

# Collaborative Food Safety Forum (CFSF)

## Collaborative Implementation of FMSA Workshop on Reliable Audits: Workshop Summary

*April 27, 2017  
Washington, D.C.*

### Background

[The Collaborative Food Safety Forum](#) (CFSF or Forum) is a platform for multi-sector engagement on issues critical to keeping our nation's food supply safe, jointly sponsored by The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF). Invited representatives from the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), state agencies, food industry, conformity assessment industry, audit industry, and food industry trade associations attended a Forum workshop on April 27, 2017 to discuss key elements of, or criteria for, "reliable audits" under the FDA Food Safety Modernization Act (FSMA) and beyond to improve food safety. Topics of conversation included limitations of audits and whether and how those limitations might be effectively addressed, audit protocols, auditor competence, access to and transparency of audit data, and how to appropriately define a "reliable audit" for agency-oversight purposes. This discussion, in some respects, built from Forum workshops on third-party certification and foreign supplier verification held between 2011 and 2014, along with FDA's on-going efforts on the Voluntary Qualified Importer Program, and other programs that use third-party auditors.

### Setting the Stage: Opening Thoughts from FDA

Following a welcome from Pew and RESOLVE, Dr. Stephen Ostroff, Acting Commissioner of Foods and Veterinary Medicine at FDA provided an update on FSMA implementation activities and the potential ways in which the agency might consider leveraging private audit information. Though acknowledging that budget decreases and Administration emphasis on reducing regulation could have a significant impact on all FDA operations, including food regulation, Ostroff affirmed the agency's continued progress in FSMA implementation and improving food safety. He noted several milestones, including the arrival of FSMA compliance dates related to sprouts and sanitary transportation, as well as approaching compliance dates for supplier verification and animal foods. He also referenced FDA's announcement that it will be reviewing the water quality standards rules under FSMA. Ostroff was pleased with the amount of energy and dialogue he saw around reliable audits in this and other forums, saying it is an important and timely topic. He reiterated FDA's intention to leverage third-party audits in its allocation of resources and decision-making, and said that the mechanism for determining the credibility of audit programs will likely vary depending on circumstance. He supported the CFSF's continued advancement of in-depth discussion and creative problem-solving.

### Audits 101: Overview of Audits and Accreditation and Certification Practices

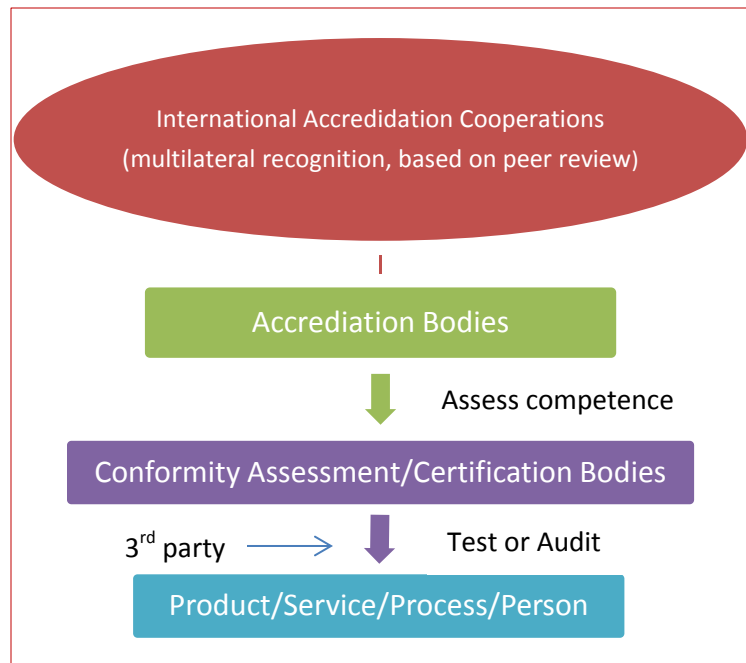
Lane Hallenbeck, Vice President for Accreditation Services at the American National Standards Institute (ANSI), provided a brief, high-level review of audits, their definition and purposes, and place within the

broader context of conformity assessment activities. Drawing language from International Organization of Standards (ISO) and International Electrotechnical Commission (IEC) standards, Hallenbeck defined conformity assessment as “demonstration that specified requirements relating to a product, process, system, person or body are fulfilled,” noting that conformity or adherence is evaluated or assessed against object-specific standards (of which there are thousands across nearly every sector, including those for accreditation and the various types of conformity assessment bodies, themselves). Audits, then, are a specific type of conformity assessment defined by ISO/IEC as a “systematic, independent, documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.”

Audits vary considerably depending on their purpose, the risk associated with the object of assessment, the audit scope, team, extent, and cost. However, Hallenbeck delineated between three categorical auditor roles: supplier’s declaration (1<sup>st</sup> party, internal), supplier audit (2<sup>nd</sup> party, external), and certification (3<sup>rd</sup> party, external).

Hallenbeck emphasized that the strength and reliability of third-party certification, the conformity assessment referenced in the parts of FSMA where audits are required (i.e., for the voluntary VQIP program) and where they are an option (i.e., the Foreign Supplier Verification

Program, as well as Preventive Controls), is built upon not just impartiality but also a system of “checks” inherent to the multi-tiered accreditation hierarchy. Within this framework, multinational accreditation cooperations use international standards and peer assessments to recognize accreditation bodies. These accreditation bodies subsequently use consensus standards and conformity protocols to assess and accredit conformity assessment bodies (referred to as certification bodies). Conformity assessment bodies, in turn, use standards to test products (or services, persons) and audit systems using an accredited program or process. He explained that accreditation of certification bodies involves document review, on-site system assessment, and witness audits (job shadowing). The latter, in addition to assessing general auditing competence and skills, must verify knowledge of, and experience with, the specific object of their audit. The ultimate output of an audit is a report that documents nonconformances with requirements for which suppliers must develop a plan for, and ultimately objective evidence of, corrective action. Hallenbeck’s presentation slides can be found [here](#).



Participants asked several questions about the practice of virtual audits performed via videoconference (WebEx, etc.) as a tool to supplement on-site audits. Participants attested that virtual audits done prior to on-site assessment could reduce the logistical and cost burdens and allow for more efficient, thorough use of on-site time; they affirmed, however, that virtual audits should not be viewed as a

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replacement for in-person audits. Virtual audits also have the potential to mitigate financial barriers to auditing for small and/or geographically dispersed suppliers.

### **Mapping the Universe of Audit Activities for Food Safety and Quality**

Representatives from industry, trade associations, and government were invited to share examples of how their organizations use, and approach ensuring the reliability of, audits. This provided Forum participants with a fuller understanding of how third-party audits are leveraged in the food safety and quality space and helped advance discussion of potential best practices that may be relevant to FSMA implementation.

**Ken Petersen, Chief of the Audit Services Branch, Specialty Crop Inspection Division at the USDA's Agricultural Marketing Service (AMS)** provided a short history of USDA's activities related to quality inspection, focusing particularly on its Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audit programs. AMS began performing commodity-specific, food-safety audits in the 1990s and 2000s, and contributed to the development of Harmonized GAP standards to provide the audit service (for all produce) in 2011, which it now offers across the U.S. and internationally. These services are completely user-fee funded and their use is voluntary. As a government program, AMS faces unique challenges to becoming externally recognized through traditional accreditation, including a governance structure under which the agency serves as both the accreditor and the certifier/auditor. However, Petersen noted AMS is working with the Global Food Safety Initiative (GFSI) to develop a technical-equivalence process to accredit U.S. government audit programs. All GAP audits under the AMS program are performed by federal or state agriculture department auditors. Petersen stressed continual auditor training and review as essential to audit reliability, acknowledging that turnover and state variances can make it difficult to achieve consistency across the workforce. Petersen also highlighted AMS's new GroupGAP certification by which multiple growers – particularly small growers without resources for individual assessment – may be audited as a group under the auspices of an organizing body. The first AMS group audits were performed last year.

**Johnna Hepner, Director of Food Safety and Technology at the Produce Marketing Association (PMA)**, explained that many suppliers perceive third-party audits as a ticket to market access. At the same time, they are experiencing growing pressure from and expectations of buyers with regard to audits. Many buyers now want to know not just whether a supplier has been audited but also the results of the audit and any corrective action plans, and increasingly buyers require an additional assessment of their particular criteria included in addendums to marketing contracts. Though food safety is not supposed to be a competitive advantage, Hepner sees audit costs, document management costs, and audit fatigue as increasing barriers to access for small growers who report not having enough time to attend their growing administrative obligations and the day-to-day farming tasks. Hepner applauded streamlining innovations like the Harmonized GAP standard and GroupGAP certification, as well as private initiatives to help small growers comply with food safety requirements, for meeting expectations, reducing burden, and consequently, minimizing barriers to market access.

**Scott Horsfall, Chief Executive Officer for the California Leafy Greens Marketing Agreement (LGMA)**, provided background on LGMA and its approach to supporting food safety practices among California

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produce growers. LGMA is a state program formed following the 2006 *E. coli* outbreak. (A sister program in Arizona was created at the same time.) LGMA developed, and continues to update, a set of clear food-safety standards for leafy greens growers, including based on FDA guidance, and is now focused on helping growers come into alignment with the FSMA Produce Rule. Like AMS audits, LGMA services are fully user funded and voluntary – although LGMA members cover 95 percent of all leafy greens grown in California and, with its Arizona members, 90 percent of all leafy greens in the country. LGMA members are regularly audited by USDA-certified state inspectors. While LGMA is a public program with government oversight, Horsfall clarified that it does not have regulatory authority. However, LGMA does work with the FDA and local health authorities to flag any immediate health risks that become evident during their audits and provides information to assist investigations. As a public entity, LGMA aims for optimal transparency, though it does not publicize audit results or scores.

Given that LGMA has had the opportunity to work with this relatively fixed group of growers over ten years, participants asked whether LGMA has analytics or has considered analyzing the data it collected to help demonstrate the benefits of being audited. Some suggested developing quality metrics to track food safety improvements associated with certification over time. Horsfall said LGMA is using data to develop workshops to address persistent non-conformities, but he pointed to data inconsistencies – mostly human variances – that, along with resource limitations, make deeper analysis challenging. Several participants expressed interest in further discussion and collaboration on the topic of audit data and analytics.

***Global Food Safety Initiative (GFSI) board members, Mike Robach, Cargill, and Gillian Kelleher, Vice President Food Safety & Quality Assurance, Wegmans Food Markets,*** described GFSI's work to recognize food-safety certification program owners (CPOs, formerly "scheme owners") and align CPOs and government regulatory requirements. In an effort to increase supply-chain efficiency and reduce audit redundancy, GFSI in collaboration with food-safety experts around the world developed benchmarking requirements against which various CPOs could be measured to determine their adherence to internally accepted food-safety principles and requirements. Though not itself a food-safety standard, GFSI's benchmarks help ensure that the programs used to certify food safety are consistent across the globe. These benchmarking requirements are continuously revised to reflect the latest science, and they extend beyond the private sector. GFSI is developing processes to recognize government certification programs and to align its benchmarks with government regulations, guidance, and safety rules. They have worked with the Dutch, German, and Chinese governments, among others, to form public-private partnerships and certification processes to help regulators apply resources more strategically. Robach also discussed GFSI's recent focus on capacity building. It has developed a stepwise progression and toolbox and offers trainings to help less sophisticated food-safety operations achieve certification.

In response to further inquiry about GFSI's work in the public sphere, Robach explained that GFSI's goal is to align expectations and to ensure food-safety management systems meet the requirements of regulatory agencies around the world, recognizing that each government will have unique needs. For instance, in Canada, GFSI-recognized audits were performed in a series of plants and compared to inspections of those plants done simultaneously to identify and close gaps between the two

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assessments' results. Robach clarified that CPO audits are meant to be complementary to inspections, not a replacement, and a tool to help agencies determine how best to deploy limited resources. GFSI's goal is to promote harmonization among food-safety management systems to increase constancy and trade efficiency. Gillian Kelleher added that GFSI assessments can be leveraged similarly on the private side to help buyers identify persistent issues or struggling suppliers and target those areas for training or other support.

### **FDA Use of Audits under FSMA and Beyond**

**Kari Barrett, Acting Third-Party Program Director at the FDA**, provided an overview of the ways in which the agency intends to use third-party audits under FSMA, including potential uses beyond those explicitly stated under the law. There are three primary areas where FDA may leverage third-party audits: 1) FDA's Third-Party Accreditation Program; 2) supplier verification activities under the Foreign Supplier Verification Program (FSVP) and Preventative Controls (PC) rules; and 3) potentially as an input to help inform the agency's risk-based decision making. First, under the Third-Party Accreditation Program, FDA will recognize accreditation bodies that will in turn accredit certification bodies to conduct food safety audits and issue product certifications to foreign food producers. This program will be used to certify foreign suppliers to participate in the Voluntary Qualified Importer Program (VQIP), and outside of VQIP in certain, rare instances, when there is concern about the risk associated with the product or country of origin. Barrett outlined the requirements that accreditation bodies and various certification bodies must meet to be recognized by FDA, including assessment requirements, corrective action plans both internally and among monitored facilities, ensuring auditor competency, and documents maintenance. Second, under the FSVP and PC rules, third-party audits are one method of verification. Auditors must be qualified, defined as having the appropriate education, training, and experience, and familiar with applicable FDA regulations. Beyond these purposes, FDA intends to explore the use of reliable audits (yet to be fully defined) to inform its risk-based decision making and compliance strategy. Barrett's presentation slides can be found [here](#).

Participants asked for further clarity on the audit types used under FSMA and FDA's reason(s) for prescribing different audit requirements for different programs. Specifically, there was confusion around what some interpreted as delineations between FDA-certificated audits (for VQIP), use of "qualified auditors" (for FSVP and PC), and "reliable audits" (for decision making). Agency representatives explained that FDA certification is statutorily required for VQIP, but not for FSVP or PC verification. As such, the term "qualified auditor" was used intentionally to allow for flexibility under these rules, because FDA did not want to assume responsibility for certifying all verification activities or mandate the use of agency services for which there were existing, private alternatives. The term "reliable audit," however, is used generically (as synonymous with robust, credible, or defensible audit), and not intended to describe a specific subset of audits or audits necessarily different from those used for FSVP or PC verification. Still, FDA continues to see value in establishing general criteria to describe reliable audits as a resource to inform decision making, and hoped to gather cross-sector input on this topic. During the conversation over the course of the day, it was further stated that "regulatory audit" as defined in association with the VQIP program is considered the "gold standard;" and while it is appropriate to apply this degree of rigor in cases where a benefit is derived from a positive audit (i.e.,

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fast-track entry into the U.S.), it may not be appropriate or desirable to require it in other circumstances (though in all circumstance the audits should be credible/reliable). Hence, participants' interest in teasing out what constitutes a "reliable audit."

Participants asked how FDA envisioned third-party audit information might fit into its overall oversight and allocation of resources. For instance, would undergoing a reliable audit mean a facility could expect less frequent FDA inspection? FDA representatives acknowledged that this remains an ongoing discussion, though reiterated that third-party audits are **not** viewed as a replacement for inspection. Facilities should not assume that having an audit FDA views as reliable will eliminate the possibility of inspection, or if merited, protection from corrective actions or enforcement. At the same time, FDA recognizes it only has resources to inspect a fraction of regulated farms and facilities. During the discussion, the group noted that buyers will drive food-safety requirements, may have more presence at facilities through their independent checks, and that other sources of information, separate from third-party audits, are collected. FDA aims then to leverage any relevant, reliable information – much of which is contained in private, third-party or other assessment data – to deploy inspection resources strategically and where most needed to promote food safety. They noted that the agency sought [docket comments](#) on how best to leverage information from private entities. More information about its initiatives in this area can be found here: [Public Hearing on Partnerships to Enhance the Safety of Imported Foods](#).

### **Improving Reliability: Technical Components of an Audit**

Here, conversation shifted to discussion of what constitutes a reliable audit, starting with examination of the technical components including audit standards and GFSI established benchmarks. Participants explored how standards and benchmarks are developed, how and how closely they should be aligned to FDA/FSMA regulations, and the frequency with which they should be reviewed and revised to enhance reliability.

Participants largely agreed that private standards and benchmarks should be, and are, closely aligned to FDA regulations (or the governmental requirements of the country in which they are used). Ultimately, government agencies are the bodies with authority to set and enforce food safety standards, and so, assuming those requirements are science based and continually reassessed, alignment to them is necessary and appropriate for a "reliable audit." GFSI, for instance, continually revises its benchmarking documents to stay consistent with agency requirements, most recently updating its benchmarks to better align with FSMA. This alignment process involved a fairly straightforward side-by-side comparison of GFSI benchmarks and FSMA requirements to identify gaps and then revise the benchmarks and work with CPOs to change their programs to comply with FSMA. Likewise, CPOs work to stay aligned with both international standards and national regulations. As one participant explained, her CPO is based on an ISO standard for fundamental food safety management to which additional requirements are added to align the program with GFSI benchmarks, and thus, FSMA.

Participants stressed that the strength and reliability of an audit, and the standards on which it is based depend predominantly on the soundness of the underlying science, along with the governance associated with setting and refreshing that standard. For this reason, international standard-setting

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organizations, GFSI, CPOs, and private management systems have adopted a policy of continuous improvement, constantly reevaluating their systems/standards against the latest science, data, and analytics. Most organizations have periodic, scheduled reviews, for instance annually or once every five years, *and* the flexibility to immediately adapt if/when a systems problem is identified.

While there is ongoing effort to adhere to regulatory requirements, participants noted that many private organizations set a higher bar for their food-safety management systems internally. In some regards, industry food safety is ahead of agency or international organization (ISO/CODEX) standards because of its ability to more quickly identify and respond to emerging issues or new science. Much of the industry, at least at the large-scale level, also benefits from relatively open information exchange, sharing food-safety approaches and best practices through GFSI, summits, associations, conferences, and other platforms. Acknowledging that regulation must unfold via a slower public process, participants suggested there may be ways for FDA to leverage private-sector agility and expertise to improve its requirements.

### **Improving Reliability: Audit Protocols, and Auditor Competency and Integrity**

By and large, participants seemed to view the technical components as less pressing to the conversation of audit reliability with regard to FSMA implementation than the issues of auditor competence, program integrity, and governance. Participants recognized that the major benchmarks, standards, and certification program owners were working to align with FDA requirements, but questions remained around how these requirements are administered and how third-parties ensure auditors produce reliable reports. If FDA intends to leverage third-party audits both for regulatory/verification purposes and potentially beyond for general risk evaluation, and does not have direct oversight of the auditors performing these assessments, what parameters are and should be in place to ensure auditor competency and ability to produce reliable information, and what guidance should be given to inspectors to help them determine whether these parameters were followed?

Participants described a framework used by GFSI and many CPOs to evaluate auditor competency, which breaks the concept into three fundamental areas: 1) auditing skills and knowledge; 2) technical skills and knowledge; and 3) systems/critical thinking. Auditing skills and knowledge are those capabilities that are common across the profession such as observation skills, interview skills, and report writing. Technical skills and knowledge cover object-specific expertise, which for food safety includes food safety management, agriculture practices, and hazard analysis and critical control points (HACCP). Lastly, systems/critical thinking involves the ability to assess a system holistically, follow an audit trail to conclusion, and problem solve. GFSI is developing tests to measure competency in all three areas. These tests involve written exams, skills assessment (witness audits), and report review. On top of these assessments, most CPOs require auditors to have considerable field experience and to demonstrate additional, industry-specific proficiencies.

Participants also viewed impartiality as inextricable from audit reliability. CPOs are cautious, often designating committees for oversight and review, to ensure auditors do not have any financial interest in the businesses they audit or other conflicts of interest, from the individual auditor level to the

accreditation body. Auditors and audit organizations enter into contractual conflict-of-interest agreements with their clients before performing an assessment.

Taking a more comprehensive standpoint, participants emphasized that competency does not begin at the individual auditor level. An auditor's reliability derives from the reliability of his/her certifying body, and ultimately, from the reliability of the overseeing accreditation body. And as previously noted, some structures such as those found in LGMA and USDA AMS are not amenable to an accreditation hierarchy and must consider alternate processes to assess reliability. That is why it is important to understand the accreditation hierarchy and ensure competency and effective protocols at each level. Further, participants stressed that assessing auditor competency is not a one-off exercise, and that even the most adept auditors should be and are subject to continual training and reassessment as science, programs, and requirements evolve.

Along with auditor competency, participants discussed developments in audit processes and protocols to improve thoroughness and credibility. Most audits are now complete process assessments that encompass a business' entire food-safety management system, and in the proper execution of which auditors are trained to follow audit trails beyond a prescribed checklist. Participants explained that program owners are also exploring ways for audits to simulate the unpredictability of FDA inspection to more closely approximate the regulatory approach. And, though not attributes of audits themselves, the growing recognition of food-safety culture and free information exchange have amplified the value of audits. Potential deficiencies identified at one site are now more likely to be shared and addressed across the industry.

### **Transparency and Information-Sharing related to Audit Reports**

The use of third-party audits for regulatory verification and to inform FDA decision making raises challenging questions related to transparency. Audits represent a series of private contractual relationships and their results belong to the audited body/purchaser. But information collected through an audit that is used by the regulator should be available to the public. If FDA uses private-audit data in its decision making processes, would and should that change the audits used from private to publically-available information – either in part or in whole? Participants grappled with this question and related industry and agency concerns, including whether and in what form industry might be willing to volunteer audit data and results and how FDA may be able to incentivize information-sharing more broadly.

CPO and industry representatives relayed feedback they gathered from clients about their comfort level in disclosing all or part of audit reports to FDA and the public. Responses varied. In one survey of 20 businesses, about half were generally comfortable with full disclosure, five were fully opposed to volunteering any information, and the remaining respondents requested further clarification. Businesses were primarily concerned with protecting proprietary information. Audit reports are comprehensive, and may contain information not directly pertinent to food safety (e.g., the company "secret recipe") but that could negatively impact or damage business if made public. Companies also reported concern with the potential for the agency to misinterpret audit information in a way that misguides regulatory efforts, and likewise, with potential public misinterpretation and resulting loss of consumer trust.



Finally, these respondents asked how FDA intended to collect, use, and store audit information. Would inspectors read through reports on-site or take copies? Would they request digital copies? Would there be any ability to redact information? They also questioned the purpose of regularly volunteering audit data that FDA already has authority to access through routine inspection activity.

Some CPOs have explored the possibility of developing an executive summary of audit reports that omits proprietary information but is detailed enough for FDA to verify the audit was executed satisfactorily and that identifies potential risks and corrective actions. According to one participant, initial summary attempts have received positive feedback from industry and lessened concern around information sharing. CPOs have also looked at potentially providing regulators with aggregated audit report data without attribution. Additionally, a participant proposed the idea of establishing clear, transparent ground rules around what information may be redacted from an audit report before it is supplied to the FDA and made public.

Participants discussed the potential risk of “audit shopping” under a private-public partnership system. Assuming FDA uses third-party audit results to guide regulatory decision making, what prevents a business from withholding reports and possibly undergoing multiple audits until it receives favorable results? In other words, how can FDA ensure the information on which it bases decisions is complete, and not only that information selected to benefit contributing organizations? A participant explained that, in theory, audit shopping should be prevented by the aforementioned benchmarking systems and efforts to ensure consistency and equivalency across certification programs. Although he acknowledged this is not a failsafe, FDA representatives also reiterated that third-party audit information is only one of many inputs the agency intends to use to inform its decision making.

While participants validated industry representatives’ concern with the potential misuse of audit information, they also maintained that reliable audits and public-private partnership, if leveraged appropriately, could add real value to food safety and food-safety regulation. As one participant noted, FSMA is a prevention-oriented law that relies on information analysis to identify and control risks. Under this type of approach the agency must be aware, at least at a trend level, of emerging food-safety issues on farms and facilities and what is being done to address them.

## Next Steps

The workshop provided participants with several key learnings, including: better understanding of and appreciation for the complexity of conformity assessments and the system in which they are developed and administered; clarification around how FDA intends to leverage third-party audits and other information, and how the term “reliable audits” referenced in the Preamble to the Produce Safety rule should be interpreted; ways in which the market is driving food safety requirements often faster than regulations; and preliminary ideas for defining and ensuring audit reliability. To conclude, participants identified potential next steps and various avenues of continued discussion:

### **Specific criteria for reliable audits**

FDA representatives affirmed their interest in continuing to engage industry expertise and other stakeholder input to develop criteria for what constitutes a reliable audit. While the workshop began

this conversation and discussed, on a high level, how to ensure auditor reliability, FDA would welcome more guidance to identify and put in place detailed criteria that define reliable audits, especially with regard to auditor competency and governance. This process to define specific criteria could also be informed by existing models such as the LGMA, AMS, GFSI and other programs.

### **Approaches to incentivizing information sharing**

The Forum touched briefly on the question of how regulators might be able to incentivize further information sharing, not only through third-party audits, but other sources of credible data as well, and expressed interest in returning to the topic. Initial ideas for incentivizing included developing some protocol to prevent third-party or other audit information from being shared externally inappropriately, and/or feeding audit results into PREDICT score formulae to potentially decrease the likelihood of inspection for participating organizations. Incentives are of particular interest as audit expectations, costs, and overall audit fatigue continue to increase.

### **Necessity of transparency in the use of audit information**

If audit information is to be used by FDA to make policy or resource deployment decisions in the implementation of FSMA, then some stakeholders believe that access to that information is essential. While participants asserted that it makes sense to maximize the use of audit data to enhance FDA decision making, doing so through the use of incomplete reports or information not made available due to private contracts could fail to fulfill FDA requirements under the law. At the same time, industry has an inherent interest in protecting proprietary or competitive information that could be revealed in audit reports. Participants were interested in discussing what data or summary of audit information would fulfill transparency expectations, to whom and how that information would be made available, and how that information could be used. It also was noted that this topic overlaps with the notion of incentivizing data/information sharing.

### **Maintaining market access for small growers**

Participants relayed a growing concern among small growers that third-party audits will become a default requirement for market access – even with no requirement in FSMA for these audits - and that increased linkage between audits and inspections will accelerate or solidify this trend. They suggested that consideration of scaling audit criteria to set appropriate expectations for different levels of operation be part of the discussion of defining reliable audits and various models to meet these criteria.

### **Data collection and analytics**

Participants saw value in further discussion and collaboration on the topic of how best to collect, combine, and analyze audit data, particularly to help demonstrate the benefits of being audited and perhaps to develop metrics to track food safety improvements associated with certification.

### **Alignment of terminology and cross-sector interpretation of FSMA**

The discussion revealed that the agency, industry, and other stakeholders' interpretations of the term "reliable audit" varied. Participants sought further guidance and clarification in these areas. It also became clear that even among relatively highly-informed stakeholders terminology related to this topic – auditor, standard, benchmark, certification, accreditation, etc. - was being used inconsistently. Future

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discussion would benefit from development of a shared lexicon, as well as improved and consistent understanding among stakeholders of the certification and accreditation framework.