

May 19, 2008

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2008-N-0183

Dear Sir or Madam:

The United Fresh Produce Association appreciates the opportunity to respond to FDA's request for comments on the potential for FDA to recognize and accept certain Third-Party Certification Programs for Foods and Feeds.

United Fresh Produce Association is an international trade association representing the interests of produce growers, shippers, fresh-cut processors, distributors and marketers throughout the total supply chain. Our members include small family-owned businesses as well as the largest national and international companies in the produce industry. The association was founded in 1904 and has worked consistently to provide a strong industry voice in government and regulatory policy, food safety and quality assurance, nutrition and health promotion, and helping member companies develop positive business growth through supply chain solutions, training and education.

In responding to FDA's request for comments, we believe there may be potential benefits to FDA, the industry and consumers by use of certain 3rd party certifiers under specific conditions. However the process must overcome many obstacles we see in implementation of such programs today, as well as ensure a consistent, science-based, and credible certification system in the future that garners the widespread confidence of consumers, industry and government. While our comments may be applicable to a wider scope of the U.S. food supply, we are providing them with a focus on the impact of such a proposal on the fresh and fresh-cut produce industry.

1. What domestic and foreign third party certification programs for suppliers are currently in use by U.S. companies?

Certification programs currently in use in the produce industry generally fall into three distinct categories:

- Businesses managed for profit that certify to different buyers'/companies' specific interests. These would include private-sector companies such as Primuslabs.com, Silliker, SCS and NSF Davis Fresh.
- Consortia that attempt to set standards on behalf of an industry sector. These groups may be legally organized as not-for-profit entities, but appear to be operated to maximize return to the sponsoring organizations. These would include Safe Quality Foods (SQF), the British Retail Consortium (BRC) and GlobalGAP.
- Government run or authorized programs that do not have a profit-making goal, but are intended to assist industry members in determining compliance. These would include USDA GAP audits and various regional, state and local agriculture department audits.

2. *Do the current third-party certification programs ensure compliance with FDA requirements?*

Most current audit programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of standards. If given authority, training and adequate oversight, we believe that USDA/state department of agriculture GAP audits could be designed to certify against FDA standards, although most would be considered more educational and benchmarking tools for individual growers at present. Perhaps the one audit program that most closely ensures compliance with FDA standards today is the California Leafy Greens Marketing Agreement (LGMA). The LGMA audit criteria have been carefully developed with FDA input to measure and monitor compliance with all practices that FDA would recommend itself.

Most other audit programs measure a wider range of practices that might be of interest to the person requiring the audit. For example, many audits measure procedures and practices outside of FDA food safety requirements, thereby diluting the assessment of a facility's compliance with those requirements. Also, many produce audits currently overemphasize documentation and testing, which seems designed more to satisfy liability concerns than compliance with FDA food safety standards.

The basic reason that current audits do not ensure compliance with FDA requirements is that FDA has not clearly established the standards that it believes must be audited against. This leaves open to interpretation to a wide range of competing interests – market players, auditing companies, etc. – to develop their own standards. Many current programs have established standards with little industry or government input, and reflect expectations that are unrealistic in agricultural practices, have been extrapolated from other foods or unrelated produce commodities, or have been developed without consideration of relative risks or consequences of implementation. We believe that the California LGMA comes the closest to an appropriately developed audit standard, in that the metrics are developed in an open, iterative process with input from affected suppliers, buyers, produce food safety scientists, and state and federal government regulatory agencies. This process best approximates the ideal process, which would be FDA initiation of proposal and public comment on specific commodity-specific GAPs. With that public and independent process, it is hoped that all auditors and companies truly interested in food safety might coalesce around the most appropriate safety standards developed through that process.

We believe that, if FDA ultimately decides to recognize 3rd party certifications, FDA must retain a definitive role in setting the standards that any certification body would audit to, and must ensure that such certification body's interpretation of those standards is consistent and appropriate.

It is also important to note that such certification bodies must not "add on" to FDA approved certification audits with additional requirements that may be specific to certain parochial needs of the certifying body or its clients. Any FDA-recognized certification program must be a truly independent 3rd party, and not tied to the business interests of clients or to other stakeholders in the supply chain. We believe FDA must be sensitive to apparent conflicts of interest among potential 3rd party certification bodies.

3. *What are the obstacles to private sector participation in these third-party certification programs?*

There are four primary obstacles to general acceptance of any 3rd party certification program currently in use in the produce industry – 1) broad acceptance of the certification, 2) auditor qualification, 3) cost, and 4) harmonization of standards.

1) Today, the produce industry faces multiple, redundant audits, which in most cases are not interchangeably acceptable to different buyers. Most buyers will only accept the results and certification of certain certification bodies, thus leading to proliferation of different audits for different buyers. In some cases, the same auditor will visit a facility multiple times to perform different audits to verify compliance with different and potentially conflicting standards. If 3rd party certification programs endorsed by FDA are to be successful, there must be a system in place that requires buying companies to recognize and approve the results of these audits without requiring their own duplicative audits to recognize the same results.

2) Even when standards under an audit protocol are consistent, the quality of the audits themselves are too dependent on auditor judgment. Even for certification programs that have provisions to “calibrate” auditors, there is no or insufficient verification that the calibration is effective. Consequently one operation, audited by two auditors auditing to the same standards, may pass one audit but fail another. Any FDA-recognized certification program must have a clearly defined system to ensure adequate training of auditors and consistency of audits. We believe that FDA itself provides a good model of auditor calibration in its procedures whereby CFSAN and ORA maintain compliance policy guides to provide instruction in interpretation and implementation of CFSAN policies; ORA investigators perform “audits” according to CFSAN policies; and then must verify with CFSAN that they have interpreted and executed those policies accurately. We believe that, if FDA ultimately decides to accept 3rd party certifications, FDA must also retain a definitive role in verifying the certification body’s auditor calibration and consistency in interpretation of the standards used.

3) Currently, produce industry food safety certification programs range in cost from a few hundred dollars per audit (generally by the government run or authorized programs) to tens of thousands of dollars (generally by the more complex certification bodies like SQF or ISO). Yet, we do not have evidence that the increased costs of some audits result in better evidence of compliance with standards or better evidence of safer food. The tremendous range in audit fees can have a significant impact on the ability of particularly small businesses to participate. We believe that, if FDA ultimately decides to accept 3rd party certifications, FDA must retain a definitive role in setting fair and appropriate audit fees to demonstrate compliance with FDA standards, or risk giving inadvertent incentive to audit companies to maximize fees at the risk of food safety. If exorbitant audit fees were required, we fear that many producers would avoid such compliance audits when FDA’s goal is really maximum participation.

4) Finally, inconsistencies in audit standards among the different certification bodies have created frustration and confusion, have unnecessarily increased operational costs, and may create an obstacle to training in food safety practices. To date, every effort to create a harmonized set of produce food safety audit standards has only added another set of standards to the list. As stressed several times in these comments, we believe that, if FDA ultimately decides to accept 3rd party certifications, FDA must retain a definitive role in setting the audit standards that will be used by the certification body, and that certification

to those standards must be consistent across all FDA-accepted certification bodies. We further believe that FDA should seek input from the industry and all stakeholders in determining how and when to recognize certification bodies and their audit standards.

4. *What incentives would increase participation in these third-party certification programs?*

As noted in FDA's request for comments, there are several business incentives that might accrue from the use of 3rd party certifications, if meeting the criteria discussed above. These include expedited treatment of imports at U.S. ports of entry, establishing a positive list of certified firms available to the public (similar to USDA GAP audits on its website), and using 3rd party certification to reduce the need for government inspections. These are all good business reasons to consider use of 3rd parties. However, we believe the strongest incentive would be if such a program were based on a harmonized set of FDA endorsed standards, and have the industrywide public recognition to preempt additional redundant audits. Participation in an FDA-accepted 3rd party certification program would be of significant value if all parties in the marketplace accept the FDA-recognized certification as sufficient verification of food safety practices.

Thank you for the opportunity to provide these comments. Please call on us at anytime for further clarification of any of these points, or for further information.

Respectfully submitted,

A handwritten signature in black ink that reads "David E. Gombas". The signature is written in a cursive, flowing style.

David E. Gombas, Ph.D.
Senior Vice President, Food Safety and Technology
United Fresh Produce Association