test 1 time and opt to treat water that is directly applied</td>
<td>289</td>
<td>$25,162</td>
<td>289</td>
</tr>
<tr>
<td>Produce farms that would test surface water that is directly applied with a weekly frequency</td>
<td>3,573</td>
<td>$6,072,813</td>
<td>7,146</td>
</tr>
<tr>
<td>Produce farms that would test surface water that is directly applied with a monthly frequency</td>
<td>3,573</td>
<td>$1,868,558</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total testing Costs Gross of Current Rates of Practice</strong></td>
<td><strong>$7,966,534</strong></td>
<td><strong>$16,762,780</strong></td>
<td><strong>$8,796,246</strong></td>
</tr>
</tbody>
</table>

Source: Informa and FDA.

### Exhibit 10: Sampling and Testing Requirement Cost by Farm Size Including Rates of Current Practice

<table>
<thead>
<tr>
<th>FDA Assumption</th>
<th>Informa Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Small</td>
<td>Small</td>
<td>Large</td>
</tr>
<tr>
<td>Number of covered produce farms that apply surface water directly to their produce during growing</td>
<td>4,983</td>
<td>868</td>
</tr>
<tr>
<td>Cost per year</td>
<td>$5,338,669</td>
<td>$929,849</td>
</tr>
<tr>
<td>Rate of current practice</td>
<td>1.30%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Total cost per farm size category</td>
<td>$5,269,349</td>
<td>$929,274</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$7,832,432</strong></td>
<td><strong>$16,480,516</strong></td>
</tr>
</tbody>
</table>

Source: Informa and FDA.
The FDA report also assumes that the average farm only has one distribution system for irrigation water. In reality, it is not uncommon for a farm to have more than one distribution system. In the case of large farms, farmland is not necessarily contiguous, and each group of fields may rely on their own independent system. For this reason, the alternative cost analysis uses one distribution system per farm, consistent with FDA’s assumptions, for very small and small farms but instead uses an assumption of two distribution systems for large farms. This assumption impacts the cost of inspecting agricultural water sources and the irrigation distribution system.

Within FDA’s economic impact report the cost per affected farm assumes a wage rate per hour of $47 for very small and small farms and $31 for large farms. It was also assumed that every farm, regardless of farm size, number of irrigation sources, and number of irrigation systems would need 15.26 hours to inspect the irrigation sources and distribution system. This caused large farms, which will have the most systems to inspect, to have the lowest per farm cost. Exhibit 11 shows the original table, as well as the alternative assumptions. Also highlighted is the cost per affected farm for the Base Small Farmer. The original table presented this number as $470, but then used $723 in the calculation. This table corrects what appears to be a typographical error by the authors of the FDA report. In fact, there are numerous examples where the assumptions in FDA’s economic assessment text do not match the numbers presented in the table. The alternative scenario used FDA’s assumption for time to inspect an irrigation distribution system (1 hour x four times per year) and multiplied the time required by large farms by a factor of two to reflect the likelihood that large farms have at least two distribution systems that would require inspection. This resulted in 19.26 labor hours needed for large farms.

---

5 This can be found on pages 163 and 164 where the FDA describes the calculations for labor costs. On those two pages, the FDA describes the assumption for farm first line supervisors as $31.60 multiplied by 1.5 to account for overhead costs. The issue is that they show a total cost per hour of $30.25 instead of $30.825, which is likely a typo where the authors left out an “8”. The final calculations appear to use the $30.25 estimate. Also, the text shows the cost for farm and ranch managers as $31.60 and that cost was also multiplied by 1.5 to capture total employee costs. The final calculation appears to have correctly used $47.4, but the text shows $41.4. Again, this is likely a typo where a “7” was confused for a “1”. Although these typos did not play into the final calculations by FDA for this example, it made the report more difficult to read and interpret.
The suggested changes in assumptions were applied to the tables presented in the FDA economic impact report. As a result, the cost for complying with the agriculture water portion of the rule increased by 22%. Additional analysis would be required for more assumptions to be either validated or corrected. The costs using the alternative assumptions developed by Informa are summarized in Exhibit 12. In the table, the increases in cost were the result of the following.

- Inspection and maintenance of agricultural water sources: increase of $920,539.
- Water sampling and testing for surface water used for direct application irrigation (other than sprouts): increase of $8,648,084.
- Water sampling and testing for farms that use water or ice in the harvest, packing, and holding operations, or for hand washing, agricultural teas, and sprouting operations: increase of $1,074,811.

The financial burden placed on farming operations as a result of the agricultural water component of the FSMA Produce Safety Rule increased for all farm size categories. The increases above FDA’s estimates were 24%, 16%, and 21% respectively for very small farms, small farms, and large farms.

### Exhibit 11: Cost to Inspect Agricultural Irrigation Sources and Distribution Systems

<table>
<thead>
<tr>
<th>FDA Assumption</th>
<th>Informa Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Small</td>
<td>Small</td>
<td>Large</td>
</tr>
<tr>
<td>Number of covered irrigated farms</td>
<td>16,623</td>
<td>3,377</td>
</tr>
<tr>
<td>Cost per affected farm</td>
<td>$723</td>
<td>$723</td>
</tr>
<tr>
<td>Hours</td>
<td>15.26</td>
<td>15.26</td>
</tr>
<tr>
<td>Rate per Hour</td>
<td>$47</td>
<td>$47</td>
</tr>
<tr>
<td>Rate of current practice</td>
<td>1.3%</td>
<td>0.06%</td>
</tr>
<tr>
<td>Total cost per size category</td>
<td>$11,869,172</td>
<td>$2,441,242</td>
</tr>
</tbody>
</table>

Source: Informa and FDA.
Beyond the actual cost of complying with the practices required by the agricultural water portion of the Produce Safety Rule, there are also recordkeeping costs to comply with the agricultural water provisions. Informa expects that farm workers will not be responsible for testing the water supply, and that the recordkeeping for agricultural water testing will be conducted by farm owners on very small and small farms, and by farm managers on large farms. This, coupled with updating the hourly wage based on 2012 estimates as presented in the labor costs section, results in a significant increase of $17.3 million in the expected cost of recordkeeping for the agricultural water testing component of the rule (Exhibit 13).
In several instances FDA’s estimate of the costs of complying with the equipment, tools, buildings, and sanitation of the Produce Safety Rule were underestimated. In some instances, alternative assumptions were available through interviews or previously conducted academic research to provide evidence of higher costs. In other instances, the cost estimates were in question but additional analysis and research would be required to develop an alternative cost estimate.

1. Recordkeeping Costs

In FDA’s cost analysis for cleaning worker tools and cleaning machinery, a number of assumptions were included that did not match the views of recordkeeping costs indicated in interviews with produce industry association members and executives.

Informa found three key areas related to recordkeeping costs for cleaning worker tools and cleaning machinery where the assumptions made by FDA are in question. Those are as follows:

- **Labor required.** The annual hours of labor required to do recordkeeping on the cleaning of worker tools and the cleaning of machinery are underestimated.
- **Number of farms affected.** The number of farms who will have to keep records is underestimated.
Person responsible for recordkeeping. The person responsible for keeping farm records will not be an average farm field worker and will require a higher pay rate than assumed by FDA.

First, the number of hours required for recordkeeping was frequently pointed out by members of the produce industry as an estimate in FDA’s cost analysis that was understated. This is based on the use of interviews with members of the produce industry. Members of several U.S. produce associations indicated that the record keeping costs fell substantially short of their expected increases in recordkeeping costs to comply with this portion of the FDA’s Produce Safety Rule. Making the conservative assumption that the hours for recordkeeping were understated by 50%, the total costs for the rule would increase by 50% as well. These costs are detailed in Exhibit 14.

### Exhibit 14: Increased Costs Due to More Hours Required for Recordkeeping

<table>
<thead>
<tr>
<th>Recordkeeping Costs of Cleaning Worker Tools</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms that need to keep tool records</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual hours to record</td>
<td>19,861</td>
<td>3,494</td>
<td>6,411</td>
</tr>
<tr>
<td>Wages</td>
<td>$14.00</td>
<td>$14.00</td>
<td>$14.00</td>
</tr>
<tr>
<td>Annual cost of record keeping per farm</td>
<td>$112</td>
<td>$350</td>
<td>$350</td>
</tr>
<tr>
<td>Total cost of record keeping</td>
<td>$2,224,376</td>
<td>$1,222,725</td>
<td>$2,243,675</td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$5,690,776</td>
<td>$8,536,773</td>
<td>$2,845,997</td>
</tr>
</tbody>
</table>

| Recordkeeping Costs of Cleaning Machinery   |                |                        |                                 |
| Farms that need to keep equipment records   | 18,712         | 3,292                  | 6,040                           |
| Annual hours to record                      | 8              | 25                     | 25                              |
| Wages                                       | $14.00         | $14.00                 | $14.00                          |
| Annual cost of record keeping per affected farm | $112           | $350                   | $350                            |
| Total cost of record keeping                | $2,095,744     | $1,152,025             | $2,114,000                      |
| Total Cost to All Farms                     | $5,361,769     | $8,042,916             | $2,681,147                      |

Note: Keeps labor cost assumption the same as FDA’s original analysis. Updating to 2013 BLS labor costs for farm workers would increase estimated cost to $8,789,827 for cleaning worker tools and $8,281,331 for cleaning machinery. 
Source: FDA, Informa Economics.

Furthermore, the number of farms that will need to begin keeping detailed records on worker tool cleaning and cleaning of machinery is expected to be higher than FDA’s current estimate. This is because although the cleaning of machinery and worker tools is a common practice, industry contacts across a range of produce crops indicated that many growers would have to keep more detailed records to be in compliance with the FDA rule (Exhibit 15). Additional research on the number
of farms enrolled in individual GAP or other voluntary food safety programs could also be used by FDA to provide additional information on the number of farms that would be affected.\(^6\)

**Exhibit 15: Increased Costs Due to More Farms Needing to Keep Records**

<table>
<thead>
<tr>
<th>Recordkeeping Costs of Cleaning Worker Tools</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms that need to keep tool records</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual hours to record</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Wages</td>
<td>$14.00</td>
<td>$14.00</td>
<td></td>
</tr>
<tr>
<td>Annual cost of record keeping per farm</td>
<td>$112</td>
<td>$112</td>
<td></td>
</tr>
<tr>
<td>Total cost of record keeping</td>
<td>$2,224,376</td>
<td>$2,243,675</td>
<td></td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$5,690,776</td>
<td>$2,536,773</td>
<td>$2,845,997</td>
</tr>
</tbody>
</table>

| Farms that need to keep tool records        |                |                        |                                 |
| Annual hours to record                      | 8              | 8                      |                                 |
| Wages                                       | $14.00         | $14.00                 |                                 |
| Annual cost of record keeping per farm      | $112           | $112                   |                                 |
| Total cost of record keeping                | $2,095,744     | $2,114,000              |                                 |
| Total Cost to All Farms                     | $5,361,769     | $8,042,916              | $2,681,147                      |

Note: Keeps labor cost assumption the same as FDA's original analysis. Updating to 2013 BLS labor costs for farm workers would increase estimated cost to $8,789,827 for cleaning worker tools and $8,281,331 for cleaning machinery.

Source: FDA, Informa Economics.

Executives of industry trade associations also indicated the assumption that the farmworkers would be in charge of recordkeeping is incorrect. Instead, it is more likely that it would be the farm manager or farm owner who would take responsibility for the recordkeeping of cleaning worker tools and cleaning machinery. Changing this assumption implies a substantially higher wage rate for the hours required for keeping the worker records. Industry contacts suggest that there would undoubtedly be at least some recordkeeping done by someone on the farm other than a farm worker related to cleaning worker tools and cleaning machinery (Exhibit 16).

---

\(^6\) A number of interviewees indicated the need for a thorough investigation of the number of farmers keeping detailed, comprehensive records, which may not be accurately reflected by simply estimating the number of farmers enrolled in GAP or other voluntary certification programs.
Exhibit 16: Increased Costs Due Changing the Individual Responsible for Recordkeeping

Alternative assumption is that on very small farms and small farms, the farm owner is responsible for recordkeeping, and on large farms the farm manager is responsible.

<table>
<thead>
<tr>
<th>Recordkeeping Costs of Cleaning Worker Tools</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms that need to keep tool records</td>
<td>19,861, 3,494, 6,411</td>
<td>19,861, 3,494, 6,411</td>
<td>8, 25, 25</td>
</tr>
<tr>
<td>Annual hours to record</td>
<td>$14.00, $14.00, $14.00</td>
<td>$50.18, $50.18, $33.47</td>
<td>8, 25, 25</td>
</tr>
<tr>
<td>Wages</td>
<td>$112, $350, $350</td>
<td>$401, $1,254, $837</td>
<td></td>
</tr>
<tr>
<td>Total cost of record keeping per farm</td>
<td>$2,224,376, $1,222,725, $2,243,675</td>
<td>$7,972,205, $4,382,786, $5,363,603</td>
<td></td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$5,690,776</td>
<td>$17,718,595</td>
<td>$12,027,819</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recordkeeping Costs of Cleaning Machinery</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms that need to keep equipment records</td>
<td>18,712, 3,292, 6,040</td>
<td>18,712, 3,292, 6,040</td>
<td>8, 25, 25</td>
</tr>
<tr>
<td>Annual hours to record</td>
<td>$14.00, $14.00, $14.00</td>
<td>$50.18, $50.18, $33.47</td>
<td>8, 25, 25</td>
</tr>
<tr>
<td>Wages</td>
<td>$112, $350, $350</td>
<td>$401, $1,254, $837</td>
<td></td>
</tr>
<tr>
<td>Total cost of record keeping per affected farm</td>
<td>$2,095,744, $1,152,025, $2,114,000</td>
<td>$7,510,997, $4,129,403, $5,053,215</td>
<td></td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$5,361,769</td>
<td>$16,693,614</td>
<td>$11,331,845</td>
</tr>
</tbody>
</table>

Source: FDA, BLS, Informa Economics.

If all three changes in assumptions related to the record keeping costs of cleaning worker tools and cleaning machinery are included, the total increase in costs above FDA’s estimate is substantial. For the recordkeeping costs of cleaning farm tools, the recordkeeping cost would be $39.9 million, a $34.1 million increase above FDA’s estimate. For cleaning machinery, the increase would be significant as well, jumping $32.2 million to $37.6 million. Additional detail is provided in Exhibit 17.

In total, Informa’s adjustments to FDA’s cost analysis for recordkeeping related to cleaning worker tools and cleaning machinery implies costs that, at $77.4 million, are $66.4 million higher than FDA’s estimate of $11 million.
Exhibit 17: Aggregate Increased Costs for Recordkeeping of Cleaning Worker Tools and Machinery

<table>
<thead>
<tr>
<th>Recordkeeping Costs of Cleaning Worker Tools</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms that need to keep tool records</td>
<td>19,861</td>
<td>29,792</td>
<td></td>
</tr>
<tr>
<td>Annual hours to record</td>
<td>8 25 25</td>
<td>12 38 38</td>
<td></td>
</tr>
<tr>
<td>Wages</td>
<td>$14.00 $14.00 $14.00</td>
<td>$50.18 $50.18 $33.47</td>
<td></td>
</tr>
<tr>
<td>Annual cost of record keeping per farm</td>
<td>$112 $350 $350</td>
<td>$602 $1,882 $1,255</td>
<td></td>
</tr>
<tr>
<td>Total cost of record keeping</td>
<td>$2,224,376</td>
<td>$17,937,462</td>
<td></td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$5,690,776</td>
<td>$39,866,838</td>
<td>$34,176,062</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recordkeeping Costs of Cleaning Machinery</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farms that need to keep equipment records</td>
<td>18,712</td>
<td>28,068</td>
<td></td>
</tr>
<tr>
<td>Annual hours to record</td>
<td>8 25 25</td>
<td>12 38 38</td>
<td></td>
</tr>
<tr>
<td>Wages</td>
<td>$14.00 $14.00 $14.00</td>
<td>$50.18 $50.18 $33.47</td>
<td></td>
</tr>
<tr>
<td>Annual cost of record keeping per affected farm</td>
<td>$112 $350 $350</td>
<td>$602 $1,882 $1,255</td>
<td></td>
</tr>
<tr>
<td>Total cost of record keeping</td>
<td>$2,095,744</td>
<td>$16,899,743</td>
<td></td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$5,361,769</td>
<td>$37,560,632</td>
<td>$32,198,863</td>
</tr>
</tbody>
</table>

Source: FDA, BLS, Informa Economics.

2. Costs to Prevent Contamination from Trash, Litter, or Waste

A number of costs are specific to the type of crop being grown. For example, some may contend that the FDA’s assumption of 2 seconds per acre per day to check a field for the presence of trash, litter, or waste is accurate for the leafy greens industry. Discussions with several produce industry groups and their surveys of farmer members indicate that this is an underestimate of the time it takes to monitor for trash for most crops, but that it is particularly troublesome for crops whose height prevents the farm manager or farm owner from seeing across the field. Tree crops are a prime example of this.
(a) Case Study: Costs to Monitor Trash, Litter, and Waste for the California Citrus Industry

Taking the California citrus industry as an example of the underestimate of the cost of monitoring trash and other waste, the California citrus industry has approximately 4,200 growers with 269,400 bearing acres of citrus trees. This results in an average farm size of 64 acres per California citrus farm. Assuming that these all meet FDA’s definition of large growers due to the high value of citrus production per acre, FDA would assume that a farm manager would be responsible for checking the fields for trash.

Industry contacts at California Citrus Mutual indicate that it would take approximately 5 minutes per acre to monitor for trash. While most growers are able to monitor for trash on a regular basis, making an assumption of only one additional check per week for the average farm has a significant impact. This suggests an estimated additional 43 seconds per acre per day are required for monitoring for trash and is starkly higher than FDA’s assumption of 2 seconds per day to comply with the rule.

Using the same calculation framework as FDA, the additional monitoring cost for the California citrus industry alone is estimated to be $19.3 million, more than $4.4 million above the FDA’s economic impact estimate for the entire U.S. produce industry.

Extending the alternative assumptions described here to the entire U.S. citrus industry of 804,300 acres at a rate of 43 seconds per acre per day to monitor for trash, litter, and waste would give an estimated cost of at least $57.7 million for the U.S. citrus industry alone to comply with this rule. This estimate, for just one sector of the U.S. produce industry, is nearly $43 million above FDA’s estimate for the entire U.S. produce industry.

A full break out of the costs estimated by FDA for the U.S. produce industry versus the costs estimated using alternative assumptions for the California citrus industry alone are provided in Exhibit 18.

It should be noted that this increased cost would apply to all tree fruits, although estimates for non-citrus tree fruits and tree crops outside of California are not included in this case study.

---

9 Makes the conservative assumption that a farm manager checks for trash on all U.S. citrus acres; on very small and small farms FDA assumes that a farm owner (who receives a higher wage rate) is responsible for checking for trash. 2012 data on the size of farms across the U.S. citrus industry was not available.
Exhibit 18: Case Study: Costs of Monitoring Trash, Litter and Waste for U.S. Produce Industry versus California Citrus Industry

<table>
<thead>
<tr>
<th>Costs to Prevent Contamination from Trash, Litter, or Waste</th>
<th>FDA Assumption</th>
<th>Alternative Assumption</th>
<th>Increased Cost over FDA Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>For U.S. Produce Industry</td>
<td>For CA Citrus Industry Only</td>
<td></td>
</tr>
<tr>
<td>Seconds per acre per day to ensure that there is no trash, litter, or waste</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Hourly wage ($/hour) of person checking field for trash</td>
<td>$47.00</td>
<td>$47.00</td>
<td>$30.00</td>
</tr>
<tr>
<td>Number of farms</td>
<td>26,947</td>
<td>4,693</td>
<td>8,571</td>
</tr>
<tr>
<td>Average Produce Acres per farm</td>
<td>17</td>
<td>83</td>
<td>462</td>
</tr>
<tr>
<td>Total Acres Monitored</td>
<td>458,099</td>
<td>389,519</td>
<td>3,959,802</td>
</tr>
<tr>
<td>Operator/Supervisor time to monitor for this (sec/daily)</td>
<td>33</td>
<td>166</td>
<td>923</td>
</tr>
<tr>
<td>Operator/Supervisor time to monitor for this (minutes per day)</td>
<td>1</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Operating days - ALL</td>
<td>90</td>
<td>180</td>
<td>180</td>
</tr>
<tr>
<td>Operator/Supervisor time cost to monitor for this (per farm per day)</td>
<td>0</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Cost per farm ($) annual</td>
<td>$39</td>
<td>$393</td>
<td>$1,397</td>
</tr>
<tr>
<td>Total Costs (Annual cost in million $)</td>
<td>1.1</td>
<td>1.8</td>
<td>12.0</td>
</tr>
<tr>
<td>Total Cost to All Farms</td>
<td>$14,900,000</td>
<td>$19,318,866</td>
<td>$4,418,866</td>
</tr>
</tbody>
</table>

Note: Calculating the estimate for the CA citrus industry without updating the hourly wage for the farm manager gives an estimated total cost of $17.3 million for the CA citrus industry costs of preventing contamination from trash, litter, and waste.

Source: FDA, USDA NASS, CDFA CASS, Informa Economics.

(b) Additional Notes on Assumptions Related to Trash, Litter, and Waste Monitoring

FDA’s estimate of 2 seconds was viewed by produce industry association contacts as an underestimate of the amount of time required for monitoring acres of other crops (besides tree fruits) as well. For example, assuming that it takes 3 seconds per acre to check ensure that there is no trash, litter, or waste is just a 1 second increase above FDA’s assumption, but that one second will increase the cost of compliance with the rule by 50 percent, or $7.5 million, to over $22 million.
D. Domesticated and Wild Animals

The economic impact analysis conducted by FDA focuses its attention on two cost centers with regard to the animal intrusion provisions. The rule requires producers to monitor for animal intrusion, assess areas where intrusion has occurred, and take necessary steps to prevent domesticated animals from contaminating growing areas. Over 98% of the costs estimated by FDA rely on an assumption based on a report by Hardesty and Kusunose\textsuperscript{10}. The report shows the costs prior to and after joining the California Leafy Green Marketing Agreement (LGMA) and was used by FDA to estimate the additional costs for compliance with this provision of the Produce Safety Rule by growers nationwide. The report found that costs of monitoring increased by $3.36 per acre. Exhibit 19 shows the per acre cost estimates for animal monitoring. Informa’s interviews indicated that some producers were already monitoring for animal intrusion. Additional assessment of the costs by conducting detailed farmer interviews would be required to verify the number of farmers currently using this practice and the costs for those farmers not currently monitoring animal intrusion to comply.

<table>
<thead>
<tr>
<th>Base</th>
<th>Base</th>
<th>Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Small</td>
<td>Small</td>
<td>Large</td>
</tr>
<tr>
<td># produce farms</td>
<td>26,610</td>
<td>4,644</td>
</tr>
<tr>
<td>Pre-acre monitoring cost increase</td>
<td>3.36</td>
<td>3.36</td>
</tr>
<tr>
<td>Average farm acreage size</td>
<td>112.50</td>
<td>375.00</td>
</tr>
<tr>
<td>Increase in cost per affected farm</td>
<td>$378</td>
<td>$1,260</td>
</tr>
<tr>
<td>Total cost per category</td>
<td>$10,058,658</td>
<td>$5,851,553</td>
</tr>
<tr>
<td>Total cost for the requirement</td>
<td>$37,170,949</td>
<td></td>
</tr>
</tbody>
</table>

Note: The average farm acreage size was not included in the original table, but the details were in the text of the FDA report and have been added to the table above.

Source: FDA and Informa

FDA’s economic impact analysis report also investigates the loss from not being able to graze livestock on ground used for produce production. This practice was not indicated in Informa’s research to be one that was very common within the produce industry groups surveyed. However, Informa acknowledges that based on Census of Agriculture estimates cited

\textsuperscript{10} (Reference 8) in the FDA report. Hardesty and Kusunose authored a report that studied the cost increases incurred by leafy green growers in California who opted to join the California Leafy Green Marketing Agreement.
by FDA, this practice is most common on very small farms. The FDA’s estimate of the cost of compliance with the grazing and working animal rule is presented in Exhibit 20.

### Exhibit 20: Grazing and Working Animal Costs for Rule Compliance

<table>
<thead>
<tr>
<th></th>
<th>Base Very Small</th>
<th>Base Small</th>
<th>Base Large</th>
</tr>
</thead>
<tbody>
<tr>
<td># produce farms that graze animals</td>
<td>2,064</td>
<td>257</td>
<td>281</td>
</tr>
<tr>
<td>Increase in per-acre cost</td>
<td>$1.12</td>
<td>$1.12</td>
<td>$1.12</td>
</tr>
<tr>
<td>Average farm acreage size</td>
<td>112.50</td>
<td>375.00</td>
<td>750.00</td>
</tr>
<tr>
<td>Cost per affected farm</td>
<td>$126</td>
<td>$420</td>
<td>$840</td>
</tr>
<tr>
<td>Total cost per category</td>
<td>$260,004</td>
<td>$108,094</td>
<td>$236,312</td>
</tr>
<tr>
<td>Total cost for the requirement</td>
<td>$604,411</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: FDA

**Potential Cost Increases**

There were a number of animal monitoring and control issues that are not explicitly described in the current form of the rule but could have significant changes to farm costs. One example would be if the final rule or other guidance documents require a buffer zone between animal operations and produce growing areas. These costs are described in the previously referenced report by Hardesty and Kusunose but were left out of the FDA report. Since costs of buffer zones, or other changes (i.e. large quarantine size from contamination by wildlife) were not included in FDA’s cost analysis, Informa assumes that these requirements will not be part of the final rule, and thus there will not be additional costs for compliance.

**E. Other Problematic Assumptions**

Several inconsistencies and errors in FDA’s preliminary economic impact analysis were noted during Informa’s review of the analysis. While all of these were not analyzed in detail, these issues should be corrected before final conclusions regarding the costs of the rule are made.
Inconsistent Use of Wage Rates. The wage rates used for each position are inconsistent across the sections of the report, despite being reported to have the same source. For example, on page 6 of the report, the Farm Supervisor Mean Wage Rate is calculated as $30.26 per hour. In the section on agricultural water testing (page 131), a wage rate of $30.83 per hour is used instead. This is problematic because it creates inconsistency in the labor costs estimates for the various components of the Produce Safety Rule.

No Costs to Replace Noncompliant Tools and Equipment. FDA assumes (page 220) that most farms are currently using tools that are properly designed, installed, stored, and bonded as appropriate. However, there are farms whose tools and machinery would not meet FDA’s standards of appropriate design, application, and storage. The cost of replacing tools/equipment/machinery that are not of adequate design, construction, and workmanship to allow them to be adequately cleaned and properly maintained does not appear to be included in cost estimates. FDA fails to account for the cost to farmers of replacing these tools and machinery with items that would be in compliance with the Produce Safety Rule.

Probability of Significant Events. The assessment of the frequency of “significant events” is in need of additional scientific credibility. The use of a simple average of the likelihood of an earthquake in Maryland and the likelihood of an earthquake in San Francisco (page 216) comes far from presenting the likelihood of an earthquake on covered produce farms, which are located in various proportions across the U.S. Further, the probability that a flood could cause damage is referenced from a US Geologic Survey seismic-hazard maps for the conterminous United States, which is an extremely improbable source for flood data. It is unclear what the actual source for this estimate is, and therefore Informa was unable to assess its reliability. The probability of other significant events that could impact produce farms and create a need to prevent contamination from sewage is ignored. For example, hurricanes and tornadoes could both generate problems with sewage and septic systems, but the cost of monitoring after these events is not included.

Number of Tools and Time to Clean Tools. FDA assumes that it takes one minute to clean and sanitize one tool, and there is one tool per farm job. Informa’s industry interviews suggest that there are sectors such as tree fruits that require more than one tool per person (e.g., ladder, bucket, clipping tool). Also, for crops that utilize reusable harvest containers such as bags or buckets, it is likely that the daily time to wash each worker’s tool would exceed one minute per tool.

Amount of Water Used for Irrigation. FDA assumes that 0.77 acre feet of water are used each season. This volume is needed to calculate the cost for treating water. While national averages were not available to replace
FDA’s assumption with an alternative, Informa received feedback from several produce industry groups that their crops would require additional irrigation beyond 0.77 acre feet per growing season. The amount of water needed from planting to harvest varies significantly by crop. For example, the water needs of beans, cabbage, and peas are significantly lower than the needs of citrus, potatoes, corn, and tomatoes.\textsuperscript{11} The need for irrigation water is also impacted substantially by the growing climate and natural rainfall, with much more irrigation typically needed for a crop grown in Arizona versus the same crop grown in Michigan. Furthermore, the amount of irrigation water needed can vary substantially from year to year for a farm depending on the amount of rainfall received that season. This has the potential to cause significant variability in the costs of any irrigation water treatments that are needed.

**F. Conclusions**

- **FDA Underestimated Costs by Millions of Dollars.** FDA significantly underestimated the costs, on the order of millions of dollars, of some provisions of the proposed Produce Safety Rule. Of the three sections examined, Informa was able to quantify significantly underestimated costs for both agricultural water and for equipment, tools, sanitation, and maintenance, and still has concerns about the costs described in the domesticated and wild animal section of the proposed rule. These underestimates can be corrected with revised assumptions, including using more recent labor costs and additional interaction with industry sources to collect cost estimates and current rates of practice for the provisions included in the rule.

- **Additional Research Needed.** Additional primary research is needed on the assumptions that are used by FDA in its economic analysis due to a lack of reliable cost estimates for some provisions. Informa investigated several assumptions made by the FDA that were in question but found a lack of verifiable research to support an alternative assumption.

- **Costs Vary by Crop and Growing Practice.** The costs of the proposed Produce Safety Rule are expected to vary by crop and growing practices. In some cases, these costs may be minor, while in other cases, they may reflect substantial differences in the cost of compliance. The most frequent examples of differences in cost were for differences in tree crops versus non-tree crops.

- **Sensitivity Analysis Could Provide Additional Insights.** Minor adjustments in FDA’s assumptions have significant implications on the estimated cost of complying with the produce safety rule. Sensitivity analysis of the costs could provide a useful metric when comparing the estimated costs to the estimated benefits of the proposed rule, and could also allow for some inclusion of the impacts when costs are significantly higher than those estimated by FDA. This would also be useful in showing the range of potential compliance costs for an individual farm.

- **Flexibility in Implementation Is Critical.** Based on feedback received from industry sources, it is clear that flexibility in implementation of the rules is critical to preventing costs that do not result in an improvement in food safety. For example, if producers are allowed to use alternatives to the water testing provisions that result in equivalent food safety but significantly reduce the costs of compliance, then those options should be considered by FDA.